Smoking Cessation in Pregnancy Incentives Trial (CPIT): a phase II RCT with economic evaluation

Lesley Sinclair & Kathleen Boyd
on behalf of the CPIT research team

ASH Scotland Conference
18th June 2015
Outline

• Background & Aims
• Methods
• Main Trial Results
• Economic Evaluation
  – Within trial analysis
  – Lifetime analysis
  – Results
• Conclusions
## Background & Aims

| **Background** | Used in other areas of public health with some success  
Positive feedback from local programmes e.g. GIUFB  
Some evidence that increase engagement, retention & cessation  
Best evidence for incentives in pregnancy  
NICE Recommendation for UK trial of incentives |
<table>
<thead>
<tr>
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<tbody>
<tr>
<td><strong>Aims</strong></td>
<td>Assess acceptability &amp; explore efficacy &amp; cost effectiveness of up to £400 of shopping vouchers added to routine NHS SSS’ support to help pregnant smokers to quit</td>
</tr>
</tbody>
</table>
Methods: Trial Design

Phase II single centre individually randomised controlled trial

1026
ELIGIBLE pregnant smokers identified

612
Pregnant smokers enrolled

Control
n= 306
Routine NHS SSS
(face to face 1h, phone x 4 wks, NRT x 10 wks)

Intervention
n= 306
Routine NHS SSS + offer of financial incentives
(up to £400 shopping vouchers based on setting quit date, abstinence at 4 & 12 wks post quit and late pregnancy)

Primary outcome: Cotinine verified cessation at 34-38 wks gestation

Secondary outcomes: Cost effectiveness, engagement, self-reported quit rates at 4 wks & 6mos post-partum, birth weight, stillbirth, miscarriage & pre-mature birth

SR smoker
CO>=7ppm
<=24wks pregnant
Age >=16yrs
Speak English

UNIVERSITY of STIRLING
NHS Greater Glasgow and Clyde
UNIVERSITY of Glasgow
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## Baseline Characteristics

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<tr>
<th>Characteristic</th>
<th>Control Group</th>
<th>Incentives Group</th>
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<tr>
<td>Age (yrs)</td>
<td>27.7 (6.1)</td>
<td>28.3 (5.8)</td>
</tr>
<tr>
<td>BMI (kg/m²)</td>
<td>26.2 (5.9)</td>
<td>26.4 (5.8)</td>
</tr>
<tr>
<td>% Most deprived quintile (SIMD)</td>
<td>65%</td>
<td>67%</td>
</tr>
<tr>
<td>Gestation at booking (wks)</td>
<td>12.6 (2.7)</td>
<td>12.3 (2.5)</td>
</tr>
<tr>
<td>CO Reading at booking (ppm)</td>
<td>13.6 (6.3)</td>
<td>13.1 (6.4)</td>
</tr>
<tr>
<td>Fagerstrom score</td>
<td>5.3 (2.2)</td>
<td>4.8 (2.2)</td>
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(Score of >=5 indicates sig. nicotine dependence)
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(Score of >=5 indicates sig. nicotine dependence)
Results: Primary Outcome

• Significantly more smokers offered incentives stopped smoking 69 (22.5%) vs 26 (8.6%) representing 14% absolute reduction in quit rates late pregnancy

• RR not smoking at end of pregnancy 2.63 [95% CI 1.73 to 4.01, p<0.001]

• Results unaffected after control for nicotine dependence

• Number Needed to Treat= 7.2 (95% CI 5.1 to 12.2)

• 46 (15%) incentives vs 43 (14%) controls lost to follow up at 1º

• Around 20% may have ‘gamed’ cotinine assay

• ‘True’ quit rate perhaps more modest 7% vs 18%?
Results: Secondary Outcomes

- No differences in engagement (81% incentives vs 78% controls)
  RR 1.0 (95% CI 0.9 to 1.1, p=0.37)

- Improved cessation rate at 4 weeks with incentives (43% vs 21%)
  RR 2.1 (95% CI 1.6 to 2.7, p<0.001)

- Improved postnatal cessation at 6 mos post delivery (15% vs 4%)
  RR 3.9 (95% CI 2.4 to 6.2, p<0.001)

- No difference in birthweight, stillbirth, miscarriage, or premature births between groups
# Shopping Voucher Spend

<table>
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<tr>
<th>Retailer</th>
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</thead>
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<tr>
<td>Argos</td>
<td>£11,053</td>
<td>Matalan</td>
<td>£3,915</td>
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<tr>
<td>BHS</td>
<td>£755</td>
<td>Mothercare</td>
<td>£4,872</td>
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<td>Boots</td>
<td>£3,312</td>
<td>New Look</td>
<td>£4,485</td>
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<tr>
<td>Comet</td>
<td>£50</td>
<td>Officers Club</td>
<td>£72</td>
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<tr>
<td>Debenhams</td>
<td>£1,842</td>
<td>Peacocks</td>
<td>£114</td>
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<tr>
<td>DW Fitness</td>
<td>£139</td>
<td>Poundstretcher</td>
<td>£1,360</td>
</tr>
<tr>
<td>Early Learning Centre</td>
<td>£153</td>
<td>River Island</td>
<td>£2,666</td>
</tr>
<tr>
<td>Ernest Jones</td>
<td>£25</td>
<td>Semichem</td>
<td>£462</td>
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<tr>
<td>H Samuel</td>
<td>£149</td>
<td>Shoezone</td>
<td>£202</td>
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<tr>
<td>Halfords</td>
<td>£248</td>
<td>Superdrug</td>
<td>£1,183</td>
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<td>HMV</td>
<td>£418</td>
<td>The Factory Shop</td>
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<td>Homebase</td>
<td>£287</td>
<td>TJ Hughes</td>
<td>£313</td>
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<tr>
<td>House Of Fraser</td>
<td>£40</td>
<td>Toys R Us</td>
<td>£3,891</td>
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<tr>
<td>Iceland</td>
<td>£8,626</td>
<td>Wilkinson</td>
<td>£461</td>
</tr>
<tr>
<td>JJB Sports</td>
<td>£170</td>
<td><strong>Total</strong></td>
<td><strong>£51,363</strong></td>
</tr>
</tbody>
</table>


Economic Evaluation

• We know that smoking cessation is cost-effective
• Can Financial Incentives offer value for money?
  – compared to other cessation support!
• Financial Incentives + usual care V’s usual care
• Incremental cost-effectiveness ratio (ICER)

\[
\text{ICER} \leq \frac{\text{Cost}_A - \text{Cost}_B}{\text{Effect}_A - \text{Effect}_B} \leq \mathbf{\£20,000\text{ per QALY}}
\]

• Within-trial analysis: Incremental cost per quitter
• Lifetime analysis: Incremental cost per QALY
Methods

Within trial

- Resource use
  - NRT (10 weeks nicotine patch)
  - Cessation support (face, phone)
  - Vouchers (up to £400)

- Combine with unit costs
  - NHS Reference Costs, BNF

- Quit rate
  - 34-38 wk cotinine validated

Incremental cost per quitter

Lifetime model

- Relapse post birth
- Quality of Life
  - Smokers & ex-smokers
- Life expectancy
  - Smokers & ex-smokers
- Costs to NHS
  - Neonatal intensive care unit
  - Smoking related disease

Incremental cost per QALY
Pregnant woman who smokes

**Within trial: decision tree**

- **Treatment**
  - Financial incentive + usual care
  - Quit 34-38 weeks: Quit: 23%
  - Not quit

- **Control**
  - Usual care
  - Quit 34-38 weeks: Quit: 9%

**Within trial analysis - trial duration**

Cost: £243pp
- NHS SSS, NRT, vouchers

Cost £85
- NHS SSS, NRT,
Lifetime analysis: Markov model

Model Specifics
- 2 Cohorts
- Mean age 28 yrs (CPIT trial)
- Time horizon 75 years
- Annual cycles
- Discount rate 3.5%

Sensitivity Analysis
- Probabilistic analysis
- 6 scenario analyses
- Postnatal relapse

£ cost Intervention
£ cost low birth weight baby
No quit 34-38 weeks
3 months postnatal relapse

Successful quit 34-38 weeks
No postnatal relapse 3 months

Utility

Ex-smoker

Risk relapse up to 8 yrs

Non-smoking Related Death

Smoking Related Death

Smoking related mortality rate

Background mortality rate

£ cost (scenario analysis)
## Results: basecase

<table>
<thead>
<tr>
<th>Intervention</th>
<th>Within trial outcomes</th>
<th>Lifetime model outcomes (discounted 3.5%)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Within trial Mean Cost</td>
<td>Prob quit 34-38 wks</td>
</tr>
<tr>
<td>Control</td>
<td>£85.38</td>
<td>0.086</td>
</tr>
<tr>
<td>Incentives</td>
<td>£242.75</td>
<td>0.227</td>
</tr>
<tr>
<td>Difference</td>
<td>£157.36</td>
<td>0.14</td>
</tr>
<tr>
<td>(95% CI)</td>
<td>(£155, £162)</td>
<td>(0.08, 0.19)</td>
</tr>
<tr>
<td>ICER</td>
<td><strong>£1127 per quitter</strong></td>
<td></td>
</tr>
</tbody>
</table>

….well below the NICE threshold of £20,000/QALY!

….but what about uncertainty?
Cost-effectiveness plane: Incentives V’s Usual Care

1000 incremental cost & QALY results from PSA

Sensitivity Analyses
* Use 6 month post-delivery self-reported follow up
  
  Incentives 28% Relapse, Usual care 48% relapse : ICER £164/QALY

  • Account for Gaming (only 18% quit rate for incentives, 7% quit for control)

  ICER: £1443
Limitations

• Phase II exploratory trial

• One geographic centre

• One model of smoking cessation service for pregnant women

• Post-natal smoking status based on self-report only - important for longer term health economic evaluation (cost per QALY gained)


Boyd, K., et al. ‘Are financial incentives cost-effective to support smoking cessation during pregnancy?’ Submitted March 2015 – WATCH THIS SPACE!!
Conclusions

• Financial incentives may double quit rates at the end of pregnancy (9% to 23%) when added to existing cessation services

• Financial Incentives are likely to be highly cost-effective & well below the NICE threshold of £20,000/QALY

• Uncertainty remains regarding post-natal relapse

• Larger trial now required to demonstrate if this can work in other areas throughout UK
Project Team/Acknowledgements

Chief Investigators - Professors David Tappin & Linda Bauld

Research Team members:
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Prof Andy Briggs, Dr Alex McConnachie,
Mr David Purves, Dr Andrew Radley, Prof
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Mrs Sue Stevenson

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NO CONFLICTS OF INTEREST

THANK-YOU

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