

# The Impact of A Web-Based Lifestyle Educational Program ('Living Better') Reintervention on Hypertensive Overweight or Obese Patients During The COVID-19 Pandemic.

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## Research Article

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## Abstract

'Living Better', a self-administered web-based intervention, designed to facilitate lifestyle changes, has already shown positive short and medium-term health benefits in patients with an obesity-hypertension phenotype. The objectives of this study were: (1) to examine the long-term (3-year) evolution of a group of hypertensive overweight or obese patients who had already followed the 'Living Better' program; (2) to analyse the effects of completing this program a second time (reintervention) during the COVID-19 pandemic. A quasi-experimental uncontrolled design was used. We recruited 29 individuals from the 105 who had participated in our first study. We assessed and compared their systolic and diastolic blood pressure (SBP and DBP, respectively), Body Mass Index (BMI), eating behavior, and physical activity levels (METs-min/week) at Time 0 (follow-up 12 months after the first intervention), Time 1 (before the reintervention), and Time 2 (post-reintervention). Our results showed significant improvements between Time 1 and Time 2 in terms of SBP [-4.7 (-8.7 to -0.7);  $P=.017$ ], DBP [-3.5 (-6.2 to -0.8);  $P=.009$ ], BMI [-0.7 (-1.0 to -0.4);  $P<.001$ ], emotional eating [-2.8 (-5.1 to -0.5);  $P=.012$ ], external eating [-1.1 (-2.1 to -0.1);  $P=.039$ ], and physical activity levels (Time 1:  $2308\pm2266$ ; Time 2:  $3203\pm3314$ ;  $P=.030$ ,  $Z=-2.17$ ). Statistical analysis showed no significant differences in SPB, DBP, BMI, and eating behavior between Time 0 and Time 1 ( $P>.24$ ). Implementation of the 'Living Better' program maintained some positive long-term (3-year) health benefits in patients with an obesity-hypertension phenotype. Moreover, a reintervention with this same program during the ongoing COVID-19 pandemic produced significant improvements in blood pressure, BMI, eating behavior, and physical activity levels beyond the 3-year follow-up.

Trial Registration: ClinicalTrials.gov NCT04571450; <https://clinicaltrials.gov/ct2/show/NCT04571450>; First Posted: 01/10/2020.

## Introduction

Obesity is now considered the great pandemic of the 21st century<sup>1</sup>. So much so, that in the last four decades its prevalence has tripled<sup>2</sup>. In addition, projections about obesity are also very discouraging given that, by 2030, this disease is expected to affect more than one billion people globally<sup>3</sup>. The detrimental effects obesity has on health, including increasing the risk of suffering cardiovascular disease (CVD), metabolic disease, and even some types of cancer, are well known<sup>2,4</sup>. Current evidence<sup>5</sup> suggests that even being overweight, rather than obese, may contribute to an increased risk of morbidity and mortality<sup>6</sup>. In addition, the presence of other associated comorbidities such as hypertension considerably intensify the consequences of obesity<sup>7</sup>.

The prevalence of hypertension (HTN) is 40% among the adult population, and its consequences, mainly strokes and coronary artery disease, cause about 7.5 million deaths per year<sup>8</sup>. Accordingly, there is a direct and close relationship between HTN and obesity in the adult population<sup>9–11</sup> such that around 60–70% of hypertension cases are influenced by obesity. Indeed, the probability that an obese person will

have HTN is 3.5-fold higher than that of the population with a normal weight<sup>12</sup>. This almost linear relationship between body weight and systolic blood pressure (SBP) has been detected in various populations worldwide (for example, in the Framingham Heart study) which have estimated that up to 65% of the risk of primary (essential) HTN in women and up to 78% in men may be the consequence of excess weight<sup>13</sup>. Together, these data give us an idea of both the extraordinary worldwide economic expenditure and the pronounced impact on populational health of these two conditions.

Given the above, the implementation of strategies that effectively promote the prevention and treatment of the obesity-hypertension phenotype are urgently required. These must have the clinical objectives of controlling blood pressure and body composition (fat loss and muscle mass gain), improving cardiorespiratory function and functional capacity, and reducing polypharmacy<sup>14</sup>. In this sense, the most recent clinical guidelines on hypertension and obesity<sup>15–17</sup> agree that promoting a healthy lifestyle should be the first step considered in obese patients with HTN. To achieve these changes, the process must be based on two fundamental pillars: regular physical exercise and healthy eating behaviors<sup>18</sup>.

At present, physical exercise is considered a polypill for the prevention and treatment of numerous health conditions, including chronic diseases such as obesity and hypertension<sup>18</sup>. Thus, it has been shown that regularly engaging in sustained physical exercise over time is essential to maintain long-term weight loss<sup>14,19</sup>. Furthermore, a recent meta-analysis<sup>20</sup> of 391 randomised controlled trials concluded that physical exercise can be as effective as the pharmacological treatments currently used to lower resting blood pressure levels while also significantly reducing all-cause mortality with a decrease in SBP of 5 mmHg<sup>21</sup>. However, even though moderate weight reductions (~1–3 kg) can be achieved with physical exercise programs without dietary modifications, the combination of regular physical exercise and healthy eating behaviors, including a decrease in caloric intake<sup>22</sup>, is the most effective strategy to address weight loss and its maintenance<sup>14</sup>. Of note, one of the most successful dietary interventions described in the academic literature was from the *Prevención con Dieta Mediterránea (PREDIMED)* study, and was precisely administered in a high-risk for cardiovascular events Spanish population<sup>23</sup>.

On the other hand, the ongoing COVID-19 pandemic has required global-level adaptation in the health, economic, and social arenas. In general, the health measures adopted by different authorities have helped reduce the spread and impact of COVID-19 among the most vulnerable individuals. However, these protective measures have also resulted in a reduction in daily physical activity levels and quality of life<sup>24</sup>. Thus, the recent academic literature indicates that there was a dramatic decrease in physical activity levels during the pandemic, which was especially worrisome in patients with associated metabolic conditions<sup>25</sup>. In hypertensive older adults, unhealthy changes manifested as a reduction in physical activity and increased sedentary behavior<sup>26</sup>. Other research suggested that unhealthy eating patterns intensified among high-risk patient groups during the pandemic<sup>27</sup>. Similarly, a related study showed that obese individuals spent less time engaging in physical exercise, exercised less intensely, and were more anxious about eating during the pandemic, all of which can make body weight control more difficult<sup>28</sup>.

In this context, online interventions can reach different populations, overcoming the barriers and limitations of the confinement and prevailing restrictions, and represent effective strategies for the prevention and/or treatment of multiple health conditions. Some of the strengths of these types of intervention are their cost-effectiveness, accessibility, flexibility (in terms when and where they can be completed, etc.), and their potential for personalisation<sup>29,30</sup>. In agreement with all of the above, the literature on the application of technologies and use of the Internet in the treatment of obesity or hypertension indicates the efficacy of online interventions promoting healthy lifestyles to improve body weight<sup>31–33</sup> and/or blood pressure figures<sup>34</sup>. However, to date, only four studies have analysed the effectiveness of such treatments in patients with both health conditions, that is, in individuals presenting an obesity-hypertension phenotype<sup>35–38</sup>. Of note, none of the four studies performed in this specific area, and only one in non-hypertensive obese adults<sup>39</sup>, followed-up patients who had completed an online educational intervention for at least 3 years. In addition, to the best of our knowledge, no research has yet analysed the effects of a second intervention (reintervention) with an online intervention program in patients with obesity, hypertension, or any other type of cardiovascular disease. Likewise, hardly any online lifestyle interventions were implemented in the general population during the pandemic<sup>40</sup> and none were performed in patients with an obesity-hypertension phenotype.

Given all the above, in this current study we set out to (1) understand the evolution at 3 years of a group of hypertensive overweight or obese individuals who had followed the 'Living Better' web-based program in 2018<sup>38</sup>; (2) analyse the effects of completing this program a second time (reintervention) during the ongoing COVID-19 pandemic—3 years after the initial intervention—, in terms of SBP, diastolic blood pressure (DBP), Body Mass Index (BMI), number of antihypertensive drugs used, level of physical activity, eating behavior, and adherence to the Mediterranean diet.

## Methods

### Study design

This was a prospective quasi-experimental study (ClinicalTrials.gov: NCT04571450). This research was approved by the Human Research Ethics Committee at the *Hospital Universitario de Sagunto* and followed the ethical guidelines established in the Declaration of Helsinki. The study describes the 3-year follow-up of 29 patients who already received an intervention with the 'Living Better' program in 2018 (N=105)<sup>38</sup>, as well as the result of completing the same program for a second time (reintervention) with the aim of helping to minimise the negative impact the COVID-19 pandemic on lifestyle. To analyse the long-term effects of the program we used the follow-up values obtained at the end of the first study as our starting point (Time 0)<sup>38</sup>. We also used the different variables analysed in 2018 and recorded just before the start of the second intervention (Time 1). Once this evaluation was completed, the participants started the 3-month online reintervention with the 'Living Better' program. Finally, in order to understand the impact of this second intervention on the health of the participants, all the variables were recorded again at the end of the program (Time 2) (Figure 1).

# **Eligibility criteria**

Because this was a reintervention study, the first inclusion criterion was that the patients had participated in the 'Living Better' online program in 2018. In addition, we used the same inclusion criteria we had applied in the first study<sup>38</sup>: overweight (BMI between 24.9 kg/m<sup>2</sup> and 30 kg/m<sup>2</sup>) or type I obese (29.9 kg/m<sup>2</sup><BMI<35 kg/m<sup>2</sup>) adults aged 18 to 65 years with HTN. HTN was defined as high systolic (SBP≥140 mmHg) or diastolic (DBP≥90 mmHg) blood pressure or patients who take antihypertensive drugs. We also used the same exclusion criteria: a diagnosis of diabetes, previous ischemic heart or cerebrovascular disease, serious psychiatric disorders, use of more than three antihypertensive medicines, physical impairments that could hinder engagement in physical exercise, receiving other treatments for weight loss, or no access to the Internet.

## **Procedure**

This study was carried out in the Hypertension and Vascular Risk Unit at the *Hospital Universitario de Sagunto* (Valencia, Spain) from January 2018 to January 2021 (reintervention period from October 2020 to January 2021). At all times, the work complied with the instructions of the Human Research Ethics Committee at the aforementioned hospital. We used the hospital postal service to contact the 105 participants who took part in the 2018 study. Of those who agreed to participate again, and after applying the inclusion and exclusion criteria, the final sample in this work comprised a total of 29 participants (Figure 2). After signing their informed consent to participation in the study and formalising their registration we incorporated the participants into a single experimental group which received a 3-month reintervention via the 'Living Better' web-based platform. Furthermore, we telephoned all these individuals to remind them of the program details and to resolve any questions they had.

## **Intervention**

We used the same 'Living Better' program, implemented via the Internet, as in the 2018 study<sup>37,38</sup>. This multimedia, interactive, and self-administered program comprises 9 intervention modules that try to gradually change the eating behavior and physical activity patterns of the participants. All the modules include videos, texts, tasks, daily records, and files that the patient can download in order for them to work on the content. Considering the suggestions of the participants after the first intervention, on this occasion we had converted a large part of the written content into audiovisual materials to help facilitate usability. However, despite these changes, the program content was identical to that of the first intervention. More details about the first intervention can be found in Baños et al.<sup>41</sup>, Lisón et al.<sup>38</sup>, and Mensorio et al.<sup>37</sup>.

## **Outcome measures**

### **Systolic blood pressure and diastolic blood pressure**

To avoid increasing coronavirus infections, the health authorities and hospital regulations prohibited access to the medical facilities for patients who did not need urgent healthcare. Therefore, the

participants were asked to go to a pharmacy close to their home so that the same person (a pharmacist or pharmacy assistant) could record these variables at Time 1 and Time 2 using the same approved device. As in the first intervention, the participants were instructed to record measurements between 8 a.m. and 12:00 p.m. noon to minimise variability in their daytime blood pressure figures. In this sense, we followed strictly the European Society of Hypertension (ESH) protocol<sup>16</sup>, so measurements were performed in the sitting position, in a quiet environment for 5 min before BP measurements, avoiding prior consumption of alcohol or smoking, drinking caffeine, or engaging in strenuous exercise. Three BP measurements were recorded, 1 minute apart, and BP was calculated as the average of the last two BP readings. Additional measurements were performed if the first two readings differed by more than 10 mmHg.

## **Weight, height, and Body Mass Index**

Because of the aforementioned COVID-19-related health concerns, these variables were also recorded in local pharmacies, following the same indications.

## **Number of antihypertensive drugs**

The patient registered the antihypertensive drugs they used through the intervention program platform.

## **Physical activity levels**

This factor was evaluated using the short version of the 'International Physical Activity Questionnaire' (IPAQ-Short)<sup>42,43</sup>, administered via the Internet through the intervention platform. This instrument reflects the time the participant spent being active in the 7 days prior to its completion. Different scores are awarded in the IPAQ-Short, depending on the time spent engaging in moderate or vigorous activities, walking, or sitting each week. The unit of measurement for this questionnaire is METs-min/week, which expresses an average of each individual's metabolic expenditure per minute while engaging in weekly physical exercise. Thus, higher figures reflect a higher level of activity, while lower values express a lower level of weekly physical activity<sup>42,43</sup>.

## **Eating behavior**

To analyse the eating behavior of the patients, we employed the 'Dutch Eating Behavior Questionnaire' (DEBQ)<sup>44,45</sup> which comprises 33 items and uses a 5-point Likert scale to evaluate 3 eating styles: emotional eating (13 items), external eating (10 items), and restrained eating (10 items), with higher scores indicating greater agreement with the eating behavior statements.

## **Adherence to the Mediterranean diet**

Eating behavior were recorded before (Time 1) and after (Time 2) the reintervention using the 'Mediterranean Diet Adherence Screener' (MEDAS) from the PREDIMED study<sup>46</sup>. This questionnaire assesses adherence to the Mediterranean diet through 14 items, 12 of which are related to the frequency of food consumption while 2 are about dietary habits linked to the Mediterranean diet. Each item is

scored with a value of 0 or 1 and, based on the final score, the patients were classified as having low (0–5 points), medium (6–9 points), or high ( $\geq 10$  points) adherence to the Mediterranean diet.

## Satisfaction with the reintervention

As in the first study<sup>38</sup>, this variable was evaluated on a scale from 0 (minimum satisfaction) to 10 (maximum satisfaction).

## Adherence to reintervention

This was analysed through the data registered by the participants on the platform. This also allowed us to gauge the degree of completion of the different program modules by each participant. In other words, how many of the nine modules they had reviewed.

## Statistical analysis

The statistical analyses were performed according to the intention-to-treat paradigm using SPSS software (version 19.0; IBM Corp., Armonk, NY) for Windows, and the statistical significance was set at  $P<.05$  for all our analyses. The data in this study are presented as mean (SD). Compliance with the assumption of normality was checked for each dependent variable using the Shapiro–Wilk test. One-way ANOVA tests followed by Bonferroni post-hoc tests were performed for the variables that met the assumption of normality (SBP, DBP, BMI, and eating behavior). The effect sizes were estimated using the  $\eta^2$  and were interpreted following Cohen's guidelines for small, moderate, and large effect sizes ( $\eta^2 = 0.01, 0.06$ , or  $0.14$ , respectively). Friedman tests followed by non-parametric Wilcoxon tests to compare the three study timepoints (Time 0, Time 1, and Time 2) were used for the variables that violated the assumption of normality (physical activity levels and number of antihypertensive drugs used). In addition, *t*-tests for related samples were performed to compare the level of adherence to the Mediterranean diet before and after the reintervention (Time 1 vs. Time 2), as well as to contrast the degree of participant satisfaction after the reintervention compared with the first intervention. Adherence to the reintervention was estimated by calculating the average percentage of the 9 'Living Better' program modules completed by the 29 participants. Finally, at Time 0, depending on whether the assumption of normality was fulfilled, *t*-tests (for independent samples) or Mann-Whitney U tests were carried out for the different study variables to compare the 29 reintervention participants to the 76 participants excluded from this study.

## Results

### Reported changes on the SBP, DBP, BMI, and eating behavior.

Table 1 shows the patient values for the variables prior to the second intervention (Time 1), while Table 2 shows the results of the post-hoc ANOVA analysis. As shown, there were significant differences between the start of the second intervention (Time 1) and the end of the program (Time 2) in all variables –except for restrained eating–, with statistically significant improvements and large effect sizes ( $\eta^2>0.21$ ) after

completing the reintervention. However, the statistical analysis did not show significant differences between the end of the first intervention (Time 0) and the beginning of the second one (Time 1) for any of these four variables ( $P>.24$ ).

#### **Differences showed on the number of antihypertensive drugs and physical activity levels.**

In addition, the Friedman test did not indicate any statistically significant changes in the number of antihypertensive drugs used between the different evaluation points (Time 0:  $1.7\pm1.2$ ; Time 1:  $1.6\pm1.4$ ; and Time 2:  $1.6\pm1.4$ ;  $P=.439$ ), although there were significant differences for physical activity levels (Time 0:  $4024\pm3676$ ; Time 1:  $2308\pm2266$ ; and Time 2:  $3203\pm3314$ ;  $P=.005$ ). Specifically, the results of the Wilcoxon tests showed differences between Times 0 and 1 ( $P=.015$ ,  $Z=-2.43$ ) and Times 1 and 2 ( $P=.030$ ,  $Z=-2.17$ ).

#### **Results analyses of the adherence to the Mediterranean diet, satisfaction, and adherence to the reintervention.**

Regarding adherence to the Mediterranean diet, *t*-tests showed that there were no statistically significant differences ( $P=.100$ ) between the time before (Time 1:  $8.2\pm2.1$ ) and immediately after the reintervention (Time 2:  $8.8\pm1.7$ ). Furthermore, participants reported a higher level of satisfaction with the program after the second intervention compared to the first one, although these findings did not reach statistical significance (first intervention:  $6.8\pm2.3$ , second intervention:  $8.0\pm1.4$ ;  $P=.080$ ). With regard to adherence to the reintervention, 7 patients withdrew before completing the first module, 66% of the 29 participants had looked at more than half of the program (at least 5 of the 9 modules) and 38% had completed all of it. Finally, at Time 0, the comparison between the 29 volunteers who agreed to participate in the reintervention and the 76 participants excluded from the study showed no statistically significant differences in any of the studied variables ( $P>.29$ ), except for the BMI which was higher in the excluded patient group ( $29.0\pm2.5$  and  $30.2\pm2.8$ , respectively;  $P=.033$ ). However, a subsequent analysis verified that the differences had already existed before the first intervention between these two groups ( $29.3\pm2.6$  versus  $30.5\pm2.6$ ;  $P=.033$ ).

Table 1  
Participant characteristics.

VARIABLES	Time 1; mean (SD) <sup>a</sup>	
<b>Sex (n)</b>	Women	8
	Men	21
<b>Age (years)</b>	57.3 (10.0)	
<b>Systolic blood pressure (mmHg)</b>	129.6 (12.2)	
<b>Diastolic blood pressure (mmHg)</b>	78.6 (8.1)	
<b>Weight (kg)</b>	84.1 (11.0)	
<b>BMI (kg/m<sup>2</sup>)</b>	29.2 (2.4)	
<b>Antihypertensive drugs (n)</b>	1.6 (1.4)	
<b>Physical activity level (METs-min/week)</b>	2308 (2266)	
<b>Eating behavior (DEBQ)</b>	Emotional eating	27.1 (10.7)
	External eating	28.4 (6.6)
	Restrained eating	27.0 (6.0)
<b>Adherence to the Mediterranean diet (MEDAS)</b>	8.2 (2.1)	

<sup>a</sup> Time 1 (average values previous to patient reintervention).

Table 2  
Comparisons for Time 0 versus Time 1 versus Time 2.

VARIABLES	Time 0 vs. Time 1		Time 1 vs. Time 2		
	Difference (95% CI) <sup>a</sup>	P-value	Difference (95% CI) <sup>b</sup>	P-value	
Systolic blood pressure (mmHg)	2.3 (-4.0 to 8.5)	1.000	-4.7 (-8.7 to -0.7)	.017*	
Diastolic blood pressure (mmHg)	2.2 (-2.0 to 6.4)	.600	-3.5 (-6.2 to -0.8)	.009**	
BMI (kg/m <sup>2</sup> )	0.3 (-0.4 to 1.0)	.895	-0.7 (-1.0 to -0.4)	<.001**	
Eating behavior (DEBQ)	Emotional eating	-0.8 (-3.7 to 2.2)	1.000	-2.8 (-5.1 to -0.5)	.012*
	External eating	-1.1 (-3.3 to 1.1)	.640	-1.1 (-2.1 to -0.1)	.039*
	Restrained eating	-1.6 (-3.9 to 0.7)	.248	-0.2 (-1.6 to 1.2)	1.000

<sup>a</sup> Difference was calculated as Time 1 (PRE-reintervention) minus Time 0 (1st intervention FOLLOW-UP).

<sup>b</sup> Difference was calculated as Time 2 (POST-reintervention) minus Time 1 (PRE-reintervention).

\*  $P \leq 0.05$ ; \*\*  $P \leq 0.01$ .

## Discussion

This study indicates that the 29 hypertensive overweight or obese patients enrolled in the reintervention had maintained long-term benefits in terms of reduced BMI and blood pressure at a 3-year follow-up after having completed the 'Living Better' online intervention <sup>37,38</sup>. Likewise, our results show that these variables significantly improved after the same group of patients repeated the program a second time (reintervention). To the best of our knowledge, this is the first work using a web-based program aimed at promoting a healthy lifestyle based on psychoeducation, regular engagement in physical exercise, and the establishment of healthy eating habits with such a long-term follow-up time. It also appears to be the first study to describe the effects of a reintervention in patients with an obesity-hypertension phenotype.

Our results did not show any significant changes in any of the study variables (SBP, DBP, BMI, number of antihypertensive drugs, or eating behavior) at the 3-year follow-up, compared to the first intervention in 2018, with the exception of the level of physical activity, which had significantly worsened. This decline may have been because of the restrictions to movements and access to sports spaces imposed by governmental authorities as a result of the COVID-19 pandemic at the time of this work. In this sense, recent research indicates that there was a significant decrease in physical activity levels at this time,

accompanied by an increase in sedentary habits, due to these restrictions<sup>25,26</sup>. However, it is important to note that the IPAQ-Short questionnaire we administered to analyse physical activity levels in this study<sup>42,43</sup> only collected data from the 7 days prior to its completion and, therefore, did not represent the total amount of physical activity these patients had engaged in during the pandemic. Thus, these levels may have fluctuated depending on the prevailing limitations at any given time. Also of note, the eating behavior of the study patients did not significantly worsen during that time. Indeed, the 'Living Better' program has already been shown to effectively improve emotional eating and other psychological variables related to eating and quality of life (anxiety and stress)<sup>37</sup>. These results are consistent with the absence of significant changes in blood pressure and BMI, together indicating the long-term effectiveness of the 'Living Better' program.

Thus, to help deal with the possible negative lifestyle effects of the COVID-19 pandemic on patients with the obesity-hypertension phenotype (for example, decreased physical activity levels), we decided to implement a second intervention with the same program. Given the self-administered, interactive, multimedia, and web-based nature of the platform, we hypothesised that repeating this program could reinforce and enhance the knowledge the patients had acquired after the first intervention, helping them to face the restrictions resulting from the presence of SARS-CoV-2 and thereby perhaps minimising the negative impact of the situation on their lifestyle and health.

The results we obtained after administering the reintervention confirmed our hypothesis. Thus, despite the restrictions imposed by the COVID-19 pandemic, the participants had significantly increased their levels of physical activity –after 3 months of reintervention– by about 30%, or around 900 METs-min/week. This may have also translated into an improvement in cardiorespiratory fitness (CRF) as a result of them engaging in moderate-vigorous intensity activities<sup>25,47</sup>. Interestingly, CRF is closely and inversely related to all-cause morbidity and mortality<sup>48</sup> and also strongly impacts the prognosis and evolution of patients with COVID-19, even more so in the presence of associated comorbidities such as obesity<sup>25,49</sup> or hypertension<sup>50</sup>. Thus, although none of the 29 participants was infected with SARS-CoV-2 before or during the study, the 'Living Better' program effectively increased the levels of physical activity of its participants during the COVID-19 pandemic. Hence, if any of these patients had been infected with SARS-CoV-2, the program may have conferred some protective effects by slightly reducing their risk of complications and improving their prognosis.

In addition to the improvements in physical activity levels, as already demonstrated in the first intervention in 2018<sup>37</sup>, reintervention with the 'Living Better' program also positively influenced emotional eating and external eating. In fact, one of the goals of this program is to change eating behaviors (generating a more conscious and less impulsive eating style) by using psychoeducation, eating tricks, and self-control strategies. This finding is relevant because eating styles are considered to be multi-dimensional, stable, and related to obesity<sup>51</sup>. The latter is important in the context of the negative emotions such as anxiety and panic generated by the COVID-19 pandemic, which have been associated with unhealthy eating behaviors in populations with higher rates of obesity<sup>52,53</sup>. Furthermore, adherence

to the Mediterranean diet before reintervention was close to the upper limit of the 'medium adherence' range (8.2 points on the MEDAS questionnaire)<sup>46</sup>, perhaps because of the effect of the first intervention. Nonetheless, the reintervention still produced a slight increase in the score by 0.6 points.

Therefore, presumably as a consequence of improvements in physical activity levels and eating behavior after the reintervention, the participants had reduced their body weight by an average of 2 kg, which translated into a significant reduction in BMI by 0.7 kg/m<sup>2</sup>. Of special note, this BMI reduction was even higher than that achieved after the first intervention in 2018 (0.4 kg/m<sup>2</sup>)<sup>38</sup>. In addition, the literature also reflects the direct impact that weight loss has on blood pressure values<sup>54</sup>. In this sense, compared to our first study<sup>38</sup>, the SBP and DBP of the reintervened patients also decreased further, possibly as a consequence of the greater BMI reduction. In these patients SBP and DBP decreased by 4.7 and 3.5 mmHg respectively ( $P=.017$  and  $P=.009$ ), compared to the non-significant reduction in SBP (-2.6 mmHg,  $P=.15$ ) and the lower reduction in DBP (-2.2 mmHg,  $P=.05$ ) we reported after the first intervention in 2018. These post-reintervention improvements also exceeded those reported in the meta-analysis by Liu et al. on internet-based lifestyle counselling<sup>34</sup> in which SBP and DBP reduced by a mean 3.8 mmHg and 2.1 mmHg, respectively. Likewise, it is important to note that the improvements we found in this research were not the result of a change in medication because no significant differences were reported in the number of hypertensive drugs used by the participants at any of the timepoints examined.

In terms of program engagement<sup>55</sup>, the percentage of participants who completed our entire program was lower (38%) than our first intervention<sup>38</sup> or similar e-counselling lifestyle interventions<sup>56</sup>. The low completion rate for the whole program during the reintervention may have been partly because of the limitations caused by the COVID-19 pandemic, perhaps forcing the population to adapt their working hours and spaces as well as reducing the availability of personal time and resources<sup>57,58</sup>. This phenomenon may also have been because the participants had remembered some of the educational content from the first intervention, leading them to complete only the modules that they considered necessary. Indeed, two-thirds of the participants completed at least half of the 'Living Better' program (5 or more modules). Moreover, the mean participant satisfaction with the reintervention was 1.2 points (out of 10) higher than the average from the first intervention, although this did not reach statistical significance. This difference may be because of the alterations we made to the program presentation by including more audiovisual content<sup>59,60</sup>, as suggested by the patients after the first intervention.

At this point, it is important to highlight that the Internet has been shown as an effective means to promote healthy lifestyles in order to help prevent and treat chronic diseases. This is because it can reach more people (including those with limited access to health services or low levels of social support) and it can provide patients with more intensive contact with clinicians at a lower economic cost than conventional face-to-face programs<sup>61,62</sup>. Additionally, internet-based platforms can provide immediate, easily accessible, individually tailored (one-on-one), and permanent (accessible at any time) support to patients in the comfort of their own homes. All these advantages were especially relevant in the context of the COVID-19 pandemic which was ongoing while this study was implemented. Therefore, the long-

term effects of the web-based ‘Living Better’ program and those obtained after a reintervention with the same program were remarkable and should be scientifically valued. They minimised the profound negative impact of COVID-19 on the health of these patients –who all had an obesity-hypertension phenotype— and even managed to improve their health profiles.

## Limitations

The main limitation of this study was the absence of a control group. Of note, since the sample size was small—because the study design was a continuation of previous work—and mostly for ethical reasons, all 29 participants were assigned to a single experimental group so that this population, which was especially vulnerable to COVID-19, would receive effective treatment during this work. Although the positive eating behavior, physical activity, BMI, and blood pressure results were similar to those obtained in our previous ‘Living Better’ randomised controlled trial, the absence of a control group must be considered when interpreting the effects of this reintervention. Controls eliminate the alternate explanations of experimental results, especially confounding variables and experimenter bias, enabling investigators to control for threats to validity. In addition, although prior to reintervention we were unable to identify any differences in the variables in the 29 participants and the 76 patients excluded from the study, we cannot rule out the possibility of a selection bias. Finally, the participants were unable to go to the hospital for BMI and blood pressure measurements before and after the reintervention because of the COVID-19 pandemic restrictions. However, this problem was mitigated by having these measurements completed by the same person (a pharmacist or pharmacy assistant) using the same approved devices both times, and strictly following the ESH protocol as in the first intervention. Nonetheless, the people performing the measurements and the devices used were not the same for all the participants.

## Conclusions

This study shows that the ‘Living Better’ web-based program had long-term (3-year) benefits on the health of patients with an obesity-hypertension phenotype. In addition, given the context of the ongoing COVID-19 pandemic, we evaluated the effects of implementing a second intervention in these patients with the same program to try to reduce the potential negative consequences of the pandemic on their lifestyles. The reintervention showed significant improvements, for the second time, on eating behavior, physical activity levels, BMI, and blood pressure.

## Abbreviations

COVID-19

Coronavirus Disease 2019

DBP

Diastolic Blood Pressure

DEBQ

Dutch Eating Behavior Questionnaire

ESH

European Society of Hypertension

HTN

Hypertension

IPAQ-Short

International Physical Activity Questionnaire short form

MEDAS

Mediterranean Diet Adherence Screener

METs

Metabolic Equivalents

*PREDIMED*

*Prevención con Dieta Mediterránea*

SARS-CoV-2

Severe Acute Respiratory Syndrome Coronavirus 2

SBP

Systolic Blood Pressure

## Declarations

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### AUTHOR CONTRIBUTIONS

PM-B and JL conceived this research methodology and wrote/prepared the original draft. MR-C and RH were responsible for the methodology. PM-B and JL conducted a formal analysis. RB, ER, and JL managed the investigation. PM-B, MR-C, and RH reviewed and edited the manuscript. RC, MV, and TE-M were responsible for visualization. JL acquired funding. All authors contributed to the article and approved the submitted version.

### COMPETING INTERESTS

The authors declare no competing interests.

### DATA AVAILABILITY

The original contributions presented in the study are included in the article, further inquiries can be directed to the corresponding authors.

## ETHICS DECLARATION

This study, where human participants were involved, was reviewed and approved by the CEU Cardenal Herrera University Ethics Committee (CEI19/085). This research was also approved by the Human Research Ethics Committee at the *Hospital Universitario de Sagunto* and followed the ethical guidelines established in the Declaration of Helsinki. The patients/participants provided their written informed consent to participate in this study.

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## Figures

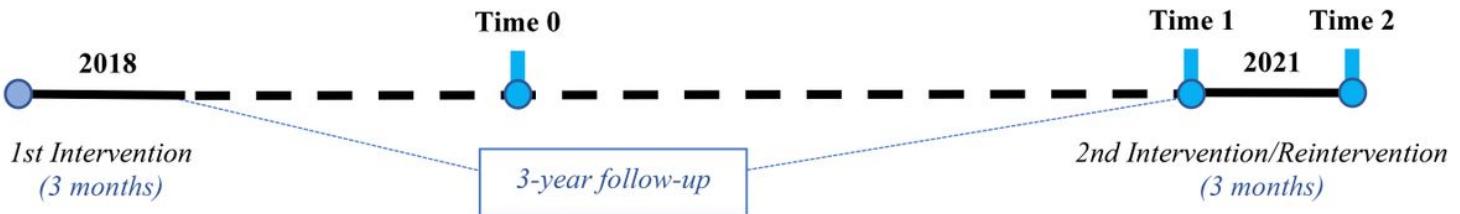
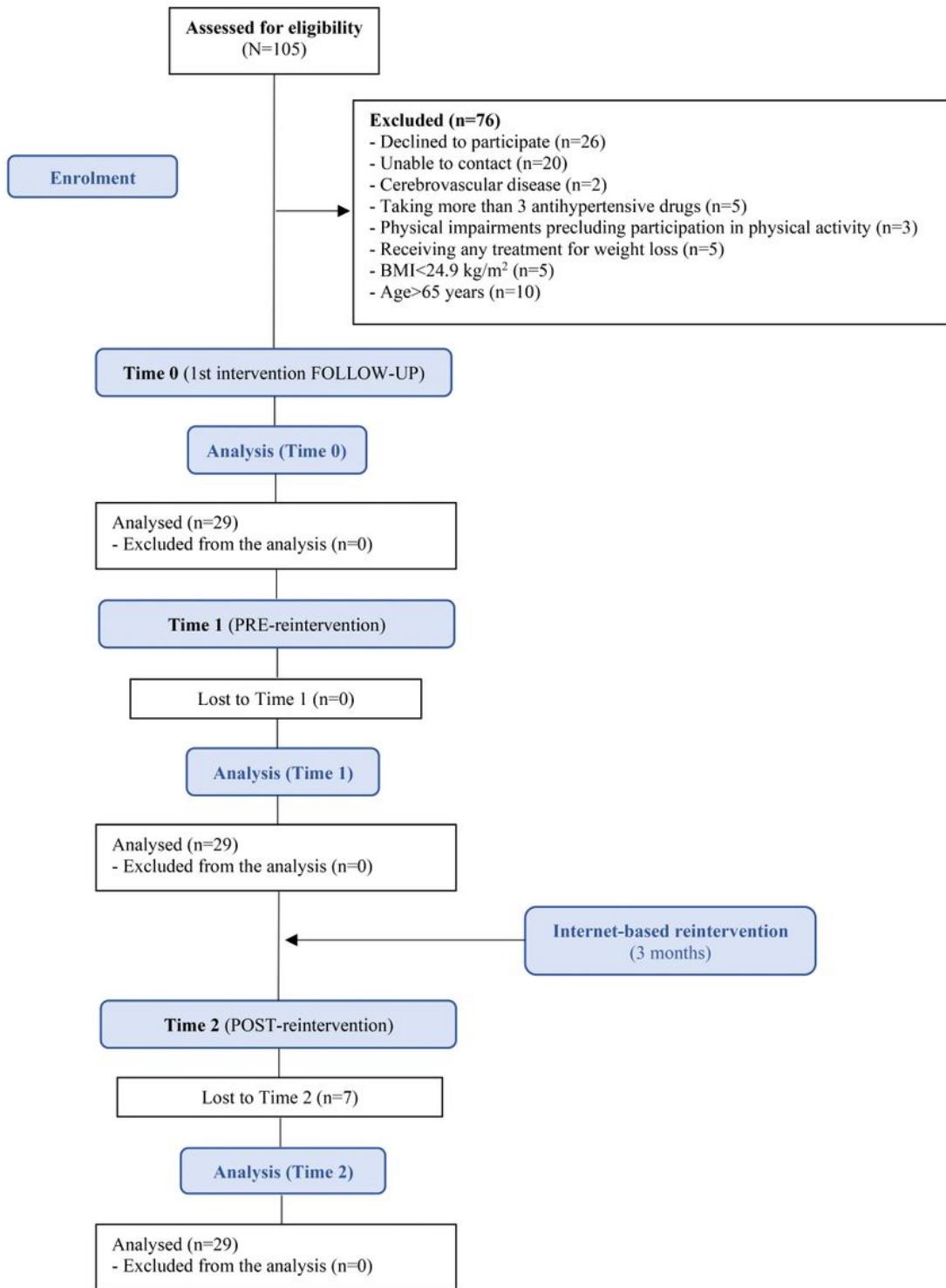


Figure 1

Measurements at trial profile (Time 0, Time 1, and Time 2). *Figure 1 shows the time periods when assessments and reintervention were carried out, along the 3-year follow-up.*



**Figure 2**

Progression of the participants through the study.