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# TELENURSING FOR THE CONTROL OF CHEMOTHERAPY-INDUCED NAUSEA AND VOMITING: A RANDOMIZED CLINICAL TRIAL

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## ABSTRACT

**Objective:** to verify the effectiveness of telenursing in the control of nausea and vomiting induced by antineoplastic chemotherapy.

**Method:** a randomized controlled trial of 61 cancer patients undergoing outpatient chemotherapy treatment, randomized into experimental group and control group. Nausea and vomiting were evaluated by the instrument *Multinational Association on Supportive Care in Cancer*. The telephone intervention was performed four times after chemotherapy. To verify the effects of this on the variables, the Mann-Whitney test and Student's t-test were used. Wilcoxon signed-rank test was applied to confirm the hypothesis of differences in the pre- and post-test intragroup scores.

**Results:** the groups were homogeneous regarding sociodemographic and clinical characteristics. The experimental group showed a statistically significant reduction in the occurrence of nausea ( $p=0.0089$ ), in the degree of nausea, in two moments, between 24 hours and three days, and three days and five days ( $p=0.007$  and  $p=0.009$ , respectively), in the occurrence of vomiting ( $p=0.008$ ) and in the number of vomiting episodes ( $p=0.020$ ).

**Conclusion:** telephone intervention is a potential nursing intervention to reduce nausea and vomiting associated with antineoplastic chemotherapy. Brazilian Clinical Trial Registry: RBR-6s8qm5.

**DESCRIPTORS:** Chemically induced disorders. Neoplasms. Nausea. Vomiting. Telephone nursing. Symptom Management in Oncology. Oncology nursing.

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# TELENFERMAGEM PARA CONTROLE DE NÁUSEAS E VÔMITOS INDUZIDOS POR QUIMIOTERAPIA: ENSAIO CLÍNICO RANDOMIZADO

## RESUMO

**Objetivo:** verificar a eficácia da telenfermagem no controle de náuseas e vômitos induzidos pela quimioterapia antineoplásica.

**Método:** ensaio clínico controlado, randomizado, realizado com 61 pacientes com câncer, em tratamento ambulatorial de quimioterapia, alocados aleatoriamente em grupo experimental e grupo controle. Náuseas e vômitos foram avaliados pelo instrumento *Multinational Association on Supportive Care in Cancer*. A intervenção telefônica foi efetuada em quatro momentos após quimioterapia. Para verificar os efeitos desta sobre as variáveis, foram utilizados o teste de Mann-Whitney e o teste t de Student. O teste dos postos assinalados de Wilcoxon foi aplicado para confirmar a hipótese de existência de diferenças das notas do pré e pós-teste intragrupos.

**Resultados:** os grupos foram homogêneos quanto às características sociodemográficas e clínicas. O grupo experimental apresentou redução estatisticamente significativa da ocorrência de náuseas ( $p=0,0089$ ), do grau de náusea, em dois momentos, entre 24 horas e três dias, e três dias e cinco dias ( $p=0,007$  e  $p=0,009$ , respectivamente), da ocorrência de vômitos ( $p=0,008$ ) e do número de episódios de vômitos ( $p=0,020$ ).

**Conclusão:** a intervenção telefônica apresenta-se como potencial intervenção de enfermagem para a redução de náuseas e vômitos associados à quimioterapia antineoplásica. Registro Brasileiro de Ensaio Clínico: RBR-6s8qm5.

**DESCRIPTORIOS:** Distúrbios induzidos quimicamente. Neoplasias. Náusea. Vômito. Telenfermagem. Manejo de sintoma em oncologia. Enfermagem oncológica.

# TELE-ENFERMERÍA PARA EL CONTROL DE LAS NÁUSEAS Y LOS VÓMITOS INDUCIDOS POR LA QUIMIOTERAPIA: UN ENSAYO CLÍNICO ALEATORIZADO

## RESUMEN

**Objetivo:** comprobar la eficacia de la tele-enfermería en el control de las náuseas y los vómitos inducidos por la quimioterapia antineoplásica.

**Método:** ensayo clínico controlado y aleatorizado, realizado con 61 pacientes con cáncer en tratamiento ambulatorio de quimioterapia, asignados aleatoriamente en grupo de control y grupo experimental. Las náuseas y los vómitos se evaluaron con el instrumento *Multinational Association on Supportive Care in Cancer*. Se efectuó una intervención telefónica en cuatro momentos de la quimioterapia. Para verificar los efectos de dicha intervención sobre las variables, se utilizaron las pruebas de Mann-Whitney y t de Student. Se aplicó la prueba de los rangos con signo de Wilcoxon para confirmar la hipótesis sobre la existencia de diferencias de las notas previas y posteriores a la prueba intragrupalmente.

**Resultados:** los grupos fueron homogéneos en cuanto a las características sociodemográficas y clínicas. El grupo experimental presentó una reducción estadísticamente significativa en la manifestación de náuseas ( $p=0,0089$ ), del grado de las náuseas, en dos momentos, entre 24 horas y tres días, y entre tres y cinco días ( $p=0,007$  y  $p=0,009$ , respectivamente), de la manifestación de los vómitos ( $p=0,008$ ) y de la cantidad de episodios de vómitos ( $p=0,020$ ).

**Conclusión:** la intervención telefónica se presenta como una potencial intervención de enfermería para reducir las náuseas y los vómitos asociados a la quimioterapia antineoplásica. Registro Brasileño de Ensayo Clínico: RBR-6s8qm5.

**DESCRIPTORIOS:** Alteraciones inducidas químicamente. Neoplasias. Náuseas. Vómitos. Tele-enfermería. Manejo de síntomas en oncología. Enfermería oncológica.

## INTRODUCTION

Nausea and vomiting represent a problem that affects about 35 to 80% of patients undergoing cancer treatment,<sup>1</sup> associated with substantial deterioration in quality of life and treatment adherence.<sup>2-3</sup>

In particular, chemotherapy-induced nausea and vomiting (CINV) may occur late, within two to five days after chemotherapy treatment, which are more common than the acute one, which occurs less than 24 hours after chemotherapy.<sup>4</sup> It is emphasized that these CINV will occur at home for those patients undergoing outpatient antineoplastic chemotherapy treatment, requiring appropriate follow-up.

Telephone intervention in daily nursing has been identified as an important resource in clinical practice, as it can provide important subsidies in health promotion, since it allows access to communication with professionals, handling of side effects, support for therapeutic adherence, proper and prompt conduct for possible side effects with pre-established clinical intervals and *follow-up*, mainly for rural and needy populations. This trend establishes that telenursing technology is a bioinformable tool that improves nursing practice by bringing nurses' skills and knowledge to out-of-range patients, such as outpatients.<sup>5</sup> It has been used in many areas of knowledge, intended to monitor and control symptoms arising from the disease and therapies.<sup>6-10</sup>

However, specifically in the area of oncology, only two recent studies were identified,<sup>6,11</sup> in which one of them focused on symptom control,<sup>6</sup> and in the other, it was accepted by the client, feasibility or usability data.<sup>11</sup>

Up to now, research focusing on the effect of telephone intervention on CINV reduction is limited. Considering that these symptoms have negative consequences, causing a worsening in the patient's quality of life,<sup>12</sup> and the gap in the literature on the use of telenursing for handling CINV in cancer patients, aimed to verify the effectiveness of telenursing in the control of nausea and vomiting induced by cancer chemotherapy.

## METHOD

Study conducted at the Center of High Complexity in Oncology, Fortaleza-CE-Brazil, from December 2016 to September 2017. The consecutive sample of patients attending the outpatient chemotherapy unit at the High Complexity Center for Oncology was evaluated for eligibility. Inclusion criteria were: patients aged over 18 years, who had scores on the Glasgow scale equal to 15, literate, with preserved hearing acuity through the whisper test, and who underwent moderate and high emetogenic potential chemotherapy, with chemotherapy regimens administered individually or in combination therapy.<sup>13</sup>

The exclusion criteria were the following: patients with gastrointestinal cancer, drug therapy with tramadol, alcohol intake during treatment, uncontrolled vestibular dysfunction and pregnant women, as these factors are involved in the nausea/vomiting variable, as well as patients with scores up to two on the *Performance Status Ecog* scale, which evaluates the capacity for self-care, whose score two refers to patients who can perform all self-care. Those individuals on daily chemotherapy regimens were excluded because of the need to measure baseline of nausea/vomiting.

Controlled clinical trial conducted with randomized patients receiving antineoplastic chemotherapy. Baseline measurement of CINV (T0) was collected and sociodemographic and clinical forms were applied. The patients were randomized with the aid of a random number table generated in the Epi Info software, version 7.1.4, in two groups: experimental group (EG) and control group (CG), with 1:1 allocation ratio, by a professional who did not maintain contact with the researchers, who made sequenced, sealed, opaque envelopes, with the designation inside of experimental group (EG) or control group (CG).

Immediately after these measurements were completed, the patients were randomized, respecting the group allocation. Blinding of participants to the allocation group was not possible due to the nature of the intervention; however, the assistant researchers who performed data collection were not involved in the intervention application. Besides the researcher, the person responsible for the statistical analysis was also blinded, since before the data were available, the CG and EG were coded in G1 and G2 to prevent them from distinguishing the group that received the intervention.

Structure of the intervention: the experimental group was informed of evidence of great scientific relevance in the following areas: a) preparing patients for nausea and vomiting as potential treatment-related effects;<sup>10,14,15</sup> b) adapting scientific knowledge about CINV to the specific needs of individuals (understanding the mechanism and triggering factors of CINV);<sup>16</sup> c) preventive dietary measures of CINV;<sup>17</sup> d) preventive environmental and behavioral guidelines;<sup>17-18</sup> e) adherence to the doctor's prescribed antiemetic regimen (pharmacological prevention);<sup>19</sup> f) ways to address the occurrence of CINV (dietary and behavioral guidelines);<sup>17</sup> g) ways to address CINV exacerbation, such as psychosocial support.<sup>15</sup>

These guidelines were provided by pre-scheduled telephone calls at the following times: five to six hours after the administration of antineoplastic chemotherapy (T1); admittedly high peak after the use of moderate and high emetogenic potential chemotherapeutic agents;<sup>20</sup> 24 hours after the administration of antineoplastic chemotherapy (T2), with the purpose of evaluating the acute CINV that appear until this period; three days (T3) and five days after CT (T4), established to assess the incidence of late CINV.

Manual detailing of the intervention was made with the aspects of the orientations, as well as the self-care algorithms, based on evidence that was provided to the two nurses responsible for the intervention (Figure 1).

The average call time was 10.25 minutes for EG and 3.05 minutes for CG.

Routine care/pre-chemotherapy health education: the control group consisted of patients with the same clinical conditions of the experimental group, since the definition of which group would remain was defined only after opening the envelope. The CG received routine care from the institution. Routine care was based on a health education session, led by nurses from the service itself, which view nausea and vomiting as side effects of chemotherapy. This session was provided on the day of treatment, in the chemotherapy infusion room or in the common waiting room.

Patients who met the inclusion criteria were approached by the assistant researcher for randomization, for the measurement of CINV (T0) and application of sociodemographic and clinical forms. After this time, the patients were oriented on the study steps: telephone calls within five to six hours after CT (T1), 24 hours after (T2), three days (T3) and five days after CT (T4), for the evaluation of the CINV and for providing guidance.

The last procedure regarding this presential phase was the opening of sequenced, opaque and properly sealed envelopes, which contained the condition selected for each participant. This designation was adopted only at this final moment to ensure concealment of the allocation of participants, not influencing their selection.

**Experimental Group****Control Group**

**Health education** (In-person intervention)  
Session with provision of general information on CINV\*.

5-6 hours after CT†

**Intervention 1** (Telenursing)

Evaluation experience of CINV\*; needs identification; preparation for occurrence of CINV\*; information on the pharmacological regimen; adapting knowledge of CINV\* to specific needs (mechanism and triggering factors); self-care strategy training provision.  
(Provision of additional information if required)

**Follow-up 1 (T1)**

Measurement of occurrence and degree of severity of CINV\*.

**Follow-up 1 (T1)**

Measurement of occurrence and degree of severity of CINV\*.

24 hours after CT†

**Intervention 2** (Telenursing)

Review of patient issues and concerns; Provision of self-care strategy training; dietary initiatives to prevent CINV\*; preventive environmental and behavioral guidelines; verification of adherence to the pharmacological prevention scheme.  
(Provision of additional information if required)

**Follow-up 2 (T2)**

Measurement of occurrence and degree of severity of CINV\*.

**Follow-up 2 (T2)**

Measurement of occurrence and degree of severity of CINV\*.

3 days after CT†

**Intervention 3** (Telenursing)

Discussion and training of relevant self-care strategies to management of CINV\*; problem identification and provision of self-care training in the management of occurrence or exacerbation of CINV\*.  
(Provision of additional information if required)

**Follow-up 3 (T3)**

Measurement of occurrence and degree of severity of CINV\*.

**Follow-up 3 (T3)**

Measurement of occurrence and degree of severity of CINV\*.

5 days after CT†

**Intervention 4** (Telenursing)

Review of patient issues and concerns; self-care training adapted to the specific needs of individuals.  
(Provision of additional information if required)

**Follow-up 4 (T4)**

Measurement of occurrence and degree of severity of CINV\*.

**Follow-up 4 (T4)**

Measurement of occurrence and degree of severity of CINV\*.

\*CINV: Chemotherapy-Induced Nausea and Vomiting; †CT: Chemotherapy;

**Figure 1** – Structure of usual care provided to patients on antineoplastic chemotherapy of moderate and high emetogenic potential versus telenursing intervention. Fortaleza, CE, Brazil.<sup>10</sup>

## Outcome measurement

The written informed consent was obtained in T0, prior to randomization and any study-related procedure, and confidentiality and anonymity were guaranteed.

Clinical data: determination of ECOG performance status, oncological disease, number of chemotherapy cycles performed, treatment regimen, other medications in use, and comorbidities were collected from patient records. The result of the whisper test, the determination of the *Glasgow* score, as well as tobacco and alcohol use were obtained through clinical examination and direct investigation with the patient.

Demographics: age, schooling, provenance, marital status, Current occupation, income and religion were collected from medical records.

Chemotherapy-induced nausea and vomiting measurement: the symptoms were evaluated according to the scale elaborated by the *Multinational Association of Supportive Care in Cancer* (MASCC), the MASCC *Antiemesis Tool* (MAT),<sup>7</sup> composed of four self-applicable items, with proven validity, reproducibility and responsiveness for use in cancer patients.<sup>14</sup> The scale was designed to respond at home if nausea and/or vomiting has been experienced since the last chemotherapy (0= yes and 1= no). If one of these symptoms is present, then patients grade the degree of severity (1= mild to 10= severe). Since there is no validated instrument in Brazil to evaluate the experience of these symptoms, this self-administered questionnaire was chosen, considering that it is extensively used in other clinical studies to evaluate the efficacy of antiemetic medications,<sup>15,16</sup> it has Portuguese translation and its psychometric properties have been evaluated, having a construct and concurrent validity established, with internal consistency in a moderately high sample from two nations (Cronbach's alpha =0.77).<sup>13</sup>

## Intervention fidelity

Two nurses trained in the application of the interventions and in communication skills, such as clarification, focusing, summarization and synthesis, participated in the intervention. Interventional nurses were not allowed to provide guidance to participants in the control group during CINV measurement calls, and they were discouraged from talking about intervention with other service nurses.

## Statistical power and analysis

In the sample calculation, for comparison of mean between groups, with confidence level of  $p < 0.05$  and 90% of statistical power, based on a similar study.<sup>21</sup> The sample group size was equal to 24 patients, however, aiming to achieve a higher number for greater efficacy, it was obtained a sample size of 30 clients per group.

$$n = \frac{(Z_{1-\frac{\alpha}{2}} + Z_{1-\beta})^2 \times 2\sigma^2}{\Delta^2} = \frac{(1.96 + 1.28)^2 \times 8.82}{2^2} = 24$$

## Statistical analysis

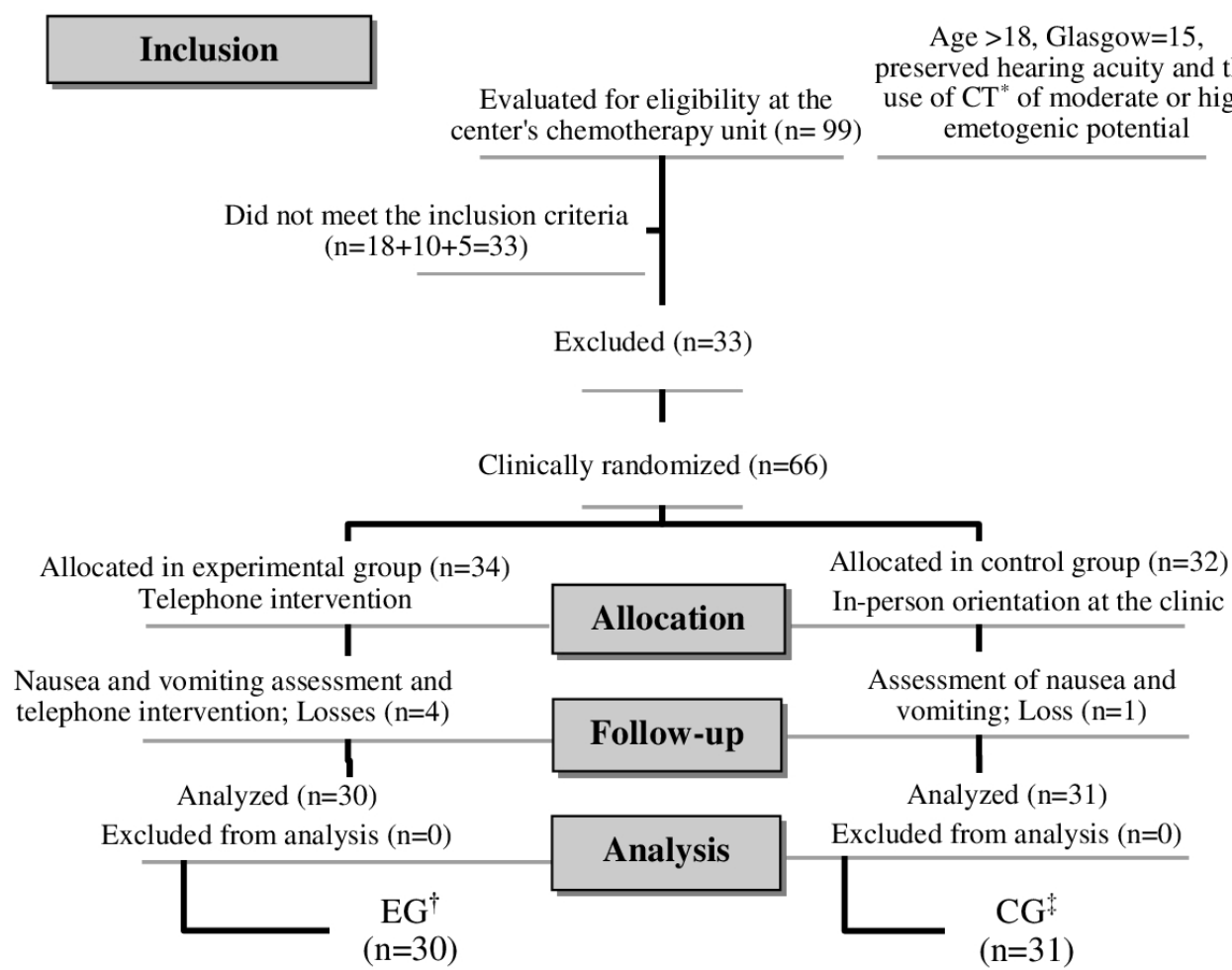
The data was processed in the program *Statistical Package for the Social Sciences* (SPSS), version 22.0. Verification of adherence to normal distribution was performed using the Shapiro-Wilk test. To verify the association between age and group variables, the Mann-Whitney U test was applied. To evaluate intergroup mean differences, the Mann-Whitney test was applied when the data presented asymmetry and the Student's t test when the data presented symmetry. Finally, the Wilcoxon signed-



rank test was applied to confirm the hypothesis of differences in the pre-test and post-test scores within groups. For the analyses, the significance level of 5% was adopted. In order to verify homogeneity between the control and experimental groups, the Bartlett homogeneity test was applied. To evaluate the significance proportions of the variables, the chi-square test of proportions was used.

## RESULTS

Ninety-nine participants were assessed for eligibility (Figure 2) and 66 consented and completed baseline measurements (T0) between December 2016 and September 2017. There were four losses in the follow-up of the experimental group and one loss in the follow-up of the control group, due to the impossibility of contact for lack of a telephone network. Three potential participants refused to participate in the research and there was no analysis of losses.



CT: Chemotherapy, †EG: Experimental Group. ‡CG: Control Group

**Figure 2** – Study Flow Diagram. Fortaleza, CE, Brazil, 2017.

The sociodemographic variables of the sample that presented homogeneity were: age ( $p=0.5894$ ), origin whose majority ( $n=40$ ; 65.58%) was from the interior of the state ( $p=0.3842 \times 0.0211$ ), occupation ( $p=0.7901 \times 0.124$ ), schooling ( $p=0.2231 \times 0.073$ ), marital status ( $p=0.9403 \times 0.124$ ), income ( $p=0.7271 \times <0.001$ ), religion ( $p=0.3228 \times <0.001$ ). There was no homogeneity between groups regarding gender ( $p=0.0395 \times <0.001$ ), predominantly female. It is noteworthy that the



predominant schooling was elementary school (n=38; 62.20%). Data with the clinical characterization of the sample can be seen in Table 1.

**Table 1** – Clinical characteristics of patients per treatment group, Fortaleza, CE, Brazil, 2017. (N=61)

	Experimental (n=30)		Control (n=31)		p*
	n	%	n	%	
Anatomical site of cancer					
Breast	12	40.00	10	32.25	0.040
Gynecological	9	29.99	13	41.93	
Thorax	4	13.33	3	9.67	
Hematologic	4	13.33	2	6.45	
Head and neck	1	3.33	2	6.45	
Central Nervous System	0		1	3.22	
Treatment					
Chemotherapy	28	93.33	23	74.19	<0.001
Chemotherapy and radiotherapy	2	6.67	8	25.80	
Emetic potential					
High risk	20	66.67	24	77.41	<0.001
Moderate risk	10	33.33	7	22.58	

\*p-value

There was homogeneity regarding the anatomical site of the cancer ( $p=0.514 \times 0.040$ ); emetic potential of chemotherapeutic agents ( $p=0.5165 \times <0.001$ ), in which high emetogenic potential chemotherapists prevailed; chemotherapy drugs used ( $p=0.2733 \times 0.004$ ) and number of chemotherapy cycles ( $p=0.116 \times <0.001$ ). There was no homogeneity regarding the type of treatment performed ( $p=0.0017$ ), in which the majority underwent chemotherapy as an isolated treatment.

Regarding the antiemetic regimen in use by the patients in this study, the two groups consisted of 5HT-3 receptor antagonists, such as ondansetron alone, in moderate emetogenic potential regimens, and corticosteroid-associated 5HT-3 receptor antagonists such as dexamethasone in high emetogenic potential regimens.

Regarding the evaluation moments, there was a progressive increase in nausea scores in both groups at T1 to T3. In T4, there was a slight reduction in relation to the mean of T3. Even with similar delineation of the occurrence of nausea in relation to both groups, the CG presented a higher mean at all times after CT (Table 2).

At T1, 31.14% of patients had nausea, which increased during T2 (42.62%) and T3 (59.67%), with reduction in T4 (50.81%). EG patients had less intensity of nausea at T1 when compared to CG (mean= 0.233 x 0.387). The same occurred in T2, with EG (mean=0.933 x 2.129), in T3 (mean=2.064 x 4.1), and T4 (mean=1.300 x 3.290). The peak occurrence of nausea in both groups occurred between T2 and T3, which refers to late nausea.

The occurrence of vomiting was significantly lower in T3, in EG (mean=0.100 x 0.3878;  $p=0.008$ ), as the number of vomiting episodes was also reduced (mean=0.300 x 1.1935;  $p=0.020$ ).

When comparing the moments before and after the intervention, a statistically significant reduction was observed in the variables of occurrence of nausea between the second and third evaluations ( $p=0.0089$ ); the degree of nausea between T2 and T3 ( $p=0.007$ ); and between T3 and T4 ( $p=0.009$ ).

**Table 2** – Comparison of the mean of nausea and vomiting over five hours, 24 hours, three and five days after chemotherapy for control and experimental groups. Fortaleza, CE, Brazil, 2017. (N=61)

Variables	Experimental Group (n=30)		Control Group (n=31)		p*	95% IC†
	Mean	SD‡	Mean	SD‡		
Nausea at first moment	0.133	0.345	0.0967	0.300	0.6615	-0.12 – 0.20
Occurrence of nausea						
5 hours after CT§ (T1¶)	0.233	0.430	0.387	0.495	0.2001	-0.39 – 0.08
24 hours after CT§ (T2¶)	0.300	0.466	0.5483	0.505	0.05**	-0.49 – 0.007
3 days after CT§ (T3††)	0.566	0.504	0.6451	0.486	0.5385	-0.33 – 0.17
5 days after CT§ (T4††)	0.4333	0.504	0.5806	0.501	0.2573	-0.40 – 0.11
Degree of nausea						
5 hours after CT§ (T1¶)	0.666	1.51	1.5483	2.392	0.9056	-1.90 – 0.14
24 hours after CT§ (T2¶)	0.933	1.760	2.129	2.499	0.0347**	-2.30 – 0.08
3 days after CT§ (T3††)	2.064	2.682	4.1	3.642	0.0295**	-3.47 – 0.18
5 days after CT§ (T4††)	1.300	2.053	3.290	3.338	0.0069**	-3.41 – 0.56
Occurrence of vomiting						
5 hours after CT§ (T1¶)	0.066	0.253	0.064	0.249	0.9735	-0.12 v– 0.13
24 hours after CT§ (T2¶)	0.100	0.305	0.0967	0.300	0.967	-0.15 – 0.15
3 days after CT§ (T3††)	0.100	0.305	0.3878	0.495	0.008**	-0.49 – 0.07
5 days after CT§ (T4††)	0.100	0.305	0.2580	0.444	0.1105	-0.35 – 0.03
Number of vomiting episodes						
5 hours after CT§ (T1¶)	0.066	0.253	0.2580	1.031	0.3235	-0.57 – 0.19
24 hours after CT§ (T2¶)	0.133	0.434	0.1612	0.522	0.8208	-0.27 – 0.21
3 days after CT§ (T3††)	0.300	1.149	1.1935	1.720	<b>0.020</b> §§	-1.64 – 0.14
5 days after CT§ (T4††)	0.166	0.530	1.1935	3.070	0.076	-2.16 – 0.11

\*p value; †confidence interval, ‡standard deviation, §chemotherapy, ¶five hours after chemotherapy, ¶24 hours after chemotherapy, \*\*significance test (p-value) related to the calculation of the *t test* for mean difference, assuming unequal variances, ††three days after chemotherapy, ††five days after chemotherapy, §§ significance test (p-value) related to the calculation of the *Wilcoxon* test.

**Table 3** – Linear regression models of the predictive variables of nausea and vomiting on the fifth day after chemotherapy in the experimental group. Fortaleza, CE, Brazil, 2017. (n=61)

Model		R <sup>2</sup>	Adjusted R <sup>2</sup>	Sum of Squares	gl	Mean Square	F	P*
Nausea	Regression	0.441	0.352	4.787	4	1.197	11.268	0.000
	Residue			2.761	26	0.106		
	Total			7.548	30			
Degree of nausea	Regression	0.398	0.354	3.375	3	1.125	11.865	0.000
	Residue			2.560	27	0.095		
	Total			5.935	30			
Vomiting	Regression	0.874	0.860	219.774	3	73.258	31.364	0.000
	Residue			63.065	27	2.336		
	Total			282.839	30			
Number of vomiting episodes	Regression	0.695	0.659	170.884	3	56.961	9.406	0.00°
	Residue			163.503	27	6.056		
	Total			334.387	30			

\*significance test (p-value) regarding the calculation of the ANOVA test.

The telephone intervention had an influence of 44.1%, based on the predictor variables. The F test revealed that  $F=11.268$ ,  $P=0.000 < 0.001$ , i.e., the multiple linear regression equation of data adjustment showed statistical significance. Regarding the degree of nausea, it was noticed that the intervention had a direct influence of 39.8% on the reduction of the degree of nausea in the sample. The test revealed that  $F=11.865$  obtained extreme statistical significance on the analyzed outcome. Regarding vomiting, it was found that the intervention indicated influence of 87.4% ( $p=0.000$ ). Moreover, it was shown that this intervention was able to reduce the number of vomiting episodes during chemotherapy treatment by 69.5% ( $p=0.000$ ). Thus, telephone intervention showed minimal and maximum influence of 35.2% to 87.4% of the study outcomes variable (Table 3).

Some limitations of the study should be pointed out, such as telephone *follow-up* time for only one chemotherapy cycle, not guaranteeing the external generalization of the findings. In addition, due to the impossibility of accessing some other variables that could be intervening in CINV, such as undocumented hydroelectrolytic disorders in the medical records, these were not measured.

## DISCUSSION

Distinct findings from this study were identified, with lower values than the incidence of nausea in the intervention group,<sup>22</sup> this fact may be explained by the higher incidence of young and female patients receiving chemotherapy for breast cancer, which is reported in the literature as a predisposing risk factor and may partly explain the high incidence of CINV in the sample studied.<sup>23</sup>

Regarding the type of nausea, there was a higher incidence of late nausea, which is described in the literature as the most severe and most resistant to pharmacological treatment.<sup>24</sup> Thus, regarding this symptom, there was a reduction in the EG after intervention ( $p=0.0089$ ), suggesting that it may be possible to manage this symptom in the clinical practice of nurses..

The Only Recovered Clinical Trial That Evaluated CINV Symptom<sup>25</sup> obtained favorable results with the use of telephone intervention to reduce these symptoms with outpatient cancer patients. The authors used a system called ASyMS® that provided instructions, such as drug use counseling, distraction techniques, relaxation and nutritional counseling, similar to the methods of the present study. One of the differences between the studies refers mainly to the intervention subsidized by electronic program, besides the guidance by professional.

In the sample of the present study, no reduction in nausea and vomiting was observed in the evaluation after 5 hours of chemotherapy, which may be related to the nature of the intervention, as the educational strategy needs time for adherence and implementation. Another factor that possibly endorsed this outcome was the fact that most of the patients were from the interior of the state (65.58%), being, in this period, still in transit, returning to the municipalities of origin.

Consideration should also be given to the nature of the interventions used. Among them, the reinforcement on the importance of adherence to the prophylactic antiemetic drug regimen. Although there is a major advance in understanding the pathophysiology of CINV associated with the discovery of a new generation of antiemetics, such as 5-HT<sub>3</sub> antagonists, there is sub-adhesion to this therapy.<sup>26</sup> For both groups (EG and CG), antiemetic prophylaxis medications were prescribed for antineoplastic chemotherapy, except for the use of neurokinin inhibitors (NK-1). However, only in EG was reinforced the importance of adherence, which may justify a better outcome in this group of patients.

Dietary counseling was also performed, including counseling on eating drier, cold or ambient-temperature foods, rich in carbohydrates and proteins, avoiding fatty foods, among others. Similar to this study, others<sup>21,27</sup> which used this measure obtained satisfactory results in both the occurrence and severity of these symptoms.

Interventions using the telephone as a strategy for glycemic control in adults with Type 2 Diabetes Mellitus proved to be effective from a systematic review of 1294 patients who had glycemic

control determined by glycated hemoglobin (HbA1c) levels. Of these, 671 were randomized for telephone follow-up and 479 for usual care. Self-control was improved and the reduction of possible complications of the disease was enhanced, a fact that shows the possibility of changing habits through telephone intervention.<sup>28</sup>

To this end, a reflective study on key factors to determine whether telephone interventions can be effectively translated into clinical practice focuses on the RE-AIM model (*Reach Efficacy, Adoption Implementation, Maintenance*), and points out that success in clinical practice depends on population reach and commitment to advance the effectiveness and maintenance of educational interventions. In this sense, it provides methodological guidelines that can assist in the development and maintenance of this intervention.<sup>29</sup>

It is noteworthy that Translational Research (TR), which aims to combine basic research with clinical practice, can contribute to provide new evidence for the management of symptoms experienced by individuals with cancer. In other words, TR can provide new information to whom and in what context interventions will work, when they should be used and for how long. In this sense, nurses will play a key role in educating patients about the risk of particular groupings of symptoms, based on assessing each individual's genomic constitution through a series of biomarkers.<sup>30</sup>

It is suggested that research is conducted within the framework of translational research, and studies that seek to evaluate the influence of telephone intervention on the number of in-person consultations, which could represent an indirect benefit to Brazil's health system.

It is noteworthy that this clinical trial was conducted based on the CONSORT statement, which enables the reproduction of this study.

## CONCLUSION

The telephone intervention benefited patients who made use of the variables occurrence of nausea, degree of nausea, vomiting occurrence on the third after CT. It is noteworthy that the intervention was effective in the period where CINV are more prevalent and have greater control difficulty.

With the relevant results for the clinical practice of the oncologist nurse and the health system in its entirety, it is expected that there is interest in implementing this intervention strategy for outpatient cancer patients.

The parallel importance of the organizational support and training of oncologist nurses for the full implementation and adherence to this type of intervention is emphasized.

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## NOTES

### ORIGIN OF THE ARTICLE

Extracted from the Nurse Residency paper in Cancerology – Telephone intervention to control nausea and vomiting associated with outpatient antineoplastic chemotherapy: a randomized clinical trial, presented in 2018 to the Ceará State School of Public Health and *Instituto do Câncer do Ceará*.

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Analysis and interpretation of data: França AC, Rodrigues AB, Aguiar MIF, Silva RA, Melo GAA.

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Review and final approval of the final version: França AC, Rodrigues AB, Silva RA, Melo GAA.

### APPROVAL OF RESEARCH ETHICS COMMITTEE

Approved by the Research Ethics Committee of the *Instituto do Câncer do Ceará*, No.1,839,017, CAAE: 62179316.0.0000.5528. Brazilian Registry of Clinical Trials, RBR-6s8qm5

### CONFLICT OF INTERESTS

There is no conflict of interest.

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