

Cessation of Smoking Trial in the Emergency Department



THE COSTED TRIAL
SWITCHING AWAY FROM SMOKING



**Process evaluation – lessons
for implementation**



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on behalf of the COSTED team

Process Evaluation: aims and methods



Aim: ‘To undertake an embedded process evaluation to assess delivery, implementation, fidelity and contamination.’

Methods:

- Trial questionnaire data
- Ethnographic site observations (x6 sites)
- Interviews with smoking cessation advisors across sites
- Participant qualitative interviews
- Thematic analysis and triangulation of data sources



Interview samples



**Participant interview sample:
n=34**

	Interview sample (n=34)
Site	
Site 1	12
Site 2	6
Site 3	6
Site 4	3
Site 5	5
Site 6	2
Sample group	
Intervention	24
Control	10
Gender	
Male	20
Female	14
Age (years)	
Mean (range)	44 (20-70)
Ethnicity	
Asian Bangladeshi	2
Asian Other	1
Black British	1
Black Caribbean	2
White British	23
White Eastern European	2
White Other	1

**Staff (COSTED adviser) interview sample:
n=11**

Site	Advisor
Site 1	2: (1xResearch nurse; 1xHealthcare Assistant)
Site 2	2 (Research nurse)
Site 3	1 (Research nurse)
Site 4	2 (2x Clinical Research Assistant)
Site 5	2 (Research Nurse)
Site 6	1 (Research Nurse)



Context and implementation: adaptability



- Contextual and implementation differences observed across sites
- Similar rates of cessation outcome across sites
- Flexible adaptations were fundamental to ensuring successful intervention delivery



Context: adaptability dimensions



1. Working within patient pathways
2. Finding space for intervention delivery
3. Flexible use of the intervention manual

The needs of the department always take precedence. You adapt to suit that....People are quite accepting of starting here but moving to here to finish things
[adviser]

Context: response to approach



- Patient response to approach could vary
- Long waiting times could facilitate acceptability and engagement
- Distraction from pain and alleviation of boredom could motivate participation

I was kind of focused on like the pain in my knee and [the intervention] helped to distract me. It helped to waste time, I really didn't mind getting approached in that way. [Participant]

I felt whilst going round patients, there were two main schools of thought...some [said] 'yes, I've been sitting here thinking about I should quit'. The other school of thought is 'I'm in so much pain, I'm waiting for someone to call me. I don't even want to think about that right now' [Adviser]

Context: staff 'buy-in'

- Observations and interviews showed extremely good commitment and 'buy in' from COSTED advisers.
- Variable reaction from other ED staff:
 - support (e.g. referring patients to trial)
 - resistance (e.g. viewed the intervention as an obstruction)

The doctors that did call are the ones that were really interested in stop smoking...that comes down to the training that they've got [adviser]

Mechanisms of impact:
Participant responses to and interactions with the intervention



OPPORTUNITY:

“Right time, right place”:

- receipt of the intervention at a time of heightened health awareness - a frame of mind to contemplate change

People are feeling perhaps more vulnerable when they're sitting in A&E. They're more aware of their own mortality, else they wouldn't be there.
[participant]

Mechanisms of impact: Participant responses to and interactions with the intervention



OPPORTUNITY:

“I don't think I would have approached anybody otherwise”:

- opportunistic engagement of hard-to-reach or low-motivated smokers, who may not have actively sought support.

I wouldn't just go out myself and look for somebody to [help] I wouldn't know where to start really. It was very helpful, someone coming to me and putting that idea in my head.

[participant]

Mechanisms of impact: Participant responses to and interactions with the intervention



CAPABILITY:

“I was unsure about using e-cigarettes”

- provision of reassurance about and direction on use of e-cigarettes
- delivered from a credible source within a healthcare setting

I was really unsure about vaping...it changed my mind because the hospital told me to start using one.

[participant]

Mechanisms of impact: Participant responses to and interactions with the intervention

MOTIVATION:

“It was the kick start I needed”:

- the style of intervention, and provision of an e-cigarette starter kit gave motivational and practical impetus to change

It made me realise. Gave me a little bit of a nudge... instead of saying ‘Go and buy this’ and then you don’t buy it. If you’ve got it, then most people will actually try it and I do like it.
[participant]

Mechanisms of impact: Participant responses to and interactions with the intervention



SUPPORT:

“Somebody cares and it's a nice feeling”:

- The advice received was described as caring, positive and ‘non-preachy’

When they asked the question of ‘Do you smoke?’ usually, that’s down to being judgmental and it wasn’t...I felt with the study, someone came to me, not to judge me. They came saying look, there is a possible solution

[participant]

Barriers to impact



- Some participants' quit attempts faltered because of limited product availability, suggesting a need for follow-up direction.
- Others reported trying the vape but finding it ineffective
- Referral to local stop-smoking services, an intervention component, was rarely taken up, indicating an important role for alternative approaches to ongoing support.

Unintended consequences: Control group and contamination



- Provision of advice to control about e-cigs or encouragement to contact stop smoking services
- Control reporting that participation increased awareness of smoking could prompt action
- Control participants switching to vaping directly because of participation

A mixed methods study of the impact of being a control participant, receiving 'usual care' as part of the COSTED smoking cessation trial
Lucy Clark, Caitlin Notley, Pippa Belderson, Emma Ward, Allan Clark, Sue Stirling, Ian Pope

BACKGROUND
• Being recruited to a randomised trial (RCT) of a smoking cessation intervention as a control participant inevitably involves questions on smoking behaviour.
• Trial assessments, and the accompanying interaction with the research team may inadvertently act as a trigger for behaviour change potentially creating bias in trial outcomes.

AIM
To evaluate the impact of being a control participant in an emergency department (ED) based smoking cessation trial on: motivation to quit, engagement with smoking cessation tools and incidence of smoking cessation.

METHODS
As part of the COSTED trial, 502 control participants were recruited at 6 UK EDs. All participants consented and completed baseline questionnaires and a carbon monoxide (CO) breath test. Following randomisation, control participants were provided, by the recruiting site staff, with information on how to contact Stop Smoking Services (SSS) local to the hospital. Participants were followed up 1, 3 and 6 months after randomisation. Semi-structured interviews were conducted with a purposive sample of 10 control participants and analysed using thematic analysis.

RESULTS
• Self-reported 7-day abstinence at 6-months was higher at all time points (see Table 1) than the quit rate in the overall UK population (9% at one year)¹.
• Mean motivation to quit did not change from baseline (3.98) to 6-months (3.96) period in those who reported still smoking.
• 13.8% of participants reported seeking support to quit smoking during their time in the trial versus 10.5% in those receiving the intervention.
• Many of those interviewed reported that taking part in the trial influenced their behaviour (see quotes to the left), indicating participating in such a trial could be a trigger for change for control participants.

CONCLUSIONS
Control participants in the COSTED trial received some dose of an intervention by entering the trial, with some going on to seek support to quit. This could have resulted in a higher quit rate at 6-months than if they had not been involved in a trial, which is supported by the participant interviews. The effect size of the smoking cessation intervention may be underestimated. Entering a trial, even as part of the control group, impacts smoking cessation, which suggests that even simply mentioning stopping smoking in a clinical environment can be a positive trigger for change.

TABLE 1: Self-reported 7 day abstinence

Reported 7 day abstinence (n = 502)	Quit smoking	Still smoking*
1 month	51 (10%)	451 (90%)
3 months	60 (12%)	342 (88%)
6 months	66 (13%)	436 (87%)

* Non responders counted as still smoking

I was really unsure about the vape until I was in hospital. When they suggested it, I thought great...if someone in hospital is offering to put you on that, it's got to be better than smoking. I left the hospital and I thought no, I'm going to try it. I went and I bought a vape and honestly, I've never looked back.

It did encourage those sort of thoughts again to think, I really should stop...it really it just flagged that I was still doing it and that maybe I should think about a way of not doing it. So, and yeah in that regard, talking about it, and there was a longer questionnaire that followed, I think they have made me think about it more, more deeply.

Just because having spoken to the people in A&E, it gave me the motivation to do it...I think it was when I did the (CO) breath testing and it was really high. I was like, OK maybe I do need to do something about it.

So yeah, it (taking part in the trial) just prompted me to switch from cigarettes and to start the process of giving up smoking.

It made me more conscious of my smoking. It just made me realise that I'm coming to an age as well where I should be stopping smoking now for not only just because of my illness, but for my health in the long run.

Scan the QR code to download the COSTED trial protocol paper

Unintended consequences: indirect impacts



Questionnaire data (n=315 responses) indicates that *directly because of their participation in the intervention*:

- 58 (18%) participants reported that family or friends had **started dual using**.
- 38 (12%) participants reported that family or friends had **quit smoking and switched to vaping**.



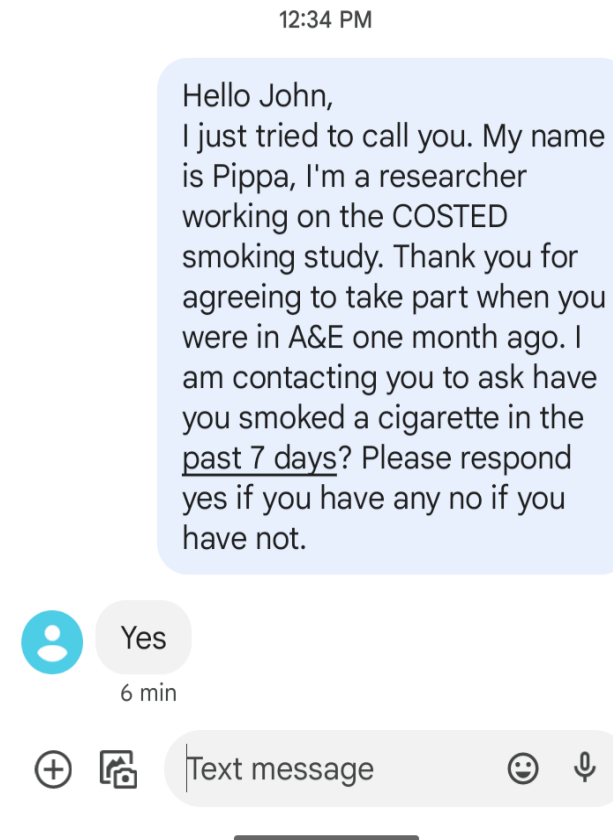
*My mum ended up
buying a vape because
of it...and she's found it
helpful
[participant]*

Unintended consequences: follow up contact



- Further contacts were for follow up purposes, not part of the intervention
- However, participants from both trial arms described follow up contacts as motivational

When I've seen the [follow up] text, ...It has made me a lot more conscious or aware of how much I smoke and trying to change my brain to cut it out.
[participant]



Thank you



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