prelim-demo

June 11, 2018

1 SYNOPSIS OF STUDY DESIGN AND PROCEDURES

1.1 Analysis Considerations

1.1.1 Types of analysis

We will compare our binary primary outcome; **entry to the smoking cessation service**, between the intervention and control groups. Thus, the proportion of people entering the smoking cessation service (over a period of 6 months from the receipt of the invitation letter) will be reported along with the difference between the intervention and control groups together with a 95% confidence interval. This will be our primary result.

```
Proportion of people entering the smoking cessation service: 0.5056

Difference in means with 95% CI: 0.009333333 ± 0.02829432
```

However, adjustment for baseline covariates is often advised, firstly to correct for any chance imbalances in important baseline variables following randomisation, and secondly, because adjusting for highly important baseline variables in an RCT can improve the precision of treatment effect estimates even when the outcome measure is binary.

Statistical testing for baseline imbalances is not advised and instead key covariates should be selected prior to analysis based on the likely magnitude of the association with the outcome measure (European Agency for the Evaluation of Medicinal Products, 2003).

We will therefore also perform a multivariable logistic regression to take into account any imbalance that may occur in important baseline characteristics known to predict smoking cessation outcomes between the groups: - gender - age - dependence score (cigs per day+time from waking) - intention to quit - determination to quit - longest previous quit - live with smokers - deprivation (IMD score) - previous NHS SSS attendance

Odds ratios will be quoted together with their 95% confidence intervals and exact P-values.

	coefficients	estimate	2.5%	97.5%
(Intercept)	(Intercept)	0.5304440	0.1660724	1.692652
treated	treated	1.0376879	0.9264529	1.162293
gender	gender	0.9737083	0.8713133	1.088122
age	age	0.9975362	0.9919944	1.003105
depscore	depscore	0.9808867	0.8934839	1.076822
intquit	intquit	1.0021600	0.9537233	1.053059
determquit	determquit	1.0023492	0.9636502	1.042604
livesmoke	livesmoke	0.9561738	0.8556823	1.068439
imd	imd	1.0004137	0.9998625	1.000966
prev	prev	0.9544624	0.8541433	1.066537

We will account for the therapist effect (see section 1.10 above), by including the allocated taster session in our model as a random effect nested within the SSS cluster. We have chosen to nest within SSS rather than practice as the therapists were SSS rather than practice based. For the analysis of the 7-day point prevalence abstinence at the 6-month follow-up we will follow the same plan as described above. If cessation shows an effect without attendance then we will examine differences in the pattern of characteristics within each arm.

Unit of analysis considerations In the multivariable analysis we will use following categorisation for the covariate analyses:

- Gender (binary): Baseline questionnaire D4 - male/female
- Age in years (continuous): Baseline questionnaire D6
- Dependence score (continuous score 0-6):

Cigs per day	Score	Time from waking	Score
5	0	>2hrs	0
6 to 10	0	1-2hrs	0
11 to 20	1	31-60 mins	1
21 to 30	2	<30 mins	2
>30	3	<5 mins	3

- Intention to quit (categorical): Baseline questionnaire B4: "Are you planning to quit: within 2weeks/30 days/ 6 months/ not within 6 months?"
- Determination to quit: Baseline questionnaire B9 "How determined are you to quit for good?" Likert scale 1 to 5
- Longest previous quit (categorical): Baseline questionnaire B3: "What is the longest you have ever quit smoking for?" less than 24 hrs/1-6 days/1-4 weeks/> 1 month
- Live with other smokers (binary): Baseline questionnaire D2 yes/no
- Deprivation (measured by IMD score) (continuous)
- Previous NHS SSS attendance (binary): Baseline questionnaire B7 'Have you attended an NHS SSS —-?' yes/no

Effect modification and sub group analyses In order to assess whether the intervention is any more effective for any particular subgroup of smokers we will explore if there is an interaction between treatment and gender, treatment and age, and treatment and deprivation. This will be carried out for the primary outcome (attendance) and 7-day point prevalent abstinence at the 6-month follow-up.

	coefficients	estimate	2.5%	97.5%
(Intercept)	(Intercept)	0.5334440	0.1608458	1.767559
treated	treated	1.0232154	0.6172014	1.696190
gender	gender	0.9312349	0.7812966	1.109846
depscore	depscore	0.9862090	0.8490991	1.145416
age	age	0.9975242	0.9919809	1.003094
intquit	intquit	1.0015919	0.9531518	1.052495
determquit	determquit	1.0023544	0.9636527	1.042612
livesmoke	livesmoke	0.9565514	0.8560103	1.068874
imd	imd	1.0004160	0.9998647	1.000968
prev	prev	0.9545049	0.8541621	1.066608
treated:gender	treated:gender	1.0773891	0.8588824	1.351563
treated:depscore	treated:depscore	0.9906725	0.8180587	1.199722

Timing of analyses Preliminary analyses will be done in January 2014. The final analysis will be done in April 2015.