Effectiveness of myofascial techniques for the prevention and treatment of breast cancer-related dysfunctions of the upper limb.

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The combination of breast surgery, radiotherapy and chemotherapy have a profound effect on the deep myofascial level and in turn, they create a vicious circle of adhesions and lack of mobility and pain in muscles, fasciae and joints around the...

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON20742

Bron
Nationaal Trial Register

Aandoening

breast cancer, unilateral lymph node dissection, upper limb dysfunctions, physiotherapy, myofascial therapy

Ondersteuning

Primaire sponsor: Kath. Universiteit Leuven,
Faculteit Bewegings- en Revalidatiewetenschappen
Tervuursevest 101
3001 Leuven-Heverlee
Belgium
Overige ondersteuning: Institute for the Promotion of Innovation by Science and Technology in Flanders (IWT), Toegepast Biomedisch onderzoek met een primaire Maatschappelijke finaliteit (TBM)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

PREVENTIVE STUDY:
Do breast cancer patients with a unilateral axillary lymph node dissection and receiving postoperatively standard physiotherapy and myofascial techniques during 4 months have a significantly lower prevalence of pain than patients only receiving standard physiotherapy and placebo?
ll patients from the control group and from the experimental group are measured first preoperatively and then postoperatively, 2 months, 4 months, 9 months and 1 year after the breast surgery.

TREATMENT STUDY:
Do breast cancer patients with chronic pain of the upper limb and with a unilateral axillary lymph node dissection, receiving standard physical therapy and myofascial techniques during 4 months have more decrease of pain of the upper limb than patients only receiving standard physical therapy and placebo?
All patients are measured before the start of the treatment programme and after 1, 3, 6 en 12 months.

Toelichting onderzoek

Achtergrond van het onderzoek

PREVENTIVE STUDY:

All patients planned for an axillary lymph node dissection at the University Hospital Leuven (UZ Leuven) will be measured preoperatively. According to the power at least 200 patients have to participate postoperatively. They will start immediatly after surgery with a standerd physical therapy programma during 4 months. Patients are randomly allocated to the intervention group, receving myofascial therapy two months after surgery, or the control group, receiving placebo therapy also two months after surgery.
Shoulder pain, shoulder mobility, shoulder function, arm volume, shoulder alignment and quality of life are measured postoperatively, 2, 4, 9 and 12 months after surgery.

TREATMENT STUDY:

According to the power analysis, fifty patients with an axillary lymph node dissection, at least

one year ago and chronic shoulder pain have to be included in the treatment study. They all receive the standard physical therapy programme during 3 months. The intervention group receives additionally myofascial therapy, also during 3 months. The control group receives additionally a placebo therapy, also during 3 months.
Shoulder pain, shoulder mobility, shoulder function, arm volume, shoulder alignment, recruitment of muscles of the shoulder girdle and quality of life are measured before the start of the treatment program and after 1, 3, 6 and 12 months.

Doel van het onderzoek

The combination of breast surgery, radiotherapy and chemotherapy have a profound effect on the deep myofascial level and in turn, they create a vicious circle of adhesions and lack of mobility and pain in muscles, fasciae and joints around the shoulder. The effectiveness of myofascial techniques on the prevention and treatment of dysfunctions of the upper limb related to the treatment of breast cancer have never been investigated. Therefore, we want to investigate whether myofascial techniques may have a preventive effect on dysfunctions of the upper limb (applied on breast cancer patients immediately after the axillary lymph node dissection) and whether they are effective to decrease existing dysfunctions of the upper limb (applied on breast cancer patients at least one-year post-surgery with dysfunctions of the upper limb).

Onderzoeksopzet

Month 1-23: Inclusion of 250 patients;

Month 1-27: Treatments (standard physical therapy from Month 1-27, myofascial techniques from Month 3-27);

Month 1-35: Measurements;

Month 36-37: Statistical analyses and interpretation;

Month 38-42: Utilisation period: writing of papers, organisation of the seminars, presentation of our results on national and international congresses, development of a brochure and website.

Onderzoeksproduct en/of interventie

PREVENTIVE STUDY:

1. Patients of the intervention group receive a standard physical therapy programme and myofascial techniques;

2. Patients of the control group receive a standard physical therapy programme and a placebo treatment.

The standard physical therapy programme (intervention and control group) is started immediately after the axillary lymph node dissection for breast cancer with a frequency of 2x/week, during 3 months and once a week during 1 month (=30 sessions). Within this programme, patients receive guidelines about the prevention of lymphoedema and exercise therapy.

Application of myofascial techniques or placebo techniques is started 2 months after the axillary lymph node dissection, with a frequency of once a week, during 2 months (=8 sessions). One session takes 30 minutes and consists of myofascial techniques applied on the diaphragm, the scar tissue at the breast, the cervical fascia, the axilla and the pectoral fasciae.

TREATMENT STUDY:

Similar to the ‘preventive group’, in the ‘treatment group’, patients of the intervention group receive a standard physical therapy programme and myofascial techniques. Patients of the control group receive a standard physical therapy programme and a placebo treatment.

The myofascial techniques and placebo treatment will be similar as applied in the ‘preventive group’, so also once a week, but during 3 months (=12 sessions). The standard physical therapy programme will differ. On the one hand, the content of the programme will be adapted for patients with dysfunctions of the upper limb, on the other hand patients receive the first 2 months 2 session per week and the next months 1 session per week (=20 sessions in total).

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

PREVENTIVE STUDY:

1. Primary breast surgery with axillary dissection in the University Hospital Leuven (UZ Leuven);

2. Patient is measured before surgery.

TREATMENT STUDY:

1. Unilateral axillary lymph node dissection at least 1 year ago;

2. Patient has pain of the upper limb.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

PREVENTIVE STUDY:

1. Metastasis of breast cancer;

2. Patients who cannot participate during the entire study period;

3. Patients who are mentally or physically not able to participate in the study.

TREATMENT STUDY:

1. Metastasis;

2. Patients who cannot participate during the entire study period;

3. Patients who are mentally or physically not able to participate in the study.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-10-2012
Aantal proefpersonen:	150
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	11-09-2012
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL3458
NTR-old	NTR3610
Ander register	METC UZ Leuven : ML8569
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A