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ORIGINAL ARTICLE

# The effect of reinforcing an educational programme using telephone follow-up on health-related quality of life of individuals using warfarin: A randomised controlled trial

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## Abstract

**Objectives:** To evaluate the effect of reinforcing an educational programme through telephone follow-up on health-related quality of life and anxiety and depression symptoms in individuals starting warfarin therapy.

**Background:** Educational interventions have improved quality of life in individuals using warfarin. Few studies have examined the addition of telephone follow-up to enhance educational interventions.

**Design:** Randomised controlled trial in outpatient setting.

**Methods:** Hospitalised adults starting warfarin therapy who agreed to participate received an educational programme about the warfarin treatment. At discharge, they were randomised to receive either five telephone follow-up calls (intervention) or no telephone calls (controls). Both groups were evaluated for health-related quality of life (using Duke Anticoagulation Satisfaction Scale) and symptoms of anxiety and depression (using Hospital Anxiety and Depression Scale) at three and six months post-discharge. Groups were compared at each time by independent-samples *t* test, and over time by repeated-measures analysis of variance, with time (three and six months), groups (intervention and control) and an interaction between time and group as factors. Level of significance was set at 0.05. The Consolidated Standards of Reporting Trials was used for reporting.

**Results:** Fifty-two individuals (26 per group) completed the study. There were no statistical differences between groups in health-related quality of life, anxiety and depression symptoms, at both times post-discharge. Participants who received follow-up telephone calls reported better positive psychological impact (a subscale of quality of life) than controls.

Trial registration: NCT03125668.

  

**Conclusions:** Reinforcing an educational programme with telephone follow-ups did not have an overall effect on health-related quality of life of individuals using warfarin but promoted positive psychological impact.

**Relevance to clinical practice:** The low cost of reinforcing educational programmes with telephone calls and the improvement in positive psychological aspects indicate that this type of intervention is still a promising intervention that could be further investigated and improved.

**KEYWORDS**
cardiovascular, medication management, patient teaching, quality of life, warfarin

**What does this paper contribute to the wider global clinical community?**

Patients in oral anticoagulant therapy who received the health education with telephone follow-up had better positive psychological impact, and less limitation and hassles/burdens with oral anticoagulation therapy than the ones who did not receive the telephone calls. When social distancing is needed, such as in the current COVID-19 (coronavirus) pandemic, telephone follow-up may be an important strategy to minimise contact while preventing social isolation of patients in oral anticoagulation therapy.

## 1 | INTRODUCTION

A recent publication from the World Health Organization (WHO, 2018) reported that 31% of the world deaths (about 17.9 million people) were due to cardiovascular diseases. Such diseases might induce thrombus formation, which can be prevented by the use of oral anticoagulants, including warfarin, one of the most used drugs in the clinical practice (Kearon et al., 2016). Warfarin is a vitamin K antagonist, and although it has low cost, its management is difficult. Warfarin toxic concentrations are very close to its efficacious doses, requiring a constant and rigorous control of the drug blood level in order to provide a safe and beneficial treatment (Macedo et al., 2015). Warfarin has been associated with frequent adverse events that might lead to hospitalisation, of which bleeding is the most common (Budnitz et al., 2005).

In the first year of treatment with warfarin, it is common that the patients have a large variation in the blood coagulation levels, and various factors can explain this variability. The main factor is the interaction of the warfarin with other medications and with foods rich in vitamin K and fats. When the oral anticoagulant therapy starts during the patient's hospitalisation, these interactions are controlled by the healthcare providers. After discharge, the patient and family become responsible for the complex management of the warfarin, sometimes without having the necessary knowledge to evaluate all possible interactions from other medications or to monitor the presence of adverse effects in the first months of the treatment (Budnitz, & Layde, 2007; Cabellos-Garcia et al., 2018).

## 2 | BACKGROUND

One of the measures of intensity of blood coagulation that can be used to describe the balance between the risk of bleeding and the risk of thromboembolism is the international normalised ratio (INR). For each condition related to blood coagulation, there is an indicated therapeutic range of the INR. When the observed INR value is below the therapeutic range, the risk of thromboembolism increases; when the INR is above the range, the risk of bleeding increases. The safety and effectiveness of warfarin therapy are closely related to the maintenance of the INR within the indicated therapeutic range between the values of 2 and 3 (Cabellos-Garcia et al., 2018; Kearon et al., 2016).

Some studies have shown that individuals who have knowledge about oral anticoagulation therapy are able to maintain the INR within the therapeutic range during the treatment (Tang et al., 2003). Other studies have demonstrated that patients often have limited knowledge of their clinical conditions and of the adequate management of oral anticoagulation therapy (Clarkesmith et al., 2017; Dantas et al., 2004; Tang et al., 2003). A person using oral anticoagulation therapy should be knowledgeable about the possible adverse events, maintenance of the oral anticoagulation therapy dosage, interactions with food and other medications, and monitoring of INR through periodical examinations (Amara et al., 2016).

The quality of life and beliefs about the illness and oral anticoagulation therapy have been shown to be associated with the person's behaviour regarding the therapy and, consequently, with the control of INR (Bartoli-Abdou et al., 2018). Among factors that might influence the stability of INR are the cognitive level, the emotional status and the level of education of the individual (Diug et al., 2011). The complexity of the warfarin management might have consequences in the person's satisfaction with the treatment and quality of life. The necessary rigorous control of the therapeutic dose and range imposes a burden on the patient during the treatment period, which can last from few weeks to a lifetime (Elewa et al., 2016; Stephenson et al., 2018).

There are only a few studies on the association of control of INR with quality of life, satisfaction with oral anticoagulation therapy and adherence to treatment in populations that use warfarin in countries in development, such as Brazil. In a study in Malaysia, researchers showed a weak correlation between the INR values and quality-of-life measures (Hasan et al., 2015). In Sudanese patients, researchers found association between measures of satisfaction with levels of anticoagulation and adherence to medication (Eltayeb et al., 2017).

Guidelines suggest that healthcare professionals who provide care to individuals who use oral anticoagulant should incorporate health education in their clinical routine, giving a more complete and efficacious healthcare service regarding management and adherence to oral anticoagulant therapies (Holbrook et al., 2012). The following strategies have been used so far: presentation of educational material via booklets, videos and slides, patient self-reported diaries and educational sessions to teach about home monitoring (Clarkesmith et al., 2017). The use of telephone calls for monitoring of anticoagulation has obtained some positive results for the patients and for the healthcare providers (Lane et al., 2006; Polek, & Hardie, 2012; Waterman, Banet, et al., 2001; Waterman et al., 2001). Health education related to the oral anticoagulation therapy and the patient's continual motivation are necessary to improve the therapy management, especially for individuals of low education level (Eltayeb et al., 2017) and older adults (Dantas et al., 2004).

Randomised clinical trials have been conducted to evaluate the effect of educational interventions based on theories of behavioural change. The focus of those interventions has been in change or acquisition of a behaviour, self-care, adherence to treatment and quality of life related to health. The extent and quality of the results from these studies have depended on the type of behaviour to be changed and on the specific characteristics of the target population of patients (Barley & Lawson, 2016).

For example, the social cognitive theory proposed by Albert Bandura (Bandura et al., 2008) has been used to develop interventions to improve self-management for individuals with chronic health conditions (Nundy et al., 2013; Rudd et al., 2004; Shon, 2003). In Brazil, nurse researchers developed and tested interventions for the management of health chronic conditions (Furuya et al., 2015; Gonçalves et al., 2016; Pelegrino, Bolela, Corbi, et al., 2014; Pelegrino, Bolela, Furuya, et al., 2014) using the construct of self-efficacy from Bandura's theory (Bandura et al., 2008). Other researchers have used the theory of planned behaviour to develop interventions, mainly with a focus on adherence to treatment (Jannuzzi et al., 2014; Lourenço et al., 2014). We chose Bandura's theory to develop our intervention for various reasons. First, the theory is suitable for situations where more than one behavioural changes are of interest. Second, our research group has extensive experience and has had many positive results with interventions based on this theory.

According to the social cognitive theory, a person's choice to execute a learned action is strongly related to the consequences of whether the action is executed or not. The person's behaviour is controlled not only by consequences directly experienced, but also by vicarious reinforcement and self-evaluation. A person might have the capability to execute a certain behaviour but will act on it only if the knowledge about that behaviour is received in a positive or favourable manner. Positive incentives are necessary for the 'learning' to became action. A reinforcement experience happens, when the individual not only responds to the reinforcement but also develops expectations of the results from their action in certain situations. When the person goes through a reinforcement experience, (s)he might observe a change in their behaviour and have a tendency to establish objectives to improve their behaviour even further (Bandura et al., 2008). Based on Bandura's theory, a telephone follow-up might be a good strategy to reinforce the information previously received and to motivate the individual starting warfarin therapy to follow the instructions for self-care. Therefore, the aim of this study was to evaluate the effect of adding the telephone follow-up to an educational programme based on Bandura's theory on the health-related quality of life and on the anxiety and depression symptoms in individuals starting warfarin therapy, at three and six months after hospital discharge.

## 3 | METHODS

### 3.1 | Design

A randomised controlled trial was conducted with two groups: one receiving an educational protocol during hospitalisation (control group) and one receiving the same educational protocol with the addition of five follow-up telephone calls within a six-month period (intervention group). We followed the Consolidated Standard Reporting Trials, 2010 – CONSORT, for the reporting of the trial (File S1). The Clinical Trial Registry number is NCT03125668.

### 3.2 | Sample and setting

First, since the minimal detectable change (MDC) or the minimal clinically important difference (MCID) in the DASS has not been established in the literature, we considered that a change of 20% in the DASS mean score of the intervention group relative to the control group would be a reasonable starting difference to consider the intervention as worthy of being used in clinical practice. For that we needed to use some estimate of the DASS mean score in the control group (usual care). Pelegrino, Bolela, Corbi, et al., (2014) studied the same population of interest with a similar intervention, but for a shorter follow-up (2 months). We considered the observed DASS mean score for the control group in that study (60 [SD = 16]) as the same for our control group and calculated that a 12-point change (20% of 60) would be an important difference to be detected. Using a difference of 12 points between the two mean groups, with a significance level of .05, power of .80, standard deviations of 16 and the *t* test for independent samples, sample sizes were calculated

to be about 26 individuals per group (calculations performed using STATA version 15.0 for Mac). Assuming, a loss to follow-up of 20%, we aimed to recruit a total of 68 individuals.

The study was performed in two teaching hospitals in the state of São Paulo, Brazil. Potential participants were identified through the hospital database system. Patients who were hospitalised between September 2015 and May 2017, and who were initiating the use of warfarin for the first time during that hospitalisation were invited to participate in the study. The inclusion criteria were as follows: 18 years of age or older, having initiated the use of warfarin for the first time during the current hospitalisation and having access to a telephone (landline or cellular). Exclusion criteria included the following: initiating the use of warfarin with another oral anticoagulant, initiating use of warfarin due to surgical procedures (such as implant of prosthetic metallic heart valve), having a diagnosis of cancer and being in chemotherapy treatment, being hearing or visually impaired (which would impede the exposition to the educational material and the telephone calls), and being cognitively impaired (assessed by asking their name, current date, day of the week, location, age and city where they lived). In the cognitive assessment, the participant was excluded if (s)he answered wrongly more than two questions.

### 3.3 | Randomisation process

A research staff member (who did not have contact with the patients) generated two random allocation lists (in SPSS version 24.0), one for each hospital, with blocks size of 14, 18 and 24 participants. The allocation was concealed from the investigators by using sequentially numbered, sealed and opaque envelopes. One of the researchers performed the first interview (baseline) during the hospitalisation. At the hospital discharge, the same researcher opened the envelope to allocate the participants to one of the two groups.

Figure 1 shows the flow chart of the participants through the study. During the recruiting period, 157 patients who were initiating therapy with warfarin were identified. Of those, 77 were excluded due to various reasons, including impaired cognition, hearing loss, sedation, cancer diagnosis, lethargy and disorientation, dependency on mechanical ventilation, dementia and lack of access to a telephone. Nine individuals refused to participate. The remaining 71 eligible individuals agreed to enter the study and participated in the first data collection at baseline. However, one person died during the hospitalisation, and at discharge, 70 individuals were randomised into the two groups (35 each). There were nine losses to follow-up in each group (see Figure 1), with 26 individuals analysed in each group.

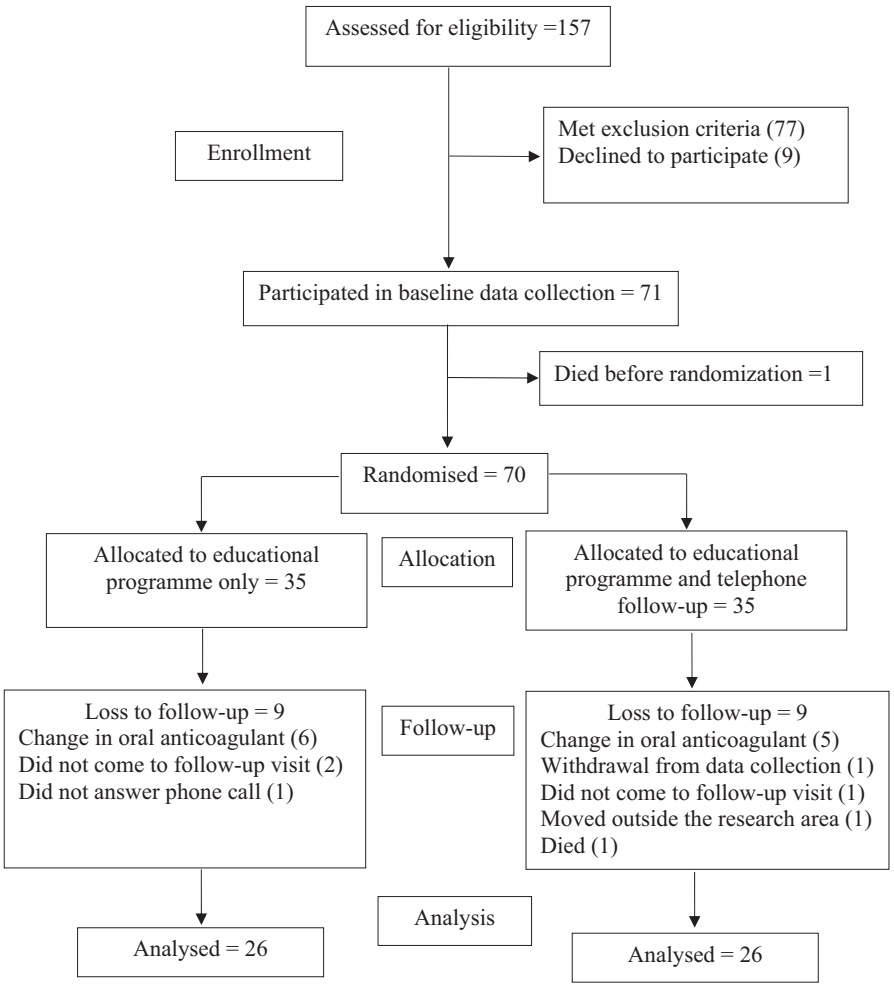


**FIGURE 1** Flow chart of the participants through the study

### 3.4 | Intervention

All patients received an educational programme developed in a previous study (Pelegrino, Bolela, Corbi, et al., 2014), which was based on the social cognitive theory (Bandura et al., 2008). Verbal persuasion was the major focus of our protocol, which had the objective to improve patient's self-care during the use of oral anticoagulation therapy. Verbal persuasion is defined as leading the patient, through suggestion, into believing that they can cope successfully with their own difficulties and are able to perform the required behaviour to achieve their goal. The educational programme was delivered individually to each participant by the same researcher (the first author).

The intervention was organised in two steps. First, all enrolled participants (control and intervention groups) received the educational programme with information on the oral anticoagulation therapy during the hospitalisation. We used a portable device (tablet) to show a 26-slide presentation (*Power Point*® for *Windows*, version 2007), which included illustrations about the treatment with warfarin. A booklet containing the same figures and information was also delivered to the participants.

Once discharged from the hospital, individuals in the control group received no further contact from the researchers, except to collect outcomes data at three- and six-month follow-ups. In the intervention group, individuals received five telephone calls over time: at one week, and at one, two, four and five months post-discharge. These contacts were focused on encouraging the self-management of the treatment with warfarin and on reinforcing the information about oral anticoagulant therapy, including signs and symptoms of complications, INR control, concomitant use of other medications that may decrease warfarin effectiveness, use of alcoholic beverages and intake of diets rich in fat and vitamin K. For the telephone calls, we elaborated a script with nine questions about the participant's behaviours regarding the correct use of warfarin. Based on the person's responses, the investigator clarified doubts and misunderstandings and gave positive reinforcement to the correct behaviours already in place.

### 3.5 | Outcome measures

The primary outcomes were quality of life related to health, measured by the Duke Anticoagulation Satisfaction Scale, and anxiety and depression symptoms, measured by the Hospital Anxiety and Depression Scale, both of which are described below.

*Duke Anticoagulation Satisfaction Scale* (DASS) (Samsa et al., 2004)—this scale, validated for Brazilian–Portuguese language (Pelegrino et al., 2012), was used to assess health-related quality of life in oral anticoagulation therapy. This instrument measures both the negative and positive aspects of the oral anticoagulant therapy (Carvalho et al., 2013; Elewa et al., 2016; Stephenson et al., 2018). The DASS consists of 25 items, distributed in three dimensions: limitations (9 items), hassles/burdens (8 items) and psychological impact (8 items). The psychological impact is divided into positive (5 items) and negative (4 items) aspects. Each item is answered on a seven-point ordinal scale: (1) Not at all, (2) A little, (3) Somewhat, (4) Moderately, (5) Quite a bit, (6) A lot and (7) Very much. The total DASS score can range from 25–175, with lower scores indicating greater satisfaction with the use of oral anticoagulants, less hassles, less burdens, lesser negative and higher positive psychological impacts. At the hospitalisation, the DASS questions (such as 'How much does anti-clot treatment limit your choice of food (diet)?' or 'How much do you feel reassured of your anti-clot treatment?') would not make sense to the individual who had not experienced the treatment yet.

*Hospital Anxiety and Depression Scale* (HADS) (Zigmond, & Snaith, 1983)—this scale, validated to Brazilian–Portuguese language (Botega et al., 1995), was used to evaluate symptoms of anxiety and depression. The instrument is a 14-item scale, divided into two subscales: anxiety and depression, with 7 items each. Items from subscales of anxiety and depression are scored from 0–3 with a total score between 0–21, with higher values corresponding to more symptoms of anxiety and depression.

*Socio-demographic and clinical data*—the socio-demographic characteristics of participants included date of birth, sex, education level, job situation (paid employment or without work), and city and state of residence. Age was calculated by the difference between date of birth and date of interview and rounded to number of completed years. Clinical data included oral anticoagulant dose, diagnosis for the indication of oral anticoagulant, comorbidities listed in the individual's medical chart and *The Outpatient Bleeding Risk Index* (OBRI) (Landefeld et al., 1989), which measured the bleeding risk before starting the warfarin. The OBRI score varies from 0–4 and is categorised into low risk (zero), medium risk (1 or 2) and high risk (3 or 4). To assess whether participants were within the therapeutic range of oral coagulant indicated for their specific condition, values of their INR from monthly medical visits were collected from the medical charts in the first six months post-discharge and transformed into dichotomic variables (within or outside the therapeutic range). In this study, the desired therapeutic range was between 2–3 for all participants (Kearon et al., 2016).

### 3.6 | Data collection and blinding

Socio-demographic and clinical data were collected at baseline, during the hospitalisation, before presenting the educational programme to the participants. Both groups had face-to-face interviews to evaluate the health-related quality of life and the symptoms of anxiety and depression. The primary outcome, health-related quality of life, was assessed at three- and six-month follow-ups using the DASS. Symptoms of anxiety and depression, the secondary outcomes, were assessed at the hospitalisation (baseline), three and six months post-hospital discharge using the HADS. The therapeutic range of oral anticoagulant therapy, measured by the INR, was collected from the medical chart during the first six months post-discharge.

Due to the nature of the intervention, the participants were not blind to whether or not they received the telephone follow-up intervention. Initially, we had planned to have a researcher who was blind to the received intervention as the assessor of the outcomes. However, logistical issues prevented us from doing so. The two hospitals were 80 km apart, and many participants had outpatient clinic appointments (when the outcome interviews were performed) at the same time. In order to minimise loss of data collection, the first author (who was not blind to the assigned intervention) participated in the outcome assessment. Since the outcome measures were self-reported by the participants, we believe that there was no bias in outcomes assessment due to the person collecting data for evaluation.

### 3.7 | Data analysis

Descriptive analyses were performed for all variables. Demographic and clinical characteristics (including HADS anxiety and depression) were compared between intervention and control groups at baseline using *t* test for independent samples for the numeric variables and Fisher's exact test for categorical variables.

To compare scores of DASS (primary outcome) and HADS for anxiety and depression symptoms (secondary outcomes) between the two groups at three- and six-month follow-ups separately, we used *t* test for independent samples. To compare the trajectory of DASS over the two follow-up times, we used repeated-measures analysis of variance (ANOVA), including the following factors: time (three and six months), group (educational programme only and educational programme plus telephone follow-up) and an interaction between time and group. The number of times that a person was within the therapeutic range among six observations (once a month) was compared between the two groups at the end of six months post-discharge, using a Fisher exact test.

Data analyses were conducted using the Statistical Package for the Social Sciences software (IBM SPSS version 24.0) and R version 3.1.2. The significance level was set at .05, and due to the exploratory nature of the study, no adjustments were made for multiple comparisons.

### 3.8 | Ethical considerations

The study was approved by the Institutional Review Board of the hospitals where the study was carried out (No. 8736914.1.0000.5393). After that, the study was explained to all participants, and the informed consent was obtained from those who agreed to participate. Participants were informed that they could withdraw from the study at any time.

## 4 | RESULTS

Thirty-five individuals were assigned to each intervention group, and 18 (9 in each group) were lost to follow-up (Figure 1). We compared the baseline age, education, income, sex, marital status, diagnostic for indication of oral anticoagulation therapy and presence of comorbidities between the individuals who finished the study and those who were lost to follow-up. The two groups were not statistically different on all variables, except for sex ($p = .04$), with a higher proportion of men among individuals who were lost to follow-up than among individuals who finished the study. In both groups, the most frequent indications for the use of warfarin were deep leg vein thrombosis and acute pulmonary embolism.

Fifty-two individuals completed all stages of the study (26 in each group). Socio-demographic and clinical characteristics of those participants are shown in Table 1 by group allocation. The two groups did not differ statistically in socio-demographic and clinical characteristics at baseline ($p > .14$ for all variables).

For our primary outcome of health-related quality of life as measured by the DASS, the means and standard deviations for three and six months post-discharge follow-ups are shown in Table 2. No statistically significant differences were found between the two groups at either follow-up time, except for the DASS subscale of psychological impact ($p = .04$ for total score and $p = .003$ for positive impact subscale), both at six-month follow-up. Scores for positive psychological impact in the group that received additional telephone calls as reinforcement for self-care were lower (better) than in the group without telephone calls.

When looking at the trajectory of the DASS total and subscales over time (three- and six-month follow-ups), none of the factors were statistically significant in the repeated-measures ANOVA models (Table 3). The exception was the model for positive psychological impact subscale, but only time and group were statistically significant, without an interaction. The addition of telephone calls had stronger positive impact than receiving only the educational programme, and scores at six-month follow-up were better than at three-month follow-up.

For the secondary outcomes of anxiety and depression symptoms as measured by the HADS, the results for three- and six-month follow-ups are shown at the end of Table 2. There were no statistical differences between the two groups at both times. When adding the information about HADS at baseline, and three- and six-month follow-ups, the repeated-measures ANOVA showed no statistically significant factors for both anxiety and depression symptoms (Table 3).

Each individual had six-monthly assessments of INR, which were classified as within or outside of the therapeutic range. Table 4 shows the distribution of times in which individuals were within the therapeutic range by intervention group. The two groups were not statistically different in the distribution of times within therapeutic range. However, there was a slightly larger percentage (15.3%) within range for 5 or 6 times out of the six-monthly assessments in the group receiving the educational programme plus telephone follow-up than in the education-only group (11.5%). We also looked at the percentage of individuals within the therapeutic range in each group by month of assessment. In every month, the percentage varied between 42–58% in each group, but there was no pattern of

**TABLE 1** Socio-demographic and clinical characteristics at baseline, by group allocation

| Socio-demographic and clinical characteristics | Education plus telephone calls (*n* = 26) | Education plus telephone calls (*n* = 26) | *p*-Value[a] |
|---|---|---|---|
| Age in years, mean (SD) | 53.0 (14.0) | 56.5 (16.2) | .39 |
| Years of education, mean (SD) | 7.4 (4.3) | 6.7 (4.8) | .61 |
| Monthly income in *Reais*, mean (SD) | 2515 (1332) | 2175 (1334) | .36 |
| Sex, % (*n*) | | | |
| Feminine | 57.7 (15) | 65.4 (17) | .57 |
| Masculine | 42.3 (11) | 34.6 (9) | |
| Marital status, % (*n*) | | | |
| Married | 61,5 (16) | 53.8 (14) | .58 |
| Single, divorced or widow(er) | 38.5 (10) | 46.2 (12) | |
| Oral anticoagulant dose (mg/wk), mean (SD) | 42.5 (15.0) | 39.7 (16.0) | .52 |
| Clinical indication for warfarin starting, % (*n*) | | | |
| Deep leg vein thrombosis | 30.8 (8) | 19.2 (5) | .69 |
| Acute pulmonary embolism | 23.1 (6) | 26.9 (7) | |
| Cerebral venous thrombosis | 19.2 (5) | 7.7 (2) | |
| Atrial fibrillation | 7.7 (2) | 15.4 (4) | |
| Heart failure | 7.7 (2) | 7.7 (2) | |
| Acute myocardial infarction | 7.7 (2) | 19.2 (5) | |
| Thrombosis in other organs | 3.8 (1) | 3.8 (1) | |
| Presence of comorbidity, % yes (*n*) | | | |
| Hypertension | 61.5 (16) | 61.5 (16) | 1.00 |
| Dyslipidaemias | 26.9 (7) | 38.5 (10) | .38 |
| Diabetes *mellitus* | 26.9 (7) | 30.8 (8) | .76 |
| *OBRI* score at hospitalisation, categorised, % (*n*) | | | |
| Low | 42.3 (11) | 46.2 (12) | .85 |
| Medium | 50. (13) | 42.3 (11) | |
| High | 7.7 (2) | 11.5 (3) | |
| *HADS*, mean (SD) | | | |
| Anxiety | 4.7 (2.9) | 6.0 (3.5) | 0.14 |
| Depression | 4.6 (2.4) | 5.1 (4.1) | 0.62 |

Abbreviations: HADS, Hospital Anxiety and Depression Scale; ORBI, Outpatient Bleeding Risk Index; *Reais*, R$1.00 (one Real) was equivalent to US$ 0.302 at the time of data collection; SD, standard deviation.

[a]*p*-Value from *Student t* test for age, years of education, monthly income, anticoagulant dose, and HADS anxiety and depression. *p*-Value from chi-square test for sex, marital status and presence of comorbidities, and from Fisher's exact test for clinical indication and OBRI score.

increasing or decreasing percentages over time, or any consistent differences between the two groups.

## 5 | DISCUSSION

Compared to the group that received only an educational programme focused on oral anticoagulant therapy management, the group that received the educational programme with the addition of follow-up telephone calls for reinforcement did not improve significantly in the measures of health-related quality of life as measured by DASS, or anxiety and depression symptoms as measured by HADS, at three- and six-month post-discharge follow-ups.

In a study conducted in one of the hospitals in this study, the same educational programme (up to three months of follow-up and two telephone calls) was compared to post-discharge usual care (monthly outpatient medical returns for follow-up) in patients starting the use of warfarin (Pelegrino, Bolela, Furuya, et al., 2014). At the end of two months, the two groups differed statistically, with the group receiving the educational programme showing better (smaller) scores of DASS. This result prompted the hospital to adopt the educational programme as part of its usual care at discharge. This motivated us to conduct this study, where we used the educational programme alone as the usual care (already in place in one of the two hospitals where this study was conducted), increased the follow-up time to six months and added five telephone calls over the six-month

**TABLE 2** Means and standard deviations for scores of DASS (total and subscales) and HADS Anxiety and HADS Depression, by intervention group and follow-up time

| Outcome | Three-month follow-up | | | Six-month follow-up | | |
|---|---|---|---|---|---|---|
| | Education plus telephone ($n$ = 26) | Education only ($n$ = 26) | $p$-Value[a] | Education plus telephone ($n$ = 26) | Education only ($n$ = 26) | $p$-Value[a] |
| | Mean (SD) | Mean (SD) | | Mean (SD) | Mean (SD) | |
| DASS | | | | | | |
| Total | 54.0 (15.8) | 61.6 (17.1) | .10 | 54.7 (12.7) | 62.8 (20.5) | .09 |
| Subscales | | | | | | |
| Limitation | 20.0 (6.4) | 22.5 (8.7) | .25 | 22.7 (6.2) | 23.8 (9.2) | .62 |
| Hassles/burdens | 15.4 (6.5) | 18.2 (6.0) | .12 | 15.3 (7.0) | 19.2 (8.0) | .07 |
| Psychological impact | 18.5 (6.5) | 21.0 (6.4) | .17 | 16.8 (4.8) | 19.8 (5.6) | .04 |
| Positive | 10.8 (4.3) | 12.7 (4.8) | .13 | 8.9 (3.0) | 11.9 (3.7) | .003 |
| Negative | 7.7 (3.6) | 8.3 (3.0) | .56 | 7.8 (2.6) | 8.0 (3.2) | .89 |
| HADS | | | | | | |
| Anxiety | 4.4 (3.6) | 5.9 (3.8) | .16 | 4.4 (3.1) | 6.0 (3.5) | .10 |
| Depression | 3.8 (3.4) | 5.3 (3.7) | .13 | 3.7 (3.2) | 5.5 (3.8) | .06 |

Abbreviations: DASS, Duke Anticoagulation Satisfaction Scale; HADS, Hospital Anxiety and Depression Scale; SD, standard deviation.

[a]$p$-Value from the *Student t* test comparing both groups within a specific follow-up time.

**TABLE 3** $p$-Values for the repeated-measures analysis of variance for DASS (total and subscales) and HADS Anxiety and Depression

| Outcome[a] | $p$-Values for factors | | |
|---|---|---|---|
| | Interaction of group by time | Group | Time |
| | .92 | .07 | .60 |
| DASS total | | | |
| Limitations | .55 | .33 | .10 |
| Hassles/burdens | .43 | .66 | .56 |
| Psychological impact: Positive | .26 | .02 | .004 |
| Psychological impact: Negative | .59 | .67 | .81 |
| HADS | | | |
| Anxiety | .98 | .08 | .89 |
| Depression | .46 | .10 | .84 |

Abbreviations: DASS, Duke Anticoagulation Satisfaction Scale; HADS, Hospital Anxiety and Depression Scale.

[a] Time for DASS included three- and six-month follow-ups. Time for HADS included baseline, and three- and six-month follow-ups.

period to test whether those simple steps would add value to the quality of life of the patients.

The mean scores for the total DASS and some of its subscales i were larger in both groups of our study than observed in a prior Brazilian study (Carvalho et al., 2013) and in other international studies (Elewa et al., 2016; Stephenson et al., 2018) with patients using warfarin for six months. This indicates that there was less satisfaction with the therapy in our study. The only statistically different means we found were for the subscale psychological impact ($p$ = .04) and its sub-domain positive psychological impact ($p$ = .003). Participants who received follow-up telephone calls reported better positive psychological impact than the ones who did not. Similar results were found in other Brazilian studies in the same population with follow-ups of two (Pelegrino, Bolela, Furuya, et al., 2014) and six months (Carvalho et al., 2013).

We use the same educational programme previously tested in Brazil (Pelegrino, Bolela, Furuya, et al., 2014), which was based on Bandura's construct of self-efficacy (Bandura et al., 2008; Pelegrino, Bolela, Corbi, et al., 2014). For patients who are initiating the use of warfarin for the first time, self-efficacy is related to the patients' belief in their own effectiveness to be able to maintain the INR within the therapeutic range during the treatment. Self-efficacy is based on four sources of efficacy information: performance accomplishments, vicarious experience, verbal persuasion and emotional arousal (Bandura et al., 2008). Persuasion was the major focus of the script of the phone call reinforcement. The telephone contacts were focused on reinforcing the information about oral anticoagulant therapy and encouraging the patient to self-manage his treatment with warfarin. For future studies, we suggest that the intervention might be improved by focusing on other aspects of self-efficacy, such as highlighting performance accomplishments, vicarious experience and emotional arousal (Bandura et al., 2008).

A literature review of the effects of programmes focusing on self-management of oral anticoagulant therapies showed that structured educational protocols are very important and fundamental to self-management of this therapy (Pozzi et al., 2016). According to that review, structured educational protocols are even more important for older adults with low education level. In

**TABLE 4** Distribution of the number of months (among six) in which a person was within the therapeutic range, by intervention group

| Number of months (among six) presenting INR within therapeutic range | Education plus telephone calls (*n* = 26) % (*n*) | Education only (*n* = 26) % (*n*) | *p*-Value* |
|---|---|---|---|
| None | 0 (0) | 3.8 (1) | .81 |
| One time | 11.5 (3) | 15.4 (4) | |
| Two times | 30.8 (8) | 15.4 (4) | |
| Three times | 15.4 (4) | 26.9 (7) | |
| Four times | 26.9 (7) | 26.9 (7) | |
| Five times | 11.5 (3) | 7.7 (2) | |
| Six times | 3.8 (1) | 3.8 (1) | |

Abbreviation: INR: international normalised ratio.

*$p$-Value from the Fisher's exact test.

our study, individuals seen in the two hospitals were generally of low income and education level, for whom educational interventions might be beneficial.

While the educational interventions might be helpful to improve self-management of oral anticoagulant therapies, the individual's willingness to change behaviour is fundamental for the success of the therapy. Changes in behaviour require time and happen in different ways for different individuals (Talboom-Kamp et al., 2017). This could be one of the explanations for the lack of differences between the groups in our study. Some authors consider six months (the total time of our intervention) as too short for behavioural changes to occur, especially when there is a period of instability during the treatment inception while the individual is adjusting to the new therapy (Rose et al., 2008, 2010, 2011). The educational programme was delivered only one time in both groups, and the intervention group received additional telephone calls for six months. It is possible that the telephone calls would be more effective if they continued over a longer period of time (say, one year or more). It is common that over time, the individual stops 'good' behaviours or starts behaviours that are not conducive to good outcomes. In a study in the same population seen at our institutions, we found that despite reporting satisfaction with the information received about the oral anticoagulant therapy, the individuals presented low levels of retention and had a superficial understanding of the risks and benefits of the treatment (Dantas et al., 2004).

Depression and anxiety symptoms often co-exist with thromboembolic disorders, atrial fibrillation and cardiovascular diseases. We found no differences between the two groups in HADS anxiety and depression at baseline or the follow-up times. Another study found that individuals who received the educational programme plus the telephone calls presented a reduction in symptoms of anxiety when compared to the usual care group at two-month follow-up (Pelegrino, Bolela, Furuya, et al., 2014). We had expected that the increase in follow-up time in our study might show lower symptoms of anxiety and depression in the intervention group, but this was not the case. It is possible that the educational material improved those symptoms in both groups and that the number and content of the telephone calls were not enough to produce a larger difference between the groups.

Some studies have shown a negative association between anxiety and depression with cognitive performance, decreasing the capacity of attention and memory, and consequently decreasing the capacity to learn new abilities or behaviours, especially in older adults (Gulpers et al., 2019; Vito et al., 2019). It is possible that anxiety and depression mediate the effects of certain interventions on the outcomes. However, this study was not designed or had the objective to study mediation effects of anxiety and depression on the health-related quality of life.

In our study, the two groups did not differ in number of times (among six) that they were within the therapeutic range based on the INR. Also, when compared at each follow-up month, they did not differ in percentage of individuals within the therapeutic range. This result was different from observed in other studies. In one study, individuals receiving telephone calls from the pharmacy during a three-month period had better maintenance of INR within the therapeutic range (Sudas Na Ayutthaya et al., 2018), while in another study, patients monitored via telephone had values within the therapeutic range less frequently than individuals accompanied via medical visits (Stoudenmire et al., 2014). Over the treatment period, the variation of the INR values can lead patients to feel unsatisfied and guilty, even when they are following the correct self-management guidelines for the therapy (Gillespie et al., 2018). However, such variation might not be due exclusively to their behaviour and actions. Therefore, learning to monitor and manage the INR is one of the primary focus of educational protocols for self-care and self-management of patients in oral anticoagulant therapy (Lansberg et al., 2012).

Ideally, the main outcome should have been improvement in self-efficacy, since this is the construct that is addressed by Bandura's social cognitive theory and it was the focus of the intervention. However, at the time we designed and initiated the study, there were no valid and reliable instruments to evaluate self-efficacy, which led us to choose the DASS (Samsa et al., 2004), as the outcome measure.

Although the DASS does not measure healthy behaviour, it does measure satisfaction with the use of oral anticoagulants, hassles, burdens and psychological impacts due to oral anticoagulation therapy. Those are aspects related to the individual's behaviour regarding the use of warfarin, showing whether the person has self-efficacy for the new treatment. Our research group has used successfully that instrument in previous studies (Furuya et al., 2015; Gonçalves et al., 2016; Pelegrino, Bolela, Corbi, et al., 2014; Pelegrino, Bolela, Furuya, et al., 2014).

One of the limitations of our study was the logistics required to perform the study in two hospitals, which did not allow for full blinding of one of the investigators who collected outcome data. To mitigate this limitation, the investigator closely followed the protocol to eliminate her influence when applying the self-report outcome instruments. Thus, we believe that any bias that could be introduced by the investigator was minimised, if it existed at all.

The loss to follow-up of 25% of the initial sample was also a limitation. However, most of the losses were due to change in oral anticoagulant medication, a reason which was not related to the study itself or over which we could not have any control. The only difference between the analysed and lost to follow-up groups was in sex distribution, and this might have been due to chance alone. The group with the added telephone follow-up had slightly better scores for DASS and HADS, although they were not statistically different.

The instrument used in this study to measure our primary outcome may not have been sensitive enough to measure small but important differences in this population. Other investigations could use specific instruments to measure self-efficacy, knowledge, warfarin adherence and change health behaviours in this population.

Despite those limitations, the study provides important information for future studies.

## 6 | CONCLUSION

We found no statistical differences in the health-related quality of life, as measured by the DASS, between a group receiving an educational programme and a group receiving educational programme plus five telephone calls, in Brazilian patients, in the first six months of warfarin use. Participants who received follow-up telephone calls reported more positive psychological impact and less limitation and hassles/burdens with oral anticoagulation therapy, than the ones who did not receive the telephone calls.

## 7 | RELEVANCE TO CLINICAL PRACTICE

While the differences in DASS and HADS scores between the two groups were not statistically significant, in general, the group that received follow-up telephone calls had, on average, slightly better outcomes than the group that received the educational protocol alone.

Given that the use of telephone calls (or even telephone contacts via apps) is relatively inexpensive and require little investment, this might good strategy to provide health education and improve self-management of symptoms, especially in situations that might prevent the individuals to make an in-person visit. In face of the current COVID-19 pandemic, telephone reinforcement of educational materials might also minimise the negative impact that social distancing and isolation could have on the self-management of therapies for chronic conditions. For patients who need constant attention monitoring the risk of adverse effects of their treatment, such as in oral anticoagulation therapies, the use of telephone follow-up is a good option.

## CONFLICT OF INTEREST

The authors report no conflict of interest.

## AUTHOR CONTRIBUTIONS

Conception and design of the study: ROM, RASD, MAC; Data collection: ROM; Data analysis: ROM, RASD, MAC, FB, CAMD, LAR; Interpretation of results and manuscript preparation: ROM, RASD, MAC, FB, CAMD, LAR; Critically revised the manuscript drafts: ROM, RASD, MAC, FB, CAMD, LAR; Read and approved the final version of this manuscript: ROM, RASD, MAC, FB, CAMD, LAR.

## DATA AVAILABILITY STATEMENT

Data are available on request from the authors.

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## SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section.

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