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Handicraft classes for colorectal cancer patients with chemotherapy-induced neuropathy: improving neuropathic symptoms in hands through exercising the hand muscles

Submission date	Recruitment status	[_] Prospectively registered
21/07/2018	No longer recruiting	[_] Protocol
Registration date	Overall study status	[_] Statistical analysis plan
31/07/2018	Completed	[_] Results
Last Edited	Condition category	[_] Individual participant data
30/07/2018	Cancer	[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Chemotherapy-induced peripheral neuropathy (CIPN) is one of the common reasons that colorectal cancer patients cannot maintain their routine chemotherapy schedules. CIPN involves pain, numbness, tingling and sensitivity to cold in the hands and feet and is often very painful and stressful. Some medications are used for pain relief, but they are often not effective. As a result, there has been renewed interest in alternative therapies that stimulate the hand muscles, such as exercise or massage to relieve the neuropathic symptoms.
This study aims to look at the effectiveness of a handicraft program as rehabilitation for colorectal cancer patients with CIPN, which involves basic craftwork to encourage the use of the minor muscles of the hands to make and decorate handicrafts.

Who can participate?
Adults with colorectal cancer who received chemotherapy

What does the study involve?
This rehabilitation program comes in the form of the handicraft class, which involves decorating crafts such as a hand mirror, a business card holder, a table clock, and a picture frame with lacquerware, using Korean traditional lacquerworks. This is performed once a week, for 2 hours per each session, for a total of 4 weeks. All volunteers will participate in same program. The effectiveness of this program will be evaluated by using a questionnaire.

What are the possible benefits and risks of participating?
The possible benefit of participating is that it may improve neuropathic symptoms in participants, along with being able to keep the handicrafts made during the program. The only possible risk of participation is physical injury from craft tools such as knives; however, this is unlikely as the program is supervised by professional instructors, specialized nurses and a surgeon.

Where is the study run from?
Ewha Womans University College of Medicine Mokdong Hospital (South Korea)

When is the study starting and how long is it expected to run for?
February 2012 to August 2018

Who is funding the study?
Ewha Womans University College of Medicine Mokdong Hospital (South Korea)

Who is the main contact?
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
1.0

Study information

Scientific Title
Efficacy of a REhabilitation PROgram using minor muscles in colorectal cancer patients with chemotherapy-induced Neuropathy: preliminary study

Acronym
REPRON

Study objectives
The rehabilitation program using minor muscles of hands can improve the symptoms of the chemotherapy-induced peripheral neuropathy.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Ewha Womans University Mokdong Hospital, 29/03/2018, EUMC 2018-03-029-002

Primary study design
Observational

Study design
Observational longitudinal study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Colorectal cancer treated with chemotherapy

Interventions
The aim of this program is to promote the use of the minor muscles of the hands by decorating handicrafts such as a hand mirror, a business card holder, a table clock, and a picture frame with lacquerware, using the Korean traditional lacquerworks. Lacquerworks were made as follows: First, participants designed his/her craft, then cut the lacquerware into various sizes and shapes according to the design. The more complicated the sizes or shapes of design was, more scrupulous and careful attention was required to handle the lacquerware. Prepared lacquerware was attached on the appropriate locations of hand mirror, a business card holder, a table clock, and a picture frame using glue. This process exercised the minor muscles of the hands and induced the effects of thermal therapy.
This was performed once a week, for 2 hours per each session, for a total of 4 weeks through outpatient clinics. The program was conducted under the supervision of a professional instructor, specialized nurses and a surgeon.

Intervention Type
Other

Primary outcome(s)
Improvement of neuropathic symptoms, assessed using the Korean version of the Short-form McGill Pain Questionnaire (SF-MPQ-2) at the baseline and after completion of the fourth handicraft class.

Key secondary outcome(s)
N/A

Completion date
31/08/2018

Eligibility

Key inclusion criteria
1. Diagnosed with colorectal cancer
2. Followed up with chemotherapy after surgical treatment

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Diabetes mellitus
2. Neurological diseases that could affect neuropathic symptoms

Date of first enrolment
01/03/2012

Date of final enrolment
30/04/2012

Locations

Countries of recruitment
Korea, South

Study participating centre
Ewha Womans University College of Medicine
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Sponsor information

Organisation
Ewha Womans University College of Medicine

ROR
https://ror.org/053fp5c05

Funder(s)

Funder type
Not defined

Funder Name
Investigator initated and funded

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated/analysed in this study are not expected to be made available as the datasets will be discarded according to the decision of the institutional review board.

IPD sharing plan summary
Not expected to be made available