National Institute for Health Research

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UNIVERSITY OF CAMBRIDGE

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

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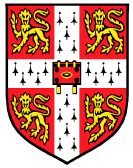

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Background

- 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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  - Physical activity interventions[3]
  - Financial incentives[5]
  - Nicotine Replacement Therapy[2]
  - 1-to-1 behavioural support[4]
  - Self-help[6]

[1] NHS Information Centre (2010), [2] Coleman et al (2015) *Cochrane Database Syst Rev*, [3] Ussher et al (2015) *BMJ*, [4] Chamberlain et al (2013) *Cochrane Database Syst Rev*, [5] Tappin et al (2015) *BMJ*, [6] Naughton et al (2008) *Addiction*

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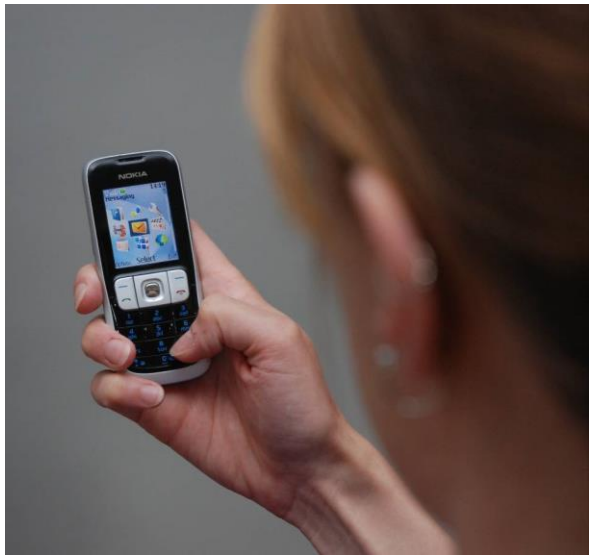
  - Varenicline and Buproprion[2] ?
  - Physical activity interventions[3] ✗
  - Financial incentives[5] ✓
  - Nicotine Replacement Therapy[2] ?
  - 1-to-1 behavioural support[4] ✓
  - Self-help[6] ✓

- Self-help effective but not routinely used
  - Text messaging has wide reach potential + effective for non-pregnant smokers[7]
  - Unknown if effective for pregnancy smokers

[1] NHS Information Centre (2010), [2] Coleman et al (2015) *Cochrane Database Syst Rev*, [3] Ussher et al (2015) *BMJ*, [4] Chamberlain et al (2013) *Cochrane Database Syst Rev*, [5] Tappin et al (2015) *BMJ*, [6] Naughton et al (2008) *Addiction,* [7] Whittaker et al (2016) *Cochrane Database Syst Rev*

MiQuit

- 12 weeks of automated, interactive, pregnancy-specific support & advice by text
- Tailored to 14 characteristics including:
  - Motivation - Nicotine dependence
  - Self-efficacy - Smoking partner
  - Most difficult situation - Gestation
  - \+ Smoking status during programme



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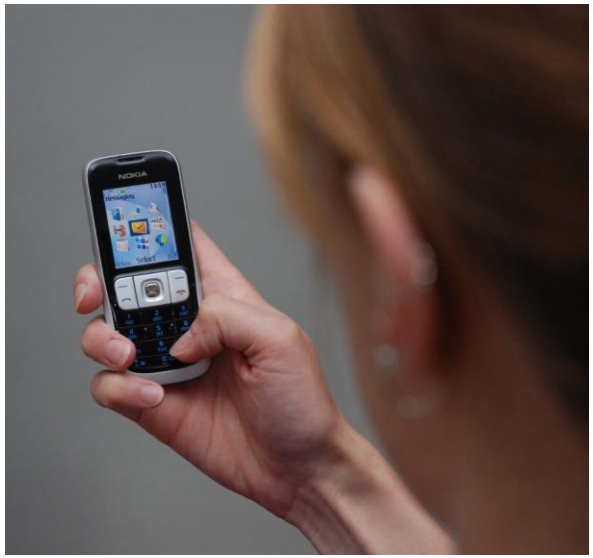
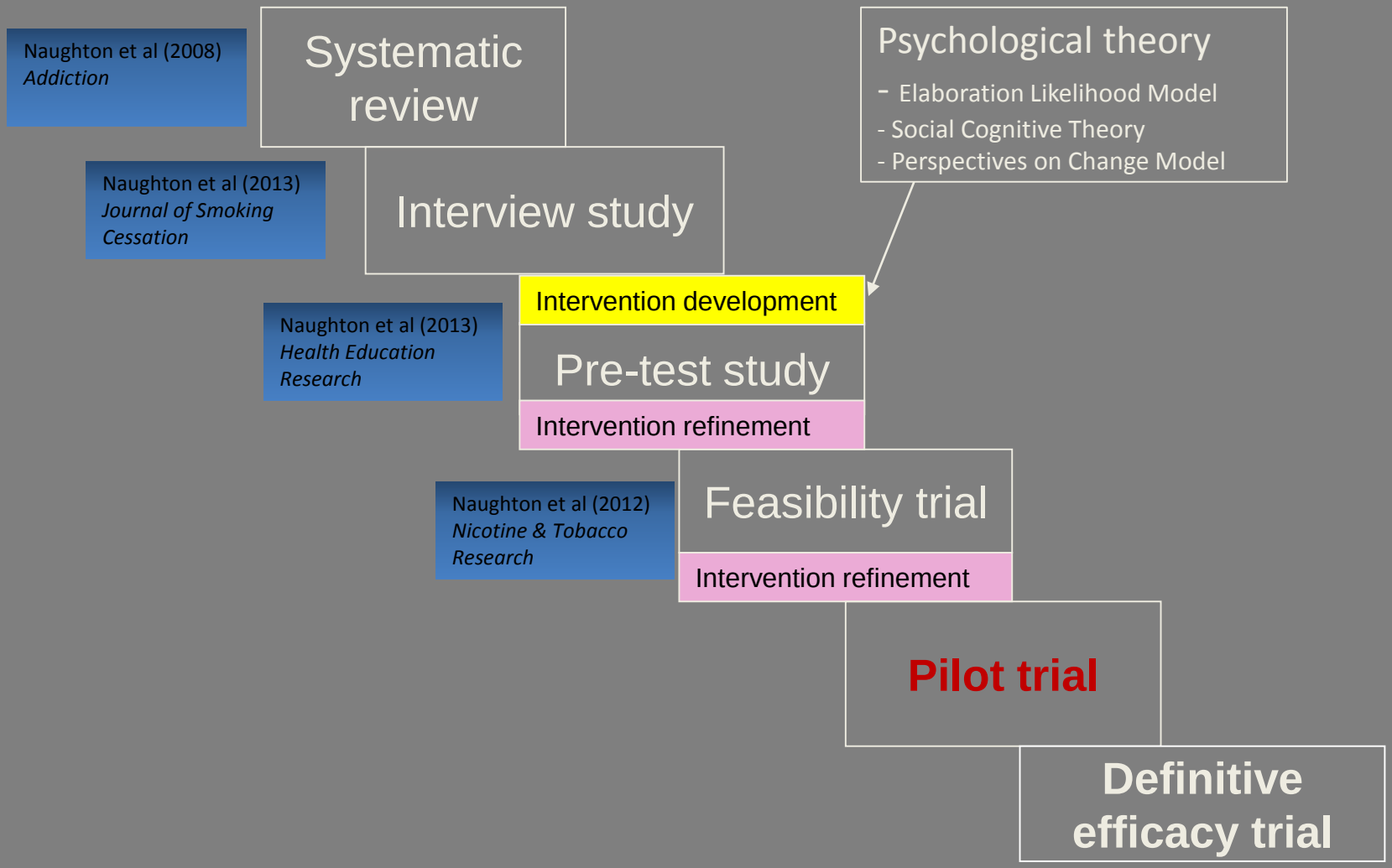
- ‘Push’ support: 6 core text types (~1-2 per day)
  - Motivation - Preparation
  - Self-efficacy enhancing - Outcome expectancies
  - Relapse prevention - Postpartum
- ‘Pull’ support: on demand automated response
  - HELP (if craving) - SLIP (if lapsed)
  - QUIZ (game for distraction)
- Additional features
  - Change text frequency - Baby development texts
  - Text in quit date for extra support



Development



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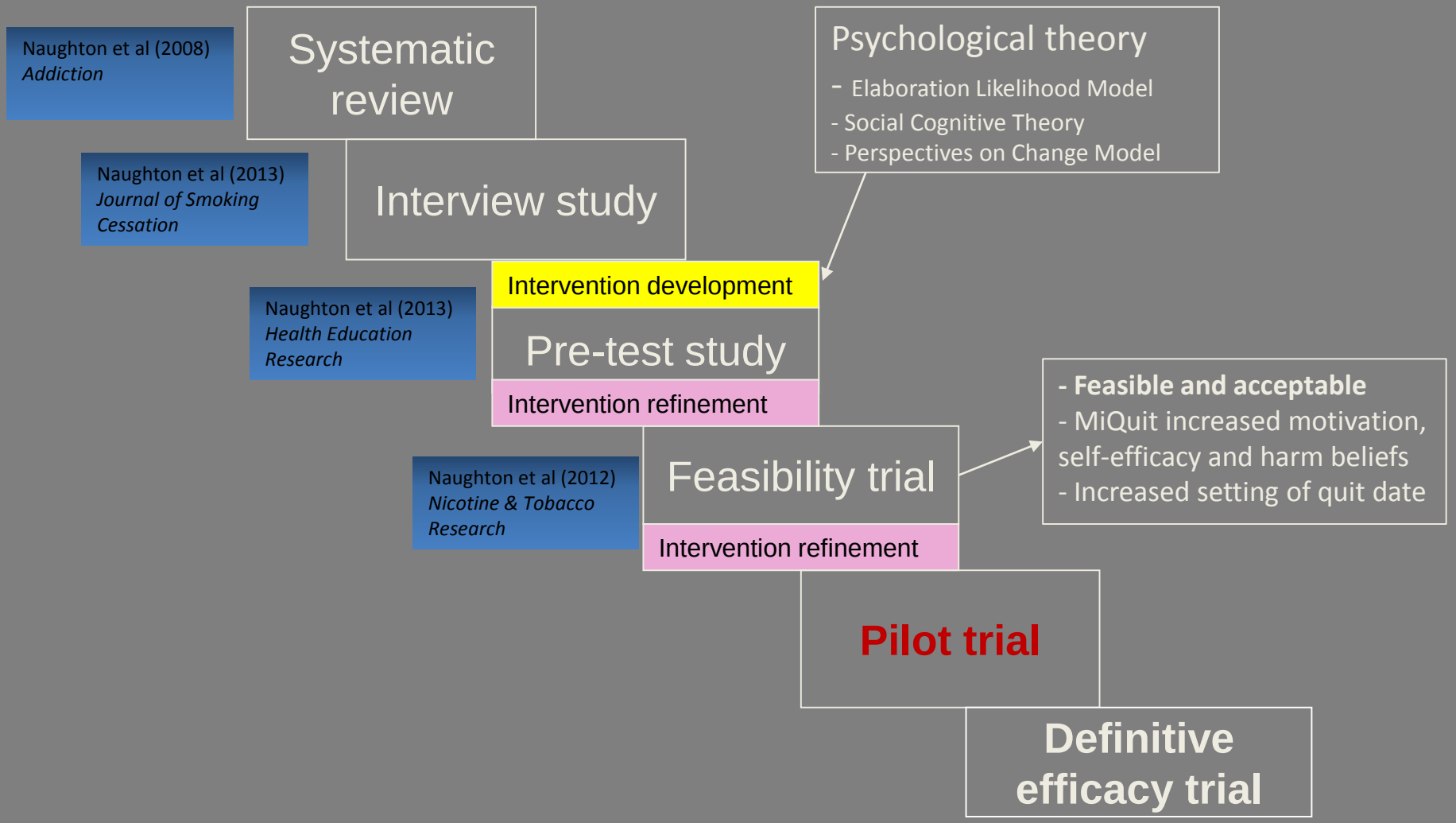


Aims

- 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

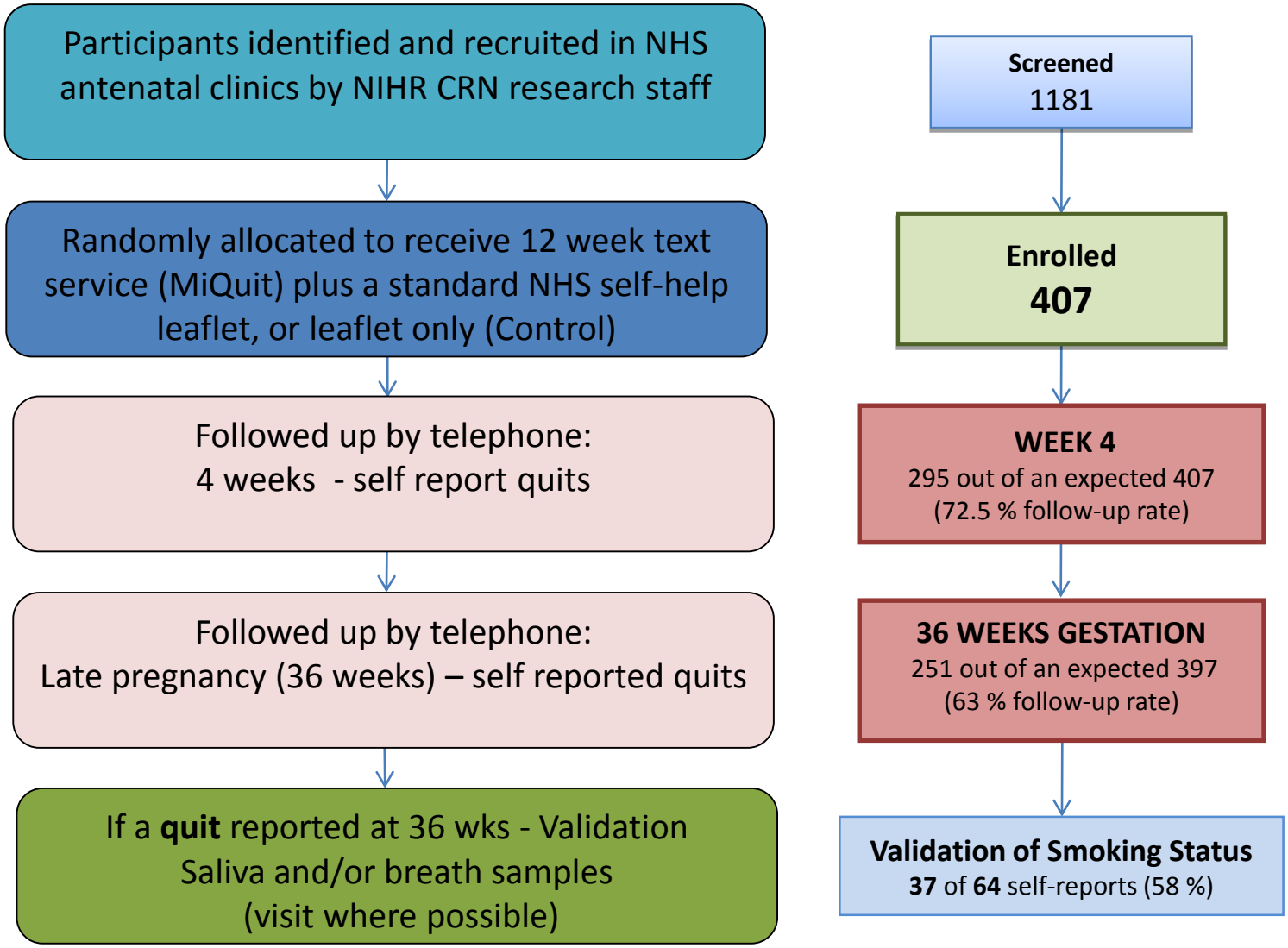
Setting

- 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

Trial Process and flow



Smoking outcomes

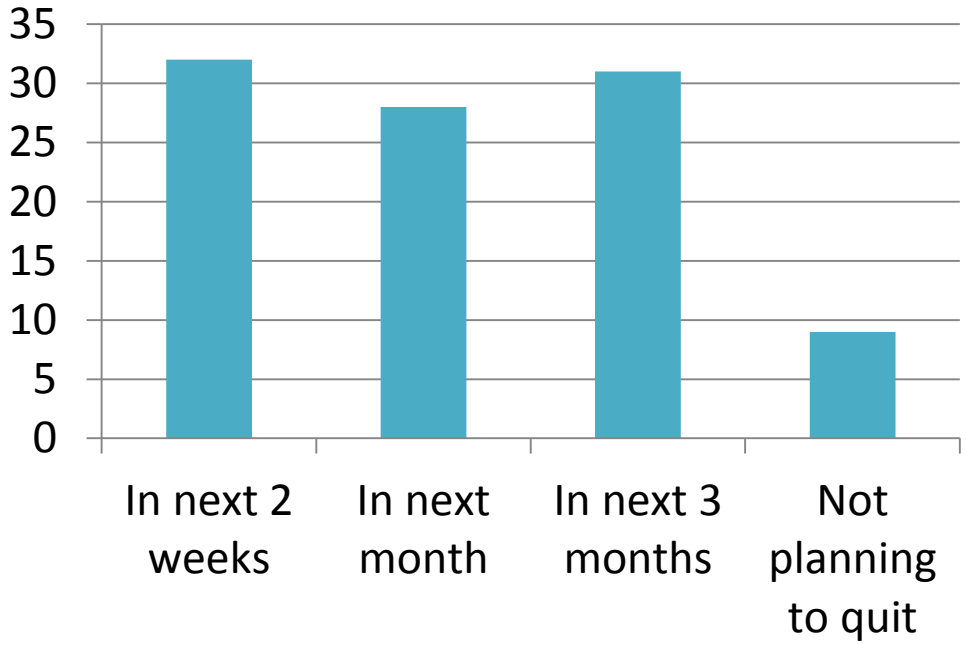
- Anticipated primary outcome for definitive trial:
  - Prolonged abstinence from 4 weeks post-enrolment till late pregnancy (36 weeks) **biochemically validated** in late pregnancy (5 cigs max permitted[8])
- Six additional smoking outcomes, including:
  - 7 day abstinence at 4 weeks post-baseline FU (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]

[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

Outcome	MiQuit N=203 (%)	Usual Care N=204 (%)	Adjusted odds ratio (95% CI)*
PRIMARY SMOKING OUTCOME Prolonged, validated abstinence from 4 weeks post-baseline until late pregnancy	**11 (5.42)**	**4 (1.96)**	**2.70 (0.93-9.35)**

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

[9] Boyd et al (2016) *Addiction,* [10] Dobbie et al (2015) *Health Technol Assess*

Summary 2

- MiQuit designed to be implemented in routine care
- 1-page info leaflet in booking notes --> 3-4% uptake[11]

- Can also reach pregnant smokers online through Google search adverts and Facebook
  - **Jo Emery's talk: Gordon A suite, Sat 09.30**

[11] Naughton et al (2015) *BMJ Open*

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'This presentation presents independent research funded by the National Institute for Health Research (NIHR) under its Programme Grants for Applied Research Programme (Grant Reference Number RP-PG 0109-10020). The views expressed in this presentation are those of the authors and not necessarily those of the NHS, the NIHR or the Department of Health.'

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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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