



Impact of Homeopathic Treatment on the Quality of Life of Women with Chronic Diseases: A Randomized Controlled Pragmatic Trial

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Abstract

Background Despite the increasing demand for complementary and integrative medicine, only a few studies have evaluated the effect of these types of treatments on the quality of life (QoL) of patients with chronic diseases. The objective of this study was to evaluate the QoL of women treated with homeopathy within the Public Health System of Belo Horizonte, Brazil.

Methods This is a prospective randomized controlled pragmatic trial. The patients were divided into two independent groups, one group underwent homeopathic treatment in the first 6-month period and the other did not receive any homeopathic treatment. In both randomized groups, patients maintained their conventional medical treatment when necessary. The World Health Organization Quality of Life abbreviated questionnaire (WHOQOL-BREF) was used for QoL analysis prior to treatment and 6 months later.

Results Randomization afforded similar baseline results in three domains of QoL analysis for both groups. After 6 months' treatment, there was a statistically significant difference between groups in the physical domain of WHOQOL-BREF: the average score improved to $63.6 \pm (SD) 15.8$ in the homeopathy group, compared with $53.1 \pm (SD) 16.7$ in the control group.

Conclusions Homeopathic treatment showed a positive impact at 6 months on the QoL of women with chronic diseases. Further studies should be performed to determine the long-term effects of homeopathic treatment on QoL and its determinant factors.

Keywords

- ▶ complementary and integrative medicine
- ▶ homeopathy
- ▶ quality of life
- ▶ randomized controlled trial

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Introduction

A small percentage of scientific articles published are randomized placebo-controlled trials which, despite being expensive, complex, and time-consuming, represent the best accepted scientific evidence for a given clinical intervention. However, it has been questioned whether the results obtained from these randomized controlled trials (RCTs) can always be applied to real clinical situations, since RCTs are often done under artificial conditions that might not reflect those patients who actually live with a given disease or condition.¹ This partly explains a greater use in recent years of *pragmatic* clinical trials, which are performed in “real-world” clinical settings.²

The demand for complementary and integrative medicine (CIM) treatments is increasing, especially among patients suffering from chronic diseases.^{3–5} Belo Horizonte, the third largest metropolitan area in Brazil, has a public health care program that has offered treatment with CIM since 1994, currently tending more than 30,000 patients every year, mainly by doctors specialized in homeopathy and acupuncture.

Assessment of quality of life (QoL) has been shown to be one of the most adequate tools for evaluating CIM, as the questionnaire includes subjective questions about the patient’s perception of their feelings, health, social conditions and the environment where they are living, besides evaluating their satisfaction with various aspects of their day-to-day lives.^{6,7}

The objective of our study was to evaluate the QoL of women treated with homeopathy at public outpatient clinics in one of the largest public health programs in the country that provides free CIM treatment. Evaluations were conducted prior to their treatment and after a 6-month period.

Materials and Methods

This is an unblinded prospective randomized controlled pragmatic trial that was approved by the Ethics Committee of the *Universidade Federal de Minas Gerais* (protocol# 747.559, ClinicalTrials.gov identifier: NCT02504515) and the *Prefeitura Municipal de Belo Horizonte* (Belo Horizonte Municipal Government). It took place in a single center and consisted of an experimental group that underwent homeopathic treatment (Group 1) and a control group (Group 2) that remained with conventional treatment only.

Patients eligible for the study were women aged 18 years and over, with at least one chronic complaint, who were not being treated with any CIM practice prior to the study and who had never been treated with homeopathy. Patients were enrolled by the research team and were assigned to intervention by a PhD student. A computer-generated list of random numbers was produced by the principal investigator for patient allocation in each of the two groups to avoid patient allocation bias. After signing the informed consent form, patients were randomized into one of the two groups, strictly following the computer randomized table.

The homeopathic intervention was the only difference between the two groups. All patients in both randomized groups maintained their conventional medical treatment of

chronic diseases when necessary. Randomized patients in Group 1 started their treatment with a homeopathic doctor within 15 days following Interview 1. There was no interference in the treatment provided by the homeopathic physicians in either group: e.g., choice of medication, number of consultations, or interval between them. In this study, all homeopaths are physicians and have taken specific specialization courses after their medical school. The vast majority of the homeopaths participating in the study follow the classical individualized homeopathy approach.

Patients, data analysts and researchers were not blinded to treatment. Only homeopathic physicians and allopathic physicians were blinded to the research protocol: these physicians tended their patients in their usual way without knowing that the research patients were participating in this study. The time between consultations was defined by each homeopathic doctor; usually patients returned for consultations every 2 or 3 months.

The World Health Organization QoL abbreviated questionnaire, named WHOQOL-BREF, was used. It is composed of questions distributed in four domains: physical, psychological, social, and environmental (**Supplementary File S1**, available online only). This questionnaire has already been translated and validated into Portuguese, possessing specific syntax analysis tools in the Statistical Package for the Social Science (SPSS) software.^{6,7} All patients were interviewed at the beginning of the study (Interview 1) and after 6 months (Interview 2) at public outpatient clinics. Interviews consisted of answering the WHOQOL-BREF questionnaire and a specific form about socio-demographic conditions and main health complaints. To make a subjective analysis of perception of their own health, the patients were asked the question “How is your health?”, to which they gave an answer on a scale of 1 to 5, with 5 being associated with best personal perception of health (1 = very bad; 2 = bad; 3 = neither good nor bad; 4 = good; 5 = very good).

The CONSORT (Consolidated Standards of Reporting Trials) flow diagram provides information about allocation, follow-up and analysis of the homeopathy research (– **Fig. 1**). The recruitment and follow-up occurred between April 2015 and November 2016. The CONSORT checklist is shown in **Supplementary File S2**, available online only.

The primary outcome was the QoL, and the secondary outcome was subjective analysis of the patients’ perception of their own health. The collected data were analyzed with SPSS using the WHOQOL-BREF syntax.⁷ Categorical variables were compared using Fisher’s Exact test. Normality of distribution was evaluated using the Shapiro-Wilk test. To evaluate the change in QoL after 6 months for each group, the paired sample *t*-test or the Wilcoxon non-parametric test was used. For comparison between groups, the independent-samples *t*-test or the non-parametric Mann-Whitney test was used. The significance level was set at $p < 0.05$.

The Minitab paired *t*-test for comparisons before and after intervention was used (Minitab version 14, Minitab Inc., State College, Pennsylvania, USA). The Minitab program and previous studies’ data were used for sample size calculation: a sample size of 49 individuals in each group

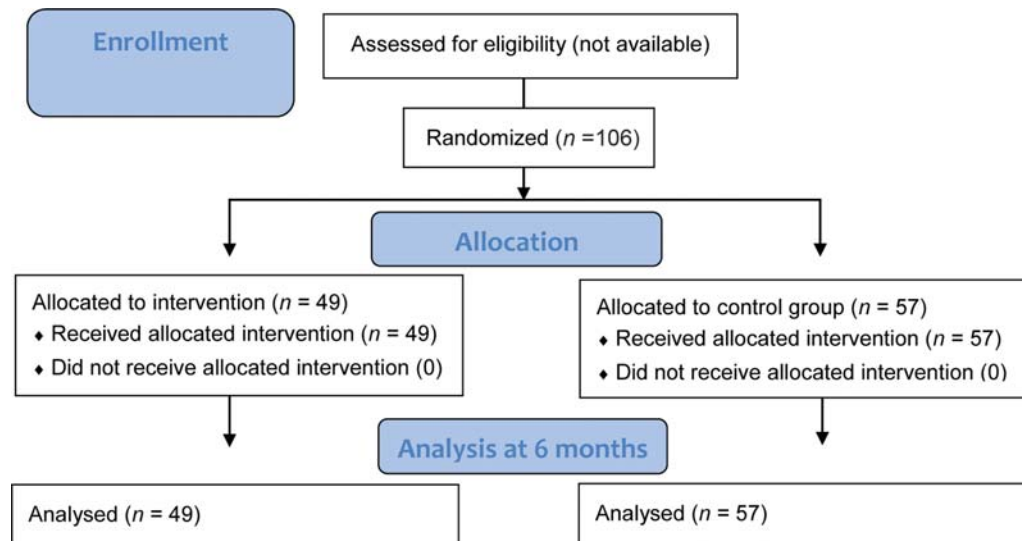


Fig. 1 CONSORT (Consolidated Standards of Reporting Trials) flowchart. Group 1 (on the left side) received homeopathic plus conventional medical treatment; Group 2 (control, on the right side) received conventional medical treatment only.

represents 80% statistical power to detect a difference from 8.7 among the means of all domains, with a standard deviation of 15.2. A possible loss of up to 20% of the sample was considered.

Results

A total of 106 patients completed Interview 2 and were included in this study. Socio-demographic characteristics of the patients demonstrate similarity between treated and control groups at baseline evaluation (►Table 1).

►Fig. 2 shows the most frequently reported health problems of the patients in each group. Most patients suffered from anxiety, joint problems, and headache. There was no significant difference between Groups 1 and 2 regarding the frequency of complaints.

►Table 2 shows a significant improvement of health perception in Group 1 after 6 months of homeopathic treatment ($p < 0.01$) but remained similar in the control group ($p = 0.954$), resulting in significant difference between groups in Interview 2 ($p = 0.001$).

The median number of homeopathic consultations was 2.0 (inter-quartile range [IQR], 1.0–3.0) for the 6-month period.

Mean and median WHOQOL-BREF scores for each domain at baseline and after 6 months of the homeopathic treatment are described below (►Table 3).

There was an improvement after a 6-month period in WHOQOL-BREF scores in physical, psychological, and social domains in Group 1. In the control group there was also a slight increase in the scores of these domains. However, the improvement in the treated group was more pronounced, especially in the physical domain, resulting in statistically significant difference between groups after 6 months.

Table 1 Socio-demographic characteristics of the patients in both groups

	Homeopathy	
	Group 1	Group 2
Women	49	57
Age, mean \pm SD	52.59 \pm 13.4	54.33 \pm 14.0
p-Value	0.515	
Years of schooling, mean \pm SD	7.50 \pm 4.5	7.29 \pm 4.4
p-Value	0.817	
BMI, median (IQR)	26.74 (25.2–30.4)	26.80 (24.1–32.5)
p-Value	0.947	
Skin color, n (%)		
White	14 (28.6)	17 (29.8)
Black	12 (24.5)	5 (8.8)
Brown	23 (46.9)	35 (61.4)
p-Value	0.081	
Marital status, n (%)		
Single	9 (18.4)	13 (22.8)
Married/stable relationship	28 (57.2)	26 (45.6)
Divorced	6 (12.2)	8 (14.0)
Widow	6 (12.2)	10 (17.6)
p-Value	0.585	

Abbreviations: BMI, body mass index; IQR, inter-quartile range; SD, standard deviation.

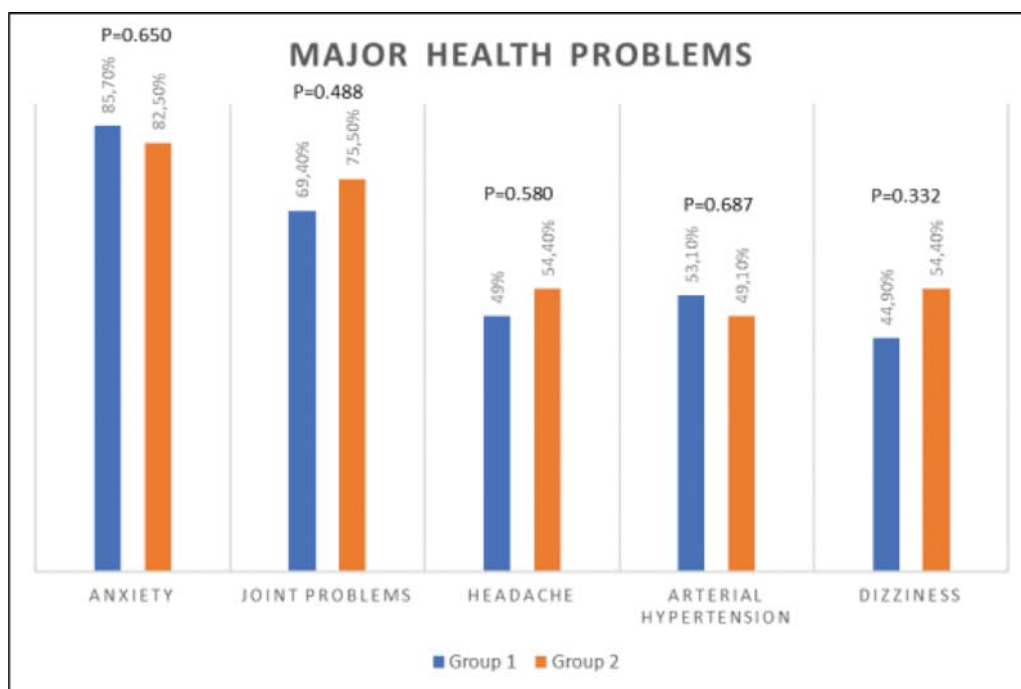


Fig. 2 Principal health problems of patients from both groups, showing percentage of those with the referred pathology.

Table 2 Patients' own subjective health evaluation between Group 1 and Group 2

	Baseline		After 6 months	
	Group 1	Group 2	Group 1	Group 2
Median	3.0	3.0	4.0	3.0
IQR	3.0–3.5	3.0–3.0	3.0–4.0	2.25–4.0
p-Value	0.65		0.001	

Note: WHOQOL-BREF QoL questionnaire scale 1 to 5, where 1 = very bad and 5 = very good.

Abbreviation: IQR, inter-quartile range.

Discussion

To the best of our knowledge, this is the largest randomized clinical trial performed to evaluate the QoL of patients with chronic diseases treated with homeopathy in a public outpatient clinic setting in our country.

Our main objective was to analyze the QoL after using homeopathy, but without the intention of evaluating a homeopathic medicine or specific homeopathic treatment for any given chronic disease. Thus, the research was designed to evaluate, in a general way, how the complementary use of homeopathy could intervene in the QoL of patients with chronic diseases.

Our data, concerning the QoL of women measured through the WHOQOL-BREF questionnaire, suggest that there is a positive impact of homeopathic treatment provided by this institution. This positive impact of homeopathy was perceived through a statistically significant improvement of the physical domain after 6 months of treatment.

Table 3 Means and median scores of WHOQOL-BREF domains after 6 months (Interview 2)

	Interview 2		
	Homeopathy	Control	p-Value
Women	49	57	
<i>Domain physical</i>			
Mean ± SD	63.6 ± 15.8	53.1 ± 16.7	<0.01
Median (IQR)	64.3 (51.8–75.0)	53.6 (42.9–64.3)	
<i>Psychological</i>			
Mean ± SD	62.1 ± 14.5	59.0 ± 15.6	0.29
Median (IQR)	62.5 (54.2–70.8)	62.5 (50.0–70.8)	
<i>Social</i>			
Mean ± SD	66.8 ± 18.9	60.4 ± 20.8	0.12
Median (IQR)	66.7 (58.3–83.3)	66.7 (50.0–75.0)	
<i>Environmental*</i>			
Mean ± SD	56.3 ± 12.5	50.1 ± 14.3	0.02
Median (IQR)	56.2 (50.0–62.5)	50.0 (43.7–56.2)	

Abbreviations: IQR, inter-quartile range; SD, standard deviation.

Note: Values in bold had statistical significance.

*The environmental domain already had a statistical difference at the beginning of the research.

These improvements are consistent with the finding of a better subjective perception of health in patients treated

with homeopathy in contrast to control group results. Our results confirm and support the data found in non-randomized studies that have already been published. In an Indian study,⁸ 34 patients with chronic allergic rhinitis were submitted to homeopathic treatment. After 1 year, that study observed statistically significant improvement of both clinical and laboratory parameters, as well as QoL scores in all domains of WHOQOL-BREF.

Another study followed 45 women with breast cancer after an average of three to five consultations of classical individualized homeopathy and demonstrated a significant improvement in the European Organization for Research and Treatment in Cancer—Quality of life Questionnaire—Core 30 (EORTC-QOL-30) scores.⁹

Another prospective, non-controlled study, which evaluated 53 patients undergoing individualized homeopathic treatment for headaches for 4 and up to 6 months, used the SF-36 questionnaire and described a significant improvement in all parameters, especially in questions related to vitality and body ache.¹⁰

A group of patients with diabetic polyneuropathy in Italy were compared with a control group that received conventional treatment. After 1-year follow-up, only the group on homeopathic treatment showed improvement in QoL scores assessed by the SF-36.¹⁰ Two multi-center studies evaluated the QoL through a specific questionnaire, which was applied to European and Brazilian patients undergoing homeopathic treatment. The authors observed improvement in QoL parameters for several clinical situations, in adults and children.¹⁰

In a randomized, double-blind, placebo-controlled trial that included 50 women aged 18 to 45 years with diagnosis of deeply infiltrating endometriosis, potentized estrogen (12cH, 18cH, and 24cH) or placebo was administered twice daily. The treatment group showed decrease of pelvic pain and significant improvement in three of eight SF-36 domains (bodily pain, vitality, and mental health) and depression symptoms.¹⁰

The main finding of our study was the pronounced improvement of the physical domain after the homeopathic treatment. The physical domain of the WHOQOL-BREF questionnaire includes items on: pain or discomfort; sleep and rest; energy and fatigue; mobility; work capacity; activities of daily living; and dependence on medicinal substances or aids.

Improvements in the QoL provided by homeopathy used in a complementary manner demonstrated an additional benefit during the treatment of patients with chronic diseases that was not observed in the control group. An improvement of global health status has been described in a pragmatic controlled trial on cancer patients randomized to receive complementary homeopathic treatment together with anti-neoplastic therapy.¹¹ Although many researchers may believe that homeopathy has only psychological effects, in this study improvement in the physical domain was more pronounced than in the psychological domain, which is a fact that can mean a real somatic effect of the homeopathic treatment used.

Little is known about the long-term effects of homeopathic treatment. One study, conducted in Germany, followed for 4 years patients with various clinical conditions treated by homeopathy or acupuncture. All QoL measures revealed substantial improvement over the first 6 months after treatment and this effect remained more or less stable over the following years.¹⁰

The loss to follow-up in patients in randomized studies is a regrettable, frequent, occurrence and is often difficult to control. This fact has limited adequate conclusions of many scientific studies. In our study, we recognize the limited conclusions that are feasible from a study of only 6 months' duration on chronic diseases.

Highlights

- A randomized pragmatic trial was performed to evaluate quality of life (QoL) of patients with chronic diseases treated with homeopathy in the Brazilian Public Health System.
- There was a positive impact of homeopathy on QoL, demonstrated after 6 months of treatment by a significantly greater improvement of the physical domain of the WHOQOL-BREF questionnaire compared with controls.
- These improvements are consistent with the finding of a better perception of health in patients treated with homeopathy than in control-group individuals.

Supplementary File 1. WHOQOL-BREF domains.
Supplementary File 2. CONSORT checklist.

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Conflict of Interest

None declared.

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