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Impact of a pre-operative mobilisation program using an educational training to improve mobility on mobility, pain, and post-operation length of stay of patients receiving a laparotomy [Auswirkung eines präoperativen Bewegungsschulungsprogrammes auf Mobilität, Schmerzen und postoperativer Verweildauer bei Patienten mit Laparatomie]

Submission date
17/07/2009

Recruitment status
No longer recruiting

Registration date
29/07/2009

Overall study status
Completed

Last Edited
30/09/2014

Condition category
Surgery

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Eva-Maria Panfil

Contact details
St. Gallen University of Applied Sciences
Rosenbergstr. 22
St. Gallen
Switzerland
CH-9001
+41 (0)71 226 15 25
evamaria.panfil@fhsg.ch

Additional identifiers

Protocol serial number
Grant no 32.5.1331.0041.0

Study information

Scientific Title
Impact of a pre-operative mobilisation program using the Viv-Arte training model based on kinesthetic mobilisation on mobility, pain, and post-operation length of stay of patients receiving an elective medial laparotomy: a prospective, randomised controlled pilot trial [Auswirkungen eines präoperativen Bewegungsschulungsprogramms nach dem Viv-Arte Lernmodell auf Mobilität, Schmerzen und postoperative Verweildauer bei Patienten mit elektiver medianer Laparotomie: eine prospektive, randomisierte und kontrollierte Pilotstudie]

Study objectives
A pre-operative educational intervention to improve mobility is effective in regard to post-operative mobility, pain and hospital residence time after elective medial incision.

Ethics approval required
Old ethics approval format

Ethics approval(s)
University Ulm (Germany) Ethics Committee, 23/03/2006, ref: 43/06 - UBB/se

Study design
Prospective interventional single-centre randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Laparatomy with medial incision

Interventions
Before surgery:
Both groups: general standard preparation by care staff, on the day before operation (shaving and laxative preparation, information on procedures with regard to operation).
Control group: written information with information and motivation for active movement to prevent from thrombosis
Experimental group: educational intervention, including exercise, written and oral information, duration about 30 minutes

After surgery:
Patients of both groups were (a) instructed to execute active movements according to the information sheet and (b) undergo mobilisation exercise without differences.

(a) + (b) carried out two times a day, while the patient was in intensive care unit
(a) + (b) carried out once a day, while the patient was in standard care unit.
End of treatment: day of hospital leave, no follow-up after hospital leave.

Secondary scientific contact details:
Dr Michael Brach
Institute of Sport Science
University Muenster
Horstmarer Landeweg 62b
48149 Muenster
Germany
Email: michael.brach@uni-muenster.de

Jörg Haasenritter MSc
Department of General Practice
Preventive and Rehabilitative Medicine
University Marburg
Robert-Koch-Straße 5 (7a)
35032 Marburg
Germany
Email: haasenri@staff.uni-marburg.de

Intervention Type
Procedure/Surgery

Phase
Not Applicable

Primary outcome(s)
1. Functional mobility: a new instrument was designed to observe the amount of assistance needed in 11 functional tasks (MOTPA, mobility test for patients in acute care):
1.1. Lying in the bed: moving to the top, moving sideward, transfer from back to lateral position, transfer from lateral lying position to sitting on the edge of the bed
1.2. Sitting on the edge of the bed: moving forward, keep sitting position, stand up
1.3. Standing position: turning 180°, going backwards three steps, short walk (6 m), walk (30 m), sitting down
The mobility profile was recorded once pre-operative, post-surgical in intensive care unit: daily in the morning and in the afternoon and post-surgical in standard care unit: daily around noon.
2. Pain, assessed by Visual Analog Scale (VAS) (0 = no pain, 10 = unbearable pain), before, during, directly after, and 10 minutes after mobilisation and conduction of MOTPA
3. Post-surgical hospital residence time; date of medical operation and date of release were documented

Key secondary outcome(s))
1. Socio-demographic data (age, sex, education, profession), recorded pre-operatively
2. Mobility-related aids, recorded pre-operatively
3. Type of surgery after cystectomy (ileal conduit), recorded once post-surgical
4. Number of drainage and access canals, recorded at each mobilisation unit
5. Pain medication before (2 hours), during and after (30 minutes) mobilisation, recorded at each mobilisation unit
6. VAS pain intensity greater than 30 mm directly before mobilisation exercise results in

cancellation of the mobilisation unit, recorded at each mobilisation unit
7. Post-operative complications (artificial ventilation for more than 6 hours after operation finish; reintubation; relaparatomy; other complications resulting in restriction of mobilisation, recorded once a day post-surgically). Presence of one of these complications results in exclusion of the patient from the trial.
8. Exercise, e.g. thrombosis, lung embolism; disorder of wound cure or suture, which are treated by a ventral bandage), recorded once a day post-surgically

Completion date
31/12/2006

Eligibility

Key inclusion criteria
1. Cystectomy planned (ICD5-576)
2. Age 18 years and above, either sex
3. Ability to understand written and spoken German
4. Written informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Impaired mobility (functional degree 2 or above, according to Gordon: dependent on personal assistance, supervision or guidance)
2. Chronic pain (duration above 3 months, with pharmacological treatment)
3. Dementia, medically documented
4. Anamnesis includes medial incision

Date of first enrolment
01/04/2006

Date of final enrolment
31/12/2006

Locations

Countries of recruitment

Germany

Switzerland

Study participating centre
St. Gallen University of Applied Sciences
St. Gallen
Switzerland
CH-9001

Sponsor information

Organisation
Hessian Institute of Nursing Research (Hessisches Institut für Pflegeforschung) (Germany)

Funder(s)

Funder type
Research organisation

Funder Name
Robert-Bosch Foundation (Germany) (ref: 32.5.1331.0041.0)

Funder Name
Hessian Institute of Nursing Research (Hessisches Institut für Pflegeforschung) (Germany)

Funder Name
University Hospital Ulm (Germany)

Funder Name
Institute of Sport Science and Sport - University Bonn (Germany)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/02/2009		Yes	No