Response to Individualized Homeopathic Treatment for Depression in Climacteric Women with History of Domestic Violence, Marital Dissatisfaction or Sexual Abuse: Results from the HOMDEP-MENOP Study

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Abstract

Background Although individualized homeopathic treatment is effective for depression in climacteric women, there is a lack of well-designed studies of its efficacy for depression in battered women or in post-traumatic stress disorder. The aim of this study was to assess the association between individualized homeopathic treatment or fluoxetine and response to depression treatment in climacteric women with high levels of domestic violence, sexual abuse or marital dissatisfaction.

Materials and Methods One hundred and thirty-three Mexican climacteric women with moderate-to-severe depression enrolled in the HOMDEP-MENOP Study (a randomized, placebo-controlled, double-blind, double-dummy, three-arm trial, with a 6-week follow-up study) were evaluated. Domestic violence, marital dissatisfaction and sexual abuse were assessed at baseline. Response to depression treatment was defined by a decrease of 50% or more from baseline score of Hamilton scale. Association between domestic violence, sexual abuse, and marital dissatisfaction and response to depression treatment was analyzed with bivariate analysis in the three groups. Odds ratio (OR) and 95% confidence interval (CI) were calculated.

Results Homeopathy versus placebo had a statistically significant association with response to depression treatment after adjusting for sexual abuse (OR [95% CI]: 11.07 [3.22 to 37.96]), domestic violence (OR [95% CI]: 10.30 [3.24 to 32.76]) and marital dissatisfaction (OR [95% CI]: 8.61 [2.85 to 25.99]).

Conclusions Individualized homeopathic treatment is associated with response to depression treatment in climacteric women with high levels of domestic violence, sexual abuse or marital dissatisfaction. Further studies should be conducted to evaluate its efficacy specifically for post-traumatic stress disorder in battered women.

ClinicalTrials.gov Identifier: NCT01635218, URL: http://clinicaltrials.gov/ct2/show/NCT01635218?term=depression+homeopathy&rank=1

Keywords

► individualized homeopathic treatment
► fluoxetine
► domestic violence
► sexual abuse
► menopause
► depression
► post-traumatic stress disorder
► Mexico

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Introduction

Menopause is a stage of hormonal changes in a woman's lifetime. A significant association between menopausal transition and a higher risk of developing depression has been demonstrated. Domestic violence (DV), history of depression (HD), sexual abuse (SA), and marital dissatisfaction (MD) have also been linked to depression. DV against women is a widespread major health problem without religious, cultural, geographic or national boundaries. It is characterized by physical, economic (having control over woman's access to economic resources), psychological (actions aimed to dominate and manipulate women), and sexual (forcing undesired sexual activities by the partner upon the woman) abuse. It has a multifactorial etiology and has been associated with factors such as women's economic situation, education, prior experience of DV, alcoholic husband, among others. Its effects are devastating for women and for family as a whole. The World Health Organization (WHO) reported that 15% to 71% of women experienced physical violence and 22% sexual violence. The consequences of DV have a great impact on women's health. It has been stated that there is a bidirectional association between mental health (depression, anxiety or post-traumatic stress disorder [PTSD]) and abuse.

According to the last survey of the National Institute of Statistics and Geography (Instituto Nacional de Estadística y Geografía [INEGI]) in Mexico, 47% of women above 15 years have experienced some kind of violence by their partner in the last relationship. Emotional violence is the most frequent type of violence in all ages. Approximately 94% of women between 15 and 24 years experienced emotional violence, but only 30% economic violence, while women above 45 years are the most exposed to economic violence (60%). Physical and sexual violence are less frequent but both are increased with age. About 38% of women above 45 years experienced physical violence and 22% sexual violence.

Women with HD are up to five times more likely to have depression during the climacteric period. Moreover, abuse and DV are risk factors associated with depression and PTSD. PTSD is a mental health condition that is triggered by a terrifying event—either experiencing it or witnessing it. There are some risk factors associated with its development: exposure to traumatic events (violent personal assault, war, torture, SA during childhood), history of psychiatric disorders, poor social support, temperament traits, among others. Abused women are up to three times more likely to report depression, and physical and SA may lead to neuroendocrine disruption affecting ovarian function and potentially leading to altered age at perimenopause. The Study of Women's Health Across the Nation Mental Health Study indicated that childhood abuse or neglect is associated with significantly increased reporting of vasomotor symptoms during midlife. The Melbourne Women's Health Project indicated that intimate partner violence was associated with more bothersome symptoms (including vasomotor symptoms) and childhood SA with poor sexual functioning during menopause.

Therefore, during transition to menopause it is mandatory to examine women's health with a comprehensive approach emphasizing mental examination interrelated with physical symptoms as well. Women in menopause with a history of DV and/or SA might be suffering PTSD with overlapped symptoms such as anxiety or depression. Several psychological and pharmacological interventions are available today to treat these conditions. New evidence indicates that psychological interventions are efficient to control PTSD and improve quality of life. Selective serotonin reuptake inhibitors have been found to be useful. In case of homeopathy, there is a lack of high-quality controlled studies to prove its efficacy for the effects of DV, SA, MD, or specifically in PTSD in the general population.

The HOMDEP-MENOP study, a randomized controlled trial comparing individualized homeopathic treatment (IHT), fluoxetine, and placebo for depression in climacteric women, assessed some risk factors for depression and PTSD (SA, DV, MD, and HD) as a part of the routine examination of the menopause transition. The objective of this secondary analysis was to assess the association between IHT versus placebo and fluoxetine versus placebo in their response to depression treatment after adjusting for SA, DV, MD and HD.

Materials and Methods

Ethics Statement

The protocol was reviewed and approved by the Research and Ethics Committee of Juarez of Mexico Hospital (JMH) (Approval Number: HJM 2030/12-A). Prior to undertaking any study procedures, each participant received a verbal and written explanation about them.

Sample

Study sample was composed of women enrolled in the HOMDEP-MENOP study. Methods used, as well as sample size calculation for the primary analysis, have been previously described in detail. One hundred and thirty-three Mexican climacteric women with moderate-to-severe depression were evaluated between March 2012 and December 2013, in the out-patient service of homeopathy at JMH. Inclusion and exclusion criteria were fully described in the above article.

Study Design

A randomized, placebo-controlled, double-blind, double-dummy, three-arm trial, with a 6-week follow-up (the HOMDEP-MENOP study), previously published.

Data Collection

All participants underwent a complete baseline medical history and clinical examination. A complete homeopathic case-taking interview was also performed. The 17-item Hamilton Rating Scale for Depression (HRSD) and the Beck Depression Inventory (BDI) were used to evaluate depression severity. Response rate was defined by a decrease of 50% or more from baseline score of HRSD. Risk factors for depression were also assessed during the baseline examination, asking the questions listed in Table 1.
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Table 1 Clinical evaluation of risk factors for depression

<table>
<thead>
<tr>
<th>Risk factor</th>
<th>Question</th>
<th>Yes/No</th>
</tr>
</thead>
<tbody>
<tr>
<td>History of depression</td>
<td>Have you ever been diagnosed with depression at any time in your life, especially during menses, pregnancy, or post-partum and/or have you ever used anti-depressant medication?</td>
<td>Yes/No</td>
</tr>
<tr>
<td>Sexual abuse</td>
<td>Have you ever been frequently forced to an undesired sexual activity at any time in your life, especially during infancy?</td>
<td>Yes/No</td>
</tr>
<tr>
<td>Domestic violence</td>
<td>Have you frequently been physically, economically (having control over women’s access to economic resources), psychologically (actions aimed to dominate and manipulate women), and/or sexually attacked by your intimate partner at any time in your life?</td>
<td>Yes/No</td>
</tr>
<tr>
<td>Marital dissatisfaction</td>
<td>Have you frequently felt unsatisfied with your intimate partner or marital relationship at any time in your life?</td>
<td>Yes/No/No partner</td>
</tr>
</tbody>
</table>

Interventions

Study medications have been carefully described elsewhere. Study participants were randomly assigned to either one of the three groups: 1) IHT plus fluoxetine dummy-loaded; 2) fluoxetine (20 mg/d) plus IHT dummy-loaded; 3) fluoxetine placebo plus IHT placebo.

Statistical Analysis

Data were analyzed using SPSS statistical software (version 17.0). Primary analysis was previously reported elsewhere. Response rates were calculated at 6 weeks and compared among the groups using the chi-squared test. Then we compared response rates among groups stratified by risk factors (HD, SA, DV, and MD), also using the chi-squared test. To test the association between treatments (homeopathy versus placebo, fluoxetine versus placebo, homeopathy versus fluoxetine) and the binary outcome (response/non-response to depression treatment) taking into account the stratification (HD, SA, DV, and MD), Mantel–Haenszel test was used. If the p-values were > 0.05 in the tests of homogeneity of the odds ratio (OR) table, statistical assumption was not violated and the analysis was continued. A p-value < 0.05 was considered statistically significant for conditional independence between the groups on the outcome. This means that the association between the predictor and outcome variable is significantly different in the different levels of the conditional variable. OR with 95% confidence interval (95% CI) was also calculated.

Results

The demographic characteristics of study participants, CONSORT flow diagram, changes in HRSD and BDI scores, as well as response rates among groups, were reported previously. Overall, in the three groups, response rate was 36.1%. A decrease of 50% or more in HRSD score was observed in 54.5% of the homeopathy group, 41.3% of the fluoxetine group, and 11.6% of the placebo group ($\chi^2 = 18.1, 2$ degrees of freedom [df], $p < 0.001$). Baseline prevalence of risk factors for depression was also previously reported: there were no statistically significant differences among groups. Placebo and fluoxetine groups had the highest percentage of HD (67 and 63%, respectively, $\chi^2 = 0.372, 2$ df, $p = 0.857$). Homeopathy and fluoxetine groups had the highest percentage of DV (75 and 74%, respectively, $\chi^2 = 0.336, 2$ df, $p = 0.883$). Five women did not agree to respond to whether they had suffered SA. One in four women in the homeopathy group suffered SA in infancy. The fluoxetine and placebo groups had similar results in the case of SA (33 and 35% respectively, $\chi^2 = 0.582, 2$ df, $p = 0.748$). The fluoxetine group had the highest percentage of MD (61%), whereas half of the women receiving homeopathy had MD (54%). The placebo group had the lowest prevalence of MD (42%) ($\chi^2 = 4.13, 4$ df, $p = 0.397$).

Table 2 shows differences among groups regarding response to depression treatment, taking into account risk factors for depression. There were statistically significant differences among groups if they had HD ($\chi^2 = 14.293, 2$ df, $p < 0.001$). Results were statistically significant among groups in response rates in both cases, having or not having a history of SA and DV ($\chi^2 = 10.554, 2$ df, $p = 0.005$), $\chi^2 = 10.322, 2$ df, $p = 0.007$; $\chi^2 = 16.072, 2$ df, $p = 0.005$ respectively). There were no statistically significant differences among groups with respect to MD.

Table 3 shows evidence of a statistically significant association between homeopathy and response to depression treatment compared with placebo after adjustment for levels of HD, SA, DV or MD. Fluoxetine in comparison with placebo had similar results. For example, after adjusting for HD, homeopathy was 9.01 (95% CI, 2.98 to 27.20; $p < 0.001$) times more likely than placebo to have a response to depression treatment and, after adjusting for DV, 32.76; $p < 0.001$) times more likely than placebo to have such a response. In the case of fluoxetine versus homeopathy, there were no statistically significant associations: this means that these interventions did not differ in their relationships with the response to depression treatment following adjustment according to risk factor.

Discussion

This is the first study to examine the association between IHT versus placebo and response to depression treatment after adjusting for DV, SA, MD or HD in peri- and post-menopausal...
women with moderate-to-severe depression. Until now there had been no randomized controlled trials (RCTs) in which efficacy of IHT was indicated in climacteric women with depression and high levels of DV, MD, or SA. The significant p-value indicates that the association between IHT and response to depression treatment remains strong after adjusting for risk factors for depression. The results also indicate that fluoxetine is associated with significantly increased improvement in depression symptoms after adjusting for DV, SA, MD or HD.

However, several limitations should be considered. First, sample size was calculated for the primary analysis, aiming to detect an effect size = 0.45, in a three-group clinical trial design (1:1:1), to test treatment efficacy. Our results would have yielded better interpretation if sample size had been calculated to determine whether homeopathy versus placebo is associated with the response to depression treatment (the outcome of interest). The value of the OR would have suggested how much more likely someone under homeopathy prescription decreases ≥ 50% HRSD score (response to treatment), and the associated 95% CI indicates the range of values within which the true value very likely lies. Nevertheless, our results showed p-values below 0.005 for both homeopathy-placebo and fluoxetine-placebo, and all ORs

<table>
<thead>
<tr>
<th>Risk factor</th>
<th>Responsea</th>
<th>Homeopathy</th>
<th>Fluoxetine</th>
<th>Placebo</th>
<th>p-Value</th>
</tr>
</thead>
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<td>History of depression</td>
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<tr>
<td>Yes</td>
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</tr>
<tr>
<td>Yes</td>
<td>15 (55.6)</td>
<td>14 (48.3)</td>
<td>3 (10.3)</td>
<td>0.001b</td>
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</tr>
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<td>12 (44.4)</td>
<td>15 (51.7)</td>
<td>26 (89.7)</td>
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<td>Sexual abuse</td>
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<td>Yes</td>
<td></td>
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<tr>
<td>Yes</td>
<td>7 (38.9)</td>
<td>6 (40)</td>
<td>0 (0)</td>
<td>0.011a</td>
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<tr>
<td>No</td>
<td>11 (61.1)</td>
<td>9 (60)</td>
<td>15 (100)</td>
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<tr>
<td>Domestic violence</td>
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<td></td>
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<td>Yes</td>
<td></td>
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<tr>
<td>Yes</td>
<td>16 (64)</td>
<td>13 (44.8)</td>
<td>5 (19.2)</td>
<td>0.005g</td>
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<tr>
<td>No</td>
<td>9 (36)</td>
<td>16 (55.2)</td>
<td>21 (80.7)</td>
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<td>Marital dissatisfaction</td>
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<td>Yes</td>
<td></td>
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<tr>
<td>Yes</td>
<td>12 (50)</td>
<td>9 (32.1)</td>
<td>3 (16.7)</td>
<td>0.075b</td>
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</tr>
<tr>
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<td>12 (50)</td>
<td>19 (67.9)</td>
<td>15 (83.3)</td>
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<tr>
<td>No partner</td>
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<tr>
<td>Yes</td>
<td>10 (62.5)</td>
<td>7 (58.3)</td>
<td>2 (10.5)</td>
<td>0.003c</td>
<td></td>
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<td>No</td>
<td>6 (37.5)</td>
<td>5 (41.7)</td>
<td>17 (89.5)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*aResponse to depression treatment. All \( \chi^2 \) with 2 df: \( \chi^2 = 14.293; \chi^2 = 5.345; \) Fisher’s exact test = 9.332; \( \chi^2 = 10.554; \chi^2 = 10.032; \)
\( \chi^2 = 10.607; \chi^2 = 5.168; \chi^2 = 11.888; \) Fisher’s exact test = 4.392.
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Table 3 Association between treatments and response to depression treatment taking into account risk factors for depression

<table>
<thead>
<tr>
<th>Risk factor</th>
<th>Homeopathy-placebo OR (95% CI)</th>
<th>Fluoxetine-placebo OR (95% CI)</th>
<th>Fluoxetine-homeopathy OR (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>History of depression Yes/No</td>
<td>9.01 (2.98 to 27.20) ( p &lt; 0.001^a )</td>
<td>5.29 (1.77 to 15.81) ( p = 0.003^a )</td>
<td>1.72 (0.74 to 3.98) ( p = 0.291^a )</td>
</tr>
<tr>
<td>Sexual abuse Yes/No</td>
<td>11.07 (3.22 to 37.96) ( p &lt; 0.001^b )</td>
<td>5.47 (1.77 to 16.92) ( p = 0.004^c )</td>
<td>1.59 (0.67 to 3.75) ( p = 0.394^c )</td>
</tr>
<tr>
<td>Domestic violence Yes/No</td>
<td>10.30 (3.24 to 32.76) ( p &lt; 0.001^d )</td>
<td>5.54 (1.82 to 16.89) ( p = 0.003^e )</td>
<td>1.75 (0.75 to 4.11) ( p = 0.280^e )</td>
</tr>
<tr>
<td>Marital dissatisfaction Yes/No/no partner</td>
<td>8.61 (2.85 to 25.99) ( p &lt; 0.001^f )</td>
<td>5.29 (1.76 to 15.90) ( p = 0.003^g )</td>
<td>1.62 (0.69 to 3.78) ( p = 0.374^g )</td>
</tr>
</tbody>
</table>

Abbreviations: CI, confidence interval; OR, odds ratio.
Test of conditional independence Mantel–Haenszel\( \chi^2 \) (all \( \chi^2 \) with \( 1 \) df):
\( ^a \)15.697; \( ^b \)15.432; \( ^c \)16.979; \( ^d \)15.369; \( ^e \)8.542; \( ^f \)8.367; \( ^g \)8.527; \( ^h \)8.893; \( ^i \)1.117; \( ^j \)0.726; \( ^k \)1.169; \( ^l \)0.509.

With 95% CI were above 1.00, with the exception of the homeopathy–fluoxetine OR \( p > 0.05 \). Therefore, further studies specifically designed to test the response to homeopathic treatment for the effects of high levels of violence and PTSD should have an adequate sample size calculation to ensure statistical power.

Second, the mental health examination did not include any standardized tool specifically used for evaluating DV, SA, or MD. Only depression severity was determined with two well-known standardized scales used worldwide (HRSD and BDI). The assessment of the exposure was general, not specific to life stage, frequency, duration, or severity. Only the question about SA asked about infancy specifically. Moreover, many women in this study could have been suffering from undiagnosed depression and PTSD. According to the Diagnostic and Statistical Manual of Mental Disorders, 5th Edition (DSM-V), PTSD is a disorder that requires the exposure to a traumatic event. It has often been linked to rape, child SA, wars, mass catastrophes, or natural disasters, but more recently studies have demonstrated that severe violence is not a determinant to experience PTSD symptoms, but it can exacerbate PTSD severity.16

Domestic violence could be declared a national epidemic based on the magnitude of its incidence in some countries, such as the United States or Iran.16 Our results show that a great number of Mexican women might have been suffering from DV, SA, and MD for a long time as something ‘normal’ in their lives. Screening was important because most women included would not otherwise have been diagnosed or treated. The National Institute of Women (Instituto Nacional de las Mujeres—INMUJERES) is a public institution that belongs to the Mexican government and coordinates compliance with the national policy on substantive equality and human rights and contributes to the eradication of violence against women. Although INMUJERES has programs to give social support as well as legal assistance to battered women, violence against women is still a huge social problem in Mexico.17

Women who have experienced severe episodes of DV present high levels of distress18 and report increased depression when they seek advocacy support.19,20 Most of the women included in the HOMDEP-MENOP study had only elementary school education and low income. It has been confirmed that socio-demographic characteristics, such as being female and less educated, are risk factors for PTSD.13 Exposure to psychological abuse, even without physical abuse, has a strong effect on mental health, which is often unrecognized.3 Psychological abuse may be as damaging as physical violence. Additionally, recent studies have demonstrated that severe violence is not a determinant to experience PTSD symptoms, but it can exacerbate PTSD severity.16

As previously stated, depression often co-occurs with PTSD. It has been published that PTSD patients with co-morbid depression experienced more severe PTSD symptoms and need higher doses of psychotropic drugs during longer periods of time.21 Furthermore, for some authors it is mandatory that the evaluation of victims includes both PTSD and depression assessment scales because co-occurrence of both disorders might be associated with difficulties in treatment.21 A meta-analysis of depressive symptom outcomes in RCTs for PTSD concluded that co-morbid depression appears to be effectively treated with existing PTSD treatments (fluoxetine, sertraline, paroxetine, among others), and that clinicians can use PTSD treatments as first-line treatment for co-morbid depressive symptoms.22

Post-traumatic stress disorder is frequently considered to be a relatively new diagnosis. Although the name first
appeared in 1980, the DSM-I published in 1952 stated the
diagnosis under the name ‘gross stress reaction’. Nowadays, with the definition of PTSD, clinical psychiatry is
raising important questions about the consequences of the individual’s experiences of different kinds of violence and
the relationship between the victim and the stressor. Individualized prescriptions in homeopathy have been giving
importance to this issue since a long time ago. Homeopathy has been in use worldwide for over 200 years. The
routine practice of homeopathy implicates treating the person as a whole. Homeopathy has always focused on the
relevance of the effects of traumatic psychological events on the individual’s health and the importance of taking them
into account when selecting a homeopathic remedy. In classical homeopathy, a comprehensive approach that gives
special importance to mental symptoms when selecting the remedy is essential. Mental symptoms have the highest
hierarchy when prescribing. The Homeopathic Materia Media (body of collected knowledge about the therapeutic
properties of homeopathic remedies) describes homeopathic medicines frequently used for mental symptoms
caused by violence, anger, humiliation, fear, grief, death, or ailments after being abused (physically, in marriage, as
children or sexually).

Although homeopathy is frequently used to treat emotional symptoms in daily practice, there is a lack of RCTs for
many psychiatry conditions. Davidson et al in 2011 stated that the studies of homeopathy and placebo for psychiatric
conditions are limited; there is evidence supporting the benefit of homeopathy for fibromyalgia and functional
somatic syndromes. Adler et al conducted a non-inferiority trial comparing IHT with Q-potencies versus fluoxetine for
depression in a general population and found that there were no statistically significant differences between them.
Grolleau et al found that 1.3% of persons in a general population used homeopathic treatment for psychiatric symptoms. Younger age, female gender, and high educational level were associated with the use of homeopathy. Half of homeopathy users presented at least one diagnosis, most frequently anxiety disorder. Another study, in Australia, reported that most homeopathic practitioners provide a pluralistic approach to management of depression. Eighty-four percent were prescribing homeopathic treatments to patients who were also receiving other therapy, most commonly anti-depressant medications. In the case of PTSD, 3.4% of war veterans reported that they were more likely to use homeopathy in the past 12 months.

In conclusion, based on the high levels of DV or SA, the clinical evaluation of climacteric women should include screening for PTSD, especially in depressed women. IHT should include a multi-disciplinary professional staff with special training in PTSD and DV assessment. Routine information on DV prevention and treatment should also be mandatory. IHT is an effective treatment for depression in women with high levels of DV, SA and MD, but further studies should be conducted to evaluate its efficacy for PTSD in battered women.

Highlights
- Women in menopause with a history of DV and/or SA might be suffering PTSD with overlapped symptoms such as anxiety or depression.
- Individualized homeopathic treatment is associated with response to depression treatment in climacteric women with high levels of DV, SA or MA.
- There is a lack of well-designed studies of the efficacy of homeopathy for depression in battered women or in PTSD.
- Further studies should be conducted to evaluate the efficacy of homeopathy specifically for PTSD.

Conflict of Interest
None.

Funding
No external funding was provided for this trial. Homeopathic medicines, fluoxetine, and placebo were kindly donated by Laboratorio Similia, Mexico City.

Authors’ Contributions
E.C.M.C. and J.A.B. participated in the design of the study. E. C.M.C. and L.L.G. evaluated study participants. E.C.M.C., J.A.B., and L.A.F. were responsible for the analysis and interpretation of data. E.C.M.C, J.A.B, and L.A.F were substantially involved in drafting and revising the manuscript and gave final approval of the submitted version of the document. All authors read and approved the final manuscript.

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