2015 NATIONAL AWARENESS AND EARLY DIAGNOSIS INITIATIVE RESEARCH CONFERENCE

CANCER RESEARCH UK

IMPROVING OUTCOMES SUMMIT

WILLIE HAMILTON

PRESENTING FOR

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NAEDI
National Awareness and Early Diagnosis Initiative

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A feasibility RCT looking at the effect on lung cancer diagnosis of giving a Chest X-Ray to smokers aged over 60 with new chest symptoms – feasibility and two-month follow-up data (ELCID)

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[on behalf of ELCID trial team]
Background & Intervention

- Fact: lung cancer in the UK has lousy outcomes

- Hypothesis: one hope for improving outcomes is more timely recognition of symptomatic disease (Chest X-Ray), and this may achieve a stage shift, higher rates of resection and improvements in survival

- Intervention: a lower the threshold for investigation (‘extra-NICE’) compared with current NICE guidance

- ‘Extra-NICE’ recommends a Chest X-Ray if:
  - Smoker or ex-smoker with 10 or more pack-years of smoking aged 60+
  - A new /altered cough and/or increased breathlessness reported to primary care
Simple design within primary care
Where this fits within the NAEDI hypothesis

Aims

- To undertake development work & a feasibility trial to determine:
  - Acceptability of trial design and materials
  - Training & recruitment of practices
  - Recruitment & randomisation of patients
  - Clinical & health economic data
  - Views of participants and non-participants, and health care professionals
Flow chart

Assessed for eligibility n=643

Randomised (n=262)
- Excluded n=7 randomised in error

Allocated to NICE n=128
- Withdrawal n=0

Allocated to extra-NICE n=127
- Received chest x-ray within 8 weeks n=115
- Received chest x-ray after more than 8 weeks n=8
- Site confirms patient did not receive chest x-ray n=3
- No confirmation of chest x-ray date received n=3
- Withdrawal n=0

Post randomisation questionnaire

Completed all questionnaires n=118 (92.2%)
- Lost to follow-up n=0, Withdrawal n=0

Completed all questionnaires n=110 (86.6%)
- Lost to follow-up n=0, Withdrawal n=0

2 month questionnaire

Completed all questionnaires n=82 (66.1%)
- Lost to follow-up n=1 (1 patient died prior to 2 months), Withdrawal n=0

Completed all questionnaires n=84 (72.3%)
- Lost to follow-up n=0, Withdrawal n=0

12 month CRF

Awaited

Awaited
Feasibility ‘yes/no?’

Acceptability of trial design and materials
- Done, working group with stakeholders

Training & recruitment of practices
- Done, 31 practices recruited in different regions of UK

Recruitment & randomisation of patients
- Done, 255 patients individually randomised over 18 months

Clinical & health economic data collection
- Acceptable completion rates
- Data on presenting symptoms & comorbidity
- No difference in HADS or EQ5D at 2 months
- 12 month follow up to follow (cancer diagnosis, ICECAP, CSRI)

Views of participants and non-participants, and health care professionals
- Done, and will inform Phase III trial design
Conclusion

- We have the demonstrated feasibility of recruiting to an individually randomised controlled trial in primary care for earlier CXR for high-risk patients

- We await 12-month follow up data on outcomes to inform sample size for a phase III trial

- This is one of the first trials of a primary care based intervention to facilitate timelier diagnosis of cancer