Multicentre, randomised controlled trial of a low-cost, smoking cessation text message intervention for pregnant smokers (MiQuit)

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Background

• 12% of women in UK smoke throughout pregnancy\(^1\)
• #1 preventable cause of pregnancy and infant ill-health

\(^1\) NHS Information Centre (2010)
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- Limited effective interventions for pregnant smokers
  - Varenicline and Bupropion\(^2\)
  - Physical activity interventions\(^3\)
  - Financial incentives\(^5\)
  - Nicotine Replacement Therapy\(^2\)
  - 1-to-1 behavioural support\(^4\)
  - Self-help\(^6\)

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  - Physical activity interventions\textsuperscript{3} ×
  - Financial incentives\textsuperscript{5} ✓
  - Nicotine Replacement Therapy\textsuperscript{2} ?
  - 1-to-1 behavioural support\textsuperscript{4} ✓
  - Self-help\textsuperscript{6} ✓

• Self-help effective but not routinely used
  – Text messaging has wide reach potential + effective for non-pregnant smokers\textsuperscript{7}
  – Unknown if effective for pregnancy smokers

MiQuit

• 12 weeks of automated, interactive, pregnancy-specific support & advice by text

• Tailored to 14 characteristics including:
  – Motivation
  – Self-efficacy
  – Most difficult situation
  + Smoking status during programme
  - Nicotine dependence
  - Smoking partner
  - Gestation
MiQuit

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• ‘Push’ support: 6 core text types (~1-2 per day)
  – Motivation - Preparation
  – Self-efficacy enhancing - Outcome expectancies
  – Relapse prevention - Postpartum

• ‘Pull’ support: on demand automated response
  – HELP (if craving) - SLIP (if lapsed)
  – QUIZ (game for distraction)

• Additional features
  – Change text frequency - Baby development texts
  – Text in quit date for extra support
Development

Systematic review

Interview study

Intervention development

Pre-test study

Feasibility trial

Pilot trial

Definitive efficacy trial

Psychological theory
- Elaboration Likelihood Model
- Social Cognitive Theory
- Perspectives on Change Model


Naughton et al (2013) Health Education Research

Naughton et al (2012) Nicotine & Tobacco Research
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Naughton et al (2008) *Addiction*

Naughton et al (2013) *Journal of Smoking Cessation*

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- Feasible and acceptable
- MiQuit increased motivation, self-efficacy and harm beliefs
- Increased setting of quit date

Pilot trial

Definitive efficacy trial

- Naughton et al (2008) *Addiction*
- Naughton et al (2013) *Journal of Smoking Cessation*
- Naughton et al (2013) *Health Education Research*
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Aims

• To estimate the likely effectiveness and cost-effectiveness of a theory-guided, tailored, text message cessation program specifically for pregnant smokers

• To estimate the key parameters for delivering a full, UK-wide trial
  – Recruitment and outcome ascertainment rates
Methods

Study design

- Multicentre, parallel group, single-blinded RCT

Setting

- 16 antenatal screening clinics in England (recruited Feb-Sept 2014)

Eligibility criteria

- Age ≥16, pregnant (<25 weeks gestation)
- Smoking at least 5/day pre-pregnancy and at least 1/day now
- NOT receiving any other text service to assist cessation
Participants identified and recruited in NHS antenatal clinics by NIHR CRN research staff

Randomly allocated to receive 12 week text service (MiQuit) plus a standard NHS self-help leaflet, or leaflet only (Control)

Followed up by telephone:
4 weeks - self report quits

Followed up by telephone:
Late pregnancy (36 weeks) – self reported quits

If a quit reported at 36 wks - Validation
Saliva and/or breath samples (visit where possible)

Screened 1181

Enrolled 407

WEEK 4
295 out of an expected 407 (72.5 % follow-up rate)

36 WEEKS GESTATION
251 out of an expected 397 (63 % follow-up rate)

Validation of Smoking Status
37 of 64 self-reports (58 %)
Smoking outcomes

• Anticipated primary outcome for definitive trial:
  – Prolonged abstinence from 4 weeks post-enrolment till late pregnancy (36 weeks) **biochemically validated** in late pregnancy (5 cigs max permitted\(^8\))

• Six additional smoking outcomes, including:
  – 7 day abstinence at 4 weeks post-baseline FU (self-report only)
  – 7 day abstinence at late pregnancy FU (self-report & validated)
  – 7 day abstinence at both follow ups (self-report & validated)

• Intention to treat. Missing = smoking assumption\(^8\)

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\(^8\) West et al (2005) *Addiction*
Results
Participant characteristics

• Mean gestation = 15 weeks, mean age = 26

• Range of motivation to quit:

- 95% had not set a quit date at baseline
Smoking outcomes

<table>
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<th>Outcome</th>
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<th>Usual Care N=204 (%)</th>
<th>Adjusted odds ratio (95% CI)*</th>
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<td>PRIMARY SMOKING OUTCOME Prolonged, validated abstinence from 4 weeks post-baseline until late pregnancy</td>
<td>11 (5.42)</td>
<td>4 (1.96)</td>
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*Adjusted by site and gestation at randomisation, 95% profile confidence intervals reported
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- Other smoking outcomes favoured MiQuit over usual care (adjusted odds ratios 1.03 to 3.28)
- 83% MiQuit, 75% usual care participants made at least one quit attempt (p=0.10)
Attitudes to MiQuit intervention

• 27 / 203 MiQuit participants (13.3%) sent a ‘STOP’ message

• Of MiQuit ppts present at late pregnancy follow up (N=120):
  – 98% reported receiving text messages
  – 81% read all messages at least once
  – 81% ‘probably’ or ‘definitely’ would recommend MiQuit
  – 62% rated the messages as ‘quite’ or ‘extremely’ helpful
  – 14% rated the messages as annoying

• Most helpful element of the text message support?
  – Messages relating to fetal development (35% participants)
Economic analysis

• Per-participant cost of sending texts:
  – £2.95 (mean 84 texts x 3.5p each)
• Annual MiQuit running cost:
  – £339 (£1.67 pp)
• Total cost per participant = £4.62
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- Incremental quit rate = 3.46%
- Incremental cost per additional quitter

£133.53 (95% CI -£395.78 - £843.62)
Summary 1

- Largest RCT of SMS intervention for pregnant smokers
- Recruitment and outcome measures feasible

- High fidelity of intervention delivery (98%)
- Suggest MiQuit could more than double quit rates
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• High fidelity of intervention delivery (98%)
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• Low cost per quitter estimate (£133):
  – ~10 times lower than £ incentives (£1,127)$^9$
  – ~5 times lower than routine NHS specialist support (£~600)$^{10}$

Summary 2

• MiQuit designed to be implemented in routine care

• 1-page info leaflet in booking notes --> 3-4% uptake

• Can also reach pregnant smokers online through Google search adverts and Facebook
  – Jo Emery’s talk: Gordon A suite, Sat 09.30

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11 Naughton et al (2015) BMJ Open
We would like to thank:

All staff involved in participating NHS Trusts
The independent trial steering committee:
- Paul Aveyard (Independent Chair)
- Ellinor Olander
- Jayne Marshall
- Lisa Szatkowski
- Kim Watts
- Susanna Mountcastle – PPI

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