Process evaluation

Methods

At each centre, the research assistant will record both ethnographic observations and more structured observations using a checklist at weeks 3-4, to assess geographical and local context, fidelity of delivery, quality and consistency of the intervention as delivered by staff. Content of staff discussions with trial participants will be recorded against the trial protocol to observe any deviations. Given the importance of EC training for intervention delivery we will also explore perceived adequacy of training through staff evaluation forms and during staff interviews conducted at weeks 4-8 (see below). The observations and training evaluation forms will help identify any early issues to be resolved.

Mechanisms of change and mediators of the outcome (and participant engagement with the intervention) will be explored quantitatively via measures inserted in baseline and follow-up questionnaires and qualitatively via semi-structured interviews with staff (n=16) and participants (n=32) between weeks 4-8 (staff) and 12-24 (participants). Questions (PPI informed) inserted into participant baseline and follow-up questionnaires will help inform understanding of hypothesised intervention mechanisms in operation and will, for example, this will include questions on thoughts and attitudes to EC including participants’ expectations about EC, confidence in EC as a stop smoking tool and perceived relative risk compared with smoking. Conducting semi-structured face-to-face interviews with participants in the EC arm of the trial between weeks 12 and 24 will allow for longer-term development of the mechanisms of change (see logic model). We will purposively sample 8 centres (4 England, 2 Wales, 2 Scotland) within which to conduct the interviews according to factors such as centre size (i.e. number of daily attenders), types of service provision, staffing and location (i.e. urban/rural if relevant). Within each centre we will speak with approximately four participants (n=32) sampled according to vaping/smoking status at week 12. Efforts will be made to conduct interviews with those who haven’t completed the week 12 follow-up or who have withdrawn from the study. We will aim for a varied sample in terms of sex, age and ethnicity. Semi-structured telephone interviews with staff in the EC arm between weeks 4-8 will focus on context, perceptions of EC training and intervention sustainability, and mechanisms of change. These interviews will be conducted within the same eight centres identified for the participant interviews and will be conducted by telephone (or online, depending on staff interviewee preference) by researchers not involved in training delivery or data collection at the same centre to reduce social desirability bias. We will aim to recruit one service manager and one other staff member involved in intervention delivery at each of the sites (n=16). To focus on sustainability, geographical context and pathways to future implementation/roll out we will hold three workshops, each with around six decision makers (n=18) in each of the three countries. At each semi-structured workshop, we will i) present a balanced overview of current findings, ii) discuss sustainability and context and iii) co-produce recommendations for pathways to implementation. Participants will include those responsible for deciding whether EC could be provided in homeless centres in the future (e.g. commissioners, homeless charity directors, NHS board).

*Data analysis*

Qualitative data from participant and staff interviews will be transcribed verbatim and analysed using thematic analysis with deductive and inductive approaches. Analysis will be conducted drawing on a Critical Realist approach, including pre-defined themes from the intervention logic model with specific focus on: contextual influences; implementation of the intervention; mechanisms of change, as well as including themes emerging from the data. A selection of transcripts will be reviewed to develop a coding framework based on emerging themes. Independently, two researchers will code 10% of transcripts, then a further 10% if coding consistency is suboptimal. Remaining transcripts will be systematically coded into themes using an iterative approach. Coded themes will be refined and interpreted by the research team until consensus is reached. Coding and analysis will be aided by qualitative analysis software, NVivo12.

Exploration of service level context will be descriptively recorded via ethnographic observations A structured observation sheet will be developed to ensure that domains including ‘culture’ of the organisation, size and structure of the organisation, staffing and physical space, are fully described. The observations will also encourage researchers at site level to track changes over time, such as local or national policy changes that may impact service delivery. The contextual descriptive data will be examined alongside other process evaluation data to fully inform the impact of centre level organisational factors on intervention delivery, and ultimately to demonstrate how service level context may impact outcomes.

Fidelity of staff delivery of the intervention will be assessed by ethnographic and structured observation and staff research evaluation forms. Where possible, quantitative assessment will use tick box metrics relating to sessions’ objectives and key outcomes for activities. Open ended responses from forms and researcher’s reflective observational field notes will be extracted and analysed thematically. This qualitative data will be combined with descriptive statistics from the structured forms to assess fidelity of intervention implementation. This data will also be combined thematically with the staff and participant interview data to explore how organisational (i.e. service-level) and geographical context influences intervention implementation in line with Research Question 2.

Process measures inserted into baseline and 12- and 24-week service user follow-up questionnaires will help to explore intervention mechanisms. These measures will be extracted from the main analysis during outcome evaluation, and descriptive statistics will be provided to the process evaluation team. This quantitative data will be combined with relevant qualitative data from staff and participant interviews to answer Research Question 3.

Workshops will be digitally recorded, written observational notes will be taken, and any flip charts/notes generated by participants will be photographed. The resulting workshop data will be examined in line with Research Question 4 with a particular focus on the barriers and facilitators to potential roll-out of the intervention and intervention sustainability. The final workshop outputs will be revised ‘pathways to implementation logic models’ for each country. These will be prepared and checked with workshop participants for consensus and then shared with service users and staff at the charities that have taken part for their comments and feedback.

The process evaluation data will not aim for triangulation but for integration, with each dataset providing additional insights that will be combined for a fuller understanding of how contextual influences, implementation processes and intervention mechanisms contribute to outcomes.