

1 **Process evaluation**

2 Following MRC process evaluation guidance [1] both qualitative and quantitative data will
3 be collected to assess implementation of the intervention, mechanisms of impact and
4 contextual influences. The specific objectives of the process evaluation are to examine: the
5 views of participants on the intervention; the views of those delivering the intervention on
6 the intervention; study how the intervention is implemented; distinguish between
7 components of the intervention; investigate contextual factors across different sites that
8 affect the intervention; and study the way effects vary in subgroups. Quantitative data will
9 include recruitment and follow-up rates. A qualitative descriptive methodology will elicit in-
10 depth account of views and experiences of both those delivering the intervention and those
11 receiving the intervention.

12

13 **(i) Interviews with trial participants**

14 **Aim of interviews:** To identify barriers and facilitators to trial recruitment and adherence
15 and to explore the acceptability of study processes and procedures.

16 Recruitment and consent

17

18 We aim to recruit ten women from each of the three trial arms, after they have completed
19 the 12-month postpartum follow-up. At the time of recruitment into the trial, all women
20 will be asked by the SSS advisor if they consent to be contacted by a researcher, after the
21 12-month follow-up, who will invite them to be interviewed about their experiences of and
22 views on the trial and intervention. Women who consent to be contacted will be reminded
23 of this if they attend the 12 months follow-up. A researcher will then telephone the woman
24 to answer any questions about the study and to obtain verbal informed consent to be

1 interviewed. The semi-structured interview, lasting up to 30 minutes, can take place at this
2 time or at another more convenient time, with the aim of completing within one month of
3 the 12-month postpartum follow-up.

4

5 **Sample size and purposive sampling**

6 We will aim for a total sample size of 30. Using the 'ten plus three' rule for data saturation, a
7 target of ten participants was set for each of the three trials arms, to achieve a point where
8 three consecutive interviews have been conducted without new themes emerging. As far as
9 possible, within each study group, sampling for interviews will be based on maximum
10 diversity, principally, in relation to quit status (i.e., whether they were abstinent at 3 months
11 and 12 months, abstinent at 3 months but not at 12 months, or not abstinent at 3 months),
12 and also in relation to hospital Trust, age, socio-economic background and ethnicity. We will
13 invite consecutive women who agree to be interviewed until we have achieved the target
14 sample and achieved data saturation.

15

16 **Theoretical framework, topic guides and interviews**

17 The interviews will be conducted via telephone. Although telephone interviews have been
18 criticised for compromising rapport and missing non-verbal cues, they are also thought to
19 allow participants the opportunity to openly disclose sensitive material in a more
20 anonymous manner compared with face-to-face [2]. We have used telephone interviews
21 successfully in previous studies with pregnant and postpartum women and as the interviews
22 were conducted during the COVID-19 pandemic a telephone method presented the most
23 practical option.

1 Interviews will be arranged and conducted by two female qualitative researchers (JM, LM,
2 non-smokers). The interviews will explore study processes and experiences of participating,
3 including reasons for taking part and dropping out, experience of recruitment and
4 randomisation (e.g., expectations and understanding of the study and its aims) and views on
5 the incentives intervention and smoking assessment.

6

7 While allowing participants to speak freely, we will use the Theoretical Domains Framework
8 (TDF) to inform the interview topic guide and data analysis. The TDF defines 14 domains into
9 which all determinants of health behaviour change can be organized (e.g., beliefs about
10 consequences, social influences, goals) [3,4]. When developing the interview topic-
11 guide/questions we will use the TDF to ensure broad coverage of the components that drive
12 smoking cessation. Analysis will also be informed by the Capability-Opportunity-Motivation-
13 Behaviour (COM-B) framework [5].

14

15 The topic guides will be reviewed by two Patient and Public Involvement representatives
16 and by the wider study team. Interviews, will be digitally recorded and transcribed verbatim
17 by professional transcribers. The resulting transcripts will be anonymised. To compensate
18 the women for their time, and as a gesture of thanks, they will be offered £30 in Love2Shop
19 vouchers.

20

21 The interviews will be digitally-recorded and transcribed verbatim by an independent
22 transcriber. The analysis will be both deductive, through being informed by the TDF and the
23 topics chosen for the interviews, and inductive, from the accounts of participants. The
24 analysis will be undertaken in five stages, using a thematic approach [6]:

- 1 (i) Reading the transcripts several times to ensure familiarity with data and identify
2 emerging themes.
- 3 (ii) Development of a coding frame work, which is informed by the TDF.
- 4 (iii) Verification of coding whereby two researchers independently code 10% of randomly
5 selected transcripts from each smoking status group. If coding consistency is suboptimal, a
6 further 10% of transcripts will be independently coded. All remaining transcripts will be
7 coded once coding consistency is satisfactory.
- 8 (iv) Codes will be grouped into clusters that reflect broader themes.
- 9 (v) Discussion within the wider research team will be used to refine, label and interpret the
10 themes and sub-themes.

11 The analysis will be assisted by QSR NVivo (v12) software and the results will be reported
12 according to the consolidated criteria for reporting qualitative research tool [7].

13

14 **(ii) Focus group with stop Smoking Service Managers/Advisors delivering the intervention**

15 **Aims of focus group:** To identify barriers and facilitators to trial recruitment and adherence;
16 to explore the acceptability of study processes and procedures; and to assess contextual
17 influences at different recruiting sites, particularly those influences that might have affected
18 the quality of the implementation of the intervention.

19

20 **Recruitment, consent and sampling**

21 When first joining the study, all SSS advisors who are delivering the trial interventions and
22 managers overseeing the trial at each Trusts, will be given brief information about the focus
23 group. At least 12 months after commencing recruitment, to ensure all the advisors and
24 managers have sufficient experience of the trial, all advisors and managers will be sent a

1 participant information sheet and will be invited to take part in a focus group, lasting up to
2 45 mins. Around 10 individuals will be selected to join the focus group and will give verbal
3 consent. We will aim to include at least two individuals from each of the four Hospital Trusts,
4 and invite advisors with the most experience of recruiting women to the trial and of
5 delivering the interventions.

6

7 **Theoretical framework, topic guides and focus group**

8 The focus group will be arranged and conducted by the same two female qualitative
9 researchers (JM, LM) who conducted the interviews with trial participants. The focus group
10 will explore complementary topics to those presented in interviews with trial participants,
11 including barriers and facilitators to conducting the trial (local capacity, organisational
12 structures and any changes to these); and fidelity to trial processes (recruitment to the trial,
13 information given to patients, training issues). The focus group topic guide and analysis will
14 also be informed by both the TDF and the Normalization Process Model (NPM) [8,9,10]. The
15 NPM is an evaluation model that asks what individuals and organisations do to make a
16 complex intervention workable and to integrate it in routine practice. The NPM addresses
17 how individuals understand and come to engage and support a new practice and how they
18 reflect on and evaluate it. For example, this includes exploration of the following processes
19 the SSS would have to go through in order to routinely embed the intervention: to fully
20 understand the nature of the incentives intervention and how it works, to engage other
21 stakeholders (e.g., maternity services) with the intervention, the work the SSS will have to
22 undertake to enact the intervention, and the evaluation of the intervention and its impact.
23 Within the umbrella of this model, focus group topics will include: the need for co-operative
24 work practices, accountability, allocation and evaluation of work tasks, the link between

1 work related to the incentives intervention and existing organisational structures,
2 procedures and interventions and the need for allocating and organizing resources in order
3 to integrate the intervention into routine SSS practice.

4

5 The focus group will be digitally-recorded and transcribed verbatim by an independent
6 transcriber. The resulting transcripts will be anonymised. The analysis will be both
7 deductive, through being informed by the TDF and NPM and the topics chosen for the focus
8 group, and inductive from the accounts of participants. The analysis method will be the
9 same as for the interviews with trial participants, except the coding framework will be
10 informed by the NPM as well as by the TDF.

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