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Official Title: Effects of dance-based multimodal exercise programme for managing chemotherapy-induced peripheral neuropathy in patients with solid tumors: A pilot randomized controlled study

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Study Protocol

1. Name of study

1.1. Scientific Title: Effects of dance-based multimodal exercise programme for managing chemotherapy-induced peripheral neuropathy in patients with solid tumors: A pilot randomized controlled study

1.1.1. Short Title: Effect of dance-based multimodal exercise for managing CIPN in cancer patients

1.1.2. Keywords: Dance, Multimodal exercise, CIPN, chemotherapy-induced peripheral neuropathy, cancers, solid tumors

2. Study Site

2.1. Study region: Local

2.1.1. Sites: Community Cancer Centers, eg. Cancer Information Charity Foundation (CICF), Hong Kong Stoma Association, Global Chinese Breast Cancer Organization Alliance, Non-governmental organizations and private oncology clinics in Hong Kong

3. Brief Summary of Study

Background: Chemotherapy-induced peripheral neuropathy (CIPN) is a significant and distressing symptom experienced by cancer patients with different cancer types. Systematic reviews demonstrate that exercise is an effective nonpharmacological strategy for managing chemotherapy-induced peripheral neuropathy (CIPN) in cancer patients. Multimodal exercise was found to be superior to a single-modality exercise programme. However, the lack of using Information-Motivation-Behavioral Skill (IMB) model and addressing the social motivation component in current multimodal exercise programmes for cancer patients with solid tumors.

Objectives: This study aims to evaluate the effects of a 6-week dance-based multimodal exercise program on CIPN symptoms over a 3-month period, comparing outcomes with usual care in cancer patients with solid tumors.

Methods: An assessor-blinded pilot randomized controlled trial with process evaluation will be conducted at Community Cancer Centers/ Community Centers and Non-governmental organizations. A total of 76 participants will be recruited, with both intervention and control groups receiving educational booklets and logbooks. The intervention group will engage in a 6-week dance-based multimodal exercise program, supplemented by goal-setting evaluations and motivational messaging. The control group will receive weekly exercise videos and motivational messages. Outcomes, including CIPN severity, quality of life, pain, balance, exercise knowledge, motivation, self-efficacy, and adverse effects, will be measured using validated tools at baseline, immediately post-intervention, 4 weeks post-intervention, and 12 weeks post-intervention. Process evaluation

will explore perceived benefits, program awareness, and facilitators and barriers to adherence.

Conclusion: This study aims to provide an evidence-based approach for managing CIPN in cancer patients through a dance-based multimodal exercise program. It underscores the importance of incorporating the IMB model to enhance exercise adherence and support self-management of CIPN in cancer survivors.

4. Study Details

4.1. Aim of Study:

The study aims to examine the effects of a dance-based multimodal exercise programme when compared to usual care for the management of CIPN in cancer patients with solid tumors across the 3-month post-intervention period. The objectives include

- (1) To examine the effects of the programme on CIPN (primary outcome) at immediately, one-month and three-month post-intervention; and
- (2) To examine the effects of the programme on pain, balance, quality of life and anxiety (secondary outcomes) at immediately, one-month and threemonth post intervention; and
- (3) To examine the effects of the programme on knowledge, motivation and self-efficacy of exercise (process outcomes) at immediately, one-month and three-month post intervention; and
- (4) To assess any adverse effects of the programme; and
- (5) To explore the perceived benefits, barriers and areas for improvement after participating the programme.

4.2. Hypothesis:

Compared to usual care, a dance-based multimodal exercise programme leads to a greater improvement of chemotherapy-induced peripheral neuropathy symptoms in cancer patients with solid tumors.

4.3. Study design and methodology

4.3.1. Study design

An assessor-blinded pilot randomized controlled trial with a repeated-measures design and a process evaluation is proposed. The process evaluation evaluates the fidelity and quality of the intervention, understand the causal mechanisms and identify any contextual factors contributing to the outcomes (Moore et al., 2015; Oakley et al., 2006). The trial is proposed to be commenced from 1st April to 30th December 2026 in Community Cancer Centers, eg. Cancer Information Charity Foundation (CICF), Hong Kong Stoma Association, Global Chinese Breat Cancer

Organization Alliance and Non-governmental organizations

4.3.2. Sampling method and recruitment

Convenient sampling will be adopted in recruiting participants. Posters will be sent to and posted in the Community Cancer Centers, eg. Cancer Information Charity Foundation (CICF), Hong Kong Stoma Association, Global Chinese Breast Cancer Organization Alliance, Non-governmental organizations and private oncology clinics will be conducted to recruit cancer patients with solid tumors from 1st May 2026 to 30th September 2026.

4.3.3. Eligibility criteria

4.3.3.1. Inclusion criteria

In this pilot randomized controlled trial, the inclusion criteria of participants include cancer patients who (1) was diagnosed with malignant solid tumor (s) which is defined as abnormal, cancerous masses of tissue, for example, all carcinomas (such as breast cancer, stomach cancer, colorectal cancer and gynecological cancer, lung cancer and so on), sarcomas and lymphomas ; and (2) experience CIPN symptoms; and (3) are able to use smart phone and WhatsApp; and (4) are able to read or understand Chinese.

4.3.3.2. Exclusion criteria

Cancer patients will be excluded from this study when they (1) suffer from severe organ failure or diseases that limit their level of activity; or (2) are diagnosed with non-chemotherapy induced peripheral neuropathy, such as sciatica and diabetic neuropathy; or (3) receive treatments that affect the severity of neuropathy, such as steroid, anticonvulsants and antidepressants; or (4) age below 18 years old; or (5) have cognitive impairments.

4.3.4. Sample size calculations

In this study, the sample size of 60 participants (30 per arm) is justified based on methodological recommendations for pilot and feasibility trials. Browne (1995) and Whitehead et al. (2016) suggested pilot randomized controlled trials with around 30 participants per arm are sufficient to estimate parameters with adequate precision and to ensure enough statistical power (80%) to detect medium effect sizes in subsequent larger trials. To anticipate 20% attrition rate, a total of 76 samples should be recruited in this study. Therefore, this study will adopt a total sample size of 76 participants to balance the feasibility of intervention and the methodological rigor, ensuring that the trial can generate reliable preliminary evidence on the effectiveness of the exercise programme for cancer patients with chemotherapy-induced peripheral neuropathy (CIPN).

4.3.5. Randomization, allocation concealment and blinding

An independent assessor will be blinded for the allocation of the participants and intervention. Cancer patients who are fulfilling the eligibility criteria and willing

to participate in the programme will be randomized in 1:1 ratio after the baseline measurement. Block randomization of a block of 4 will be used in the randomization process. Allocation numbers are concealed in opaque sealed envelopes which only the principal investigator will open them and inform the participants about the program details.

4.3.6. Treatment allocation

Upon recruitment, participants in intervention and control groups will be provided with booklets about the information on management of CIPN and exercise recommendations and logbooks, which provide information for the participants in the exercise training and the symptom management.

4.3.6.1. Intervention group---Dance-based multimodal exercise programme.

This study adopts the components in Information-Motivation-Behavioral Skills (IMB) model in a dance-based multimodal exercise program, which integrates the dance-components in a multimodal exercise program. Zumba Gold dance which encompasses endurance, resistance, balance and flexibility training will be adopted in this study. Before the intervention, participants will be asked to set exercise goals. It is a six-weekly Zumba Gold dance carried out in the community cancer centers. Each dance group consists of five participants. In total, there are six face-to-face dance sessions. Each session lasts for 75 minutes. The 75-minute class will be structured as follows: approximately ten minutes dedicated to vital sign measurement and revision of previously learned skills, followed by a 50minute multimodal exercise session that includes warm-up, workout, and cooldown exercises based on the Zumba Gold manual (Zumba Fitness, 2011), and concluding with a 15-minute sharing session. A study by Zimmer et al. (2018) demonstrated that a similar 50-minute multimodal exercise program was welltolerated among patients with advanced cancer patients. After each session, videos of dance skills will be sent to participants for the revision via Whatsapp. Participants will be encouraged to do self-practice at home. Safety precautions about self-practice are included in the videos. Participants will learn all dance skills, including warm-up dance, Merengue, Salsa, Cumbia, Belly dance, Flamenco, Tango and cool-down dance in first four sessions, followed by two revision sessions of all dance skills in fifth and sixth sessions. Participants with balance problems (baseline Time up-to-go test > ten seconds) or physical limitations are advised to have chair dance, which upper limb movements are the same as the usual Zumba Gold dance. Motivational and support sessions in 10th week and 14th week will be provided through the evaluation of the goal and encouragement messages via WhatsApp. An oncology nurse, who has at least three-year clinical oncology experience and receive Zumba Gold training, will provide the tele-support to participants about the enquiry about the dance techniques and the symptom management related to the CIPN via Whatsapp to promote self-efficacy in managing CIPN by dance. Participants may send messages to the oncology nurse at anytime. The oncology nurse will check the

message at 6pm everyday and reply all the messages at 6-8pm everyday. Table 1 shows the details of the intervention in intervention group.

Sessions	Week	Content	
Upon recruitment		Educational booklets about the information on management of CIPN and exercise recommendations and logbooks will be provided to all participants.	
Weekly dance session 1-4	Week 1-4	<p>Weekly 75-minute dance session will be provided to participants in intervention group. The rundown of the dance session is as followed:</p> <ul style="list-style-type: none"> - First 10 minutes: basic physical assessment and revision of skills - 50 minutes: Dance skills learning and practice <ul style="list-style-type: none"> • Warm-up and cooldown: week 1 • Merengue and Salsa: Week 2 • Cumbia and Belly dance: Week 3 • Flamenco and Tango: Week 4 - Last 15 minutes: peer sharing <p>Videos of dancing skills will be sent to participants in intervention group via WhatsApp after each session for self-practice.</p>	Ongoing telesupport by an oncology nurse for the symptom management and enquiry about the dance skills

Weekly dance session 5-6	Week 5-6	Weekly 75-minute dance session will be provided to participants in intervention group. The rundown of the dance session is as followed: <ul style="list-style-type: none"> - First 10 minutes: basic physical assessment and revision of skills - 50 minutes: Dance practice with all learnt skills Last 15 minutes: peer sharing Videos of the whole Zumba Gold Dance will be sent to participants in intervention group via WhatsApp after each session for self-practice.	
4 weeks after the dance program	Week 10	Motivational and encouragement messages will be sent to participants in intervention group via WhatsApp.	
8 weeks after the dance program	Week 14	Motivational and encouragement messages will be sent to participants in intervention group via WhatsApp.	

Figure 1 illustrates different strategies to fulfill the core components of IMB model for this study. Information and videos on dance techniques and tele-support provide the “information” to the participants. Exercise goal setting and evaluation enhance participants’ “personal motivation”. Sharing sessions and interaction with interventionists provides the social support and “social motivation” to the participants. The dance program, dance videos and the tele-support facilitate participants to acquire the essential “behavioral skills” and enhance their self-efficacy in performing the skills.

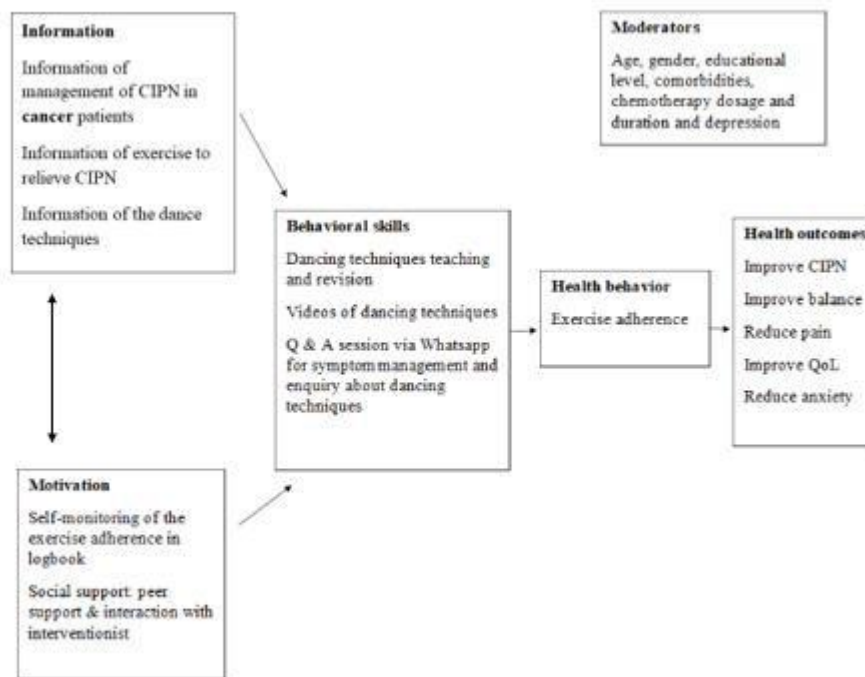


Figure 1. The conceptual framework of IMB model in a dance-based multimodal exercise program

4.3.6.1.1. Intervention fidelity. To ensure the intervention was delivered as conceived and planned, intervention fidelity will be measured in the aspects of intervention design, interventionists and participants (Robbins-Welty et al., 2018). Content of the educational materials and the dance videos will be validated by an external panel using the content validity form to ensure the intervention is developed by evidence and aligns with the IMB model, guidelines of American College of Sports Medicine and Zumba Gold Manual. To ensure consistent content delivery by interventionists, all interventionists are registered Zumba Gold instructors. They will receive training about the core components of the

IMB model and how it should be adopted in the dance programme (Neal et al., 2023). Video training will be provided to interventionists to ensure the consistency of the dance sessions (Neal et al., 2023). Classes will be randomly selected for video recording to review the instructions, feedback and observations by interventionists using a treatment implementation checklist (Brach et al., 2024; Neal et al., 2023). In addition, the video recording allows the principal investigator to review participants' proper movement and alignment during dance to ensure their understanding in dance sessions. Exercise adherence will be recorded as it will affect the efficacy of the exercise intervention (Brach et al., 2024; Neal et al., 2023).

4.3.6.2. Control group. After receiving the educational booklet and logbook, weekly

Whatsapp message with videos of exercises recommended for elderly by Department of Health, HKSAR (Elderly Health Service, 2025) will be provided for participants in control group in the first six weeks. Participants are encouraged to follow the NCCN and ACSM guidelines for cancer survivors to enhance their health and well-being through exercise. These recommendations include engaging in at least 150 minutes of moderate-intensity activity each week or alternatively, performing 75 minutes of vigorous-intensity exercise, or a combination of both. Each exercise session should begin with a light-intensity aerobic warm-up and stretching, with stretching exercises included on at least two non-resistance training days. Additionally, resistance training should be performed 2 to 3 times per week, consisting of 2 to 3 sets of 10 to 15 repetitions per exercise, with rest intervals of 2 to 3 minutes between sets. For survivors experiencing chemotherapy-induced peripheral neuropathy (CIPN), balance training is particularly important. Those with neuropathy and balance issues may benefit from alternative exercises, such as stationary cycling and water exercises, if walking is not feasible. Encouragement messages will be sent in 10th and 14th week.

4.3.7. Outcome measures

4.3.7.1. Primary outcome

4.3.7.1.1 Chemotherapy-induced peripheral neuropathy. In the main randomized control trial, the primary outcome is chemotherapy-induced peripheral neuropathy (CIPN). The Functional Assessment of Cancer Therapy/Gynecologic Oncology Group-Neurotoxicity subscale (FACT/GOG-Ntx) subscale contains 11 items measuring the CIPN symptoms on a 5-point Likert scale (from 0= not at all to 4= very much) (Huang et al., 2007). A higher score indicates the worse CIPN symptoms (Huang et al., 2007). Its Chinese version was demonstrated with good internal consistency (Cronbach's alpha= 0.82-0.89) over 12-month follow-up in Hong Kong cancer patients (Cheng et al., 2020).

4.3.7.2. Secondary Outcomes

4.3.7.2.1. Pain: Douleur Neuropathique en 4 Questions (DN-4) contains ten items in four questions with dichotomous answers (Yes=1; No= 0) assessing the symptoms, associated symptoms and the aggregating factors of neuropathic pain in cancer patients (Abolkhair et al., 2021; Pergolizzi et al., 2023). Its Chinese version is specific and sensitive in measuring neuropathic pain with cut-off score at 3 (Wang et al., 2019), demonstrating satisfactory internal consistency (Cronbach's alpha = 0.7) in Taiwan samples with neuropathic pain (Wang et al., 2019).

4.3.7.2.2. Quality of Life: Quality of life: European Organization for the Research and Treatment of Cancer Quality of Life Questionnaire (EORTC-QLQ C30) contains of 30 items assessing five functioning (physical, role, emotional, cognitive and social), nine symptom burdens (fatigue, nausea and vomiting, pain, dyspnea, insomnia, appetite loss, constipation, diarrhea and financial difficulties) and one global health status using 4-likert scale (from 1= not at all to 4= very

much), except two items in global health status using the 7-point scale (from 1= very poor to 7= excellent) (Bjordal et al., 2000; Cocks et al., 2023; Müller et al., 2017). Higher scores in functioning subscales indicate better functioning; while higher scores in symptom subscales indicate higher level of impairment (Müller et al., 2017). Its Chinese version was demonstrated with good internal consistency (Cronbach's alpha 0.72-0.87) in seven items, while two subscales did not meet the standard (physical function: $\alpha = 0.67$ and cognitive functioning: $\alpha = 0.45$) in cancer patients in Beijing. The overall mean Cronbach's alpha was 0.76, indicating satisfactory internal consistency (Zhao & Kanda, 2000). The correlation coefficient of multiple items in EORTC-QLQ C30 was 0.4-0.7, indicating satisfactory convergent validity (Zhao & Kanda, 2000).

4.3.7.2.3. Anxiety: Hospital Anxiety and Depression Scale (HADS) is a self-reported measure consisting of 14 items, in which seven of them assess the anxiety level. Higher scores in anxiety subscale indicate the higher level of anxiety. Individuals have borderline anxiety when the overall anxiety subscale is 8-10. It would be considered as anxiety if overall anxiety subscale above 11. It was tested to be valid and reliable in assessing anxiety and depression in cancer patients (Singer et al., 2009; Wondie et al., 2020). Its Chinese version demonstrated good internal consistency (Cronbach's $\alpha \geq 0.84$ in all subscales) (Li et al., 2016) in Chinese cancer patients and family carers (Li et al., 2016). Additionally, Li et al. (2016) suggested the moderate correlation between HADS-anxiety, HADS-depression, HADS-total and SF-12 ($r = 0.41-0.55$) in assessing the concurrent validity in Chinese cancer patients. A significant correlation between subscales in HADS was demonstrated in two-factor ($r = 0.83$) and modified two-factor ($r = 0.82$) models, indicating the strong construct validity (Li et al., 2016).

4.3.7.2.4. Balance: Time up-to-go is used to assess cancer patients' gait and balance when changing positions from sitting to standing, turning, walking and from standing to sitting. The time taken that participants start from sitting on the chair, then standing and walking for 3m, followed by turning around and walking back, lastly sitting on the chair is recorded. Participants are asked to perform two trials. The quicker measurement is counted (Blackwood et al., 2021; Hendriks et al., 2022). It was proven with satisfactory test-retest reliability was greater than 0.85, interrater reliability was greater than 0.96 and intra-rater reliability was greater than 0.85 (Christopher et al., 2021) in patients with neurological diseases.

4.3.7.2.5. Knowledge of exercise, exercise motivation and exercise self-efficacy: Perceived Physical Literacy Instrument (PPLI) contains nine items measuring knowledge and understanding, self-expression and communication with others, and sense of self and self-confidence (Sum et al., 2018). Participants rate each item using 5-point Likert scale (from 1= strongly disagree to 5=strongly agree). Higher scores indicate better knowledge, motivation and self-efficacy in exercise skills (Sum et al., 2018). The Chinese version was demonstrated with strong internal consistency (Composite reliability > 0.6) across the three factors model

and acceptable convergent validity (Average variance extracted= 0.430.54) in Hong Kong samples (Sum et al., 2018). Additionally, confirmatory factor analysis demonstrated the acceptable to good fits of proposed three-factor model (knowledge and understanding, self-expression and communication with others and sense of self and self-confidence) for the observed data comparing with the one-factor model (Comparative Fit Index=0.95; Root Mean Square Error of Approximation= 0.08) (Sum et al., 2018).

4.3.7.2.6. Adverse effects: Participants are encouraged to report any adverse events such as unusual fatigue and pain, and fall. The nature and the number of adverse events will be documented and evaluated to determine the safety of the intervention.

4.3.8. Process evaluation

All participants in the intervention group will be invited to join the focus-group interview (6-8 participants) (Busetto et al., 2020) to explore participants' perceived benefits from the programme, the awareness of the programme and factors facilitating and hindering their adherence to the programme. An independent assessor will conduct the focus-group using the semi-structured interview. The focus-group interview enables us to obtain qualitative data towards a specific topic through facilitated discussion (Gill et al., 2008; Leung & Savithiri, 2009). Audio-recording of the interview is required for data analysis.

An independent assessor is responsible for the focus-group interview to ensure the consistency of the data collection. The credibility of data is verified by asking different questions on the same topic to ensure the information is equivalent to different questions (Ahmed, 2024; Morse, 1991). Transcripts will be sent to participants to confirm the confirmability of the information and findings (Ahmed, 2024).

4.3.9. Data analysis

4.3.9.1. Quantitative data

The data collected will be analyzed using IBM SPSS version 29 (IBM Corp., Armonk, NY, USA). Appropriate descriptive statistics, such as mean (standard deviation), median (inter-quartile range) and frequency (percentage), will be used to summarize the participants' baseline characteristics and their outcome data across study time points. The normality of continuous data will be assessed based on their skewness and kurtosis statistics. Skewness and kurtosis values within -2 to 2 and -7 to 7 respectively indicate the underlying variable is not deviated from normal distribution (Curran et al, 1996). The homogeneity of baseline characteristics between the intervention and control groups will be evaluated by using independent t, Mann-Whitney, chi-squared and Fisher's exact tests, as appropriate. Generalized estimating equations (GEE) models will be used to compare all the repeated measures outcomes between groups over the study time points. The missing data, if any, will be accounted for by using quasi-likelihood

method in the GEE analyses. All the statistical tests involved will be 2-sided with level of significance set at 0.05.

4.3.9.2. Qualitative data

Thematic narrative analysis will be adopted in data analysis of the process evaluation. Verbatim transcription will be performed by the principal investigator and the research assistant. Inductive coding will be used to identify codes by reading the transcription line by line. A codebook will be developed and applied to all transcripts. Themes will be developed by identifying the patterns of the codes and collapsing codes (Bingham, 2023). Themes will be validated through collaborative discussion within the research team to identify the recurrent patterns. In case of disagreement, research team members will refer to the audio recordings to check the transcripts and engage in repeated discussion to ensure consistency and consensus in interpretation.

5. Ethical considerations

5.1. Voluntary participation

All participants will be provided with a verbal explanation of the study and a written information sheet, which provides the outline of the study, objectives and content of the study. All participants will be assured that there will be no consequences if they choose to withdraw their participation at any point during the study. After the explanation, participants will be provided with written consent. Participants would participate in the study only if they signed the informed consent. Their participation is voluntary.

5.2. Handling and Storage of Personal Data and Study Data

Personal information, such as name and phone number, will be collected and saved in a separate encrypted file. Data other than name and phone number will be stored in an encrypted file with the use of study code for identification. All data will be stored in the encrypted USB which will be locked in a cabinet.

Coordinating investigator, coordinating investigator's delegate and site PI will have the access to and safekeeping of the personal and study data during and after the study. All data will be destroyed securely five years after the completion of study according to the guidelines of Research Data Management in CUHK. The study will comply to the guidelines of Declaration of Helsinki and ICH-GCP.

5.3. Measures to reduce potential risks

To ensure safety during the exercise program, physical fitness will be monitored before and during the dance class. Before the dance class, basic vital signs including blood pressure, pulse, respiratory rate and saturation will be measured. For participants with abnormal vital signs, instructor will ask them not to attend the class on that day and reschedule class to another day with physical fitness. During the class, participants are advised to report any discomfort and discontinue

the exercise at any time. Instructor may advise participants to seek medical help if needed. Participants's balance will be assessed by Time-Up-to-Go test and the walking gait the instructor with nurse background before the commencement of the programme. Participants who score more than 10 seconds in Time-Up-To-Go test or with unsteady gait are advised and required to perform the chair dance. Additionally, the environment of activity rooms in the community cancer centers are assessed before the commencement of the programme to ensure the environment is safe for the dance class. The activity rooms in the community cancer centers have been used for group exercise before and no adverse effects due to the environmental issues were reported. All instructors are qualified instructors with first-aid certificates or registered nurse licenses. Each class has maximum 5 participants and the instructor to participant ratio is 1:5. Previous study examining the adapted Tango on breast cancer patients with CIPN suggested 5 cancer survivors in each class (Lantis et al., 2023). Additionally, a feasibility study about the effect of the dance-based multimodal exercise on CRC patients with CIPN was conducted from October 2025 to March 2026 (CRE Ref. No.: CRE-2025.393) and the class size was 5 participants per class with the instructor to participants ratio 1:5. Total 9 participants were recruited in two dance groups and three participants were of the potential balance problems and assigned to chair dance. No adverse effects, particularly fall, were reported. Tele-support is provided for participants for their symptom management. Participants are advised to seek medical help for emergency situations. Clinical trial insurance will be provided for each participants to cover the physical injury directly caused by this study.

5.4 Potential benefits

Participants in the intervention group will receive the education booklet, a 6week dance-based multimodal exercise, tele-support for symptom management and dance videos for self-practice. It may facilitate them in improving the exercise adherence and the long-term management of CIPN. Participants in control group also receive education booklet and videos about the flexibility training, resistance training and balance training from Department of Health, HKSAR. The recommended exercise may facilitate participants to effectively manage the CIPN.

5.5 Incentives

“Participants will receive a \$50 supermarket coupon after completing all assessments (qualitative and quantitative) as appreciation for their participation.

6.0 Source of Funding: NO.

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Participant Information Sheet

Effects of dance-based multimodal exercise programme for managing chemotherapy-induced peripheral neuropathy in patients with solid tumors: A pilot randomized controlled study

Principal Investigator: Ms. LAU Ka Yan, Doctor of Nursing Student, The Nethersole School of Nursing, Faculty of Medicine, The Chinese University of Hong Kong

Co-Investigator and Supervisor: Prof. CHONG Yuen Yu, Associate Professor, The Nethersole School of Nursing, Faculty of Medicine, The Chinese University of Hong Kong

Invitation

We cordially invite you to participate in this research study. Before you decide whether to participate, it is crucial for you to understand the reasons for conducting this research and what the study entails. Please take the time to read the following information carefully and decide whether you wish to participate. If anything remains unclear, or if you would like to obtain more information, please do not hesitate to ask the research personnel.

Introduction to the Study

Chemotherapy-induced peripheral neuropathy (CIPN) is a common symptom among cancer patients who have undergone chemotherapy. During treatment, over 60% of cancer patients are affected, and more than 40% may experience this chronic symptom for months or even years after their chemotherapy has concluded. This neuropathy negatively impacts a patient's pain perception, balance, and overall quality of life.

Research indicates that multimodal exercise—which includes endurance training, balance training, resistance training, and flexibility training—has a potential effect on helping cancer patients manage CIPN. This study utilizes a multimodal exercise program with dance-based components to promote your physical activity levels while effectively managing CIPN. Since you are a cancer patient who is receiving or has received chemotherapy, we sincerely invite you to participate in this study.

Study Objective

The objective of this study is to evaluate the effectiveness of a dance-based multimodal exercise program in helping cancer patients improve chemotherapy-induced neuropathy, as well as its impact on pain, balance, anxiety, and quality of life.

Study Procedures

- **Eligibility:** Participants must be cancer patients who have previously received chemotherapy, are aged 18 or above, and can be contacted via WhatsApp on a smartphone.
- **Recruitment & Screening:** Researchers will recruit eligible cancer patients from cancer-related community centers, non-governmental organizations (NGOs), and

private oncology clinics. After obtaining consent to join the program, a simple screening will be conducted. If you are screened as an eligible participant and are interested in joining, you must sign an Informed Consent Form before the program begins.

- **Randomization:** Participants will be randomly assigned to one of two different research groups (the Experimental Group or the Control Group) in a 1:1 ratio, in cohorts of 4 people. You will receive an envelope containing a number randomly generated by a computer program, representing your assigned group. Participants will only discover their group allocation upon opening the envelope, and no requests to switch groups will be permitted.
- **Experimental Group:** This group will receive an educational booklet and attend a 6-week dance course, meeting once a week for approximately 1 hour and 15 minutes per session. Each session includes a basic physical assessment, dancing, and a post-class discussion. Participants will receive dance videos after each class for home practice. It is recommended to practice at home at least twice a week (50 minutes per session).
- **Control Group:** This group will receive a relevant educational booklet and weekly exercise information videos over a 6-week period. Participants in the control group are recommended to follow the guidelines of the National Comprehensive Cancer Network (NCCN) and the American College of Sports Medicine (ACSM) for cancer patients. This involves performing at least 150 minutes of moderate-intensity activity per week, 75 minutes of vigorous-intensity exercise, or a combination of both. Each exercise session should begin with a light aerobic warmup and stretching, with stretching also performed on at least two non-resistance training days. Additionally, resistance training should be performed 2 to 3 times per week, consisting of 2 to 3 sets of 10 to 15 repetitions, with 2 to 3 minutes of rest between sets. The educational booklet and exercise videos provide relevant details.

To assess the effectiveness of the program, you will be asked to complete a questionnaire at baseline (before the program), upon completion of the program, and at 1 month and 3 months post-completion. The questionnaire primarily focuses on your chemotherapy-induced neuropathy symptoms, pain, balance, anxiety, quality of life, and any adverse events related to the program. The entire assessment takes approximately 45 minutes.

Participants in the Experimental Group will also be invited to take part in a focus group interview to help researchers understand the program's effectiveness and areas for improvement. The focus group interviews will be audio-recorded for data analysis. The recordings will be stored anonymously on a confidential USB flash drive, which will be kept in a locked storage cabinet.

During the program, some exercise groups will be randomly selected for video recording to evaluate implementation quality and improve the study. By participating, you will have the opportunity to benefit from the educational information provided in either the Control Group (booklet and exercise videos) or the Experimental Group (booklet, live dance classes, and dance videos) to help manage your neuropathy. Concurrently, your participation will provide data that will support future research development.

Expected Duration of the Study

Your participation in this study will last for approximately 18 weeks.

Alternative Procedures/Treatments

Whether you choose to participate or not, your standard medical care, routine treatment, and received services will not be affected in any way.

Expected Benefits

Past literature indicates that multimodal exercise allows cancer patients and survivors to effectively manage chemotherapy-induced neuropathy. You will have the opportunity to benefit from the health education materials provided in either group to help manage your CIPN symptoms.

Potential Risks / Discomforts / Side Effects

This is an evidence-based intervention program. Existing literature shows that colorectal cancer patients suffering from chemotherapy-induced neuropathy during or after treatment can engage in multimodal exercise to effectively manage neuropathy issues. Past literature has not reported any patient side effects due to exercise, and participants with balance issues can participate in seated chair dancing.

Clinically, patients with chemotherapy-induced neuropathy are more prone to balance issues and fatigue. At the beginning of learning dance, balance-focused movements may be challenging to master or may increase the risk of falls. Therefore, to ensure safety during the exercise program, participants' physical conditions will be monitored before and during each dance class. Vital signs—including blood pressure, pulse, respiratory rate, and oxygen saturation—will be measured before class. If any abnormal vital signs occur, the instructor will advise the participant not to attend that day and will reschedule the class when the participant is physically fit. During class, participants are advised to report any discomfort immediately to the instructor and may stop exercising at any time; if necessary, the instructor may also advise the participant to seek medical assistance.

Before the program starts, an instructor with a nursing background will assess participants' balance and gait using the "Timed Up and Go (TUG) Test". Participants who score over 10 seconds, or exhibit gait instability or balance issues, will be advised and required to participate in seated chair dancing. Furthermore, the environment of the activity rooms within the community cancer centers will be evaluated before the program begins to ensure safety. These rooms have previously been used for group exercise activities, and no adverse events caused by environmental factors have ever been

reported. All instructors are fully qualified, holding valid first-aid certificates or registered nurse licenses. Each class will have a maximum of 5 participants, maintaining an instructor-to-participant ratio of 1:5.

Additionally, before participants fully master the dance steps, instructors will advise them to perform simpler movements and use sturdy household furniture for support during home practice. The contents of the educational booklet and dance videos have been reviewed by experienced clinical oncologists, registered nurses, and physical therapists to ensure that the educational material and exercise modes align with NCCN and ACSM safety recommendations. After the course concludes, a telephone consultation service provided by a registered nurse will be available to assist with symptom management and exercise program queries. In case of an emergency, participants will be advised to seek immediate medical advice.

Clinical Trial Insurance Coverage

To ensure participant safety, comprehensive clinical trial insurance is provided for every participant in this study. Because this study involves dance exercise and home-based fitness activities, there is a potential risk of injury. The insurance coverage is designed to protect participants against any adverse effects that may arise directly from the research process. This measure underscores our commitment to participant safety and highlights the importance of conducting trials in a secure environment.

Voluntary Participation / Withdrawal

Your participation in this study is entirely voluntary. You have the right to refuse to participate or withdraw from the study at any time without giving any reason. This will not affect your current or future routine medical care and services. Any data collected about you prior to your withdrawal will continue to be used unless a specific request is made to destroy it. You will be given sufficient time to consider whether to participate. After signing the consent form, you will receive a copy of this Participant Information Sheet and the signed, dated Consent Form for your records.

Cost of Participation

This research program is completely free of charge. You do not need to pay any fees to participate.

Incentives

To encourage participation, each participant who completes all study assessments will receive a \$50 supermarket cash voucher.

Termination of the Study

The researchers reserve the right to terminate the study at any time if any unforeseen circumstances arise or if the researchers determine that stopping the study is in your best interest.

Confidentiality and Privacy

To safeguard your privacy, all information collected in this study will remain strictly confidential. All identifiable data collected during this study will be handled confidentially in accordance with legal requirements and will not be disclosed publicly. Video recordings will absolutely not be made public, and you have the right to review and delete your recordings. All original video files will be encrypted, stored securely, and will only be accessible by the research team. To ensure high confidentiality, your name will be replaced by a unique ID code during data analysis and on questionnaires; this code can only be decoded by the research team.

The consent form you sign will be kept separate from your interview summaries and personal data, and will only be accessible to the researchers of this study. All audio recordings, interview contents, and personal data will be stored on a computer accessible only to the research team. Data can be extracted and destroyed upon your request, and all data will be destroyed five years after the completion of the study.

According to Hong Kong laws (specifically the Personal Data (Privacy) Ordinance, Chapter 486), you have or may have the right to ensure the confidentiality of your personal data, such as rights regarding its collection, monitoring, retention, management, control, use (including analysis or comparison), transfer into or out of Hong Kong, non-disclosure, erasure, and/or handling or disposal in any manner. If you have any questions, you may consult the Privacy Commissioner for Personal Data or their staff (Tel: 2827 2827) regarding the proper monitoring or regulation of your personal data protection, ensuring you fully understand and recognize the importance of complying with laws regulating personal data privacy.

By consenting to participate in this study, you explicitly provide the following authorization:

- The principal investigator, their research team, and the Joint Chinese University of Hong Kong – New Territories East Cluster Clinical Research Ethics Committee will oversee the access, use, and retention of your personal data in accordance with the provisions of this study and this consent form.

New Information

- If any new information becomes available regarding this study that might affect your willingness to continue participating, you will be informed in a timely manner. You may be asked to sign a revised Informed Consent Form to indicate that you have been notified of the new information.

Contact Information

- If you have any questions about this study in the future, please contact the Principal Investigator, Ms. LAU Ka Yan (Email: 1007615222@link.cuhk.edu.hk; Tel: 3702 4260). If you wish to know more about the rights of research participants, please contact the Joint Chinese University of Hong Kong – New Territories East Cluster Clinical Research Ethics Committee at 3505 3935.

- Thank you very much for considering participation in this study!

Informed Consent Form

Project Title: Effects of dance-based multimodal exercise programme for managing chemotherapy-induced peripheral neuropathy in patients with solid tumors: A pilot randomized controlled study

I, _____ (Name), agree to participate in the above-mentioned research project supervised and conducted by Ms. LAU Ka Yan, a PhD Student at The Nethersole School of Nursing, Faculty of Medicine, The Chinese University of Hong Kong.

I clearly understand that the data obtained from this program may be used for future academic research and publications; however, my personal data will remain strictly confidential, and my right to privacy is fully preserved.

- For the purpose of monitoring this study, I authorize the principal investigator, their research team, and the Joint Chinese University of Hong Kong – New Territories East Cluster Clinical Research Ethics Committee to access, use, and retain my personal data in the manner prescribed by this study and this Informed Consent Form.

I understand that I have the right to raise questions about any part of this program and have the right to terminate my participation at any time without affecting my current or future welfare, benefits, and medical treatments. The researchers have clearly explained the attached details of the program to me, and I understand all the benefits and risks involved.

I am participating in this study entirely on a voluntary basis.

Participant Name:	Signature:	Date:
_____	_____	_____

Researcher Name:	Signature:	Date:
_____	_____	_____