Meeting needs of people with inoperable lung cancer through an innovative supportive care intervention: a randomised controlled trial

Assoc. Prof. Penelope Schofield
A Ugalde, K Sharkey, J Reece, M Krishnasamy, M Carey, D Ball & S Aranda

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Mortality of lung cancer

- Lung cancer is now the leading cause of cancer death worldwide
  - Even with best available treatments, approximately 15% alive after 5 years
  - Presentation occurs usually when disease is advanced and inoperable.

Parkin et al 2005; Ries et al., 2006
Burden of Illness

- Presentation occurs usually when disease is advanced and inoperable
- Experience high physical symptoms: pain, breathlessness, fatigue, persistent cough, weight loss, sleeplessness
- Poor prognosis and high symptoms cause: restricted activity, high unmet needs; high psychological distress, panic attacks and fears of impending death.
High level of distress

- Prevalence of distress is high: 43% in lung cancer patients compared with 35% across other tumour groups
- Higher burden of needs: higher psychological needs and physical/daily living needs compared with other tumour groups

Aim & Hypotheses

Aim:
To evaluate the impact of a multi-disciplinary, supportive care intervention for people with inoperable lung cancer

Hypotheses:
The intervention would:
1. Reduce unmet perceived needs
2. Reduce psychological distress
3. Improve quality of life
Methods

Design:
Two-group randomised controlled trial
  i. pre-randomization baseline assessment
  ii. follow-up 1 - 8 weeks post-baseline
  iii. follow-up 2 - 12 weeks post-baseline

Setting: Specialist oncology treatment centre, Melbourne, Australia
Sample

**Inclusion Criteria:**

i. Diagnosis of inoperable lung cancer
ii. EBR; palliative chemotherapy; or radical EBR and chemotherapy treatment
iii. Sufficient English

**Exclusion Criteria:**

i. Current psychiatric diagnosis or serious cognitive impairment
ii. Low performance status (ECOG >= 3)
iii. Recent treatment (within 2 months)
CONSORT Flow Chart

Enrolment
- Assessed \(n = 1009\)

Allocation
- Randomised \(n = 108\)
  - Standard care \(n = 53\)
  - Intervention \(n = 55\)

Follow-up 1
- Loss \(n = 15\)
  - 8-week FU \(n = 38\)
- Loss \(n = 12\)
  - 12-week FU \(n = 41\)

Follow-up 2
- Analysis
  - Analysed \(n = 43\)
    (Excluded \(n = 10\))
  - Analysed \(n = 45\)
    (Excluded \(n = 10\))

Excluded \(n = 890\)
- Not eligible \(n = 744\)
- Refused \(n = 77\)
- Other \(n = 72\)
Measures

• Needs Assessment for Advanced Cancer Patients (NA-ACP)- short form

• Hospital Anxiety and Depression Scale (HADS)

• Distress Thermometer (DT) – single item

• EORTC Quality of Life C30 (EORTC QLQ C30)

• Demographic & clinical characteristics
Intervention

• Self assessment of supportive care needs

• Tailored evidence-based information

• Intervention tailored to patients needs:
  i. Emailed report to MDT on symptom needs
  ii. Modules for psychosocial/informational needs
Intervention

- Two sessions with psychologist at treatment commencement and completion
- Individual summary of concerns as guide
- Standardised, manualised modules
- Take-home leaflets on self-care strategies
- Techniques: active listening, empathy, basic CBT and reinforcement
Intervention

**Modules**
- HP communication
- Family communication
- Emotional distress
- Sleeplessness
- Breathlessness
- Goals for the future

**MDT Referrals**
- Nurse/oncologist
  - symptom relief
- Social work
  - practical support
- Psychology
  - emotional support
- Pastoral Care
  - spiritual support
### Sample

**Age in years - mean (range):** 63 (39-83)

**Gender: % (n)**
- Female 40% (43)
- Male 60% (65)

**Type of lung cancer: % (n)**
- Small-cell lung cancer 4% (4)
- Limited stage 5% (5)
- Extensive stage 4% (4)
- Non-small-cell lung cancer
  - Stage I 35% (38)
  - Stage II 42% (45)
  - Stage III 6% (6)
  - Stage IV 6% (6)
- Mesothelioma 4% (4)

**Type of treatment: % (n)**
- Palliative chemotherapy 22% (24)
- Palliative radiotherapy 37% (40)
- Radical radiotherapy +/- chemotherapy 41% (44)

**ECOG performance status - mean (+/- SD)** 1.16 (+/- 0.61)
Medical Communication Needs

Baseline Follow-Up 1 Follow-Up 2
Mean Medical Information Needs Score

Control
Intervention

p=0.84
Psychological / Emotional Needs

<table>
<thead>
<tr>
<th>Control</th>
<th>Intervention</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>1.7</td>
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<tr>
<td>Follow-Up 1</td>
<td>1.8</td>
</tr>
<tr>
<td>Follow-Up 2</td>
<td>1.9</td>
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</tbody>
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Mean Psychological / Emotional Needs Score

p=0.90
Symptom Unmet Needs

F(1, 71) = 5.46, p = .022, d = 0.55

Baseline Follow-Up 1 Follow-Up 2

Mean Symptom Score

Control Intervention
Psychological Distress - DT

p=0.29

Mean Distress Thermometer Score

Baseline Follow-Up 1 Follow-Up 2

Control Intervention

p=0.29
Psychological Distress – Total HADS

Baseline Follow-Up 1 Follow-Up 2

Mean HADS - Total Score

Control
Intervention

p=0.36
Global – Quality of Life

Mean Global QoL Score

Baseline | Follow-Up 1 | Follow-Up 2

Control | Intervention

p=0.33
Appetite Loss

$F(1, 71) = 4.61$, $p = .035$, $d = 0.51$
Summary of Findings

Hyp 1: Reduction of need
- Significant reduction in symptom needs at 8 weeks
- No difference in medical information, psychological/emotional, family/social needs

Hyp 2: Reduce psychological distress
- No difference in psychological distress

Hyp 3: Improve quality of life
- Significant reduction in appetite loss at 8 weeks
- No difference in global QoL; functional scales or other symptom scales
Clinical Implications

- Systematic assessment of needs and communication to MDT reduces post-treatment symptom needs and *may* improve quality of life.
- Active listening, empathy and simple coping strategies *may* reduce psychological distress.
- Patients with inoperable lung cancer require ongoing management after treatment completion.
Future Research

• Improve the intervention:
  - Delivery by a trained nurse
  - Extend the number of sessions to post-treatment
  - Use validated screening tool just prior to each intervention point
  - Electronic screening and automated feedback
For more details please contact:
penelope.schofield@petermac.org