

Complementary care at the oncological-surgical department Oost 53

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Achieving an improvement on quality of life and a positive effect on pain, nausea, fatigue, sleeping disorders, mood and experience of stress by offering complementary care.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Miscellaneous and site unspecified neoplasms malignant and unspecified
Study type	Interventional

Summary

ID

NL-OMON42701

Source

ToetsingOnline

Brief title

Complementary care at the oncological-surgical department

Condition

- Miscellaneous and site unspecified neoplasms malignant and unspecified
- Gastrointestinal therapeutic procedures

Synonym

Gastrointestinal malignancy; gastrointestinal cancer

Research involving

Human

Sponsors and support

Primary sponsor: Zuyderland Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Complementary therapy, Hand and foot massage, Music therapy

Outcome measures

Primary outcome

Primary endpoints are quality of life: psychological condition, functioning in daily life, and pain.

Secondary outcome

Secondary endpoints are patient satisfaction about the received care and their need of complementary care.

Study description

Background summary

Complementary care is additional care, given in addition to regular care. Complementary care is based on a holistic approach whereby the care includes physical, emotional, mental, spiritual and social needs. With this kind of care stimulating different senses (smell, hear, see and feel) is central. The main goal is relaxation and a positive influence on the experience of illness. Complementary care may reduce symptoms as pain, anxiety, depressive mood and a possible positive effect on quality of life. Additionally, complementary care focusses on promoting relaxation and comfort.

The effect of massage are: stimulating blood circulation, providing mental relaxation and muscle relaxation, reducing stress and providing more energy. In music therapy classic music of the composer Mozart, will be heard as evidenced proved relaxation. It also gives a reduction in anxiety and improves well-being.

East 53 in the Zuyderland Medical Centre in Sittard is an oncological-surgical ward where we think patients need complementary care. In this study we want to offer patients at this ward this complementary care. The therapy's we want to provide are hand/foot massage and music therapy.

Study objective

Achieving an improvement on quality of life and a positive effect on pain, nausea, fatigue, sleeping disorders, mood and experience of stress by offering complementary care.

Study design

This study is a randomized trial with an intervention group and a control group. Patients in the intervention group will be given complementary care. Within the intervention group hand/foot massage will be given as complementary care. After 102 participants (intervention n=51 control n=51) the complementary care "music therapy" will be given. Patients in the control group will not receive complementary care.

Intervention

In the first phase of the study, patients in the intervention group will receive a relaxing hand/foot massage of 30 minutes on the ward. The massage will be performed by a trained Zuyderland volunteer.

In the second phase of the study (after intervention n=51 and control n=51) patients in the intervention group will receive music therapy of 30 minutes with music of the composer Mozart.

Patients in the control group will not receive complementary care.

Study burden and risks

On admission, the patients will be asked to fill in the EQ-5D-3L and HADS questionnaire. During the admission patient will be asked to fill in the questionnaires at day 1, 3 and 5 after surgery.

At discharge patients will be asked to fill in a short questionnaire about their satisfaction about the received care. They also will receive the EQ-5D-3L and HADS and asked to complete them and bring them to their next outpatient appointment (approximately 14 days after surgery).

In total there will be five measurement moments on which patients will fill in the questionnaires.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

All patients over 18 years who will have surgery of the gastro-intestinal tract because of cancer.

Exclusion criteria

Patients whom are not able to sign an informed consent or deaf patients.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL
Recruitment status: Recruitment stopped
Start date (anticipated): 25-04-2016
Enrollment: 204
Type: Actual

Ethics review

Approved WMO
Date: 21-01-2016
Application type: First submission
Review commission: METC Z: Zuyderland-Zuyd (Heerlen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL55936.096.15