

RESEARCH ARTICLE

Effectiveness of an eHealth intervention to improve subjective well-being and self-efficacy in cardiovascular disease patients: A pilot non-randomized controlled trial

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Funding information

Ministerio de Ciencia, Innovación y Universidades, Grant/Award Number: PDI2019-107304RB-I00; Ministerio de Economía y Competitividad, Grant/Award Number: PSI2014-58609-R

Abstract

Aim: To evaluate the effectiveness of a multicomponent, eHealth-based self-efficacy intervention to promote subjective well-being and self-efficacy in patients with cardiovascular disease, exploring sex differences.

Design: A pilot study of a two-arm non-randomized controlled trial.

Methods: Forty-two cardiovascular patients (31% women) participated in the study. The experimental group received a personalized psychoeducational session and a 14-days eHealth intervention. Subjective well-being (positive and negative affect) and self-efficacy (chronic and cardiac) were assessed at baseline, post-psychoeducational session, post-eHealth intervention and at two follow-ups.

Results: The levels of the experimental group in positive affect, at post-eHealth and follow-up 1, and self-efficacy, at post-eHealth, and both follow-ups, were statistically significantly higher compared to the control group (all $ps < .05$). When considering sex, the intervention was effective only for men. The results highlight the potential of eHealth interventions for cardiac patients and underline the importance of considering a gender perspective in their treatment.

KEYWORDS

cardiovascular disease, eHealth, nursing, self-efficacy, sex differences, subjective well-being

1 | INTRODUCTION

Population ageing and increased life expectancy are signs of an improvement in health care and quality of life (QOL) but this also means having to manage chronic disease for longer (Atella et al., 2019). This supposes a challenge to public health systems and to the patients who have to live and struggle with their health condition.

Cardiovascular disease (CVD) is the most prevalent of the chronic diseases and the leading cause of death worldwide (World Health Organization, 2019), forming most of the burden on healthcare systems (Roth et al., 2017). Non-adherence to treatment (Al-Ganmi et al., 2020; Leslie et al., 2018), low acceptance and adjustment to the disease and poor self-efficacy for coping with the new requirements of the diagnosis, are some of the variables that may affect to

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the morbidity of CVD. Therefore, to support these patients in this process focusing on variables related to the engagement with medical treatment and healthcare behaviours (i.e. healthy diet, exercising, etc.) should be a priority.

2 | BACKGROUND

From a biopsychosocial model of health, several studies have proved a well-established relationship between cardiovascular disease and psychological distress such as anxiety/depressive symptoms, poor emotion regulation and low self-efficacy to manage the disease (Appleton et al., 2014; Hare et al., 2013; Wierenga et al., 2017). Variables closely related to the prognosis of the disease and QOL. Considering the interaction between biomedical conditions and psychosocial functioning, and vice versa (O'Leary, 1985), to include a psychological approach when intervening with cardiac patients is vital. In this sense, to take into account variables that affect subjective well-being (i.e. life satisfaction, happiness, affective balance) (Diener, 2009) and self-management and self-efficacy, could facilitate the adjustment to the disease as also minimize the psychological distress related to CVD diagnosis.

Self-efficacy is a psychological factor known to have an influence on management of the chronic disease (Survonen et al., 2019), cardiac rehabilitation and perceived health-related QOL (Cuadrado et al., 2018). Defined by Bandura in the framework of the social learning theory of causation, self-efficacy explains the influence of people's perception of their capabilities on their behaviour, motivation and emotional and cognitive patterns (O'Leary, 1985). Research has found a relationship between stronger self-efficacy and better psychological well-being (Krok & Zarzycka, 2020) and life satisfaction (Castillo-Mayén et al., 2014) in patients with CVD. Other studies have shown, also for cardiac patients, positive influence of self-efficacy on adherence to healthy diet (Castillo-Mayén et al., 2014), exercising (Bergström et al., 2015), health-related QOL (Taberner et al., 2020) and self-care activities (Banik et al., 2018). These results highlight the important role that self-efficacy has on CVD patients' well-being, reinforcing their perception of their ability to cope with the different situations that may occur throughout their disease (Banik et al., 2018).

Recently, there is a growing body of research assessing the effectiveness of cardiovascular programs. Some studies have shown that multicomponent programs that include different kinds of intervention (psychotherapy, psychoeducation, symptom recognition, weight control, etc.) are more efficient than single-component programs for improving adherence (Jafar et al., 2017). Tailored or person-centred interventions are now the focus and have become the strongest challenge for intervening in CVD, with promising results (Cioe et al., 2021). Such interventions would allow to be more accurate in terms of attending patient's needs and circumstances,

resulting in better outcomes of the interventions and greater impact on the quality of life of these patients.

Recently, eHealth-based interventions are gaining support, given their online nature and especially after the recent COVID-19 pandemic (Rauschenberg et al., 2021). The low cost and positive results shown for improving management of chronic diseases, adherence to prescribed medication and the physical and mental well-being of patients place them as a good option for CVD (Baretta et al., 2019; Palmer et al., 2018). However, self-efficacy programs based on tailored, eHealth or multicomponent interventions in CVD patients remain scarce.

Equally limited is research evaluating gender and/or sex differences in the efficacy of interventions with CVD patients. Attending to previous literature, men and women differ in how they experience this type of health condition, showing differences in prevalence, symptoms and prognosis (Gao et al., 2019; Peters et al., 2019). According to several studies, this is due not only to purely biological factors, but also to psychosocial factors that are undoubtedly related to gender, such as the burden derived from the dual work/domestic role, socio-economic status or emotional distress caused by exposure to stressful life conditions (Luque et al., 2020; Medina-Inojosa et al., 2019).

In this pilot study, we propose a multicomponent intervention based on a personalized psychoeducation and an eHealth psychological intervention on self-efficacy. Thus, this paper presents a two-arm non-randomized controlled trial study aimed at designing, developing and pilot testing the effectiveness of the intervention to improve cardiac patients' subjective well-being and self-efficacy for managing the disease. Furthermore, in order to apply a gender perspective on cardiovascular health and be more sensitive and accurate in our study results, sex differences in the effectiveness of the intervention were also assessed.

We hypothesized better subjective well-being and better self-efficacy for managing CVD in the experimental group compared to the control group. In particular, we expected these differences to be maintained over time. Furthermore, differences in both variables between men and women were expected consistent with gender socialization, with better self-efficacy outcomes for men and greater improvement in subjective well-being for women.

3 | THE STUDY

3.1 | Design

This pilot study employed a two-arm non-randomized controlled trial design. The experimental group received a combined psychological intervention in self-efficacy, including a personalized psychoeducational face-to-face session with a subsequent eHealth intervention, while the control group continued with their treatment as usual.

3.2 | Method

3.2.1 | Study setting and participants

The study setting was the Clinical Research Building of the Maimonides Biomedical Research Institute of Cordoba, Spain. Patients were enrolled from The Cardiology Unit of the University Reina Sofia Hospital in Córdoba and the Association of Cardiac Patients of Córdoba and Province. Inclusion criteria were, (1) women and men with a diagnosis of a CVD (angina pectoris, myocardial infarction, heart failure, arrhythmia, etc.) aged >18, (2) fluent in Spanish, (3) having a smartphone compatible with the APP used for the eHealth intervention (WhatsApp) and daily access to internet and (4) having the required digital skills to follow the eHealth intervention. Exclusion criteria were, (1) women and men with a diagnosis of a CVD <18 years, (2) not having a smartphone compatible with WhatsApp, (3) not having the required digital skills, (4) currently participating in another clinical trial and (5) currently receiving other psychological treatment. According to the rules of thumb (Whitehead et al., 2016), sample sizes between 24 and 50 are recommended for pilot studies (Browne, 1995; Julious, 2005; Sim & Lewis, 2012). Eligible participants were recruited between September and November 2019. Of those initially approached ($N = 64$), 42 patients agreed to participate and provided their written informed consent at the beginning of the first study phase. Participants were assigned to either the self-efficacy group ($n = 21$) or the control group ($n = 21$) based on their availability to participate in the face-to-face psychoeducational intervention. The program G-power 3.1 (Faul et al., 2009) was implemented to confirm that the statistical power was at least 0.8 for PANAS, SECMD and CMSES analyses with the actual sample size.

3.2.2 | Intervention

Experimental group—Self-efficacy intervention

The experimental group received a multicomponent intervention including a personalized psychoeducational session in self-efficacy and a subsequent 14-days eHealth-based psychological intervention in self-efficacy. Both components of the intervention were designed and developed following the Bandura's theory of self-efficacy (1997).

Personalized psychoeducational intervention in self-efficacy: It was performed by a General Health Psychologist in a private room at the Clinical Research Building of the Maimonides Biomedical Research Institute of Cordoba. The aims of the psychoeducational session were to: (1) familiarize patients with the self-efficacy concept and its influence in the course of CVD; (2) identify patients' health needs and provide the resources to improve their self-efficacy and achieve their health-related goals; and (3) explain the eHealth intervention procedure.

The sessions were carried out individually, allowing the intervention to be personalized to the patient's needs. Once the patients

were familiar with the concept of self-efficacy, the rest of the contents were adapted based on the participant's own objectives and experiences. At the end of this session, patients were given a brochure containing key information of the psychoeducation received and a scheme of the eHealth intervention procedure.

eHealth-based psychological intervention in self-efficacy: It started the day after the psychoeducational session and lasted 14 days. We opted for a brief intervention because of its cost effectiveness and promising results shown in cardiac rehabilitation programs (Armitage, 2015; Fernandes et al., 2017). The main objective of this intervention was to train patients in self-efficacy in order to improve their management of CVD. This practice focused on the principal sources of self-efficacy (Bandura, 1997)—mastery experiences, vicarious experiences, verbal persuasion and emotional-physiological states—all of which were adapted to health issues, such as, following a healthy diet, stop smoking, increasing physical activity etc. The patients received a daily message (14 messages in total) at the same time (10 am) through *WhatsApp*. Each message contained a brief explanation with an activity they had to perform, a suggestion and/or advice linked to self-efficacy and health (Table 1). Patients were asked to do the activities considering their own cardiovascular health-related goals identified in the psychoeducational session.

Control group—Treatment as usual

Patients of the control group continued with their usual treatment: medication and their ordinary medical follow-up. They did not attend to the psychoeducational session and did not receive the eHealth *WhatsApp* intervention.

This study included five points of evaluation for the experimental group: at baseline; after the psychoeducational session (post-session); after the 2-weeks eHealth-based psychological intervention (post-eHealth); and at 2-week and 4-week follow-up evaluations (Follow-ups 1 and 2, respectively). The participants of the control group were assessed at the same points except for the 'post-session', maintaining the same time elapse between each point than in the experimental group. Study evaluations were carried out via phone calls, except for the baseline and post-session evaluation, which were collected in situ for the experimental group. Data collection of the experimental condition was conducted by the psychologist that performed the psychoeducational session and the control group by an independent researcher who was blind to the group assignment. Data analysis was also blinded and performed by a third independent researcher.

3.2.3 | Study instruments

Socio-demographic and CVD characteristics

Socio-demographic information, such as sex, age, employment status and educational level, and CVD-specific characteristics, such as type of CVD and level of limitation in the activities of daily life (ADL), were provided by the participants.

TABLE 1 Examples of the eHealth self-efficacy intervention online messages

Sources of self-efficacy	Message content type
Mastery experiences	Remember a situation in your life that has been particularly difficult and that you had overcome successfully. Try to visualize it and reflect on how you felt (worried, tense, nervous) and how you felt when you overcame it (relieved, calm, etc.). Remembering moments of success can generate a pleasant feeling of security and confidence. If you did it then, why not now?
Vicarious experiences	Choose a situation that you find difficult to cope with or stressful in your life in any domain. Think of a person close and important to you who copes effectively with that situation. Observe and record the behaviours and strategies that person uses to cope with this situation. Practice the behaviours you have observed and assessed as effective
Verbal persuasion	Giving ourselves positive messages is important for self-esteem and self-efficacy. Repeat to yourself phrases such as 'I am able to cope and overcome difficult situations' or 'even though sometimes things do not go my way, I am able to find solutions, bounce back and thrive in the face of difficulties'. Believing and trusting in yourself will make it easier for you to cope with difficult life situations
Emotional-physiological states	It is time to become aware of our body and the sensations we experience on a regular basis to be able to recognize when things are not going as they should. How does your body feel right now? Take a few minutes and calmly review your body sensations, how do they relate to your current mood? Becoming aware of how we feel can help us improve our self-efficacy

Subjective well-being

Subjective well-being was measured with the Positive and Negative Affect Scale (PANAS) (Taberner et al., 2009; Watson et al., 1988). This is a self-report questionnaire with 20 items assessing positive and negative affect on two subscales of 10 items each. Positive affect is the dimension of subjective well-being referring to the degree to which a person feels excited, active, influenced and alert. Negative affect, on the other hand, reflects the subjective discomfort that include a range of unpleasant emotions (i.e. anger, disgust, guilt, fear and nervousness) (Watson et al., 1988). Response statements were from 1 (nothing) to 5 (totally) with a total score from 10 to 50 points on each scale. Higher values in positive affect scale and lower values in negative affect scale indicate a better subjective well-being, a state of high energy, concentration, serenity and calmness (Watson et al., 1988). The Cronbach's alpha in the original study for the positive and negative scales were 0.88 and 0.89, respectively. In this study, Cronbach's alpha coefficient was 0.89 for positive affect and 0.93 for negative affect.

Self-efficacy

For self-efficacy, we decided to use two different scales in order to enrich the information about this construct considering the study sample clinical population. The Self-Efficacy for Managing Chronic Disease (SEMCD) scale (Lorig et al., 2001, 2003) and the Cardiovascular Management Self-Efficacy Scale (CMSES) (Steca et al., 2015). The SEMCD is a six-item Likert-type scale that measures self-efficacy for managing a chronic disease, from 1 (not at all confident) to 10 (completely confident) with a total range score from 6 to 60. The results of this scale would provide information related to the confidence perception to cope with the chronic condition with items encompassing this construct from an overall perspective (i.e. How confident are you that you can keep the fatigue caused by your disease from interfering with the things you want to do?). The CMSES, on the other side, assesses self-efficacy for managing CVD specifically and is a nine-item Likert-type scale measuring three different factors: cardiac risk (four

items), adherence to therapy (two items) and recognition of cardiac symptomatology (three items). The range goes from 1 (not at all confident) to 5 (completely confident) with a total score from 9 to 45. The results of this scale would offer more concrete information about subjective self-efficacy to cope with cardiovascular disease, with items that englobe the principal characteristics and symptoms of this condition (i.e. How well can you recognize illness symptoms, such as palpitations, tachycardia and short breath? How well can you always recognize the symptoms of your illness, such as a chest pain?). Both scales, which complement each other, would provide well-rounded approach to the self-efficacy construct. Higher values in SEMCD and CMSES indicate a better self-efficacy to manage the chronic and cardiac disease. SEMCD Cronbach's α coefficient in the original study was 0.88 and 0.89 in this study. CMSES Cronbach's alpha were from 0.68 to 0.79 in the original study and 0.60 in this study.

3.3 | Data analysis

Descriptive analyses were performed to identify the characteristics of the sample and of each group. Number, percentage, mean and standard deviations were calculated for patients' baseline data involving socio-demographic and CVD characteristics. The normal distribution of each variable at each evaluation moment was tested. The Shapiro-Wilk test indicated that normality was violated in 14 out of 16 assessments (4 scales \times 4 time point evaluation). Following the recommendations when assumptions of normality is violated (Nahm, 2016; Rana et al., 2016), especially in small samples (Derrick et al., 2020; Happ et al., 2018), non-parametric tests were performed. Mann-Whitney U test was used to compare age, chi-square tests and Fisher's exact Test were used to compare dichotomized and categorical variables. To examine the effect of the psychoeducational session in the experimental group, a paired sample Wilcoxon test was used. To test differences between groups and phases of the study, a Mann-Whitney U test was used. Finally, a Wilcoxon signed-rank

test was used to analyse the time effect of the intervention in the experimental group. A p value of $<.05$ was considered statistically significant. All analyses were conducted using IBM SPSS v25.0.

3.4 | Ethics

This study was approved by the Andalusian Health Service's Research Ethics Committee and the Reina Sofia Hospital in June 2015 (Acta 242, Ref. 2,886, June 29, 2015).

4 | RESULTS

Figure 1 shows the flow chart of the participants and instruments used over the different phases of the study. According to the socio-demographic and CVD characteristics, the results showed differences in age and marital status between groups (Table 2).

4.1 | Effects of the intervention in the general sample

4.1.1 | Personalized psychoeducational session

About the 1-hour self-efficacy psychoeducational session, results from the Wilcoxon test showed statistically significant differences between baseline and post-session phases in subjective well-being (PANAS) and in self-efficacy on the SEMCD, with higher scores in the post-session evaluation for positive affect and self-efficacy and lower scores for negative affect (Table 3).

4.1.2 | Effects of eHealth intervention: Between-group differences

About subjective well-being, for positive affect the Mann-Whitney U test showed differences between groups at post-eHealth, where the experimental group ($Mdn = 4.10$) showed higher scores compared to the control group ($Mdn = 3.70$), and at Follow-up 1, where the experimental group also showed higher scores ($Mdn = 4.30$) compared to the control group ($Mdn = 3.70$). For negative affect, no differences were found between the groups in any evaluation phase.

According to self-efficacy variables, both scales evaluated showed differences between groups. For the SEMCD, the Mann-Whitney U test showed differences at post-eHealth, with higher scores in the experimental group ($Mdn = 9$) compared to the control group ($Mdn = 7.33$), at Follow-up 1, where the self-efficacy group showed higher scores ($Mdn = 8.83$) compared to the control group ($Mdn = 7.83$), and finally at Follow-up 2, with greater scores ($Mdn = 9$) in the experimental group compared to the control group

($Mdn = 7.66$). For the CMSES, results indicated differences between groups at post-eHealth, where the experimental group showed higher scores ($Mdn = 4.66$) than the control group ($Mdn = 4.33$). The results are shown in Figure 2 and Table 4. No differences were found at baseline between groups on the self-efficacy variable.

4.1.3 | Effects of eHealth intervention: in-group differences in the experimental group

About subjective well-being, for positive affect a Wilcoxon signed-rank test indicated that the post-eHealth and Follow-up 1 scores were statistically significantly higher than baseline scores. For negative affect, a Wilcoxon signed-rank test indicated significant differences when comparing post-eHealth, Follow-up 1 and Follow-up 2 with baseline, the negative affect scores being lower at all three post-evaluation assessments.

For self-efficacy variables, the SEMCD results showed statistically significant higher scores at follow-up 1 compared to baseline. Finally, the CMSES results indicated statistically significant differences when comparing post-eHealth, Follow-up 1 and Follow-up 2 with baseline, the scores being higher at all the evaluations compared to baseline. No differences were found between post-eHealth, Follow-up 1 and Follow-up 2 in any variable evaluated. The results are shown in Figure 3 and Table 5.

4.2 | Effects of the intervention according to sex

4.2.1 | Personalized psychoeducational session

The psychoeducational session had a different effect for men and women. Women showed an improvement of their subjective well-being, with statistically significant differences in both positive and negative affect, whereas men showed not only an increased subjective well-being but also higher scores in both self-efficacy measures (Table 6).

4.2.2 | Effects of eHealth intervention: Between-group differences

Considering subjective well-being, men in the experimental group showed greater scores at post-eHealth and both follow-ups for positive affect ($p = .051$, $p = .006$, $p = .018$) compared to men in the control group. No differences between any variable of subjective well-being were found when comparing women of both groups.

About self-efficacy variables, differences between groups in men were shown on the SEMCD ($p = .046$, $p = .005$, $p = .001$). No differences between groups were found in women. The results are shown in Figure 4.

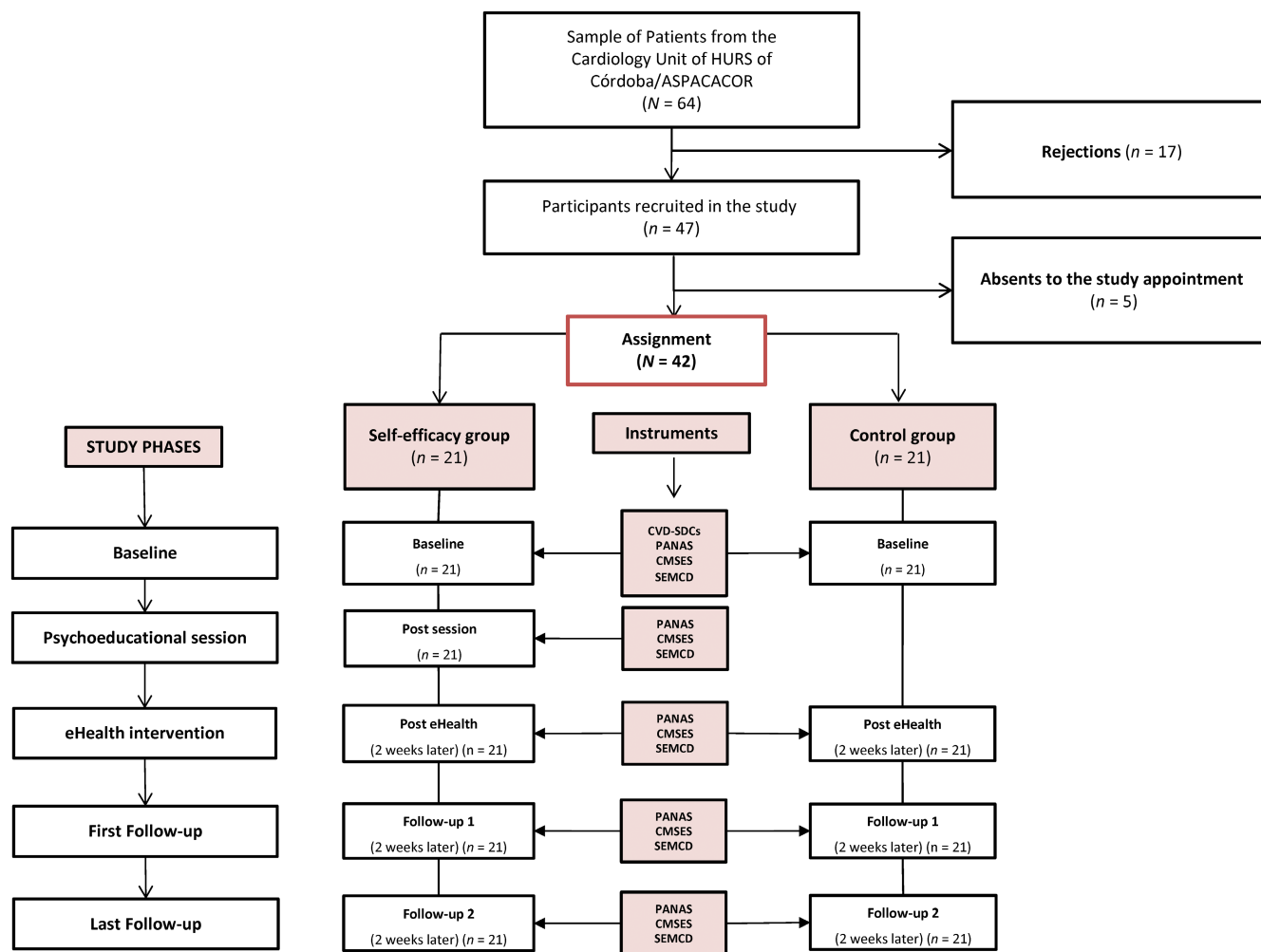


FIGURE 1 Flow chart of the sample phases and instruments of the study. ASPACACOR, Association of Cardiac Patients of Córdoba and province; CMSES, cardiovascular management self-efficacy scale; CVD-SDCs, cardiovascular disease and socio-demographic characteristics; HURS, university hospital Reina Sofía; PANAS, positive and negative affect; SEMCD, self-efficacy for managing chronic disease scale

4.2.3 | Effects of eHealth intervention: in-group differences in the experimental group

According to the effect of the intervention when comparing each phase evaluation with baseline, it was observed that men improved at some of the time points in all variables. Women, on the other hand, only showed statistically significant improvements in self-efficacy on the CMSES at post-evaluation that are maintained until the end of the study at Follow-up 2 (Table 7).

5 | DISCUSSION

The aim of this pilot study was to design, develop and evaluate the effectiveness of a multicomponent self-efficacy intervention to improve the subjective well-being and self-efficacy for patients to manage their CVD. The preliminary results showed that the 1-hour personalized psychoeducational session had a positive effect on the experimental group, showing increased subjective well-being

and improved self-efficacy variables, especially on the SEMCD. These improvements were maintained over time with the eHealth intervention so that the experimental group showed better subjective well-being and self-efficacy across all the evaluations. When comparing the experimental and control groups, the eHealth intervention was effective for enhancing positive affect. Furthermore, focusing on self-efficacy variables, the experimental group showed greater self-efficacy on the SEMCD in all phases of the evaluation. For self-efficacy on the CMSES, the results followed the same direction, except for the last follow-up where no difference between groups was found.

The different results in both self-efficacy variables could be explained by the fact that the changes that patients need to make in order to achieve self-efficacy in CVD involve high investment in time, personal effort and commitment. In fact, the constructs that define the CMSES variable are related to structural changes in people's lives, such as changing habits, either by acquiring new healthy behaviours (e.g. having a healthy balanced diet and exercising) or by avoiding harmful or risky behaviours (e.g. giving up smoking) (Steca

TABLE 2 Socio-demographic and cardiovascular disease (CVD) characteristics of the sample, showing statistical differences between experimental and control groups

	Total (N = 42)	Self-efficacy group (n = 21)	Control group (n = 21)	Group comparison
Age (M.SD)	63.6 (10.61)*	61.8 (6.61)	65.43 (13.42)	$U = 124.00. z = -2.43. p = .015^{*a}$
Sex. n (%)				
Male	29 (69%)	14	15	$\chi^2 = .111. df = 1. p = .739^b$
Female	13 (31%)	7	6	
Marital status. n (%)				
Single	2 (4.8%)	1	1	$p = .016^{*c}$
Married	32 (76.2%)	14	18	
Divorced	6 (14.3%)	6	0	
Widowed	2 (4.8%)	0	2	
Employment status. n (%)				
Retired	27 (64.3%)	12	15	$p = .594^c$
Full-time work	10 (23.8%)	6	4	
Unemployed	3 (7.1%)	2	1	
Home care	1 (2.4%)	0	1	
Part time job	1 (2.4%)	1	0	
Educational level. n (%)				
Basic primary school	35 (83.3%)	17	18	$p = 1^c$
High school or higher	7 (16.7%)	4	3	
Type of CVD. n (%)				
Angina pectoris	5 (11.9%)	3	2	$p = .659^c$
Myocardial infarction	25 (59.5%)	14	11	
Heart failure	3 (7.1%)	1	2	
Arrhythmia	4 (9.5%)	2	2	
Other	6 (14.3%)	3	3	
Level of limitation of ADL. n (%)				
Level 1	15 (37.5%)	8	7	$p = .664^c$
Level 2	13 (32.5%)	7	6	
Level 3	10 (25%)	4	6	
Level 4	2 (5%)	2	0	

Note: The type of CVD percentage was more than 100% because it was a multiple-answer question. Two participants of the control group did not answer the questions type of CVD and level of limitation of activities of daily living (ADL; N = 40).

^aU Mann-Whitney test.

^bChi-squared test.

^cFisher's exact test.

*Statistically significant differences.

et al., 2015). On the other hand, the positive results found on the SEMCD variable raise the opportunity of adapting this type of intervention and promote self-efficacy in other long-term diseases, such as diabetes, cancer, obesity, etc. (Jackson et al., 2014; Young et al., 2020).

When considering the in-subject effects of the eHealth intervention in the experimental group, improvements can be observed also in subjective emotional well-being and in both self-efficacy variables. Nevertheless, it should be noted that the positive effect of self-efficacy was higher on the CMSES than on the SEMCD. Given

that this intervention was specifically focused on and developed for patients with cardiovascular problems and that the personalized intervention was targeted at achieving goals related to CVD, this difference appears to be coherent.

Although we carried out a pilot study, the results obtained support evidence from previous research that relates the improvement of self-efficacy with better psychological well-being in CVD patients (Krok & Zarzycka, 2020). This research also contributes to support the influence of self-efficacy on the adherence of important healthy behaviours in order to cope with CVD (Bergström

	Baseline			Post-session (psychoeducation)			z	p
	M	SD	Mdn	M	SD	Mdn		
Positive affect	3.43	0.89	3.50	4.04	0.73	4.10	-2.91	.004*
Negative affect	2.33	1.09	2.20	1.36	0.59	1.10	-3.83	<.001*
SEMCD	7.52	2.07	7.83	8.13	1.44	8.00	-2.14	.003*
CMSES	4.14	0.58	4.30	4.23	0.58	4.22	-1.65	.098

TABLE 3 Comparison of subjective well-being and of self-efficacy on the SEMCD and CMSES at baseline and post-session in the experimental group

Abbreviations: CMSES, Cardiovascular Management Self-Efficacy Scale; M, mean; Mdn, Median; SD, standard deviation; SEMCD, Self-Efficacy for Managing Chronic Disease.

*Statistically significant differences.

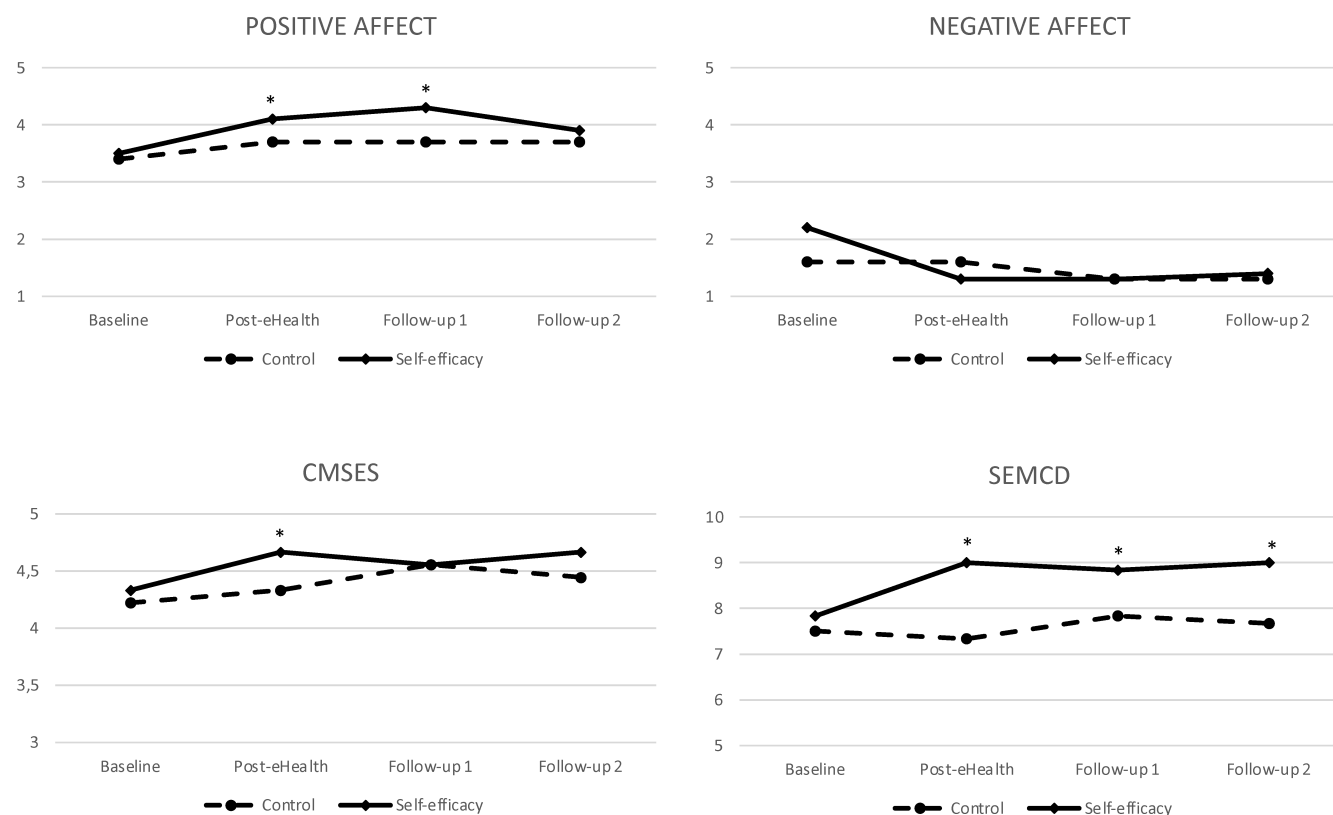


FIGURE 2 Graphical representation of differences between groups for subjective well-being and for self-efficacy. CMSES, Cardiovascular management self-efficacy scale; SEMCD, Self-efficacy for managing chronic disease scale. *statistically significant differences

et al., 2015; Castillo-Mayén et al., 2014; Taberero et al., 2020). Moreover, the results of this study add evidence to the growing body of research that supports the approach of personalized intervention to improve adherence to treatment and a better prognosis of the disease (Cioe et al., 2021; Xu et al., 2020). Finally, the current study provides additional evidence in this area of research that defends the combination of different types of intervention (Jafar et al., 2017) and specifically those that highlight the benefits of incorporating eHealth tools, which involve an update of the therapeutic process in chronic diseases (Baretta et al., 2019; Palmer et al., 2018; Rauschenberg et al., 2021) while economizing on resources. Compared to traditional approaches, eHealth interventions might be better tailored to characteristics of CVD patients, where the average age is frequently high and autonomy

and mobility are often impaired, which can complicate health attendance. In addition, this type of intervention may facilitate direct contact with patients even when geographical limitations exist, such as that they live in rural areas far from the hospital complex, easing the access to health care and cost saving (Farley, 2019). Moreover, the fact of receiving messages on a daily basis may be perceived by patients as an additional support, which is sometimes missing with traditional interventions, and this may have an effect on therapeutic adherence (Farley, 2019). However, human direct contact is always important, and eHealth interventions are known to be more effective when they are combined with in situ interventions. Therefore, health providers can reinforce this type of intervention to obtain better results given that the positive effect on therapeutic alliance that face-to-face sessions already produces

TABLE 4 Results showing significant differences between groups in all phases of the study for SWB and of self-efficacy on the SEMCD and CMSES

	Control group (n = 21)	Self-efficacy group (n = 21)	U	z	p
Subjective well-being					
Positive affect					
Post-eHealth	17.60	27.40	138.50	-2.07	.039*
Follow-up 1	17.24	25.76	131.00	-2.26	.024*
Self-efficacy					
SEMCD					
Post-eHealth	16.79	26.21	121.50	-2.49	.013*
Follow-up 1	16.52	26.48	116.00	-2.64	.008*
Follow-up 2	16.26	26.74	110.50	-2.77	.006*
CMSES					
Post-eHealth	17.17	19.07	129.50	-2.30	.021*

Abbreviations: CMSES, Cardiovascular Management Self-Efficacy Scale; SEMCD, Self-Efficacy for Managing Chronic Disease; SWB, Subjective well-being.

*Statistically significant differences.

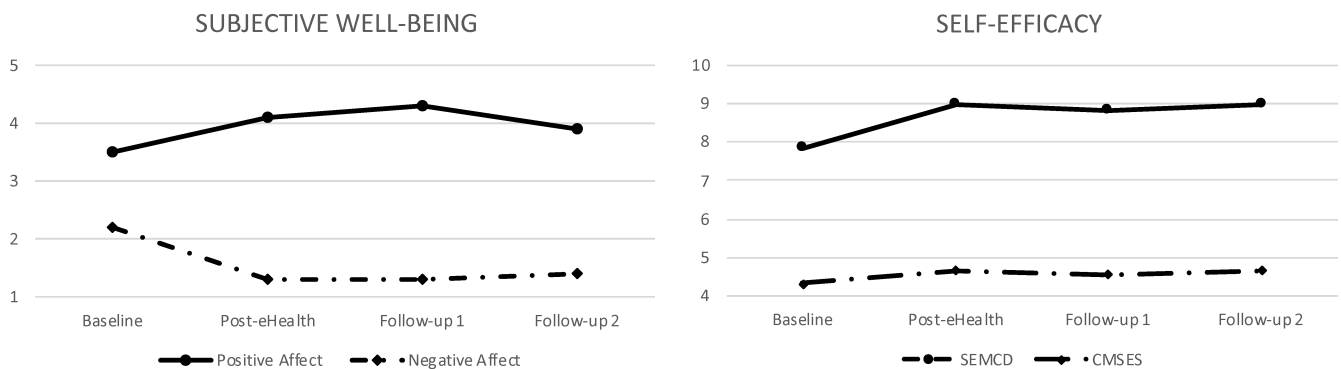


FIGURE 3 Graphical representation of in-group differences in the experimental group for subjective well-being and for self-efficacy. CMSES, Cardiovascular management self-efficacy scale; SEMCD, Self-efficacy for managing chronic disease scale

(Mohr et al., 2011). The benefits of eHealth have been reflected in previous research where its efficacy in improving adherence in chronic patients has been demonstrated (Baretta et al., 2019; Palmer et al., 2018; Peng et al., 2020). Nevertheless, it is important to emphasize that the effectiveness of eHealth may also depend on other factors that should be considered when interpreting the results. For instance, effectiveness could depend on how familiar patients are with the use of new technologies (Lancaster et al., 2018; Peng et al., 2020).

5.1 | Sex differences

Regarding the effectiveness of the multicomponent program we have developed for CVD patients, as expected, the findings revealed certain differences when analysing the data by sex. The results obtained indicate that the program seems to be more effective for men than for women in this study. Even in the first phase of the intervention—the personalized psychoeducation—the

results showed that women's improvement appeared in the area of emotional subjectivity whereas men improved in both subjective well-being and self-efficacy. This is consistent with gender socialization, which frequently implies the assumption of the socially accepted gender roles and stereotypes, according to which women are more related to the emotional sphere and men to action, the achievement of goals and other agency attributes (Castillo-Mayén & Montes-Berges, 2014), being these last constructs closely connected to self-efficacy. Comparing both groups, the results of the eHealth intervention showed that men improved on positive affect and self-efficacy measures but no enhancement was found in these measures for women. Previous literature shows differences in the prevalence of CVD between men and women (Gao et al., 2019; Peters et al., 2019); also, over and above prevalence, many studies have evaluated sex and gender differences concerning the symptoms, course and consequences of this health condition (Luque et al., 2020; Medina-Inojosa et al., 2019; Peters et al., 2019; Zhao et al., 2020). This fact should be carefully noted for practitioners as they might influence the accuracy of the

response to symptoms and even clinical gender biases in establishing treatments, thus affecting the prognosis and QOL of female patients (Peters et al., 2019; Zhao et al., 2020).

5.2 | Limitations and future research

As a principal limitation, we acknowledge that without a random allocation of the study participants, there is a risk of bias in the results. Additionally, the fact that we excluded patients who did not have the digital skills to follow the eHealth intervention, could represent a

TABLE 5 Results showing statistically significant differences in the experimental group in all phases of the study for SWB and of self-efficacy on the SEMCD and CMSES

	T	z	p
Subjective well-being			
Positive affect			
Post-eHealth- Baseline	184	-2.96	.003*
Follow-up 1- Baseline	172.5	-3.12	.002*
Negative affect			
Post-eHealth- Baseline	27	-2.74	.006*
Follow-up 1- Baseline	18.5	-3.08	.002*
Follow-up 2- Baseline	42	-2.56	.011*
Self-efficacy			
SEMCD			
Follow-up 1- Baseline	142	-2.46	.014*
CMSES			
Post-eHealth- Baseline	173	-3.15	.002*
Follow-up 1- Baseline	153.5	-2.97	.003*
Follow-up 2- Baseline	152.5	-2.91	.004*

Abbreviations: CMSES, Cardiovascular Management Self-Efficacy Scale; SEMCD, Self-Efficacy for Managing Chronic Disease; SWB, Subjective well-being.

*Statistically significant differences.

sampling bias. A limitation about a potential bias in the data collection also needs to be mentioned given that the assessment of the experimental group was conducted by the psychologist/researcher who performed the psychoeducational session. Certainly, future studies should implement a double-blind procedure to avoid this risk of bias. Also, due to the small sample size, results should be interpreted with caution. However, the findings of this pilot study seem favourable for the improvement of the well-being and self-efficacy of patients with CVD. Previous pilot studies testing mHealth interventions in patients with chronic diseases, including CVD (Jonker et al., 2020; Licskai et al., 2013) also used a similar sample size. Notwithstanding, it is necessary to test the replicability and robustness of the results in future experimental studies with a wider sample size, which would allow to improve the statistic power of the results. Finally, we did not consider previous mental health issues of participants, which could have interfered with the effectiveness of the intervention. Therefore, future research would benefit from including psychological well-being-related variables as a control.

Future research aiming to work from a multicomponent and personalized approach may need to include personalization in all phases of the intervention to guarantee a stronger therapeutic alliance and to obtain more solid results. For future research it would be very enriching to add other kinds of variables related to CVD, QOL and mental health to observe if this multicomponent personalized intervention positively influences other important aspects such as anxious-depressive symptomatology. The pandemic situation due to the COVID-19 has highlighted the need to bring interventions closer to patients. eHealth tools have been proved to be a powerful ally for reducing costs and efforts, and facilitating patient recovery during these times of pandemic. Due to the massive use of new technologies during the confinement and the safety measures implemented, it would be very useful to determine if the effects found in this study could be enhanced after the pandemic to replicate this intervention. Finally, further studies in this direction should analyse sex and gender variables in order to personalize the intervention and close the gap about the gender breach on health.

TABLE 6 Comparison of SWB and of self-efficacy on the SEMCD and CMSES at baseline and post-session for women and men

		Baseline			Post-session			z	p
		M	SD	Mdn	M	SD	Mdn		
Positive Affect	Women	3.35	0.72	3.10	4.01	0.35	4.40	-2.37	.018*
	Men	3.49	0.97	3.95	4.06	0.87	4.25	-1.89	.059
Negative Affect	Women	2.28	1.06	2.70	1.33	0.49	1.40	-2.21	.027*
	Men	1.90	0.93	2.20	1.37	0.65	1.05	-3.19	.001*
SEMCD	Women	7.08	1.77	7.83	7.90	0.88	9.00	-1.05	.293
	Men	7.25	2.23	8.50	8.24	1.68	9.08	-1.78	.075
CMSES	Women	4.21	0.24	4.11	4.06	0.22	4.22	-0.55	.581
	Men	4.12	0.63	4.44	4.31	0.69	4.56	-2.67	.008*

Abbreviations: CMSES, Cardiovascular Management Self-Efficacy Scale; M, mean; Mdn, Median; SD, standard deviation; SEMCD, Self-Efficacy for Managing Chronic Disease; SWB, Subjective well-being.

*Statistically significant differences.

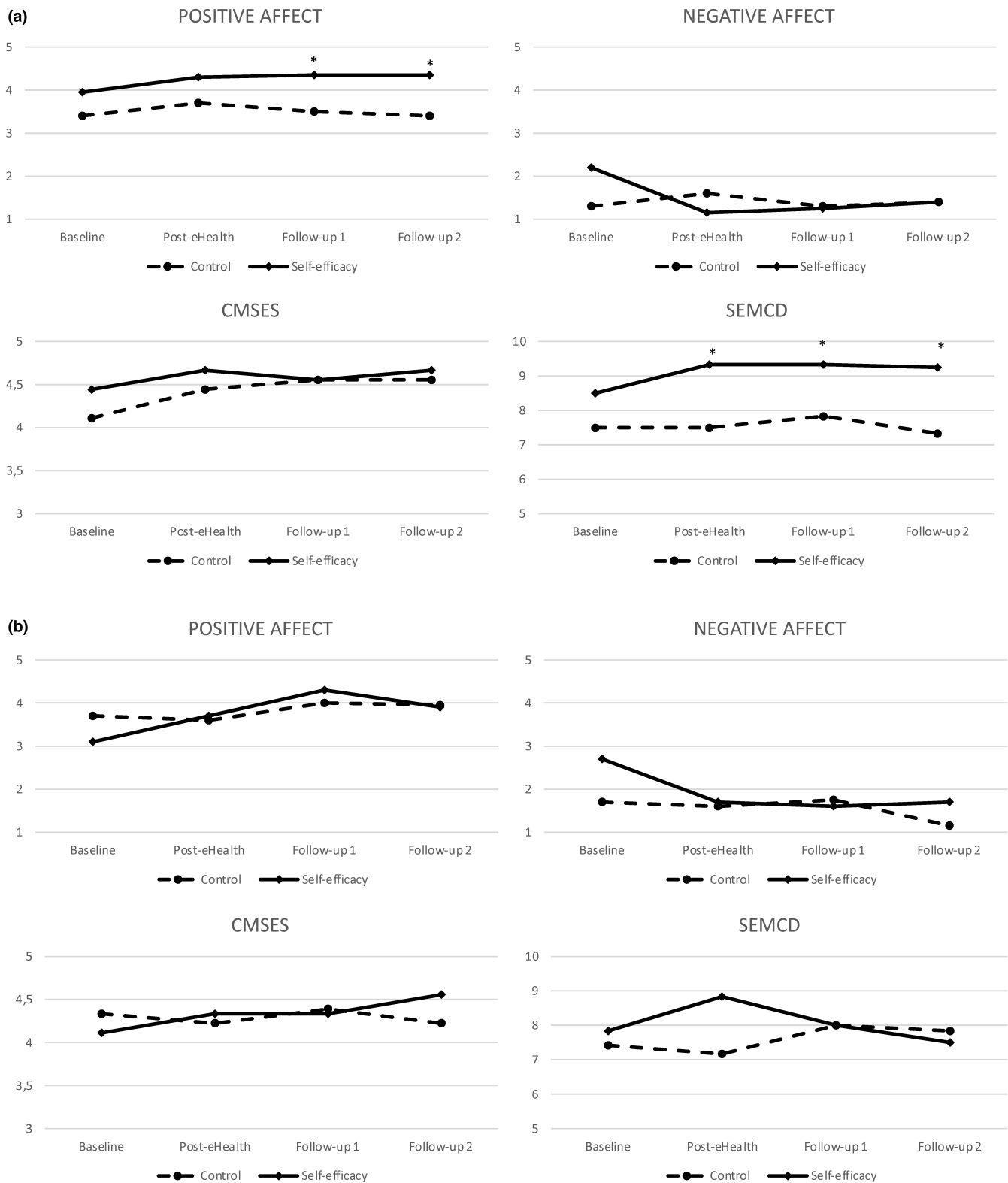


FIGURE 4 Between-group differences in men (a) and women (b) for subjective well-being scales and for self-efficacy scales. CMSES, Cardiovascular management self-efficacy scale; SEMCD, Self-efficacy for managing chronic disease scale. *statistically significant differences

6 | CONCLUSIONS

In accordance with the limited evidence in this new area of research, this study provided preliminary evidence of the effectiveness of a

multicomponent intervention that combined a personalized intervention with an eHealth tool. These results present a relevant advancement for intervention programs with CVD patients, with the advantage of being cost-effective due to the implementation of

TABLE 7 Differences in the experimental group in all phases of the study for SWB and for self-efficacy on the SEMCD and CMSES in men and women

		z	p
Subjective well-being			
Positive affect			
Post-eHealth- Baseline	Men	-1.824	.068
	Women	-2.371	.018*
Follow-up 1- Baseline	Men	-2.625	.009*
	Women	-1.892	.058
Follow-up 2- Baseline	Men	-1.090	.276
	Women	-1.355	.176
Negative affect			
Post-eHealth- Baseline	Men	-2.308	.021*
	Women	-1.572	.116
Follow-up 1- Baseline	Men	-2.864	.004*
	Women	-1.352	.176
Follow-up 2- Baseline	Men	-1.916	.055
	Women	-1.521	.128
Self-efficacy			
SEMCD			
Post-eHealth - Baseline	Men	-1.295	.195
	Women	-1.051	.293
Follow-up 1- Baseline	Men	-2.405	.016*
	Women	-1.051	.293
Follow-up 2- Baseline	Men	-1.822	.068
	Women	-.847	.397
CMSES			
Post-eHealth - Baseline	Men	-2.422	.015*
	Women	-2.003	.045*
Follow-up 1- Baseline	Men	-2.501	.012*
	Women	-1.693	.090
Follow-up 2- Baseline	Men	-1.998	.046*
	Women	-2.379	.017*

Abbreviations: CMSES, Cardiovascular Management Self-Efficacy Scale; SEMCD, Self-Efficacy for Managing Chronic Disease; SWB, Subjective well-being.

*Statistically significant differences.

eHealth. This pilot study emphasizes the value of facilitating patients to become active agents of their own therapeutic process by personalizing the objectives in order to achieve greater adherence and health benefits. This research also highlights the benefits of making psychological interventions more attractive and adapted to new realities, such as the growing use of new technologies in older populations or the need to adjust interventions to the current pandemic situation. Given the characteristics and limitations of this pilot study, the results should be interpreted with caution, being the purpose to continue testing the efficacy and effectiveness of this type of interventions. In summary, this study underlines the need to develop

cardiac rehabilitation programs from a biopsychosocial perspective due to the high rates of comorbidity that surround this disease, both in causes and consequences, and with a gender perspective to take into account the psychosocial factors involved in the differences between men and women. This approach is fundamental when developing personalized interventions. Finally, in line with previous research on health-related behaviour, this study focuses on self-efficacy as a therapeutic goal for better adaptation to the disease and thus better prognosis and QOL in CVD patients.

AUTHOR CONTRIBUTIONS

C.T., B.L. and R.C.-M involved in conceptualization, supervision and methodology. S.J.R provided the software. C.T., B.L., R.C.-M., N.Z.F-M., E.C., T.G.-D., S.J.R and A.A involved in validation. N.Z.F-M., R.C.-M and B.L. formally analysed the data. C.T., B.L., R.C.-M., N.Z.F-M., S.J.R, T.G.-D, E.C. and A. A. involved in investigation. B.L. and C.T. provided the resources. N.Z.F-M. and T.G.-D. involved in data curation. N.Z.F-M. prepared the original draft. B.L., R.C.-M and N.Z.F-M. reviewed and edited the manuscript. B.L., R.C.-M., C.T., N.Z.F-M, E.C., T.G.-D, A.A. and S.J.R involved in visualization. C.T. and B.L administered the project and acquired the fund.

All authors have agreed on the final version and meet at least one of the following criteria [recommended by the ICMJE (<http://www.icmje.org/recommendations/>)]:

- substantial contributions to conception and design, acquisition of data or analysis and interpretation of data;
- drafting the article or revising it critically for important intellectual content.

FUNDING INFORMATION

This research was funded by the Spanish Ministry of Economy and Competitiveness, grant number PSI2014-58609-R and by the Spanish Ministry of Science, Innovation and Universities, grant number PDI2019-107304RB-I00.

CONFLICT OF INTEREST

The authors declare no conflict of interest.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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How to cite this article: Farhane-Medina, N. Z., Castillo-Mayén, R., Tabernero, C., Rubio, S. J., Gutiérrez-Domingo, T., Cuadrado, E., Arenas, A., & Luque, B. (2023). Effectiveness of an eHealth intervention to improve subjective well-being and self-efficacy in cardiovascular disease patients: A pilot non-randomized controlled trial. *Nursing Open*, 10, 1503–1516. <https://doi.org/10.1002/nop2.1400>