

# Randomised controlled trial of a tailored SMS intervention (MiQuit) for pregnant smokers in routine antenatal care

Katharine A Foster<sup>1,2</sup>, Felix Naughton<sup>3,2</sup>, Sue Cooper<sup>1,2</sup>, Joanne Emery<sup>3,2</sup>, Jo Leonardi-Bee<sup>4,2</sup>, Stephen Sutton<sup>5,2</sup>, Matthew Jones<sup>1,2</sup>, Michael Ussher<sup>6,2</sup>, Rachel Whitemore<sup>1,2</sup>, Matthew Leighton<sup>7</sup>, Alan Montgomery<sup>7</sup>, Steve Parrott<sup>8,2</sup>, Tim Coleman<sup>1,2</sup>

1. Division of Primary Care, University of Nottingham, Nottingham, UK 2. UK Centre for Tobacco and Alcohol Studies, University of Nottingham, Nottingham, UK 3. School of Health Sciences, University of East Anglia, Norwich, UK 4. Division of Epidemiology and Public Health, University of Nottingham, Nottingham, UK 5. Behavioural Science Group, University of Cambridge, Cambridge, UK 6. Population Health Research Institute, St George's University of London, London, UK 7. Nottingham Clinical Trials Unit, University of Nottingham, Nottingham, UK 8. Department of Health Sciences, University of York, York, UK

## BACKGROUND

- Smoking in pregnancy is a major health issue and a priority for many health systems worldwide.
- Self-help smoking cessation interventions can be effective during pregnancy<sup>1</sup>
- Text message smoking cessation programmes are effective in non-pregnant smokers<sup>2</sup> but there is insufficient evidence of their effectiveness in pregnancy. Text message programmes are low cost and highly scalable.
- MiQuit is a 12 week, automated, responsive, text message programme that provides tailored smoking cessation support and advice to pregnant women who smoke.
- MiQuit was shown to be feasible and acceptable to pregnant smokers<sup>3</sup>, however robust feasibility testing in an NHS setting is needed prior to an effectiveness trial.

## AIMS

To undertake a randomised controlled trial (RCT) in order to provide estimates of key parameters for a definitive effectiveness trial of the MiQuit intervention.

## METHODS

- A multi-centre, parallel group RCT across 16 NHS Acute Trusts. NIHR CRN research staff recruited in antenatal clinics.
- Pregnant smokers were allocated to receive an NHS stop smoking leaflet (usual care) or leaflet plus MiQuit (intervention).
- Women were followed-up at 4 weeks post baseline and again in late pregnancy (36 weeks gestation). Smoking status was validated biochemically in those who self-reported abstinence in late pregnancy.
- Primary outcomes were recruitment rates, follow-up (including biochemical validation) rates and combined cessation rates. Participant views on the MiQuit intervention were explored.

## RESULTS

### Recruitment Rates

- Target recruitment reached *early*
  - 407 participants in 7 months (scheduled for 12 months)

### Follow-up Rates

- 72% of participants were followed-up at 4 week follow up, 64% in late pregnancy
- Biochemical validation achieved in 58% of self reported quitters
- 13% sent "STOP" texts (i.e. ended MiQuit prematurely)

### Participant Attitudes to MiQuit (late pregnancy)

- 81% "definitely would" or "probably would" recommend MiQuit
- 62% found MiQuit helpful, 15% found it unhelpful
- 66% thought the number of texts was "about right" (21% thought too many & 13% thought too few)
- Type of texts found helpful (% participants):
  - development of baby (79%),
  - supportive (73%), risk information (65%),
  - advice on things to do instead of smoking (58%)

### Smoking Cessation Rates

Outcome	Total n (%)	MiQuit n (%)	Usual Care n (%)
Self-reported 7-day point prevalence abstinence at 4 weeks post-randomisation	22 (5.4%)	15 (7.4%)	7 (3.4%)
Validated 7-day point prevalence abstinence at late pregnancy	24 (5.9%)	15 (7.4%)	9 (4.4%)
Validated abstinence from 4 weeks post-randomisation until late pregnancy	15 (3.7%)	11 (5.4%)	4 (2.0%)

Note/All 407 randomised participants were included in the analysis (MiQuit n = 203, usual care n = 204)

### Quit attempts

- Number of quit attempts:
  - MiQuit median = 2 (IQR = 1,3), n = 124; usual care median = 1 (IQR = 0,3), n = 130; Mann-Whitney U-test P = 0.118

## CONCLUSIONS

We have demonstrated that carrying out a large definitive RCT of a text message intervention for pregnant smokers would be feasible within NHS antenatal care. In this large pilot, recruitment targets were found to be both robust and achievable. Women found the intervention acceptable and relatively few stopped it prematurely, suggesting this type of self-help is likely to be a valuable approach to help pregnant women quit smoking. However, the low smoking cessation rates highlight the challenge of changing smoking behaviour in pregnancy. Although this study was not powered to detect group differences in cessation rates, results suggest a positive impact on smoking behaviour in the MiQuit arm which further warrants the undertaking a definitive effectiveness trial. Some issues for refinement in future research were identified, including the importance of participant engagement in the study to enhance data collection.

## REFERENCES

- Naughton F. *et al*, *Addiction*, 2008 103:566-579.
- Whittaker R. *et al*, *Cochrane Database Systematic Reviews* 2012;11:CD006611.
- Naughton F. *et al*, *Nicotine & Tobacco Research*, 2012 14:569-577.

