

## CARDIOVASCULAR AND ANTHROPOMETRIC ANALYSIS OF INTERVENTION WITH TECHNOLOGICAL SUPPORT IN HYPERTENSIVES: A RANDOMIZED CLINICAL TRIAL

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**ABSTRACT:** This study compared the effect of interventions with different technological stimuli on cardiovascular and anthropometric variables of hypertensives. 23 hypertensive adults were randomized into three groups: standard intervention group – with no follow-up; telephone group – with follow-up by phone calls; application group – with follow-up by WhatsApp messages. The variables were evaluated before and after a period of 12 weeks. There was no significant difference between the groups with and without professional follow-up, and the same applied to the types of follow-up with different technological stimuli. However, there was a significant reduction of systolic blood pressure ( $p = 0,040$ ), heart rate ( $p = 0,010$ ) and waist circumference ( $p = 0,039$ ) of the hypertensives from the standard intervention group, as well as a behavior change effect. The intervention had influence on the volunteers' behavior change. They became more physically active and improved their eating habits. Yet, there was no difference in the cardiovascular and anthropometric responses among the groups.

**KEY WORDS:** Blood pressure; Cell phones; Exercises; Hypertension; Nutritional recommendations.

## ANÁLISE CARDIOVASCULAR E ANTROPOMÉTRICA DE INTERVENÇÃO COM APOIO TECNOLÓGICO EM HIPERTENSOS: ENSAIO CLÍNICO RANDOMIZADO

**RESUMO:** O estudo comparou o efeito de intervenções com diferentes estímulos tecnológicos sobre variáveis cardiovasculares e antropométricas de hipertensos. 23 adultos hipertensos foram randomizados em três grupos: grupo intervenção padrão - sem acompanhamento; grupo ligação – com acompanhamento por ligação telefônica; grupo aplicativo – com acompanhamento por mensagem no grupo do WhatsApp. As variáveis foram avaliadas Pré e Pós um período de 12 semanas. Não houve diferença significativa entre grupos com e sem acompanhamento profissional, e nas formas de acompanhamento com diferentes estímulos tecnológicos. Entretanto, houve uma redução significativa da pressão arterial sistólica ( $p = 0,040$ ), frequência cardíaca ( $p = 0,010$ ) e da circunferência abdominal ( $p = 0,039$ ) de hipertensos do grupo intervenção padrão, assim como um efeito na mudança de comportamento. A intervenção influenciou a mudança de comportamento dos voluntários, que se tornaram mais ativos fisicamente e melhoraram hábitos alimentares, contudo não houve diferença nas respostas cardiovasculares e antropométricas entre os grupos.

**PALAVRAS-CHAVE:** Exercício; Hipertensão; Pressão arterial; Recomendações nutricionais; Telefone celular.

## INTRODUCTION

Systemic arterial hypertension (SAH) is considered a public health issue in Brazil and all around the world<sup>1</sup>, be it because of the number of hypertensives or the consequences that this disease can bring. Prevention and control of high blood pressure (BP) come from a combination of behavioral strategies, life style and drug intervention<sup>2</sup>. Changes in one's life style, such as adopting a healthy diet and exercising, are recommendations of a non-pharmacological treatment method for SAH<sup>3</sup>, for they reduce blood pressure, improve the efficiency of some antihypertensive drugs, promote other aspects of vascular and metabolic health<sup>4</sup>, cause just a few adverse effects<sup>5</sup>, and even reduce the need for drugs<sup>6</sup>.

Interventions in life style are usually required as a parameter in the treatment of hypertensives, although adhering to healthy habits is considered the main difficulty for the maintenance of these patients in face of technological advancements. In parallel, interventions with technological support (cell phones and text messages, websites and computer learning technology) have been presenting good results in terms of following and stimulating healthier behaviors<sup>7</sup>.

Numerous interventions in health have been applied to hypertensive individuals, but just some of them have associated nutrition to physical exercises and, as far as we know, there are no records of strategies by counselling with the use of technological stimuli, such as a cell phone app and telephone calls. Moreover, there has been a call for intensification of programs to control SAH and other cardiovascular risk factors<sup>8</sup>, such as the development of new methodologies with technological support aiming to change the behavior of hypertensive patients.

In light of the foregoing, the aim of this study was investigating the effect of a nutritional intervention associated with physical exercising with different technological stimuli for the reduction of BP and anthropometric indicators of hypertensive adults.

## METHODOLOGY

### SAMPLE

23 sedentary hypertensive adults, of both sexes, participated in the study. They were patients of a university

hospital, and all of them had a cell phone with android system and access to the internet. The participants were recruited and randomized into three groups: standard intervention (n=8), phone call (n=8) and application (n=7). All the protocols were approved by the Research and Ethics Committee, under the number 2.267.561 CEP, also registered in the Brazilian Clinical Trials Registry (ReBEC) with the code RBR-8v2qmk.

### EXPERIMENTAL PROTOCOL

First of all, the volunteers underwent anamnesis and answered 3 questionnaires: one of physical activity readiness (PAR-Q)<sup>9</sup>, another one concerning socioeconomic aspects<sup>10</sup> and the last one for physical activity level (IPAQ – short version)<sup>11</sup>, besides a 24-hour dietary recall (R24). They also signed a free and informed consent (FIC). Afterwards, they were subjected to a 12-week intervention BP measurement and anthropometric evaluations before the beginning (pre stage) and after the end of the intervention (post stage).

#### Intervention

All the groups received the same nutritional and exercising counselling at the beginning of the intervention. However, for 12 weeks, the standard intervention group had no follow-up; the phone call group received weekly phone calls as a stimulus; and the application group had an interactive conversation on a WhatsApp group during the week in order to get them stimulated.

The standard intervention and phone call groups also received a booklet. As for the application group, the members received an application of nutritional intervention associated with physical exercises (AppINEF). The content of both resources was similar to the counseling, and all participants received an elastic band. Two skilled professional, of Physical Education and Nutrition, were responsible for the first guidelines and the follow-up.

The booklet had seven pages and contained a detailed description and pictures showing the initial and final position of the physical exercises, besides nutritional orientations, eating suggestions and a records sheet for the sessions and exercises intensity. As for the application, it was possible to record daily meals, exercises and their intensity. There was also an eating report, guidelines for

physical exercises by text messages, graphics exchange format and explanatory audios, alert messages with nutritional recommendations and for exercising, a contact icon, updating of registration data and an online chat. Both educational materials had a score chart for the exercises and were developed especially for this research.

#### Nutritional counseling

We took into consideration the recommendations by the 7<sup>th</sup> Brazilian Guideline for Arterial Hypertension<sup>12</sup> for the *Dietary Approaches to Stop Hypertension* (DASH diet), aiming to reach the recommendations for sodium, potassium, calcium, magnesium, vitamin D, cholesterol and dietary fiber, as well as the adequate proportion of proteins, carbohydrates and lipids, for it has a high degree of evidence in the reduction of the BP<sup>13</sup>.

#### Physical exercising counseling

The exercises were adapted and proposed in accordance with international recommendations<sup>14</sup> for the prescription of physical exercises and of the specific guidelines on exercises for hypertensives<sup>15,12</sup>. The physical exercises program comprises an aerobic exercise, nine dynamic resisted exercises and six body-stretching exercises. They were all easy to be executed, and the participants should do them three times a week, with an interval of 24 hours between the sessions. Each session lasted 50 minutes on average, and each exercise was done within series and repetitions, with intervals between the exercises and their series. During intervention, there was an increment of load in the exercises with an increase in the number of repetitions at the beginning of the 7<sup>th</sup> week.

#### Blood pressure measurement

Blood pressure measurement at rest was done with the device BP Microlife BP 3AC1-1 PC, which is an electronic and digital monitor of arm blood pressure with automatic air inflation and deflation. The measurement method of the aforementioned device is oscillometric, with pressure variation of 0-280 mmHg, validated for adults<sup>16</sup>, according to the recommendations of the 7<sup>th</sup> Brazilian Guideline for Arterial Hypertension<sup>12</sup>. In each evaluation, PA and heart rate (HR) were measured three times, with an interval of one minute between the measurements. Previously, the participants were instructed not to do any vigorous physical activity, not to drink caffeinated and alcoholic

drinks in the 24 hours prior to the evaluation days, and not to be in urinary continence at the moment of the BP measurements.

#### Anthropometric evaluation

Body Mass (BM) was measured with a Balmal scale (model 104A), with precision of up to 100g, and the participants' stature was determined with a stadiometer coupled with the scale with precision of 0,1 cm. The body mass index (BMI) was determined by the quotient BM/stature<sup>2</sup>. BM was expressed as kilograms (Kg) and stature as meters (m). Waist circumference (WC), abdominal circumference (AC) and hip circumference (HC) were measured with a Cescorf (*Porto Alegre/RS/Brazil*) inextensible metallic tape measure with precision of 0,1 cm. The waist-to-stature ratio (WSR) was calculated by the WC-to-stature ratio, and the hip-to-waist ratio (HWR) by the WC-to-HC ratio, both in centimeters.

#### STATISTICAL ANALYSIS

Initially, we performed a multiple imputation of the data with an intent-to-treat analysis<sup>17</sup>. Normality of the data was verified by the *Shapiro-Wilk* test, and the data were expressed through mean, standard deviation, median, quartiles, absolute and relative frequency. Data analysis was done through the two-way ANOVA analysis of variance (time / group) with repeated measures. Student's t test (parametric variables) and *Wilcoxon's* test (non-parametric variables – mean blood pressure (MBP) of the standard intervention group, systolic blood pressure (SBP) of the phone call group, and HR of the application group) was applied to compare the intragroup variables. We used the SPSS software version 22.0, and adopted the significance level of  $p < 0,05$ . We also carried out a descriptive analysis of the data registered in the R24 and records sheet of the exercising sessions to help with the results discussion.

#### RESULTS

The volunteers had been diagnosed as hypertensives for  $7,26 \pm 4,79$  years. 18 (78,3%) of them had been taking two to four anti-hypertensives, with an

average age of  $43,6 \pm 5,7$  years, IMC  $32,5 \pm 6,9$  kg/m<sup>2</sup> classified as obese, and HWR  $0,86 \pm 0,06$  cm, considering high risk for women and low to moderate risk for men at the age group from 30 to 49.

Most participants were women, who studied until high school, with a monthly income of R\$ 1.626,00 to 2.705,00. As for food consumption, evaluated by the R24, the participants presented calories consumption averages of  $1771,33 \pm 499,73$  Kcal,  $214,02 \pm 72,02$  g of carbohydrates,  $82,90 \pm 26,36$  g of proteins,  $67,58 \pm 23,79$  g of lipids, and  $2182,6 \pm 946,0$  mg of sodium.

#### EFFECT OF NUTRITIONAL INTERVENTION AND EXERCISING ON THE PARTICIPANTS' BEHAVIOR CHANGE

During intervention, the phone calls lasted on average  $5 \pm 1,20$  min, quick, low cost, and only a part of the volunteers answered the calls, expressing just a few doubts. As for the interactive conversations on WhatsApp with the application group, there was little interaction with the participants due to lack of questions or interest.

The analysis of the R24 done before, at the beginning of the 7th week and after the intervention period, showed that the participants changed some eating habits, which included eating more fruits and vegetables, oilseeds consumption included in their routine, a decrease in sugar drinks consumption, predilection for skimmed dairy products and a decrease in the consumption of industrialized products (processed food / sausages and sauces). There were changes in the consumption of macronutrients in the standard intervention group (-232,1 calories, -37,6 g of carbohydrates, and -18,1 g of lipids); phone call group (- 206 calories, - 20 g of carbohydrates

and - 4,2 g of lipids); and application group (- 290,4 calories, - 34,8 g of carbohydrates and - 12g of lipids) after 12 weeks of intervention.

As for the exercises records, considering the recommendations of three sessions a week with moderate intensity, we carried out analyses in two periods (six and twelve weeks), during intervention. After six weeks, we observed that, in the standard intervention group, the volunteers did on average seven exercises sessions, with efforts intensity considered very tiring or a little tiring, and difficulty in the execution of unilateral squat. The phone call group executed, on average, 11 exercising sessions, with efforts intensity considered exhaustive at the beginning and, then, tiring, with difficulty in the execution of unilateral squat and marching. As for the application group, there were just a few accesses with an average of 4 sessions of activity and exhaustive intensity.

After twelve weeks of research, there were fewer exercising records compared to the six first weeks. It was possible to notice that, in the standard intervention group, the volunteers had an average of 10 sessions with very tiring intensity; the phone call group had around 14 sessions, with a little tiring to tiring intensity, besides difficulties in executing unilateral squat; there were no accesses among the volunteers of the application group. Effect of the nutritional and exercising intervention on blood pressure and anthropometric indicators

The data analysis evidenced that there was no interaction between time and group, nor significance in the cardiovascular variables (SBP, DBP, MBP and HR) and anthropometric (BM, WC, AC and WSR) of the hypertensives after the 12-week intervention (Table 1).

**Table 1.** Mean of the participants' variables pre and post intervention of each group, and among the groups (n=23)

(Continuation)

Variable	STANDARD INTERVENTION (n = 8)		PHONE CALL (n = 8)		APPLICATION (n = 7)		ANOVA		
	Pre	Post	Pre	Post	Pre	Post	F	P	n <sub>p</sub> <sup>2</sup>
<i>Cardiovascular</i>									
<b>SBP</b> (mmHg)	123.50 ± 17.44	114.60 ± 13.74	131.72 ± 11.21	131.14 ± 11.32	140.73 ± 14.01	136.80 ± 16.35	1.777	0.195	0.151
<b>DBP</b> (mmHg)	84.46 ± 11.82	84.56 ± 11.15	87.68 ± 7.29	83.10 ± 6.32	88.04 ± 11.87	86.92 ± 12.39	0.816	0.456	0.075
<b>MBP</b> (mmHg)	97.47 ± 13.39	98.61 ± 11.34	102.36 ± 7.59	101.04 ± 6.94	105.60 ± 11.98	104.67 ± 16.16	0.162	0.851	0.016

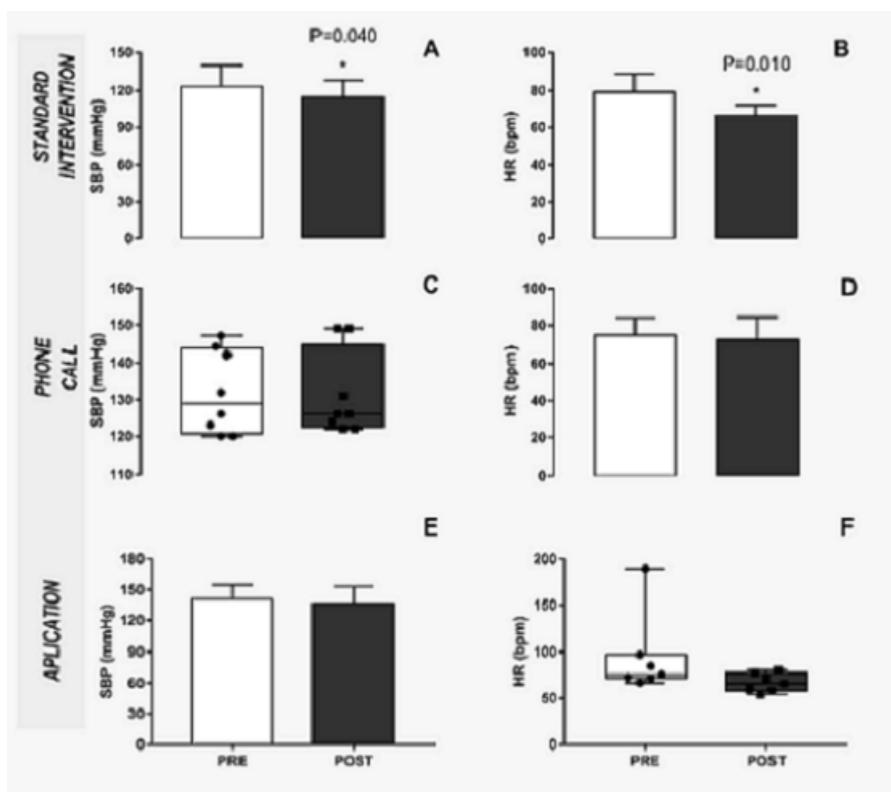
(Conclusion)

Variable	STANDARD INTERVENTION (n = 8)		PHONE CALL (n = 8)		APPLICATION (n = 7)		ANOVA		
	Pre	Post	Pre	Post	Pre	Post			
<b>HR</b> (bpm)	79.18 ± 9.85	66.80 ± 5.42	74.48 ± 9.78	72.01 ± 12.34	94.31 ± 43.34	66.71 ± 10.35	1.515	0.244	0.132
<i>Antropométricas</i>									
<b>BM</b> (kg)	92.68 ± 23.17	87.10 ± 15.52	79.20 ± 14.44	79.18 ± 14.76	83.23 ± 14.21	83.68 ± 14.88	2.753	0.088	0.216
<b>AC</b> (cm)	108.15 ± 15.35	102.53 ± 10.80	96.74 ± 10.17	96.00 ± 10.26	101.81 ± 9.91	102.95 ± 13.48	3.345	0.056	0.251
<b>WC</b> (cm)	99.30 ± 13.26	95.80 ± 12.12	92.26 ± 9.85	90.50 ± 8.06	98.71 ± 11.85	98.31 ± 13.91	1.916	0.323	0.107
<b>WSR</b> (cm)	0.61 ± 0.09	0.59 ± 0.07	0.57 ± 0.47	0.56 ± 0.4	0.61 ± 0.08	0.61 ± 0.10	1.806	0.190	0.153

Source: Authors' data. All the values are expressed as mean ± standard deviation. SBP: systolic blood pressure; DBP: diastolic blood pressure; MBP: mean blood pressure; HR: heart rate; BM: body mass; AC: abdominal circumference; WC: circumference; WSR: waist-to-stature ratio.

Besides the intragroup results, we analyzed intragroup cardiovascular variables after intervention, in which the standard intervention group presented a reduction of the SBP of -8,9 mmHg (p = 0,040) and of the HR of -12,38 bpm (p = 0,010) with significant statistical difference, and DBP (p = 0,973) and MBP (p = 0,674)

with no statistical differences. On the other hand, the phone call and application groups presented discreet reductions in the values of SBP (p = 1,000; p = 0,300), DBP (p = 0,180; p = 0,615), MBP (p = 0,669; p = 0,747) and HR (p = 0,213; p = 0,176) respectively, with no statistical difference (P > 0,05).



**Figure 1.** Mean ± SD of the systolic blood pressure (A, C and E) and heart rate (B, D and E) of the participants of the standard intervention group (n=8), phone call group (n=8) and application group (n=7) pre and post intervention. SBP: systolic blood pressure; HR: heart rate. \*Significant difference - p<0,05: Students' t test .

For the values of the anthropometric variables, the volunteers of the standard intervention group had a reduction of the BM values (- 5,58 Kg), AC (- 5,62 cm), WC (- 3,5 cm) and WSR (- 0,02) after 12 weeks of intervention, but only AC showed a significant difference ( $p = 0,039$ ). As for the phone call group, the participants basically did not have any changes in BM, AC, WC and WSR after intervention, and did not present statistical difference ( $p > 0,05$ ). Finally, in the application group, the values of most of the variables remained unchanged and with no statistical difference after 12 weeks of intervention ( $p > 0,05$ ).

## DISCUSSION

In this study, we verified that there was no difference between the groups with and without professional follow-up. The same applies to the follow-up modalities with different technological stimuli, comparing the use of a cell phone application with weekly phone calls. However, there was a significant reduction of SBP, HR and AC of the members of the standard intervention group. The nutritional intervention associated with physical exercises, with and without technological support, seems to have a potential to change some eating habits and make people more physically active, as shown by the records of the volunteers.

The intervention involving nutritional counseling and physical exercises seems to have caused a behavior change of a good part of the volunteers, who started consuming healthier food and doing exercises, thus, showing positive results in changing their life style for watching and treating cardiovascular diseases. Trindade Radovanovic et al.<sup>18</sup> highlight that an intervention based on health, nutritional and physical training guidelines is effective in changing life habits. The authors point that it can prevent cardiovascular diseases, especially when the intervention involves a group<sup>19</sup>. Finally, they stress that a change in life style is an important factor for the treatment of people who suffer from chronic non-communicable diseases.

The phone call and application groups, which had a professional follow-up through phone calls and

chats on WhatsApp, respectively, were not statistically different from the group of hypertensives that had no assistance. We believe that such result is possibly due to the technological stimuli, for they did not ensure contact with the participants. It is supposed that in the phone call group, the follow-up was not very successful because the participants who occasionally answered the calls were unwilling to cooperate. As for the application group, the volunteers usually did not express many doubts during the interactive chats on WhatsApp.

Some studies have been reporting good results of interventions in the health area, which use standard initial counseling and follow-up by using phone calls and applications. In a research by Wister et al.<sup>20</sup>, telephone counseling was effective for the primary prevention of cardiovascular disease in middle aged people exposed to risk factors. Parra-Medina et al.<sup>21</sup> report that the intervention based on phone calls improved physical and leisure activity and the diet of Afro-American women with multiple chronic conditions when compared to the standard intervention, which was important only for maintenance. The beneficial effect of telephone interventions has also been proven in self-care related to physical activity and eating habits in patients who suffer from diabetes<sup>22</sup>.

Some other research have also shown the potential effectiveness of applications both for the increase in the frequency of weekly exercises in healthy volunteers<sup>23</sup>, and regarding the ease of implementing dietetic recommendations for healthy adults<sup>24</sup>. Besides, other applications increased the duration of physical activity and enhanced knowledge on nutrition and diet quality of healthy adults<sup>25</sup>, motivated adults users to change or maintain their healthy behaviors<sup>26</sup>, and also led to a slight increase in the adhesion to anti-hypertensive drugs<sup>27</sup>.

Through this perspective, Casey et al.<sup>28</sup> emphasize that the use of an application, tested to promote physical activity, was effective in changing exercising behaviors in patients under primary attention, as well as a cascade effect, leading to positive changes in the life style of their family and community.

In a similar research with patients under high risk of cardiac diseases, two groups were compared. They both received standard health guidelines based on primary

care for physical activity and diet. The only difference is that one of the groups received phone calls once a week<sup>21</sup>. There were improvements in both interventions with no statistical differences between the groups, even though the phone calls group presented better results, probably due to the additional counseling.

As for the effects of the intervention in the hemodynamic variables of the participants, in all groups there were reductions of the BP values, with a significant difference only in the SBP of the members of the standard intervention group. It was surprising that the group that had no follow-up presented better SBP results compared to the groups that were weekly assisted through technological stimuli, although all the participants received orientations at the beginning of the intervention on how to improve their diet and how to do exercises.

A research that tested an application to increase cardiorespiratory fitness and physical activity among healthy adults compared two groups that used applications with feedback. Yet, one of them had no specific usage instructions, whereas the other group had supervised training and personal feedback, and did not show interaction time / group for SBP and DBP, even though they reduced the pressure values of both<sup>23</sup>. A meta-analysis based on controlled studies showed that dynamic resistance training of moderate intensity, which was used in our research, caused small to moderate reductions in SBP (-3,0 mm Hg) and DBP (-2,1 mmHg) compared to control groups in hypertensive adults<sup>29</sup>.

Regarding the anthropometric indicators, there was an improvement of the results in most participants after intervention, with significant difference only in the AC of the standard intervention group. This result in the control group is an interesting finding, for some researchers have reported discreet beneficial effects for participants of control groups in randomized trials and, often, similar results in research that adopt care groups or standard intervention, which initially receive the same habitual guidelines as the other groups of the intervention.

Busnello et al.<sup>30</sup> ascertained two diet therapy intervention models in patients with metabolic syndrome, control group (diet and nutritional guidelines) and intervention group (diet, nutritional guidelines, phone calls and educational material), in which both

showed a significant improvement of the clinical and anthropometric parameters, significantly associated with previous motivation of the nutritional guidelines. As for a study by Trindade Radovanovic et al.<sup>18</sup> with hypertensive adults, which compared an intervention group (health and nutritional guidelines and physical exercises) with a control group (with no guidelines), there was a decrease in the mean values of all anthropometric variables in the intervention group, with a significant difference for HC and HWR, whereas the control group had statistically significant reduction only in fat percentage and HC.

The study has some limitations, such as the size of the sample, which was relatively small, although it is necessary to consider the extensive recruitment and the difficulties for new recruitment. A considerable part of the participants were not available when they were expected to answer the phone calls or take part in the interaction on WhatsApp, even though they were told to do so at least 24 hours before the days and times scheduled. It is also important to mention the impossibility to have an online chat on the application. That was why we had interactive conversations on it.

## CONCLUSION

Nutritional intervention associated with physical exercising showed that the initial counseling was important for making the volunteers more physically active and changing some of their eating habits, thus, improving their life style. In that sense, there was no difference when we compare the professional follow-up through phone calls and that on WhatsApp. Besides, there was a decrease in the SBP and a reduction of the AC in the standard intervention group when we verify the behavior of the intragroup variables.

The application and the booklet devised for the intervention can be used for free by hypertensive people, once the nutritional and physical exercising counseling is preconized as primary health care. When it comes to multi-professional interventions, it is recommended a follow-up by professionals who are specialists in the area for a greater potential and better results in behavior change.

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