A multidisciplinary rehabilitation program for patients following surgery for abdomino-pelvic cancer

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Helena Frawley PhD, FACP

- A/Prof Physiotherapy, Monash University, Melb.
- NHMRC Early Career Research Fellow
- Head, Centre for Allied Health Research and Education, Cabrini Institute

Background

- Oncology rehabilitation is a rapidly growing, new, and very important area of patient care
- Guidelines recommend cancer patients engage in regular and moderate intensity physical activity following treatment
Nutrition and Physical Activity Guidelines for Cancer Survivors

Cheryl L. Rock, PhD, RD; Colleen Doyle, MS, RD; Wendy Demark-Wahnefried, PhD, RD; Jeffrey Meyerhardt, MD, MPH; Kerry S. Courneya, PhD; Anna L. Schwartz, RN, PhD, FAAN; Elias V. Bander, MD, PhD; Kathryn K. Hamilton, MA, RD, CSS, CDN; Barbara Grani, MS, RD, CSEO, LD; Marij McCullough, ScD, RD; Tim Byers, MD, MPH; Ted Gansler, MD, MBA, MPH

Guidelines

Abdomino-pelvic cancer: Evidence for Effect of Physical Activity

- Prostate cancer (Keogh 2012)
- Colorectal cancer (Cramer 2013)
- Gynaecological cancer (Lin 2016)
- Minimal data on effect on pelvic floor function
- No RCT evidence yet re survival (CHALLENGE)
- No feasibility of implementation studies
- Not routinely implemented in clinical practice
Aims of our study

1. To investigate the feasibility of an oncology rehabilitation program for patients following surgery for abdomino-pelvic cancer
   - Colorectal, gynaecological, prostate

2. To assess the impact of rehabilitation on:
   - functional capacity, muscle strength, psychological distress, level of physical activity, self efficacy, and HRQoL in patients following surgery for abdomino-pelvic cancer
   - in the short-, medium-, and long-term.

Methods (1)

Design:
- a prospective pre-post study
  - 2 cohorts
  - Nested PFM study

Setting:
- Private hospital
- Large volume cancer surgery

Recruitment:
- Participating surgeons

Local HREC
ANZCTR

Participants:
- surgery for histologically confirmed, stage I-III abdomino-pelvic cancer
  - Colorectal, gynaecological, prostate
- Completion of all surgical and medical treatments
  - > 6 weeks post-op
- an Eastern Cooperative Oncology Group performance status of 0 – 2
- sufficient English language skills to participate
- Age ≤ 85
Methods (2)

Pre-intervention:
- Screening: Essa.org.au
- Medical clearance sought when required
- Physiotherapy assessment

Methods (3):
INTERVENTION - Supervised

- 8 week oncology rehab group program
- Exercise: 2 sessions per week
  - Cardio-vascular
  - Strengthening
- Gym supervision: Physiotherapist & Exercise Physiologist
- Home instruction: exercise sheets, Fitbit™, Theraband™
- Exercise diary for recording
Methods (3):
**INTERVENTION - Supervised**

- Education: 1 session per week
  - Physiotherapy x 1
  - Health Psychology x 3
  - Exercise Physiology x 2
  - Dietetics x 2
  - Onward referral if required

- Not part of ACS guideline

Methods (4):
**HOME PROGRAM**

- Post-supervision – 6 months post-baseline:
  - Exercise diary:
    - Steps per day (FitBit)
    - Met cardio guideline (duration and intensity)
    - Met strength guideline
  - 6 x telephone motivational coaching sessions (1 to 2 calls per month) from a physiotherapist

- 6 – 12 months post-baseline:
  - Exercise diary

- Long-term follow-up: postal questionnaires
  - 1, 2, 5 years
Methods (5):
OUTCOME MEASURES

• Feasibility:
  • Trial: Referral, recruitment, retention, adherence, adverse events

• Clinical outcomes:
  • Primary:
    • 1. Functional capacity: 6MWT
  • Secondary:
    • 2. Physical Activity: IPAQ
    • 3. Muscle strength: Dynamometry
    • 4. Psychological distress: HADS
    • 5. Health-related quality of life (HRQoL): EORTC QLQ-C30
    • 6. Self-efficacy: Nutrition & exercise
    • 7. Pelvic floor symptoms: APFQ; ICIQ-UI SF; ICIQ-B
    • 8. Global response change score
    • 9. Overall survival

Methods (6):
Sample size & Statistical analysis

• Sample size
  • based on difference in the 6-MWT distance after intervention CRC cohort: 37m ± 70m (Li 2013)
  • 60 participants required; 80 participants to be recruited

• Changes to each measure across time:
  • Rehab group changes: within-group
  • Rehab vs Questionnaire groups: between-group changes:
    • repeated measures analysis of variance (ANOVA) comparing different assessment time-points

• Reporting:
  • STROBE
  • TEND
Results

- Flow diagram of study
  - 1 July 2014 – 31 March 2017
  - 1° aim:
    - Feasibility
  - 2° aims:
    - Clinical results

Potentially eligible patients identified from hospital database n=637

Excluded n=450
- Ineligible as assessed by surgeon n=37
- Eligible but not recruited n=413

Total recruited n=187

T1 Ax

Consented to Oncol Rehab program n=83

Lost to follow-up n=11

T2 Ax (post-intervention) n=72

Lost to follow-up n=0

Waiting, n=5

T3 Ax (6 mths post-baseline) n=67

T4 Ax (12 mths post-baseline) n=35

Consented to questionnaire group n=104

Lost to follow-up n=15

T2 Ax n=89

Lost to follow-up n=7

T3 Ax n=89

T4 Ax n=60
Broadening of recruitment

- Initial population chosen: colorectal cancer
- By 5 months, referral and recruitment slow ++
- Decision to broaden recruitment to gynaecological and prostate groups to reach target n=80
- Due to low consent rate, decision to include a ‘non-intervention’ – Questionnaires only – group to add to data collection
  - Quasi-control

Results:
Feasibility – Consent to study

- Potentially eligible cohort n=637
- Eligible and contacted n=600
  - Consented n=187 (31%); Declined n=413 (69%)
    - Not interested n=180
    - Too busy / time demands of rehab program n=81
    - Unable to contact n=69
    - Distance, felt too old, already meeting PA guideline, ESL, too unwell
  - No difference between consented vs declined:
    - Age, sex, type of tumour, type of surgery
Results:

- For handouts: results not available for the handouts as data are pre-publication and undergoing further analyses

Limitations

- Study design: non-randomised, uncontrolled
  - Bias of self-selected to join rehab program group
    - Less well, therefore greater benefit?
  - Heterogeneity of tumour type and surgery amongst participants
Conclusions: Clinical implementation (Lewis 2015)

- Acceptability
- Adoption
- Appropriateness
- Cost
- Fidelity
- Feasibility
- Penetration
- Sustainability

Where to from here...

- Proposition as a clinical service
  - Target process barriers to recruitment; pathway of care
  - Target high risk?
  - Offer out-of-business-hours; individualised rehab models
- Future research:
  - Pilot data for fully powered RCT
  - Prehabilitation / during active treatment
  - Include PFMT in general exercise program
  - Adherence strategies
Allied Health Pelvic Oncology
Rehabilitation

Colleagues on this project

- Kuan-Yin Lin 2,3
- Catherine Granger 2
- Linda Denehy 2
- Michael Butler 1,4
- Rosemary Higgins 4
- Isabella Lees-Trinca, Hema Navaratnam, Sophie Jennings 1

1 Centre for Allied Health Research and Education, Cabrini Institute, Melbourne
2 Monash University
3 The University of Melbourne
4 Physiotherapy Department, Royal Melbourne Hospital
5 Rehabilitation and Allied Health, Cabrini Health, Melbourne

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- Participants
  - Intervention
  - Questionnaire