Het effect van bekkenbodemspiertraining op darmklachten na laag anterieure resectie voor rectal kanker.

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Ethische beoordeling	Positief advies
Status	-
Type aandoening	Maagdarmstelselneoplasmata maligne en niet-gespecificeerd
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON26845

Bron
Nationaal Trial Register

Aandoening

- Maagdarmstelselneoplasmata maligne en niet-gespecificeerd

Aandoening

rectal cancer, bowel symptoms (fecal incontinence, urgency, frequency, fragmented defecation, soiling), Low Anterior Resection Syndrome

Betreft onderzoek met
Mensen

Ondersteuning

Primaire sponsor: Research Foundation Flanders
Overige ondersteuning: FWO (Fonds Wetenschappelijk Onderzoek)

Onderzoeksproduct en/of interventie

- Bewegingstherapie

Toelichting

Uitkomstmaten

Primaire uitkomstmaten

"Low anterior resection score (LARS): Alle uitkomstmaten werden beoordeeld op 1, 4, 6 en 12 maanden na sluiting van TME/stoma. De primaire uitkomst was gedefinieerd als het percentage deelnemers met een verbetering van de de LARS-categorie na 4 maanden (van grote LARS tot kleine LARS, van grote LARS naar geen LARS, of van kleine LARS naar geen LARS) vergeleken met de LARS-score gemeten na 1 maand postoperatief. De primaire uitkomst was de dichotome classificatie van de verandering in de LARS-categorie (1: verandering in categorie, 0: geen verandering in categorie)."

Secundaire uitkomstmaten

"De LARS-score zelf (continue variabele) werd geregistreerd als een secundaire uitkomst. Andere secundaire uitkomsten waren darmsymptomen geëvalueerd door (1) de COREFO-vragenlijst,6 (2) een numerieke beoordelingsschaal (NRS) met betrekking tot de subjectieve last van darmsymptomen, en (3) een ontlastingsdagboek. Een 7-daags ontlastingsdagboek beoordeelde frequentie van stoelgang, consistentie van de ontlasting (gescoord op de Bristol Stool
Schaal), urgentie/incontinentie/vervuiling, fragmentatie van ontlasting (clustering). De kwaliteit van leven werd geëvalueerd door de Short Form-12 (SF-12).
Fysieke activiteit werd geëvalueerd m.b.v. de Flemisch Physical Activity Computerized Questionnaire (FPACQ). "

Toelichting onderzoek

Onderzoeksopzet

Preoperative assessment of bowel symptoms, urinary symptoms, sexual symptoms, physical activity Assessment at 4 weeks after surgery/closure ileostomy (start PFMT for the intervention group) and at 16 weeks (primary endpoint) after surgery/closure ileostomy (end PFMT): bowel symptoms, urinary symptoms, sexual symptoms, physical activity, muscle tone/force/endurance pelvic floor muscles Follow-up assessments after 6 and 12 months: bowel symptoms, urinary symptoms, sexual symptoms, physical activity, tone/strength/endurance pelvic floor muscles Study outcomes: Control group + intervention group: LARS-score, Colorectal Functional Outcome Questionnaire, International Consulation on Incontinence Questionnaire, Female Sexual Function Index/ Interternational Index of Erectile Function, Flemish Physical Activity Questionnaire, Numeric Rating Scale, Bowel Diary, Bladder Diary, 1 hour Pad test, Evaluation pelvic floor muscles (tone, strength, endurance)

Intervention group: pelvic floor muscle training (9 times in 12 weeks)

Onderzoeksproduct en/of interventie

Bekkenbodemspiertraining

Contactpersonen

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Deelname eisen

Leeftijd
Volwassenen (18-64 jaar)
Volwassenen (18-64 jaar)
65 jaar en ouder
65 jaar en ouder

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- patients planned for a low anterior resection for rectal cancer (TME, total mesorectal excision)
- patients who have an expected survival of at least 1.5 years
- patients who are able to come to the hospital once a week during the complete treatment period (12 weeks)
- patients with a minimal LARS score of 21/42

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- having a HARTMANN procedure, abdominiperineal excision or transanal microsurgical resection or sigmoïd resection
- patients with neurological conditions
- patients with cognitive problems
- patients with preoperative fecal incontinence
- patients who have had precious pelvic surgery, previous pelvic radiation or LAR for non-cancer reasons

Onderzoeksopzet

Opzet

Fase onderzoek:	4
Type:	Interventie onderzoek
Onderzoeksmodel:	Enkelvoudig
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Actieve controle groep
Doel:	Behandeling / therapie

Deelname

Europa

Status:	Werving gestopt
(Verwachte) startdatum:	29-01-2017
Aantal proefpersonen:	120
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Positief advies

Datum:	23-01-2017
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	NL6227
NTR-old	NTR6383
Ander register	Number Ethical Committee of University Hospitals Leuven S59761

Resultaten

Datum resultaten gemeld:	06-03-2024
Totaal aantal deelnemers:	125

Samenvatting resultaten
"The main study of this project was a multicentre randomized controlled trial, investigating the effectiveness of PFMT on low anterior resection syndrome. Initially, 120 patients were foreseen to be included. Eventually, a total of 104 patients was recruited due to time- and COVID-19-restrictions and a lower than predicted drop-out rate. Patients were randomly

assigned to an intervention group (n = 50, receiving 12 weeks of PFMT, including pelvic floor muscle exercises, advice, biofeedback, electrical stimulation, bowel training and balloon training) or a control group (n = 54, not receiving PFMT, nor any of the abovementioned treatment modalities). The nine PFMT-sessions were started one month after TME/stoma closure and consisted of a variety of techniques among which pelvic floor muscles exercises, balloon training, biofeedback and evacuation techniques. Regarding bowel symptoms, the LARS- and COREFO- questionnaire, the Numeric Rating Scale (NRS) regarding the subjective bother of bowel symptoms as well as stool diary items were analysed. The SF-12 questionnaire was analysed in relation to the quality of life. All of these outcome measures were assessed at 1, 4, 6 and 12 months after TME/stoma closure. The results demonstrated the effectiveness of PFMT in reducing the proportion of patients with major bowel complaints as per categorized LARS-scores. Stool frequency, incontinence and clustering were also positively influenced by PFMT. Moreover, PFMT ensured a faster recovery process regarding those bowel complaints up to six months after surgery/stoma closure. As regards to quality of life scores, no significant results were found.
A 2nd study was conducted to investigate whether bowel symptoms related to LAR for RC could be sufficiently well evaluated by the LARS-questionnaire or the COREFO-questionnaire, compared to the stool diary. Patients were asked to fill out the stool diary and the LARS- and COREFO-questionnaire at 1, 4, 6 and 12 months after TME/stoma closure. Data from a subgroup of 95 patients of the previously mentioned RCT was analysed. Following items were significantly correlated between the LARS-/COREFO-questionnaire and the stool diary: anal incontinence for faeces and frequency of bowel movements. Furthermore, items on soiling were significantly correlated between the COREFO-questionnaire and the stool diary. No significant association was found with the information provided by the stool diary for either questionnaire on items on clustering of bowel movements and urgency. Lastly, overall moderate associations were found between the questionnaires and the stool diary, although the amount of overlapping information was rather limited.
Finally the progression of all PA levels (total, sport, occupational and household) was investigated over time, together with the exploration of possible predictive factors for a decrease in those PA levels. Patients were asked to fill out the Flemish Physical Activity Computerized Questionnaire (FPACQ) and the LARS- and COREFO-questionnaire regarding the preoperative period and at 1, 4, 6 and 12 months after TME/stoma closure. Results from the 125 included RC patients showed that total physical activity levels remained significantly lower than preoperative values up to 12 months postoperatively. Furthermore, occupational and sports physical activity levels remained significantly lower until 6 and 4 months postoperative, respectively. Predictive factors for decreased physical activity levels at a specific timepoint were: younger age and no stoma (total physical activity, 1 month), low/mid rectal tumour, no stoma, non-employed status (total, 4 months), higher COREFO-scores (occupational, 4 months) and non-employed status (total, 12 months)."

Karakteristieken onderzoekspopulatie
Mean age was 58.49 years (SD 11.07), 66.40% of patients were males. Median BMI was 24.58 kg/m².

Deelnemers doorstroom
"For the main study (RCT): 370 patients assessed for eligibility, of which 104 patients could be enrolled and randomized: 50 in the experimental group (pelvic floor muscle training) and

54 in the control group (no training). Three patients in every group

Ongewenste voorvallen
No adverse events

Datum eerste publicatie onderzoek
22-01-2021

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