Randomized clinical trial quantifying the effectiveness of a self-monitoring intervention on cancer patients with peripheral neuropathy: Quantitative study

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Abstract

Purpose: Chemotherapy-Induced Peripheral Neuropathy (CIPN) is a highly distressing condition that has no effective or helpful pharmacotherapy, alongside no established non-pharmacological treatment. Thus, there is an urgent need to develop supportive care. While self-monitoring has been verified as an effective management method, it has not been studied as a mode of managing CIPN. This study quantified the effectiveness of a self-monitoring intervention for the management of persistent CIPN.

Methods: A randomized, controlled clinical trial was conducted wherein the participants were using Taxanes or platinum-based anticancer drugs in an outpatient setting. They were randomly assigned to either a control group (CG) (n=32) or a self-monitoring group (SMG) (n=33), wherein the participants recorded their symptoms daily, goals were set in collaboration with the researcher, and feedback (behavioral approval and modification, emotional support) was provided twice every three weeks. The study lasted for six weeks, and the control group received conventional nursing support. Self-management ability, self-efficacy, and Functional Assessment of Cancer Therapy-General (FACT-G) scores were used for evaluation; ANOVA analysis was conducted.

Results: There was an interaction effect between the CG and SMG regarding self-efficacy scores. Scores were significantly higher in the SMG than in the CG after three weeks. Quality of life (QOL) scores were also higher in the SMG than in the CG.

Conclusions: The self-monitoring intervention maintained the participants' self-efficacy and QOL. This suggested its effectiveness on patients with peripheral neuropathy.

Implications for Cancer Survivors: Self-monitoring interventions enable the maintenance of self-efficacy and QOL for participants associated with CIPN.

Introduction

Peripheral neuropathy was rated as the primary cause of physical distress among 4,000 cancer patients receiving outpatient anticancer drugs [1]. Lung, colon, and breast cancer, which have high incidence rates worldwide [2] and in Japan [3], are commonly treated with platinum-based drugs or Taxanes. Peripheral neuropathy is often observed among those using antineoplastic agents. Reportedly, its prevalence is 93.7% or higher for the drug Oxaliplatin [4]. In general, the incidence of peripheral neuropathy increases and symptoms worsen as the dosage increases. In a meta-analysis of 31 cases involving 4,179 patients [5], including those suffering from colorectal and breast cancer, 68.1% showed symptoms in the first month after chemotherapy, 30.0% had symptoms for more than six months, and patients suffered from these symptoms even after the treatment ended.

Peripheral neuropathy mainly entails sensory disturbances, such as numbness and tingling in the limbs. However, it may also cause weak motor skills. Its impact on daily and social life is far-reaching, causing limitations in dressing and undressing, cooking, elaborate hand movements, work, and relationships with

family members [6–9]. Moreover, as the severity increases, the patient may be forced to discontinue treatment due to the inability to ensure safety in daily life, resulting in falls, burns, and maloperation while driving [10]. This can lead to psychological anguish and spiritual pain, threatening self-existence [11] and significantly lowering individual quality of life (QOL) [12, 13].

Unfortunately, Duloxetine is the only supportive drug with good evidence in terms of its palliative effect [14, 15].There are few effective and helpful medications regarding peripheral neuropathy [16, 17]. In recent years, non- pharmacological interventions such as cryotherapy [18–20] and exercise therapy, including balance training [21–23], have been reported to have some effect. However, there is currently no established intervention method.

Patient-driven self-management is essential, and it includes monitoring signs and symptoms, preventing falls, ensuring safety, and maintenance of physical and mental health. As with chronic diseases, the management of peripheral neuropathy requires a partnership wherein medical professionals provide their expertise and skills. Patients recognize peripheral neuropathy as an unknown sensation that they have never experienced before [24]. For this reason, it is important for medical professionals to provide information and education about the sensation of symptoms, helping them accurately recognize their own symptoms. Self-monitoring, a form of cognitive-behavioral therapy, is one such method. In recent years, several web-based studies have been conducted for the management of cancer symptoms and side effects of chemotherapy [25–27]; the improvement in distressing symptoms [25, 27] and QOL [26] have been verified. Kolb et al. [28] conducted a study focusing on the neuropathic symptoms of peripheral neuropathy and reported the intervention group experienced fewer days of moderate to severe CIPN symptoms and fewer days of distress associated with those symptoms. Participants called the automated telephone symptom-monitoring system daily to report their numbness and tingling. However, this study cannot be generalized to the management of peripheral neuropathy.

In our previous study [29, 30], we reported that an approach combining self-monitoring with goal-setting and feedback techniques is effective in improving symptoms. In this study, we quantitatively clarified whether self-monitoring interventions that incorporate symptom management records and observations into daily life are effective in improving self-management skills, mental stability, and QOL in patients with Chemotherapy-Induced Peripheral Neuropathy (CIPN), for whom there are few supportive medications.

Purpose

The purpose of this study was to quantitatively clarify the effects of self-monitoring intervention on the management of persistent CIPN.

Operational Definitions of Terms

Chronic peripheral neuropathy

This is defined as numbness and discomfort in the hands and feet; difficulty in writing; motor skills-related disturbances, such as muscle weakness; and autonomic disturbances, such as dizziness that persists for more than seven days. Additionally, it has a comprehensive impact on various aspects of life, including the psychological and social aspects [31].

Self-monitoring

It is the process of acquiring information and regularly observing and measuring (recording) one's own behavior, cognition, and mood to proactively implement self-management. Through this, one can objectively recognize one's own symptoms or physical sensations and strengthen one's behavior.

Conceptual Framework of Research (Fig. 1)

This framework theory is based on the theories of Wilde et al. [32] on self-monitoring concept, cognitive behavioral therapy (CBT) [33], and Andragogy of Malcolm Knowles [34].

CBT is a psychological treatment using structured techniques based on cognitive, emotional, and behavioral interactions [33]. CBT includes effective self-monitoring, goal setting, and feedback. The self-monitoring is used to help patients objectively understand the facts of their own behavior and problems to drive changes in a patient's cognitive behavior. Adult learners [34] are capable of learning, are self-determined, and their experience presents a resource for learning. Interventions are based on the researcher's relationship with the participant and include 1) education regarding CIPN and self-monitoring, 2) dialogue-based feedback on records (analysis, approval, and correction), and 3) goal-setting to address symptoms, reinforcing self-management awareness and behavior by objectively assessing one's own thoughts, reactions, and actions.

Methods

Research Design

This was a comparative randomized, parallel, and controlled study.

Study Participants

Eligibility criteria

Eighty-one patients undergoing anticancer drug therapy that is likely to cause peripheral neuropathy, in outpatient clinics of three hospitals in Japan were included in the study. The selection criteria were as follows: (1) patients aged 20 years or older who had been diagnosed with cancer, understood the purpose of the study, and consented to it; (2) patients who had received at least three courses of Taxanes (Paclitaxel and Docetaxel) or platinum-based drugs (Cisplatin, Carboplatin, and Oxaliplatin), (3) those determined to be free of mental or cognitive problems by a physician or nurse, (4) those who were capable of answering the interview and questionnaire, and (5) those who could cooperate continuously for six weeks and respond to three surveys based on the starting date of the survey.

Sample size determination

Since the effectivity rate of self-monitoring in a similar setting is unknown, the required sample size was calculated using G*power [35], and power was determined using ANOVA. The target number of study subjects was set at 80 (40 each in the target and intervention groups) based on a sample size of 73 determined from calculations with parameters of effect size 0.4, α-error probability 0.05, and power 0.8.

Randomized allocation

A random number table and sequential enrollment method was used by the researcher and the outpatient chemotherapy nurse to randomly assign subjects to the self- monitoring group (SMG) or the control group (CG).

Intervention Methods

The SMG was imparted education about (1) treatment and symptoms/ prevention of CIPN and self-management (application and pamphlet), (2) self-monitoring techniques, (3) goal-setting, and (4) homework.

In self-monitoring, participants took the initiative to carry out continuous observation and recording as homework. Study participants were told that it was a collaborative process in which they, along with the researcher, would set goals together through dialogue, and the researcher would provide feedback based on the diary and record notebook (hereinafter referred to as the record) through individual sessions of about 15–30 minutes every three weeks.

The individual sessions consisted of goal-setting, recording of homework, and feedback. Goal-setting consists of (1) understanding the appearance and status of CIPN symptoms and signs, (2) coping with its impact on their lives, (3) understanding their emotional state and making efforts to stabilize the same, and (4) increasing awareness and coping behaviors. Goals (1) to (4) were set flexibly depending on the participant's complaints and response.

In the "homework" section, participants recorded (1) the degree of their CIPN symptoms, (2) their daily life behaviors, (3) their emotions and coping behaviors (moods and feelings), and (4) how they spent their time every day after dinner.

The researcher provided feedback based on the symptoms, coping strategies, and feelings pertaining to the CIPN recorded by the participant. The researcher emphasized dialogue, confirmed that goals had been achieved, approved and praised what had been documented and addressed, and suggested ways to address unachieved goals. The intervention began on the first day and continued up to six weeks.

Only knowledge and education were provided to the CG in the first session. All content were discussed in advance and conducted by one researcher in the outpatient consultation room at each facility after training.

The study was conducted from August 9, 2017 to March 30, 2020.

Data Collection

Characteristics (age, occupation) and medical findings (stage, treatment regimen) of the consented participants were collected from the medical records. The investigators administered a questionnaire on the participants during examination that confirmed the presence of paresthesia of the hands or feet due to peripheral neuropathy (CTCAE, ver. 4).

Evaluation indicators and measurement tools

The primary outcome was the improvement of symptoms and self-management, which included recognition of CIPN, stability of mental state assessed by the Distress and Impact Thermometer, and symptom relief and daily life safety behaviors. The secondary outcomes were the Self-efficacy scale for Advanced Cancer (SEAC) and Quality of life, and were assessed using The Functional Assessment of Cancer Therapy-General (FACT-G).

CIPN

CIPN was measured using two scales. The first was the **C**omprehensive **A**ssessment **S**cale for Chemotherapy-Induced Peripheral Neuropathy (CAS-CIPN). The CAS-CIPN was developed by Kanda et al. [24]. This scale comprehensively measures the impact of peripheral neuropathy. Its reliability and validity have been confirmed, and the Cronbach's α for the entire scale was 0.826. Its subscales comprised 15 items grouped into four factors: threatened interference with daily life by negative feelings, impaired fine motor skills of the hand, confidence in choice of treatment/management, and dysesthesia of the palms and soles. *It was scored on a five-point* Likert scale (minimum score of 0 and a maximum score of 60), with higher scores indicating stronger impact of peripheral neuropathy. The second scale was the FACT/GOG-Ntx (GOG-Ntx) [36]. This is an additional subscale of FACT-G, an 11-question survey of the neurotoxicity of taxane-based chemotherapy drugs. Its reliability and validity have been demonstrated with Cronbach's α of 0.84–0.90. Each item is scored from 0–4 points to provide a total score out of 44, with higher scores indicating more severe neuropathic symptoms.

Distress and Impact Thermometer (DIT)

We used the scale developed by Akizuki et al. [37] to screen for adjustment disorder and depression in cancer patients. The scale is a self-administered questionnaire with one item for the distress thermometer and one item for the impact thermometer. It measures distress and obstacles in daily life caused by pain in the preceding week, using a scale ranging from 0 to 10. Higher scores indicate greater pain and obstacles. The validity of the scale has been verified.

Symptom relief and daily life safety behaviors

This is a questionnaire originally developed by the researcher. It consists of six items: symptom relief (keeping warm, promoting circulation, and preventing constipation) and daily life safety (preventing falls,

burns, and elaborate movement disorders) behaviors on peripheral neuropathy. For each behavior, participants were asked to select from among “not able,” “almost do,” or “often do.”

The SEAC

Developed by Hirai et al. [38], the SEAC is a measure of disease self-efficacy in patients with advanced cancer, and has been proven reliable and valid. It consists of 18 items and is assigned 0-100 points; the higher the score, the higher the self-efficacy. In this study, the six items of the subscale Efficacy of Emotional Control (α = 0.76) were used as indicators for judging effectiveness. Responses to the questionnaire items were on a 10-point scale from 0 (not confident at all) to 100 (completely confident), with a minimum score of 0 and maximum of 600.

FACT-G (version 4) [39, 40]

This scale measures cancer-specific health-related QOL, and the Cronbach’s α for the entire scale was 0.89. Its subscales comprise 25 items grouped into four factors: physical, functional, emotional, and social/family well-being. It is scored on a five-point Likert scale (0: Not at all true 4: Very true).

The minimum score is 0 and maximum is 100, with higher scores indicating better QOL. There is a Japanese version of this scale, and its reliability and validity have been confirmed.

Evaluation period

The CAS-CIPN, GOG-Ntx, DIT, SEAC, and FACT-G quantitative assessments were measured three times: at baseline (T0) before the start of the survey, three weeks later (T1), and six weeks later (T2). Lifestyle behaviors were compared twice: at baseline (T0) and six weeks later (T2).

Data Analysis

Total analysis was performed using IBM SPSS Statistics, with two-tailed tests and a significance level (p-value) of less than 5%. G*Power 3.1.9.2 was used to determine the required sample size.

Analysis of basic characteristics and medical findings of the participants *(hereinafter referred to as attributes)*

Descriptive statistics were conducted for the target and intervention groups. Comparisons of attributes in the target and intervention groups before the intervention were made through unpaired t-test, χ^2 test, and Fischer’s direct probability method.

Comparison of evaluation items

Two-way ANOVA was performed between the SMG and CG before the start of the study (T0), three weeks after the study started (T1), and six weeks after the study started (T2) for the primary outcome of CAS-CIPN, GOG-Ntx and DIT, and the secondary outcome of FACT-G and SEAC. Multiple comparisons with Bonferroni’s correction were performed as a subsequent test for any identified interactions.

For the primary outcome, the incidence of responses before and after six weeks (T2) was obtained, and the Wilcoxon signed rank test, was conducted. The $\chi 2$ test was used for comparison between T0 and T2.

Ethical Considerations

The ethics review committee at the university and research institutions with which the authors are affiliated, approved this study. We obtained written consents from the hospital director, head nurse, and physicians and nurses in charge of the implementation department after explaining the outline, objectives, and content of the study. The participants were provided with verbal and written explanations of the study outline, objectives, and content; the fact that the researchers would review their medical records; and that they would be assigned to either an intervention or control group. Before they provided written consent, we explained that participation was voluntary, data would be anonymized, and personal information would be protected. This research was started by pre-registering with UMIN: Registration number (000028618)

Results

Flow Diagram and Participants' Attributes (Fig. 2 and Table 1)

Study details were explained to a total of 81 female cancer (breast and gynecological) and colorectal cancer patients who received outpatient treatment and met the requirements for the study; 77 consenting patients were selected for participation. The patients were randomly assigned to the CG (n = 38) or the SMG (n = 39) as a sequential enrollment method at each institution. However, certain participants did not complete the study period as they either declined to participate after the first and second time (control n = 2, intervention n = 3) or declined any treatment (intervention n = 1). After excluding those with incomplete data, the final number of participants was 32 in the CG and 33 in the SMG. We did not supplement the dropouts or incompletely recorded the data (missing). Table 2 shows their characteristics.

The mean age of the participants was 59.8 ± 11.1 years in the CG and 55.3 ± 11.4 years in the SMG. Approximately 85% of the participants in both groups were female, and about 25% suffered from colorectal cancer. There were more cases of advanced stage (III-IV) cancer in the SMG than in the CG, and there was a significant difference between the groups. There were no significant differences in other attributes between the two groups.

Primary Outcomes of Self-Monitoring Interventions

Three assessments were conducted to measure improvement in symptoms and self-management:

1. Peripheral Neuropathy recognition: CAS-CIPN and GOG-Ntx scores (Table 2, Fig. 3)
The CAS-CIPN scores of the CG and SMG were lowest at T0 and increased in T1 and T2 as the treatment progressed. SMG scores were always higher than the CG scores, but their trends were similar. Two-way

ANOVA revealed a significant difference in the time course (F = 22.842 P = 0.000), with no significant difference between the CG and SMG.

The GOG-Ntx scores of CG and SMG were lowest at T0 and increased in T1 and T2 as the treatment progressed. SMG scores were always higher than the CG scores, but the trends were similar. Two-way ANOVA revealed a significant difference in the time course (F = 24.158 P = 0.000), with no significant difference between the CG and SMG.

Figure 3 shows the correlation between the GOG-Ntx and CAS-CIPN scores. CG T0 to T2: Total n = 96, r = 0.691 (p = 0.001); SMG T0 to T2: Total n = 99, r=0. 821(p = 0.001), both of which were highly correlated.

2. Stability of mental state: DIT (Fig. 4)
The Distress Thermometer Score was lowest at T0 for both the CG and SMG, and increased at T1 and T2 as the treatment progressed. As a result of a two-way ANOVA of the Distress Thermometer Scores, there was no difference between the CG and SMG. There was a significant difference observed only over time (F = 6.641, p = 0.002). There was no interaction effect.

Changes in the Impact Thermometer Scores were lowest at T0 for both the CG and SMG, but highest at TI for CG, and T2 for SMG. A two-way ANOVA of the Impact Thermometer Scores showed that there was no difference between both groups. A significant difference was observed only over time (F = 7.931, p = 0.001).

3) Symptom relief and daily life safety behaviors (Table 3)

At T2, there were many “almost do” and “often do” responses for both the CG and SMG regarding the six items of symptom mitigating and safety behaviors for CIPN. At both T0 and T2, no significant differences were found between the CG and SMG for all items, as assessed by the χ^2 test. No significant difference was observed in any item when analyzed using the Wilcoxon signed rank test, at T0 and T2 in the CG and SMG.

Secondary Outcomes from the Self-Monitoring Intervention (Table 2, Fig. 4)

Self-efficacy scores

For the CG, the score at T0 was the highest, that at T1 was lower, and that at T2 remained low; for the SMG, the score at T0 remained the same until T2. The two-way ANOVA revealed an interaction between the CG and SMG (F = 5.689 p = 0.004), with SMG values being significantly higher than those of the CG at T1 (t=-3.372 p = 0.001).

QOL (FACT-G) scores

The transition between the CG and SMG values was the highest at T0, but the scores remained almost the same at T1 and T2. SMG scores were significantly higher in T0, T1, and T2. The two-way ANOVA

revealed a significant difference between the CG and SMG (F = 7.914, p = 0.007).

Discussion

Improvement of Symptoms and Self-Management

Peripheral Neuropathy recognition (CAS-CIPN and GOG-Ntx scores) and DIT were measured as indicators of improvement in symptoms. In the two-way ANOVA of the CAS-CIPN and GOG-Ntx scores, no significant difference were found between the CG and SMG. As treatments increased, the scores in both groups indicated a stronger recognition of symptoms (over the course of T0,T2,T3 : F = 24.158 p = 0.000). In addition, the correlation coefficient between the GOG-Ntx and CAS-CIPN scores (CG: r = 0.691, p = 0.001; SMG: r = 0.821, p = 0.001) was also significantly higher in both groups. The participants thought that their symptom recognition was appropriate.

Two factors may have contributed to the lack of differences between the groups: first, the drugs used by the participants produced acute and chronic peripheral neuropathy, making them more aware of their symptoms. Taxanes such as docetaxel and paclitaxel were used in 22 patients (68.8%) for the CG, and 18 (55.2%) for the SMG; oxaliplatin in four patients (13.8%) for the CG and six (20.0%) for the SMG; and a combination of paclitaxel and carboplatin in four patients (13.8%) for the CG and nine (30.0%) for the SMG. Taxanes and oxaliplatin showed acute and chronic symptoms. The chronic symptom of taxanes involves numbness and tingling, characterized by a “glove and stocking syndrome” that extends to the lower extremities and wrists [41]. This symptom is experienced by 60% of all treated patients [42]. Symptoms occur in 97% of patients when the cumulative dose exceeds 1,400 mg/m^2, which is easy to recognize because of the symmetrical damage to the axons and the bilateral nature of the symptoms.

On the other hand, as the cumulative dose of oxaliplatin increases, chronic sensory axonal neuropathy leads to persistent symptoms and subsequent functional impairment, including significant sensory dysfunction in the hands and feet. The incidence is approximately 40–93%, and the symptoms worsen within 3–6 months even after treatment [43]. Characteristically, peripheral neuropathy leads to dose reduction, delay, and cessation of treatment [44]. Therefore, it is essential that symptoms are understood effectively.

Second, in this study, both the CG and SMG were provided education on treatment and symptoms/prevention of peripheral neuropathy and self-management, which may have increased their interest in symptoms. A study by Tanay et al. [45] revealed that CIPN involves vague symptoms, an unknown experience, a lack of information, and an insignificant risk due to patients’ perception of risk. Researchers also reported that patients with CIPN experienced suffering from an inability to cope with the previously unknown sensation of numbness. They also reported that 75% of patients with CIPN experienced unpleasant emotions such as fear, helplessness, and dismay to the inability to manage numbness, and that it implied losing one’s sense of control [24]. Therefore, it is suggested that there was no difference between the groups because both of them were provided with specific education related to

symptom sensation and self-management of CIPN. The DIT also showed no difference between the groups.

Due to the cumulative nature of any drug, it is likely that the more a patient is treated, the more CIPN symptoms are recognized and the stronger the DIT becomes. For this reason, it is important for healthcare providers to monitor symptoms, including mental stability, over time and effectively use dose reduction and drug suspension as part of treatment.

Next, the results of symptom relief and daily life safety behaviors for peripheral neuropathy showed no difference between the groups. Self-monitoring has been applied to the self-management of chronic diseases such as arthritis, asthma, diabetes, blood pressure control, and overweight/obesity as a form of cognitive-behavioral therapy [46]. Recently, web-based self-monitoring methods have been developed, and their application is expanding [47].

Cognitive-behavioral therapies have also been used to ameliorate the side effects of chemotherapy, such as taste disorders [30] and fatigue [48] in cancer disease. These interventions can improve knowledge, promote positive emotions, enhance skills in self-management behaviors, and reduce the severity or impact of symptoms.

In the present study, the effect of self-monitoring, one of the cognitive-behavioral therapies, was not clear in terms of reducing symptoms and restoring the mental stability of peripheral neuropathy patients for the two reasons mentioned earlier. This was in line with a self-monitoring intervention paper on the WEB [28, 49] that showed no effect on the perception of symptoms.

Conversely, the alleviation of depression [49] and reduction in the Distress score [28] have been indicated to maintain physical function. A review of behavioral interventions [50] reported that interventions included self-reporting of CIPN symptoms, education about CIPN and management, safety, and methods for reporting physical function and symptoms. We aim to continue refining our study by reviewing the control group and intervention content.

Improvement of self-efficacy and QOL

The effect of the intervention, as clarified in this study, was the maintenance of self-efficacy and QOL. In other words, there was an interaction effect between the CG and SMG ($F = 5.689$, $p = 0.004$) for self-efficacy scores. Scores were significantly higher in the SMG than in the CG after three weeks ($t=-3.372$, $p = 0.001$). QOL scores were also higher in the SMG than in the CG. The results of the two-way ANOVA showed a significant difference between the CG and SMG ($F = 7.914$, $p = 0.007$). The self-monitoring intervention thus maintained participants' self-efficacy and QOL

The intervention group retained their self-efficacy and QOL compared to the CG, even if their symptoms did not improve. The SMG participants observed their symptoms at home, organized their feelings at that time, and recorded them as homework. Together with the researcher, we provided feedback and confirmed their coping strategies. At that time, we approved and praised the participants' self-management. We

believe that this helped the participants to maintain their self-efficacy because it gave them the confidence that they were doing the right thing. This was also the case in a previous self-monitoring intervention for taste disorders [30]. By setting goals for how to spend time in a way that is unique to each individual, it is thought that a change in attitude toward “doing what I can” rather than emphasizing “what I cannot do” was created, and QOL, including daily life functions, was maintained.

As described above, the self-monitoring intervention was implemented according to the set research framework; although no change in the intensity of CIPN symptoms was observed, self-efficacy and QOL in terms of being able to cope with the symptoms were maintained. We believe this could have been achieved through timely feedback, educational activities including how to stay safe, and maintaining ongoing engagement and positive interaction.

Our findings suggest that self-monitoring interventions may be effective as nursing support for CIPN, particularly for those who have not been able to establish effective non-intervention methods.

Limitations and Challenges of the Study

This study collected both quantitative and qualitative data simultaneously. However, the limitation of the study is that the amount of qualitative data collected was huge, but only quantitative evaluation could be performed. As a future goal, based on the study design, evaluation index, and clinical applicability, we believe it is necessary to increase the number of participants and conduct the study at multiple sites to further demonstrate its effectiveness.

Conclusion

Self-monitoring interventions can contribute to the maintenance of self-efficacy and QOL among participants suffering from CIPN. The guideline lists duloxetine as the only effective drug for treatment (“weak recommendation”). Self-monitoring can be an effective nursing support for peripheral neuropathy in this situation.

Declarations

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Author Contributions: All authors contributed to the study conception and design. Material preparations were performed by Kiyoko Kanda, Kazuko Ishida, Keiko Fujimoto and Ruka Mochizuki. Data collection and analysis were performed by Kiyoko Kanda, Kazuko Ishida, Chiaki Ishihara, Ayumi Kyota, and Mai

Hosokawa. The first draft of the manuscript was written by Kiyoko Kanda and all authors commented on previous versions of the manuscript. All authors read and approved the final manuscript.

Data Availability: The datasets generated and/or analyzed during the current study are available from the corresponding author on reasonable request

Ethics approval: This study was performed in line with the principles of the Declaration of Helsinki. Approval was granted by the Ethics Committee of University A (May 02,2017./No.HS2017-028) and the Ethics Committee of B Hospital (December08,2017./No.12)

Consent to participate: Informed consent was obtained from all individual participants included in the study.

Consent to publish: The authors affirm that human research participants provided informed consent for publication of data processed so that it cannot be identified by an individual.

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Tables

Table 1-3 are available in the Supplemental Files section.

Figures

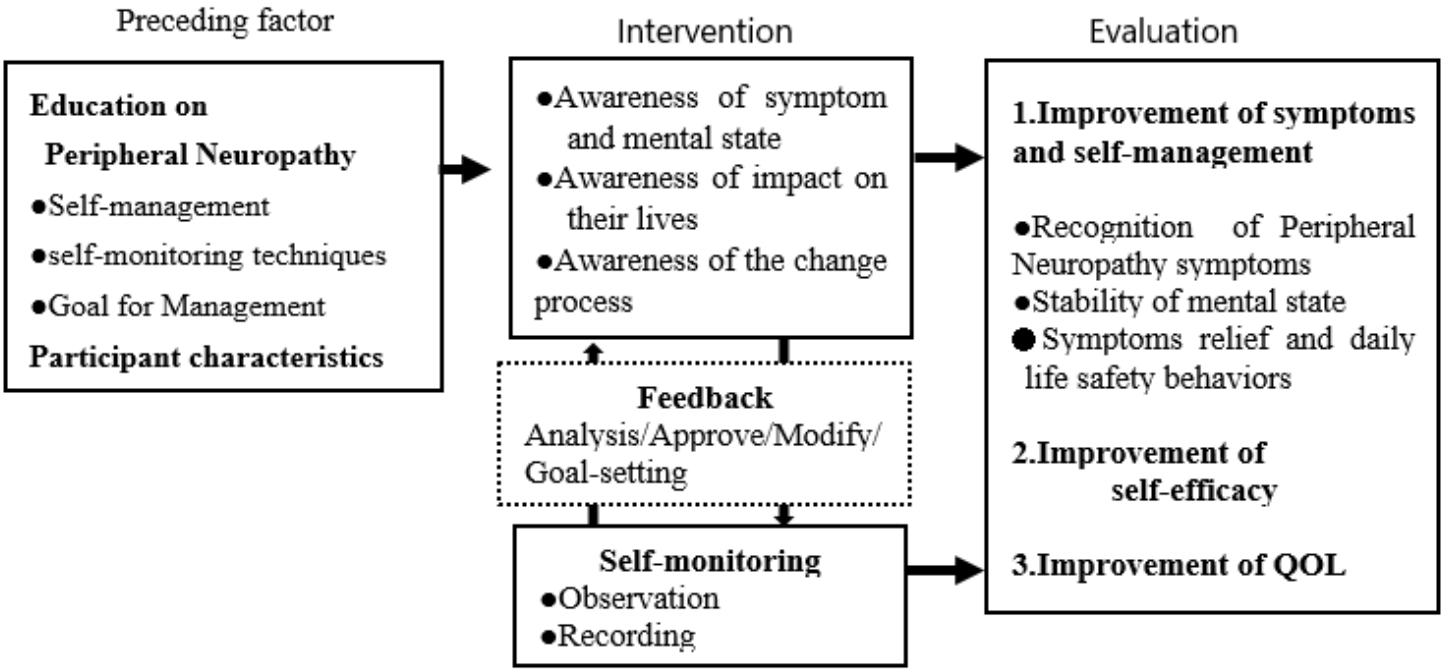

Figure 1

Conceptual framework of self-monitoring intervention for Chemotherapy-Induced Peripheral Neuropathy

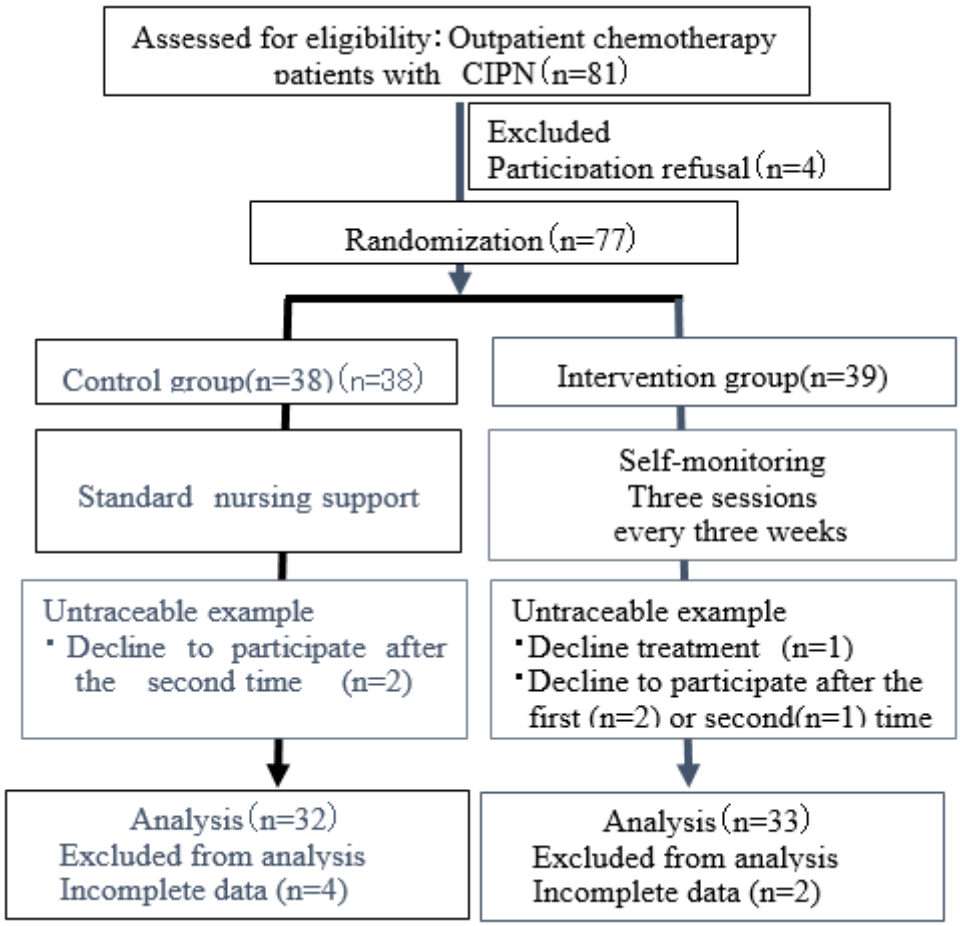

Figure 2

Flow diagram of the parallel randomized trial between two groups

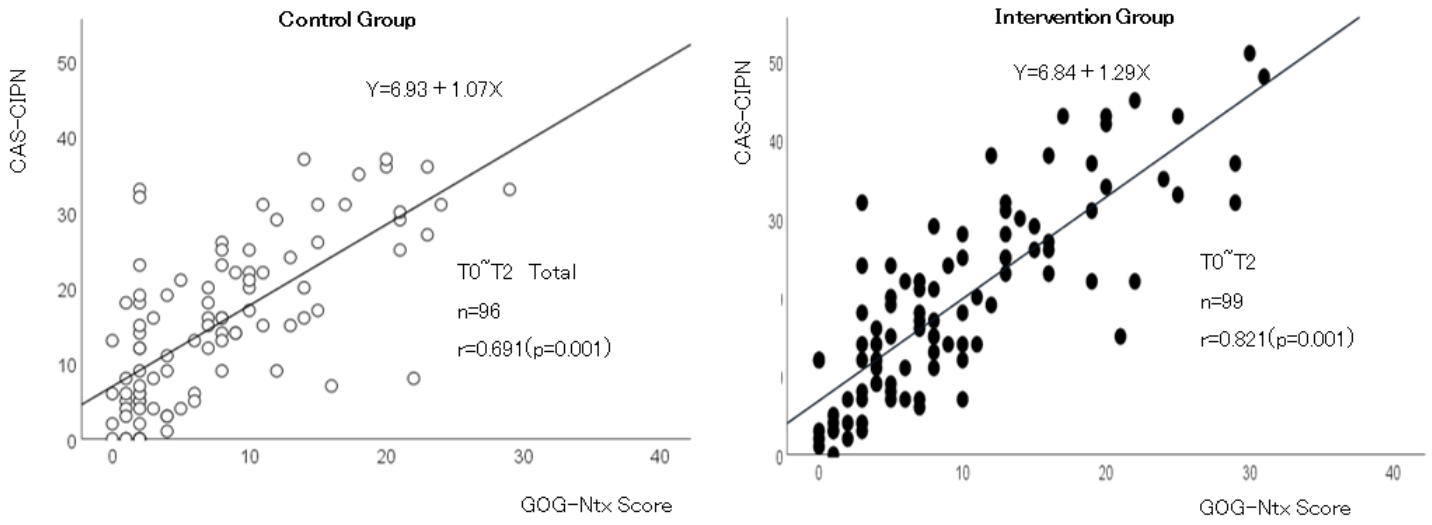

Figure 3

The correlation between the GOG-Ntx and CAS-CIPN scores in cancer patients

Abbreviations: CAS-CIPN, Comprehensive Assessment Scale for Chemotherapy-Induced Peripheral Neuropathy; T0, baseline; T1, Points 3 weeks after baseline; T2, Points 6 weeks after baseline

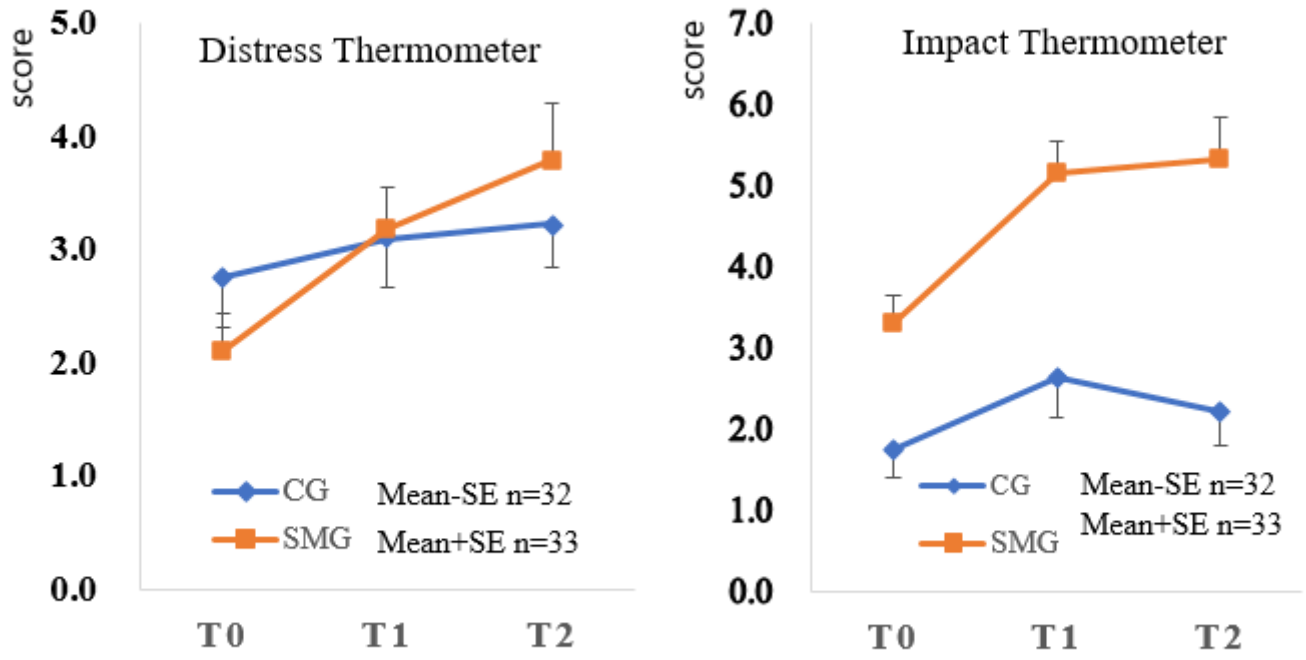

Figure 4

The Distress and Impact Thermometer scores for CIPN in cancer patients

Analysis was performed with the two-wayANOVA of the values of Distress Thermometer and Impact Thermometer of CG and SMG. Two-way ANOVA of the Distress Thermometer and Impact Thermometer Score showed no difference between CG and SMG, but only a significant difference over time (Distress Thermometer :F=6.641 P=0.002, Impact Thermometer F=7.931 p=0.001).

Abbreviations: CIPN, Chemotherapy-induced Peripheral Neuropathy; CG, Control Group SMG, Self-Monitoring Group; T0, baseline; T1, Points 3 weeks after baseline; T2, Points 6 weeks after baseline

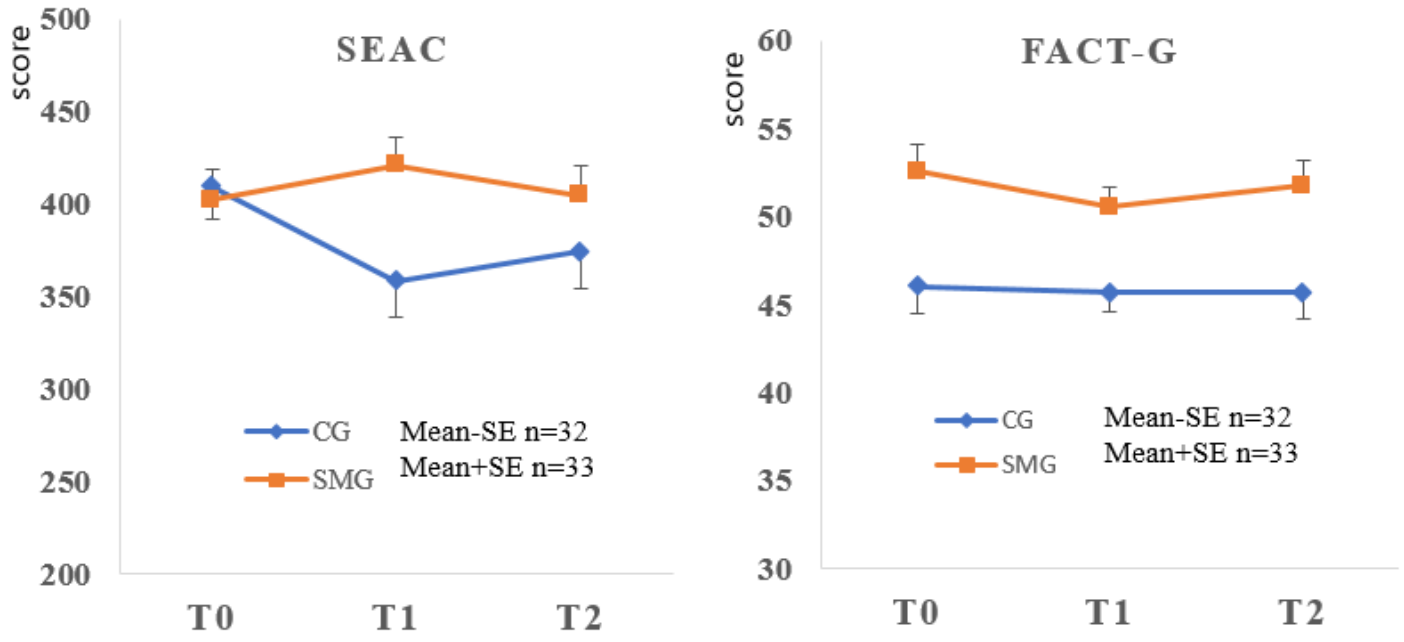

Figure 5

The SEAC and FACT-G scores for CIPN in cancer patients

Analysis was performed with the two-way-ANOVA of the values of the SEAC and FACT scores of the CG and SMG.

The SEAC score revealed the interaction between the CG and SMG (F = 5.689 p = 0.004), and the SMG value was significantly higher than the CG at T1（t = -3.372 p = 0.001）.

FACT-G score revealed a significant difference between the CG and SMG [F = 7.914, p = 0.007].

Abbreviations: CIPN, Chemotherapy-induced Peripheral Neuropathy; CG, Control Group; SMG, Self-Monitoring Group; T0, baseline; T1, Points 3 weeks after baseline; T2, Points 6 weeks after baseline; SEAC, Self-efficacy scale for advanced cancer; FACT-G, Functional Assessment of Cancer Therapy-General.

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- Table1.pdf
- Table2.pdf
- Table3.pdf