

Effect of anti-smoking health education on infant size at birth: a randomised controlled trial

presented by

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Background in 1979

- Many observational studies consistently showing infants of smokers smaller and higher perinatal mortality rates
- Dept of Health 1977
 - ‘Evidence suggests that persuading expectant mothers not to smoke cigarettes would do more to reduce infant mortality in the UK than any other single action’

Background

- Women who smoke in pregnancy differ in ways that are also associated with these adverse outcomes
- RCT evidence needed - one group given anti-smoking education

Background

- UK RCT (Donovan 1977)
 - specially employed doctor gave intervention
 - substantial reported reduction in smoking but 12g mean *lower* birthweight
- US RCT (Sexton, Hebel, 1984)
 - specially employed counsellors gave intensive ongoing home-based tailored intervention
 - 27% vs 3% stopped by 8mths and mean birthweight 92g greater

Aim of our study

- To determine whether infant size at birth could be increased by persuading a group of women to reduce their smoking

Content of Intervention

- Anti-smoking information, advice and discussion delivered by woman's obstetrician
- Supported by specially designed leaflet to remind women of what she was told
- Placed in notes to prompt obstetrician to give intervention – if not midwives gave
- All obstetricians and midwives visited individually by researcher to gain agreement and to explain protocol

Pragmatic RCT

- Intervention to be delivered by routine antenatal care staff
- Additional member of staff to deliver anti-smoking consultations unlikely because of resource implications
- No consent needed hence biased reporting in behaviour changes less likely

Biochemical validation

- Cotinine validation now available
- Biochemist worked with us to validate behaviour using urinary cotinine but methods not well-developed and test ultimately very crude

Ethical considerations

- Intervention was routine care for those women- consent not needed
- Data collection was post-delivery and women not told what the study was about to minimise bias

Randomisation

- Individual randomisation not feasible
- Obstetricians needed prompts to deliver intervention – leaflet placed in notes by admin staff as women completed hospital registration
- Allocation - 4 weekly block alternation

Contamination?

- Given that same obstetricians also saw women in control group would they also increase the anti-smoking advice for these women?
- Not new knowledge for obstetricians

Findings

- Only women having first births changed their smoking behaviour – consistent with literature
- Marginal differences found in birthweight and infant length only among first births

Changes in smoking behaviour in the intervention and control groups by pregnancy number

Group	<i>n</i>	Type of change (%)				Mean daily reduction of cigarettes
		Stopped	Reduced	No change	Increased	
<i>Intervention</i>						
First pregnancy	181	13	34	40	12	3.2
Later pregnancy	312	7	24	56	13	1.6
Total	493	9	28	50	13	2.2
<i>Control</i>						
First pregnancy	197	7	24	53	16	1.7
Later pregnancy	292	6	17	63	15	0.8
Total	489	6	19	59	16	1.1

Infant size at birth in the intervention and control groups by pregnancy number

	Intervention (<i>n</i> = 493)	Control (<i>n</i> = 489)	Difference		One-tailed <i>P</i> **
			Crude	Corrected*	
Infant size					
Mean birthweight (g)					
First births	3164	3068	96	68	<0.06
Later births	3163	3171	-8	-0.5	0.50
Total	3164	3130	34	28	0.15
Mean length (cm)					
First births	50-69	49-88	0.81	0.75	<0.01
Later births	50-67	50-31	0.36	0.29	0.13
Total	50-68	50-13	0.55	0.49	0.01
Mean head circ. (cm)					
First births	33-80	33-78	0.02	0.06	0.36
Later births	34-00	33-97	0.03	0.04	0.35
Total	33-92	33-89	0.03	0.01	0.26

Concluding issues

- Possible contamination- controls given 'enhanced' standard care
- Cochrane review (Lumley) with many more subsequent RCTs shows that interventions do have an effect
- Similar statements on smoking in pregnancy still made by UK health bodies