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Efficacy of Cognitive Behavioral Therapy for Habit Modification and Drug Adherence in Obesity

Eficacia de la Terapia Cognitivo Conductual para Modificación de Hábitos y Adherencia Farmacológica en Obesidad

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Abstract

The obesity is a global health problem, also it is increasing in adults and pediatric population, reducing life quality. Treatment must be interdisciplinary with elements of behavior modification on self-control, habit modifications, support networks and highlighting to adherence. Cognitive behavioral therapy, specifically on problem solving model, is efficient in treatment of anthropometric control, metabolic and behavioral indicators. Methods: Quasi-experimental, comparative, clinical and randomized study, n=100 adults of both sexes with an exogenous obesity diagnostic. The intervention was performed with an interdisciplinary treatment of cognitive behavioral therapy on problem solving model and 3mg. (0-0-1) of melatonin (50 subjects), comparing it with a group that only received the treatment by melatonin 3mg. (0-0-1) (50 subjects) per 8 months; the anthropometry and blood biochemical values (glucose, triglycerides, HDL and LDL) was evaluated after and before; dropout rate and adherence to the drug was evaluated every month. A bioimpedance machine was used. Results: The analysis demonstrated in eight months that the problem solving model with melatonin group got an adherence average of 80% (p= .05); in comparison with melatonin group that showed an average of 48% (p= .05). Relating to anthropometry and blood biochemical values, problem solving model and melatonin group got better effectiveness
Obesity grows year after year in the world on a par with its comorbidities. On its being a multifactorial nosological entity, the regulations, and agreements, including Official Mexican Regulation (Norma Oficial Mexicana, NOM) for the treatment of obesity (SEGOB, 2010), the World Health Organization (WHO, 2004) and the SEEDO Consensus, among others (Gargallo et al., 2012) indicate that the treatment should be implemented with an interdisciplinary methodology, which includes, within the health team, the Psychologist, with competencies in the area, whose behavioral objectives comprise the increase in self-control of the ingestion of food, behavioral modification, (Foster, Sánchez-Collins & Cheskin, 2017), and the management of therapeutic adherence, which includes pharmacological treatment (Hurren & Dunham, 2017).

Adherence (ADH) is defined as the behavioral degree at which the patient, consciously and motivatedly, directs the taking of their medication in terms of the time, form, and grade it entails in order to carry out the guidelines of the treatment at the short, medium, and long term (OMS, 2004; Sieverink, Kelders & van Gemert-Pijnen, 2017). In chronic degenerative diseases, ADH is 30 and 50% at 4 months of treatment (OMS, 2004); however, these percentages could improve significantly with the use of Cognitive Behavioral Therapy (CBT), whose specific techniques are based on the problem-solving and decision-making model, with the addition of social reinforcers,
the strengthening of self-confidence, self-control and self-efficacy, behavioral registries, and cognitive restructuring (Aguilera-Sosa et al., 2011; Murawski et al., 2009).

CBT through a meta-analysis showed to be efficient on diminishing the rate of treatment abandonment, in addition to improving motivation in terms of the change and in the prevention of relapse (Burgess, Hassmén, Welvaert & Pumpa, 2017). However, it is noteworthy that this work did not focus on data derived from the ADH evaluation concerning the medication, which is an important omission according to the World Health Organization (WHOOMS, 2004) and of the FEDNAD-SEEDO Consensus (Gargallo et al., 2012).

On its part, in medical environments, it is postulated as an intervention model for ADH; the psychoeducation that surrounds the importance of the treatment for controlling the signs and symptoms of obesity (Schaub, Hippius, Möller & Falkai, 2016). However, these methods have not exhibited therapeutic efficiency in the medium term.

To evaluate ADH in terms of the medication, direct (specific metabolic measurement) and indirect (validated instruments) methods are employed; notwithstanding this, observation of the behavior can be more efficient utilizing indirect methods (Brown & Bussell, 2011; Nagpal, Prapavessis, Campbell & Mottola, 2017), being that of no taking of tablets in relation to the time, which is that recommended by the Mayo Clinic (Brown & Bussell, 2011).

The recent use of Melatonin (ML) has been increasing as a drug for the control of OB, mainly as a pathway of control of the harmful effects of inflammation and due to its antioxidant activity (Favero et al., 2015), as well as for its effect on the metabolism of the adipocytes, contributing to lipid diminution in blood, thus improving the Atherogenic Index (IAT) (Szewczyk-Golec et al., 2017; Valenzuela-Melgarejo, Caro-Díaz & Cabello-Guzmán, 2018). In comparison with other drugs, ML exhibits low adverse effects; therefore, the objective of the present work was to evaluate the effectiveness of an interdisciplinary intervention of CBT with treatment with ML alone in ADH of the medication, and the anthropometric and blood-chemistry values. The hypothesis, is that CBT with ML will have greater statistical significance in the anthropometric, blood-chemistry and ADH, than the treatment of ML alone, in obese.

Method

Quasi-experimental research design, clinical, probabilistic, and comparative-efficiency study, between two groups.

Participants

Mexicans residing in Mexico City, Mexico, with a diagnosis of exogenous Obesity (Ob), of both sexes and without comorbidities: n = 100; between the ages of 25 and 55 years; who attended the meetings convened, and who complied with the inclusion criteria, comprising simple Ob, the signing of informed consent for participation in the study; not having received treatment for Ob for 6 months prior to study initiation; availability of the time required for attending a medical consultation and psychological treatment. Exclusion criteria included the following: the psychiatric diagnosis described in the patient’s clinical history; gestational state; anomalies in the electrocardiogram; daytime hypersomnolence; diabetes; hypertension; metabolic syndrome; cirrhosis of the liver; cancer; smoking; alcoholism, and drug addiction (Figure 1).

Procedure

An announcement was made in electronic networks, flayers were given in the immediate vicinity of the Lázaro Cárdenas Unit and the subways, patients from the schools’ clinics were invited (Figure 1). The study subjects were randomly divided into two groups by picking numbers from a bowl: 1) the experimental group submitted to CBT and to pharmacological treatment with ML (n = 50), and 2) the treatment group with ML alone (3 mg daily) (Cronocaps®) (n = 50). The average age of the
CBT+ML group was 35.53±10.22 years and, in the ML alone group, this was 35.33±8.90 years. A total of 46.9% of the patients were married, and 44.9% were single. The duration of the study was 8 months, and it was carried out at the installations of the Escuela Superior de Medicina del Instituto Politécnico Nacional (ESM-IPN). The procedures were approved by the Institution’s Committee (CEI-CICS-010); similarly, the patients’ personal data were managed in a confidential manner, and those who participated in the study received the complete intervention and the medication without cost.

**Evaluations and Instruments**

We evaluated the following: (I) number of returned tablets monthly in the study groups; (II) percentage of treatment abandonment during the 8 study months; (III) differences in the Body Mass Index (BMI); (IV) percentage of fat by means of the bioimpedance scale (Tanita, model BC533), as well as (V) the blood chemistry of glucose, lipids, triglycerides, cholesterol, and High-Density Lipoproteins (HDL) and Low-Density Lipoproteins (LDL). We carried out the medical clinical and psychological history of each of the patients medical (based on the Structured Clinical Interview for the Diagnostic and Statistical Manual of Mental Disorders of the DSM-V). The first group attended a 2½-h session weekly during 8 months to receive the CBT intervention. The consultations for medical control and for returning the unused tablets were held monthly or in case of the need of the patient. The percentage of returned tablets was evaluated monthly, anthropometric measurements were performed prior to the initiation of the intervention and at 8 months, and blood-chemistry measurements were being conducted at the beginning of the intervention and at 8 months. The psychological therapy was carried out by four Psychologists who had received their formation in the Psychology of Health and in CBT.

The CBT program followed the line of a previously developed program (Aguilera-Sosa, Leija, et al., 2009; Leija-Alva et al., 2011), with the addendum of ADH management. The CBT-group assistants were provided with a participant’s manual that included the contents of the 32 sessions. Every 2 weeks, the Psychologists met to supervise and homogenize the system of psychological intervention. The framework for the application of the problem-solving therapy was based on the elements by Murawski et al. (2009) (Table 1).

![Figure 1. Proces diagram. Process Flowchart from selection of n to application of instruments at end of treatment.](image)
Statistics

For the statistical analysis performed by means of the SPSS ver. 22.0 statistical software program, we used central trend measurements, dispersion, frequencies, and percentages. We applied the Kolmogorov-Smirnov test to evaluate data distribution; in the comparative analysis, we applied the Student t test for independent samples, and the Student t test for related samples; for the monthly analysis of the number of returned tables with regard to the type of intervention, we employed the Analysis Of Variance (ANOVA) assay of repeated measurements. We established a value of \( p = 0.05 \) as statistically significant.

Results

Dropout percentages were taken, from users that did not finish the treatment. With respect to the ADH, we may observe in Table 3 the average of tablets returned to the treating physician and its comparison between the groups (CBT+ML vs. ML alone), taking the monthly evaluation into account. It can be observed that the CBT+ML group exhibited a significant diminution of returned tablets between the initial and the final month (2.93±1.54 vs. 1.62±1.18; \( p = 0.0001 \)), while the ML alone group presented an increase (2.73±1.21 vs. 9.11±1.14; \( p = 0.0001 \)); it is also shown that the average number of returned tablets was different (\( p = 0.005 \)) between both treatments from month 3, this less in the CBT+ML group (2.18±0.89 vs. 3.30±1.73; \( p = 0.05 \)); this tendency was maintained until month eight.

Table 2
Percentages by sex of the groups

<table>
<thead>
<tr>
<th></th>
<th>Women</th>
<th>Men</th>
</tr>
</thead>
<tbody>
<tr>
<td>CBT+ML (( n = 50 ))</td>
<td>86% (43)</td>
<td>14% (7)</td>
</tr>
<tr>
<td>ML (( n = 50 ))</td>
<td>88% (41)</td>
<td>12% (9)</td>
</tr>
</tbody>
</table>

Note: CBT = Cognitive Behavioral Therapy; ML = Melatonin
In Tables 4 and 5, the results are presented of Body Mass Index (BMI) and the percentage of initial and final fat, as well as the results of glucose, triglycerides, HDL, and LDL, before and after the 8-month intervention.

In the initial anthropometry evaluation, which involves BMI and the percentage of fat, significant results were not found in measurements between the groups, while in the final measurements of these values, we identified significant results in favor of the CBT+ML; however, in the ML alone group, the final differences were significant, although less than those of the CBT+ML group.

Table 3
Comparison of the repeated measurements of the number of tablets returned to the treating physician in relation to the treatment group and the monthly evaluation

<table>
<thead>
<tr>
<th>Measurement</th>
<th>CBT+ML Mean ± SD (n = 50)</th>
<th>ML Mean ± SD (n = 50)</th>
<th>p</th>
<th>F</th>
</tr>
</thead>
<tbody>
<tr>
<td>September</td>
<td>2.93±1.54</td>
<td>2.73±1.21</td>
<td>0.58</td>
<td>0.30</td>
</tr>
<tr>
<td>October</td>
<td>2.71±1.22</td>
<td>3.15±1.75</td>
<td>0.27</td>
<td>1.22</td>
</tr>
<tr>
<td>November</td>
<td>2.18±0.89</td>
<td>3.30±1.73</td>
<td>0.002</td>
<td>10.03</td>
</tr>
<tr>
<td>December</td>
<td>2.37±1.80</td>
<td>3.53±1.67</td>
<td>0.01</td>
<td>6.32</td>
</tr>
<tr>
<td>January</td>
<td>1.68±1.28</td>
<td>4.23±1.53</td>
<td>0.0001</td>
<td>47.45</td>
</tr>
<tr>
<td>February</td>
<td>1.56±1.10</td>
<td>5.15±2.14</td>
<td>0.0001</td>
<td>67.604</td>
</tr>
<tr>
<td>March</td>
<td>1.53±1.52</td>
<td>6.53±2.17</td>
<td>0.0001</td>
<td>105.76</td>
</tr>
<tr>
<td>April</td>
<td>1.62±1.18 (n = 40)</td>
<td>9.11±1.14 (n = 31)</td>
<td>0.0001</td>
<td>591.83</td>
</tr>
</tbody>
</table>

Note: CBT = Cognitive Behavioral Therapy; ML = Melatonin; SD = Standard Deviation. n = 50 initially for each group. $F$ = variance estimation.

On performing the Analysis of Variance (ANOVA) of the blood-chemistry measurements, we found significant differences ($p < 0.05$) in the final measurement between groups, especially in CBT+ML, in which the levels of triglycerides and LDL diminished, while those of HDL increased in this group. In both groups, the levels of glucose and HDL increased significantly.

Table 4
Comparison of the anthropometric measurements

<table>
<thead>
<tr>
<th>Measurement</th>
<th>CBT+ML Mean±SD (n = 50)</th>
<th>ML Mean±SD (n = 50)</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initial BMI</td>
<td>34.13±2.85 (n = 50)</td>
<td>34.02±2.67 (n = 50)</td>
<td>0.8425</td>
</tr>
<tr>
<td>Final BMI</td>
<td>30.24±2.97 (40)</td>
<td>33.15±2.96 (31)</td>
<td>0.0001</td>
</tr>
<tr>
<td>% Initial body fat</td>
<td>42.33±4.23 (50)</td>
<td>42.27±3.24 (50)</td>
<td>0.93</td>
</tr>
<tr>
<td>% Final body fat</td>
<td>33.27±3.92 (40)</td>
<td>40.88±5.07 (31)</td>
<td>0.0001</td>
</tr>
</tbody>
</table>

Note: CBT = Cognitive Behavioral Therapy; ML = Melatonin; SD = Standard Deviation; BMI = Body Mass Index

Table 5
ANOVA of the means of glucose, triglycerides, cholesterol, HDL, and LDL before and after the intervention

| Glucose Initial | 84.81±7.27          | 88.04±11.51          | 0.09  |
| Glucose Final   | 90.33±5.94          | 108.64±23.23         | 0.04  |
| Triglycerides Initial | 152.81±77.48   | 161.08±117.51        | 0.75  |
| Triglycerides Final | 134.09±43.20  | 192.68±100           | 0.004 |
| HDL Initial     | 31.81±8.76          | 36.12±10.34          | 0.09  |
| HDL Final       | 88.20±0.20          | 40.68±14.59          | 0.001 |
| LDL Initial     | 104.31±32.80        | 114.36±27.37         | 0.22  |
| LDL Final       | 101.47±18.96        | 119.72±28.60         | 0.006 |

Note: CBT = Cognitive Behavioral Therapy; ML = Melatonin; SD = Standard Deviation; ANOVA = Analysis of Variance; HDL = High-Density Lipoprotein; LDL = Low-Density Lipoprotein
Discussion

One of the greatest challenges for the treatment of chronic disease, is the management of ADH; thus, it has been suggested that these diseases be cared for by means of an interdisciplinary vision (SEGOB, 2010). To this effect, the FESNAD-SEEDO Consensus mentions that the behavioral treatment be directed by means of self-control, eating habits, and physical exercise, and the strengthening of the ADH at the short, medium, and long terms (Gargallo et al., 2012). However, despite there being diverse models and the empirical evidence of the effectiveness of CBT and its effect on anthropometry many of the reports have been unidisciplinary or short-term, and not combined with the use of drugs for the control of Obesity (Ob). On the other hand, in hospital environments, the majority of the medical interventions for ADH do not have technically well-defined behavioral elements, such as the work conducted by Ford et al. (Ford, Haskins & Nahar, 2017), which obtained an ADH percentage of 51% (2017), in contrast with that obtained in this investigation in the CBT+ML at 8 months of 80%. This result was achieved through a behavioral model, structured by four general objectives: behavior modification; self-control; the establishment of social limits, and the control of ADH. Problem-solving therapy impacted positively on the percentage of tablets of ML returned monthly, which was observed as decreasing, with statistically significant high levels, in contrast with the ML alone group, which demonstrated an inverse response, with an average ML tablet return in the last month of nearly seven tablets.

As correctly pointed out by Jacob & Isaac (Jubbin & Rajesh, 2012), the successful management of ADH is based on the promotion of consciousness of the disease, analysis, and the search for novel solutions to the contingencies that curtail the treatment and that importantly impact motivation. Problem-solving therapy for the treatment of Ob is effective for control of the anthropometry, as demonstrated by Murawski et al. (2009); however, unidisciplinary interventions fail in the medium and long term. Contrariwise, the sum of the components of our intervention that combined ML and CBT in the problem-solving method strengthened behavioral adherence by the users, who learned to solve, in an efficient manner, contingencies related with their habits, ingestion control, the management of social networks, of assertive limits, and in primordial fashion their ADH behavior on taking the medication, whose results exerted an impact on anthropometry, triglycerides, HDL, and LDL (Leija-Alva et al., 2011).

In the present study, we determined that the interdisciplinary intervention, which combines the use of ML and CBT, is effective for maintaining the reduction of returned tables with an index above 90% in ADH at 8 months. For the case of the management of anthropometric and blood chemistry levels, we also demonstrated that CBT in combination with ML results effective; notwithstanding this, we were able to observe that, on its own, ML exerted a positive effect on anthropometry and HDL. Therefore, it is suggested as a pharmacological treatment for Ob, in combination with behavior modification.

Limitations: it is necessary to expand the sample, follow up to one year and evaluate with drugs of greater potency but with more side effects.

Referencias


