

**Brief Title: Qigong and Social Isolation: Mental Health
Benefits**

NCT number: Not assigned yet

01/08/2021

Study Protocol

The study's objective is to understand if Chikung (Qigong) may be helpful on the psychological state control of the participants in a relative state of isolation imposed by the government on the fight against covid-19.

Methods:

Data is gathered via the Mental Health Inventory (MHI) adapted to the Portuguese population [1] to assess quantitative mental health scores and a simple structured interview to assess qualitative mental health benefits of Chikung (Qigong).

Qigong was the chosen technique to be studied as an intervention. Qigong is a Traditional Chinese Medicine therapeutic tool that has been studied for its several health benefits [2]. As a traditional vegetative biofeedback therapy [3], Qigong can be useful for the maintenance of mental health of people with several conditions such as anxiety and depression [4, 5], autism spectrum disorder [6] and even conditions related to behavioral control [7].

Design:

First moment: recruitment and group allocation (3 groups).

Second moment: data gathering of demographics and mental health scores.

Third moment (until the fifth): start of intervention for groups 1 and 2.

Fourth moment: second data gathering of mental health scores.

Fifth moment: final data gathering and small interview is performed to obtain qualitative data (this interview is applied only to some randomly chosen participants of groups 1 and 2).

Group Allocation cannot be randomized due to the specific characteristics of the participants.

- Group 1 was composed of Qigong practitioners (for at least 3 months).
- Group 2 was composed of participants who would receive the Qigong intervention (never practiced Qigong).
- Group 3 was composed of control participants (who would not receive the intervention).

Statistical Analysis Plan (SAP)

The primary dimensions being analyzed and compared are positive affect (1), emotional ties (2), loss of emotional/behavioral control (3), anxiety (4) and depression (5).

Secondary dimensions are psychological well-being (1) and psychological distress (2).

Statistical analysis should be conducted according to data distribution. If normality is observed, parametric tests should be employed, otherwise, non-parametric tests will be utilized. Another possible intervenient in the choosing of tests may be the final sample size (after considering drop-out numbers)

Normality will be assessed through data exploration tests, namely the Shapiro-Wilk test. If normality assumptions are not observed or if the sample is too small, non-parametric tests should be employed.

Parametric tests:

Comparing each group between moments of evaluation will be conducted using ANOVA of independent measures. For the analysis of the evolution across time, the comparison between moments of evaluation will use ANOVA of repeated measures.

Non-parametric tests:

Comparison between groups for each moment of evaluation will be conducted using the Kruskal-Wallis test and post hoc tests (Mann-Whitney test) with Bonferroni correction. For the analysis of the evolution across time, comparison between moments of evaluation will use Friedman test and post hoc tests (Wilcoxon test) with Bonferroni correction.

INFORMED CONSENT, FREE AND CLEARED FOR PARTICIPATION IN TEACHING AND/OR RESEARCH PROJECTS

in accordance with the Declaration of Helsinki¹ and the Oviedo Convention²

Please read with attention the following information. If you think something is incorrect or is not clear, do not hesitate in asking for more information. If you agree with the proposal that has been done to you, please sign this document.

Title of the study: Assessment of the effects of Chikung (Qigong) on the mental health of people in a state of relative social isolation.

Framework: Research in the field of Traditional Chinese Medicine, at the Institute of Biomedical Sciences Abel Salazar of Porto University, under the supervision of Professor Jorge Machado.

Study explanation: Application of a demographic questionnaire at the beginning phase, and a mental health inventory at the beginning, middle and final phases of the study. The allocation of the participants are not randomized, as the participant will be placed according to his situation (Qigong practitioner – new Qigong practitioner – and non-practitioner of Qigong as control). The transmission of the sessions, for the experimental groups, will be conducted through the internet, live, where there will be possible real-time interaction between participant and instructor.

Terms and financing: There will not be any kind of financial compensation to and from the participants, as well as there is no funding for the study. Participation is voluntary and does not imply any kind of harm to the participant if he decides to drop out, which can be done at any moment. The study is under the evaluation of the ethics committee of ICBAS-UP.

Confidentiality and anonymity: The collected data is anonymous, ensuring complete confidentiality and exclusivity in its use. Any contact with the participant will be made in a private environment.

Researcher identification: Jorge Manuel de Sousa Magalhães Rodrigues, therapist and researcher in Traditional Chinese Medicine, Portuguese Institute of Taiji and Qigong, and Institute of Biomedical Sciences Abel Salazar of Porto University.

Signature:



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*I declare that I have read and understood this document, as well as verbal information that was given to me by the person that signed above, finding them enough. It was granted to me the possibility of, at any time, refuse to participate in this study without any type of consequence. Therefore, I accept to participate in this study and allow the utilization of the data that I voluntarily provide, trusting that it will only be used for this research, and trusting in the confidentiality and anonymity assured by the researcher.*

Name: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_ / \_\_ / \_\_\_\_

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ONE COPY TO THE RESEARCHER AND ANOTHER TO THE PERSON WHO CONSENTS**