PEER REVIEW HISTORY

ARTICLE DETAILS

Title (Provisional)

Effects of Baduanjin on motor function in children with developmental coordination disorders: study protocol for a randomised controlled trial

Authors

Gao, Jiaxin; Ke, Xiaohua; Huang, Dunbing; Wu, Yangxin; Xu, Xiaqing; Ren, Hongfei; Zhang, Anren; Song, Wei

---

VERSION 1 - REVIEW

Reviewer **1**

Name **Ito, Tadashi**

Affiliation **Aichi Prefectural Mikawa Aoitori Medical and Rehabilitation Center for Developmental Disabilities, Three-dimensional motion analysis laboratory**

Date **21-Feb-2024**

COI **None.**

I am reviewing the article “Effects of Baduanjin on motor function in children with developmental coordination disorders: study protocol for a randomised controlled trial”. Here are some comments on the article.

1. In the introduction, there are several citations to papers that are not related to DCD. These citations should be replaced with relevant papers that are related to DCD and emphasized accordingly.

2. The target age range for this program is 5 to 10 years old.

Please explain the reason for selecting this age range. Developmental Coordination Disorder (DCD) is frequently observed in preschoolers and early elementary school students.

3. Please provide citations for articles that demonstrate the validity of the data for all endpoints.

4. Were all participants able to complete the Baduanjin training?

5. The authors explained in the discussion that "The anticipated outcome of this study is an improvement in the motor function of children with DCD, consequently enhancing their self-care abilities and social adaptation. Thus, this program holds promise as an exercise intervention, offering new perspectives for the rehabilitation of children with DCD." However, the authors did not provide any specific information about how these would be successful recruitment process.

6. The authors explained in the discussion that "Furthermore, this study will employ an innovative approach by using fNIRS to capture haemodynamic data from the motor-related cortex in children with DCD during functional tasks such as manual dexterity, balance, and coordination. " However, the authors did not provide any specific information about how these would be useful for evaluation. Also, this discussion is clearly too much of a leap and misleads the reader.

7. “The analysis will encompass the evaluation of cortical activation levels and the strength of functional connectivity. These metrics will be correlated with changes in motor function, providing a comprehensive assessment of the efficacy of Baduanjin exercise in improving the motor function of children with DCD. This approach aims to explore the cerebral blood oxygenation mechanisms that underlie the effectiveness of Baduanjin exercise, covering both peripheral manifestations and central features.” Unfortunately they are insufficient. This conclusions is neurophysiological explanation is inadequate.

8. What is the most newly found in this study? It was not at all clear what does which of the information presented in the manuscript support the newly found in this study.

Reviewer	**2**
Name	**Cao, Jianguo**
Affiliation	**Shenzhen Children's Hospital**
Date	**11-Apr-2024**
COI	**No**

Gao et al. aim to investigate the effectiveness of Baduanjin on motor skills and activities of daily living (ADL) in children with developmental coordination disorders (DCD). The study protocol is well-structured, but I have some concerns regarding the study design and ethics:

1. On page 13, line 4, for the control group, the author mentions that "The intervention ... will be health education, and subjects will participate in 45-min health education session every 2 weeks for 8 weeks, totaling 4 sessions" and the content will include knowledge of "the etiology, pathogenesis, clinical manifestations, and preventive and curative measures of DCD." It needs clarification: who will receive this education - the children or their parents? Will each session cover different topics or repeat the same material? Is a 45-minute session

too long for young children to focus on complex medical concepts? Is there a standardized approach to ensure consistent delivery of health education?

2. On page 13, line 12, it states that the control group will not engage in any planned training activities during the eight-week trial period and won't receive instructions for home training programs. This raises ethical concerns as leaving children with DCD without any intervention may be deemed unacceptable by ethics committees unless evidence shows no harm would result from an absence of treatment within this timeframe. The committee asserts that every patient has the right to receive necessary healthcare, and health professionals are obligated to provide treatment. Typically, a waitlist control design can be used to address this issue. Alternatively, conventional training (e.g., task-oriented training) or instructions for a home training program can serve as controls.

3. On page 16, line 17, the author uses the original DCDDaily-Q to evaluate ADL outcomes. It is important to acknowledge that there are significant cultural differences between Dutch (the origin of DCDDaily-Q) and Chinese children in daily activities. For example, items one and two in the DCDDaily-Q assess tasks like "Buttering a sandwich" and "Cutting a sandwich," which may not be familiar to many children aged 5-8 in China. This makes it unsuitable for assessing their eating and utensil abilities. A culturally adapted Chinese version could resolve this issue; Dr Jianguo Cao's team at Shenzhen Children's Hospital has translated and validated such a tool tailored specifically for Chinese contexts.

I hope these suggestions are helpful in refining your research methodology.

Reviewer **3**

Name **Tai, Xiantao**

Affiliation **Yunnan University of Traditional Chinese Medicine, School of Acupuncture-Tuina and Rehabilitation**

Date **11-Apr-2024**

COI **There is no competitive interest.**

Thank you very much for giving me this opportunity to review this manuscript. It is innovative to study the effect of Baduanjin on DCD motor function, which is worthy of popularization and application. However, the following aspects need to be further improved.

1.The registration time of the clinical trial is inconsistent with the start time of the trial. Does the collection of cases begin between September 1 and December 22 ?

2.Why 5-10 years old ? Does it consider how to refer to the DPF index when the optical density is converted to oxyhemoglobin density in fNIRS data analysis for children older than 6 years old ?

3.The (X ± SD) mean indicates the lack of a horizontal.

4.The qualifications and level of the coach are not mentioned in the method.

5.In the manuscript, there is no description of the type, channel and channel arrangement of fNIRS equipment ?

6.How to divide ROI partition ?

7.There are some small problems in the grammar. For example, there are several different tenses in a sentence, and the grammar needs to be polished by professionals.

VERSION 1 - AUTHOR RESPONSE

Reviewer #1:

1. In the introduction, there are several citations to papers that are not related to DCD. These citations should be replaced with relevant papers that are related to DCD and emphasized accordingly.

Response 1:
Thanks for your suggestion and we have replaced some of the literature in the article. However, there is a portion of the literature that, although not directly related to DCD, was necessary to explain the rationale for using the Baduanjin intervention and the fNIRS outcome measurement tool, so we included these citations in the manuscript.

2. The target age range for this program is 5 to 10 years old. Please explain the reason for selecting this age range. Developmental Coordination Disorder (DCD) is frequently observed in preschoolers and early elementary school students.

Response 2:
Thank you for raising this important issue. The International Clinical Guidelines on DCD, issued by the European Academy of Childhood Disability, recommend against making a formal diagnosis of DCD in children under 5 years of age. Additionally, the normative database for children's motor coordination in China provides data only for two age groups: 3–6 years and 7–10 years. Therefore, we selected preschoolers and early elementary school students aged 5 to 10 years.

3. Please provide citations for articles that demonstrate the validity of the data for all endpoints.

Response 3:
Thank you for raising this important issue. This study is a research protocol to explore the effects of Baduanjin training on motor function in children with DCD, and we elucidated that motor skill training is a core tool for improving motor ability in children with DCD in the manuscript (Yu J J, et al. Arch Phys Med Rehabil, 2018. DOI:10.1016/j.apmr.2017.12.009). Baduanjin is a traditional exercise training with distinctive Chinese medicine characteristics, which has been proven to have therapeutic efficacy in improving balance as well as neuromuscular coordination in the rehabilitation of a variety of diseases (Yuen M, et al. Neurorehabil Neural Repair, 2021， DOI:10.1177/15459683211005020; Lai J, et al. BMJ Open, 2022. DOI:10.1136/bmjopen-2022-067280; Lin H, et al. BMC Complement Med Ther. DOI:10.1186/s12906-023-03866-4), which precisely corresponds to the motor deficits of children with DCD with insufficient balance and coordination, therefore, the efficacy of Baduanjin on the motor function of children with DCD is yet to be explored in our study. The study is ongoing and no valid conclusions have been drawn.

4. Were all participants able to complete the Baduanjin training?

Response 4:
Thank you for raising this important issue. Before the trial begins, a training session will be conducted, during which the researcher will provide personalized, on-site instruction to each child. Parents will be encouraged to participate in this session to gain a better understanding of Baduanjin movements and to help supervise their children's practice at home. After the instruction, another researcher will assess whether each child has mastered every movement of Baduanjin. Each child's parents will receive a pre-recorded instructional video and a notebook during the training session, with the expectation that they will guide or assist their children in practicing Baduanjin exercises at home. The 8-week trial period will then begin, with sessions taking place both at home and in the hospital. Children in the trial group will attend the hospital twice a week for Baduanjin training, while their parents will supervise the remaining three sessions at home. Parents will record these sessions and share them with researchers via WeChat. Record sheets will be completed after each session, and researchers will routinely check the children's daily record books to ensure compliance with home practice requirements.

5. The authors explained in the discussion that "The anticipated outcome of this study is an improvement in the motor function of children with DCD, consequently enhancing their self-care abilities and social adaptation. Thus, this program holds promise as an exercise intervention, offering new perspectives for the rehabilitation of children with DCD." However, the authors did not provide any specific information about how these would be successful recruitment process.

Response 5:
Thank you for raising this important issue, which will be crucial in guiding the subsequent execution of this study. During the recruitment process, the team will create advertisements targeting children with DCD and post them on the official platform of the Shanghai Fourth People's Hospital affiliated with Tongji University. Additionally, user-friendly materials will be designed for display in the pediatric outpatient areas. Trained researchers will also distribute paper versions of the Developmental Motor Coordination Disorder questionnaire to parents of children visiting the pediatric outpatient area of the hospital and in the surrounding community. This will be used for the initial screening of suspected cases. Suspected children will then be brought to the Pediatric Rehabilitation Unit of the Shanghai Fourth People's Hospital to undergo the MABC-2 test. Children who meet the eligibility criteria will be included in the study.

6. The authors explained in the discussion that "Furthermore, this study will employ an innovative approach by using fNIRS to capture haemodynamic data from the motor-related cortex in children with DCD during functional tasks such as manual dexterity, balance, and coordination. " However, the authors did not provide any specific information about how these would be useful for evaluation. Also, this discussion is clearly too much of a leap and misleads the reader.

Response 6:
Thank you for raising this important issue. In this study, fNIRS will be used to capture the hemodynamic data of the motor-related cortex in children with DCD before and after the Baduanjin intervention, as they perform functional tasks such as manual dexterity, balance, and coordination. By observing cortical activation in children with DCD, the study aims to elucidate the cerebral blood oxygenation mechanisms associated with Baduanjin, providing a strong scientific basis for its effectiveness in improving motor function in children with DCD.

7. “The analysis will encompass the evaluation of cortical activation levels and the strength of functional connectivity. These metrics will be correlated with changes in motor function, providing a comprehensive assessment of the efficacy of Baduanjin exercise in improving the motor function of children with DCD. This approach aims to explore the cerebral blood oxygenation mechanisms that underlie the effectiveness of Baduanjin exercise, covering both peripheral manifestations and central features.” Unfortunately they are insufficient. This conclusions is neurophysiological explanation is inadequate.

Response 7:
Thank you for raising this important issue. This study is a research protocol aimed at exploring the cerebral blood oxygenation mechanisms underlying the efficacy of the Baduanjin intervention. We will monitor

real-time changes in cortical oxyhemoglobin (HbO) and deoxyhemoglobin (HbR) concentrations during movements using fNIRS, which will reflect regional cortical activation. This study focuses on the cerebral blood oxygenation mechanism to explain the clinical efficacy of Baduanjin in improving motor function in children with DCD, without addressing the neurophysiological mechanisms. We greatly appreciate your suggestion, and in future studies, we will include more neurophysiological indicators for further evaluation.

8. What is the most newly found in this study? It was not at all clear what does which of the information presented in the manuscript support the newly found in this study.

Response 8:
Thank you for raising this important issue. As a clinical trial research protocol, this study is currently underway. Building on the theoretical foundation established by previous research, this study aims to explore how the Baduanjin intervention improves motor function in children with DCD. By monitoring the activation levels and functional connectivity of the motor-related cortex in the brains of children with DCD before and after the Baduanjin intervention, we seek to elucidate the cerebral blood oxygenation mechanisms through which Baduanjin influences motor function in these children

Reviewer #2:

1. On page 13, line 4, for the control group, the author mentions that "The intervention ... will be health education, and subjects will participate in 45-min health education session every 2 weeks for 8 weeks, totaling 4 sessions" and the content will include knowledge of "the etiology, pathogenesis, clinical manifestations, and preventive and curative measures of DCD." It needs clarification: who will receive this education - the children or their parents? Will each session cover different topics or repeat the same material? Is a 45-minute session too long for young children to focus on complex medical concepts? Is there a standardized approach to ensure consistent delivery of health education?

Response 1:
Thank you for raising this important issue. In this study, children in the control group received to participate in a 45-min health education session every 2 weeks for 8 weeks, totalling 4 sessions, in which parents brought their children to participate, including knowledge of “the etiology, pathogenesis, clinical manifestations, and family intervention methods of DCD”, each class will cover a different topic, the health promotion of the course is pre-recorded video will be viewed at the scene, and at the same time there are professionals to answer the questions of the parents.

2. On page 13, line 12, it states that the control group will not engage in any planned training activities during the eight-week trial period and won't receive instructions for home training programs. This raises ethical concerns as leaving children with DCD without any intervention may be deemed unacceptable by ethics committees unless evidence shows no harm would result from an absence of treatment within this timeframe. The committee asserts that every patient has the right to receive necessary healthcare, and health professionals are obligated to provide treatment. Typically, a waitlist control design can be used to address this issue. Alternatively, conventional training (e.g., task-oriented training) or instructions for a home training program can serve as controls.

Response 2:
Thank you for raising this important issue, with which we fully agree. In this trial, children in the control group did not participate in any planned training activities during the trial period. However, our health education program included guidance on home training exercises. The program covered topics such as the etiology, pathogenesis, clinical manifestations, and family interventions for DCD. This allowed children and their parents to apply the knowledge gained from the health education sessions to train independently in their daily lives.

3. On page 16, line 17, the author uses the original DCD Daily-Q to evaluate ADL outcomes. It is important to acknowledge that there are significant cultural differences between Dutch (the origin of DCD Daily-Q) and Chinese children in daily activities. For example, items one and two in the DCD Daily-Q assess tasks like "Buttering a sandwich" and "Cutting a sandwich," which may not be familiar to many children aged 5-8 in China. This makes it unsuitable for assessing their eating and utensil abilities. A culturally adapted Chinese version could resolve this issue; Dr Jianguo Cao's team at Shenzhen Children's Hospital has translated and validated such a tool tailored specifically for Chinese contexts.

Response 3:
Thank you very much for your suggestion, but we have not obtained permission to use this tool and cannot use it in this study for the time being, we will apply for permission to use it later and apply it in future studies.

Reviewer #3:

Major issues

1. The registration time of the clinical trial is inconsistent with the start time of the trial. Does the collection of cases begin between September 1 and December 22 ?

Response 1:
We thank you very much for bringing this to our attention. The cases in this study were collected from January 1, 2024 to September 1, 2024.

2. Why 5-10 years old ? Does it consider how to refer to the DPF index when the optical density is converted to oxyhemoglobin density in fNIRS data analysis for children older than 6 years old ?

Response 2:
Thank you for your valuable comments, which we fully agree with. The International Clinical Guidelines on DCD issued by the European Academy of Childhood Disability state that it is not recommended to make a formal diagnosis of DCD in children under 5 years of age, and that and the normative database of children's motor coordination in China contains normative data for only two age groups, 3-6 years and 7-10 years, so we chose 5-10 years as the age range. Based on the data obtained from the research and practice of HuiChuang Medical Laboratories, the DPF value for children was set at 6.0.

3. The (X ± SD) mean indicates the lack of a horizontal.

Response 3:
Thank you very much for your suggestion, we have made changes in the manuscript.

4. The qualifications and level of the coach are not mentioned in the method.

Response 4:
We thank you very much for bringing this to our attention. The interventionist of this trial is a graduate student of rehabilitation majoring in Chengdu Sport University, School of Sports and Health, class of 2017, who has been engaged in group therapy of Baduanjin in children's rehabilitation, has a solid theoretical foundation and technical skills of Baduanjin, has rich experience in teaching, and is able to control the training intensity to ensure the safety of the movement.

5. In the manuscript, there is no description of the type, channel and channel arrangement of fNIRS equipment ?

Response 5:

We thank you very much for your kind reminder and explanation, with which we completely agree. We have added accordingly in the article. In this experiment, NirSmart-6000A equipment (Danyang Huichuang Medical Equipment Co., Ltd., China) was used to continuously measure and record theconcentration changes of brain oxygenated hemoglobin (HbO) and deoxyhemoglobin (HbR) during the task. The system consists of a near-infrared light source (light emitting diodes, LED) and an avalanche photodiodes (APD) as detectors, with wavelengths of 730 nm and 850 nm, respectively, and a sampling rate of 11 Hz. The experiment uses 23 light sources and 15 detectors to form 49 effective channels, the average distance between the source and the detector is 3 cm (range 2.7-3.3 cm), with reference to the international 10/20 system for positioning.

6. How to divide ROI partition ?

Response 6:
Thank you for raising this important issue. ROI will be chosen from the bilateral SMC (BA4) region, PMC + SMA (BA6) region, and PFC region.

7. There are some small problems in the grammar. For example, there are several different tenses in a sentence, and the grammar needs to be polished by professionals.

Response 7:
Thank you for your thorough scrutiny, we have made changes to the revised version.

In all, we believe we have vastly improved our manuscript and have made critical revisions that did not influence the content or framework of the paper. We greatly appreciate the Editor's and Reviewers' earnest comments and hope that these corrections will exceed expectations.

Finally, I would like to thank you for taking the valuable time to review my paper, and look forward to your response.

Best wishes，
Wei Song

VERSION 2 - REVIEW

Reviewer **1**

Name **Ito, Tadashi**

Affiliation **Aichi Prefectural Mikawa Aoitori Medical and Rehabilitation Center for Developmental Disabilities, Three-dimensional motion analysis laboratory**

Date **18-Sep-2024**

COI **I agreed.**

The following concerns are raised regarding this study:

1. Please provide clarification on how the duration of training for the intervention was determined.

2. It is unclear which skills this training was designed to improve, and thus which would present a challenge for children with DCD. It is similarly unclear where the elements to improve the coordinated movement of children with DCD are located.

3. Please confirm whether all of the interventions with parental observation at home were actually conducted. It is important to acknowledge the potential limitations of parental records and to discuss this issue throughout the course of the study.

4. What was the participation rate in this intervention? Were there any dropouts? It is important to note that many children with DCD are clumsy and therefore may be less motivated to participate in interventions. It is recommended that the participation and dropout rates be made public.

5. It is inadvisable to utilize the DCD Daily-Q without first confirming its reliability and validity.

6. The Pro-Kin 254 Balance Test System lacks sufficient information to ensure its reliability and validity. Additionally, the measurement device utilized is unclear.

7. The study's results are not discussed, and the study is not sufficiently discussed. It is unclear what changes the training intervention brought about in the DCD children and how it differed from the control group.

Reviewer	**2**
Name	**Cao, Jianguo**
Affiliation	**Shenzhen Children's Hospital**
Date	**03-Sep-2024**
COI	**No.**

The authors have addressed most concerns, but one minor revision is still needed.

Please specify which version of the DCDDaily-Q will be used for this trial. The author mentioned not having obtained permission to use it and plans to do so in a future study. If they no longer intend to use the DCDDaily-Q in this study, please delete it.

VERSION 2 - AUTHOR RESPONSE

Reviewer #2:

5. Please specify which version of the DCDDaily-Q will be used for this trial. The author mentioned not having obtained permission to use it and plans to do so in a future study. If they no longer intend to use the DCDDaily-Q in this study, please delete it..

Response 1:

Thanks for your suggestion and we fully agree with it. After our careful consideration, due to copyright restrictions and the unknown reliability and validity of the scale for Chinese children, our group finally decided to delete the scale DCDDaily-Q after discussion.

Reviewer #1 :

1. Please provide clarification on how the duration of training for the intervention was determined.

Response 1:
Thank you for raising this important issue. The duration of the intervention in this study will be 8 weeks, and this intervention duration is based on the duration of training in which previous studies have reported positive effects of motor training on children with DCD. (Balayi, E., et al. BMC Musculoskelet Disord, 2022. https://doi.org/10.1186/s12891-022-05569-2; Maharaj, S. S., & Lallie, R. S Afr J Physiother, 2016. https://doi.org/10.4102/sajp.v72i1.304; Hession, C. E., et al. J Altern Complement Med, 2019. https://doi.org/10.1089/acm.2017.0242.)

2. It is unclear which skills this training was designed to improve, and thus which would present a challenge for children with DCD. It is similarly unclear where the elements to improve the coordinated movement of children with DCD are located.

Response 2:
Thank you for raising this important issue. The intervention of this study, Baduanjin, is a traditional health maintenance technique with distinctive characteristics of traditional Chinese medicine, and a large number of studies have reported that regular Baduanjin exercise can effectively improve the body's balance and neuromuscular coordination (Yuen M, et al.Neurorehabil Neural Repair 2021. DOI: 10.1177/15459683211005020; Lai J, et al. BMJ Open 2022. DOI: 10.1136/bmjopen-2022-067280; Lin H, et al. BMC Complement Med Ther 2023. DOI: 10.1186/s12906-023-03866-4), which coincides with the motor function deficits of children with DCD who have insufficient balance and coordination abilities. Baduanjin exercises involve a series of movements encompassing flexion and extension of the shoulder, hip, knee, and ankle joints. These movements alternate between a horse stance and an upright posture, incorporating shifts in the center of gravity and occasional heel lifts. These actions induce static contraction of the muscles in the lower limbs, simultaneously stimulating proprioception and vibratory sensation. This comprehensive approach contributes to the effective enhancement of organismal balance function, neuromuscular coordination, and motor control ability. (Ye Y, et al. Front Public Health 2022. DOI: 10.3389/fpubh.2022.965544).

3. Please confirm whether all of the interventions with parental observation at home were actually conducted. It is important to acknowledge the potential limitations of parental records and to discuss this issue throughout the course of the study.

Response 3:
Thank you for raising this important issue. As stated in this study protocol, children in the trial group will be ensured to visit the hospital for Baduanjin training twice a week, and the remaining three times will be completed at home under the supervision of their parents, who will record the whole process and send the video to the researchers through the WeChat platform. Record forms were to be filled out after each session, and the researcher would check the children's daily record books at regular intervals throughout the week to ensure that they had complied with the home practice requirements. The program will be strictly adhered to throughout the study.

4. What was the participation rate in this intervention? Were there any dropouts? It is important to note that many children with DCD are clumsy and therefore may be less motivated to participate in interventions. It is recommended that the participation and dropout rates be made public.

Response 4:
Thank you for raising this important issue. Our trial is still in progress and this paper is only a study protocol, so participation and dropout rates are not known. The results of this study, as well as participation and dropout rates, will be published after the trial is officially completed.

5. It is inadvisable to utilize the DCD Daily-Q without first confirming its reliability and validity.
Response 5:
Thanks for your suggestion and we fully agree with it. After our careful consideration, due to copyright restrictions and the unknown reliability and validity of the scale for Chinese children, our group finally decided to delete the scale DCDDaily-Q after discussion.

6. The Pro-Kin 254 Balance Test System lacks sufficient information to ensure its reliability and validity. Additionally, the measurement device utilized is unclear.

Response 6:
Thank you for raising this important issue. The Pro-Kin 254 Balance Test System was widely used in several studies to test static balance ability as well as dynamic postural stability (Chen Z, et al. Biomed Res Int 2020. DOI: 10.1155/2020/1890917). The measuring device used for the study will be the Pro-kin 254, TecnoBody Company, Italy, which has been supplemented in the text.

7. The study's results are not discussed, and the study is not sufficiently discussed. It is unclear what changes the training intervention brought about in the DCD children and how it differed from the control group.

Response 7:
Thank you for raising this important issue. We strongly agree that a discussion of the results is an extremely important part of the article, but this article is a study protocol that the study is still ongoing and has not yet yielded valid results. The findings of this study will be published after the trial has officially ended.

In all, we believe we have vastly improved our manuscript and have made critical revisions that did not influence the content or framework of the paper. We greatly appreciate the Editor’s and Reviewers’ earnest comments and hope that these corrections will exceed expectations.

Finally, I would like to thank you for taking the valuable time to review my paper, and look forward to your response.

Best wishes，
Wei Song