

**Does use of 'non-trial' cessation support help explain the lack of effect from offering NRT to quitline callers in a RCT?**

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## **INTRODUCTION**

Quitlines help smokers to stop but few studies have explored how behavioural and medicinal interventions can be optimally delivered via this route [1]. One of these was the PORTSSS trial, which found that offering free Nicotine Replacement Therapy (NRT) vouchers did not increase cessation rates when compared to no offer [2]. It also found that a 'proactive', more intensive, call regime from/to clients did not improve cessation rates over 'usual care'. Was it possible that participants who did not receive a voucher for NRT, sought out and used other forms of cessation support, which minimised any effect of receiving the NRT voucher? Use of 'non-trial' support varied across PORTSSS trial intervention groups and, in this analysis, we sought to determine whether or not use of this substantially affected trial findings.

## **METHODS**

Our secondary analysis included all 2591 randomised participants of the PORTSSS trial. PORTSSS was a RCT of an English, government-funded quitline, comparing two forms of behavioural support, with and without the offer of a free NRT voucher using a parallel group, factorial 2x2 design. Non-trial support used by participants included (n; %): 'over the counter' NRT (498; 19.2%), NRT from health professionals (479; 18.5%), bupropion (37; 1.4%), varenicline (165; 6.4%), NHS stop smoking service support (125; 4.8%), NHS one-to-one therapy (221; 8.5%) and non-NHS quitline (40; 1.5%); any support (978; 37.7%). Binary variables were created for each support type with recipients coded as 1 and non-recipients, 0. We used the same multivariable regression model as in the original trial analysis with the effect of treatment group adjusted for age, gender, age of finishing education, and heaviness of smoking, and then additionally adjusted for each of the binary indicators of use of non-trial support to assess whether this altered the effect of treatment.

## **RESULTS**

Comparison of the two adjusted models (Table 1) shows little difference to the trial findings with respect to the primary outcome, prolonged cessation at 6 months (trial model OR 0.86, 95% CI 0.7-1.06; additional model OR 0.84, 95%CI 0.66-1.07) or any of the secondary outcomes, irrespective of whether self-reported or validated smoking outcomes are used.

## **DISCUSSION**

To our knowledge, this is the first analysis to investigate the effect of additional cessation support on the impact of free NRT provision from a quitline. The findings suggest that use of such support does not explain the negative PORTSSS trial findings with respect to NRT. We have identified only one other paper investigating associations between quitline outcomes and use of other forms of support [3]; it found that smokers who had used other types of cessation support prior to quitline enrolment, were more likely to subsequently stop smoking with quitline help. Little is known about the relative contributions of quitline and non-quitline support to smoking cessation; monitoring and evaluating the relationship of 'non-trial' cessation support to outcomes in future quitline studies is important.

## **Acknowledgement**

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## **Contributors**

GD conducted the analysis and led writing of the manuscript. TC assisted with the study design, and advised on the analysis. SL supervised the analysis. All authors were involved in the review of the manuscript prior to submission.

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### **Competing interests**

Tim Coleman has, within the last 5 years, spoken at a two conferences which were organised and funded by Pierre Fabre Laboratories, a company which manufactures NRT products. He has also advised a Public Relations company on the (lack of) evidence for using Nicobloc as an aid for smoking cessation.

Andy McEwen receives a personal income from Cancer Research UK via University College London. He has received travel funding, honorariums and consultancy payments from manufacturers of smoking cessation products (Pfizer Ltd, Novartis UK and GSK Consumer Healthcare Ltd) and hospitality from North51 who provide online and database services. He also receives payment for providing training to smoking cessation specialists; receives royalties from books on smoking cessation and has a share in a patent of a nicotine delivery device.

Linda Bauld is vice-chair of the Cancer Research UK Tobacco Advisory Group and serves as Scientific Adviser to the Department of Health on tobacco control.

Graeme Docherty and Sarah Lewis have no conflicts of interest to declare.

All authors have completed the ICMJE uniform disclosure form at [www.icmje.org/coi\\_disclosure.pdf](http://www.icmje.org/coi_disclosure.pdf) (available on request from the corresponding author) and declare: no support from any organisation for the submitted work; no

financial relationships with any organisations that might have an interest in the submitted work in the previous three years; and no other relationships or activities that could appear to have influenced the submitted work.

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**Table 1: Smoking cessation outcomes in relation to Nicotine Replacement Therapy**

	<b>Total</b> <b>N=2591</b>	<b>No NRT</b> <b>N = 1296</b>	<b>NRT</b> <b>N = 1295</b>	<b>Unadjusted OR</b> (95% CI; p value)	<b>Adjusted OR*</b> (95% CI; p value)	<b>Adjusted OR**</b> (95% CI; p value)
<b>Outcomes at 6 months n (%)</b>						
Prolonged cessation (inc. questionnaire data) (Primary outcome)	490 (18.9%)	261 (20.1%)	229 (17.7%)	.85 (.70, 1.04; p = 0.11)	0.86 (0.70, 1.06; P = 0.16)	0.84 (0.66-1.07; p = 0.17)
CO Validated prolonged cessation	207 (8.0%)	122 (9.4%)	85 (6.6%)	.67 (.50, 0.90; p = 0.008)	0.65 (0.48, 0.88; P = 0.005)	0.63 (0.45-0.86; p = 0.004)
Self-reported cessation for >= 7 days	531 (20.5%)	283 (21.8%)	248 (19.1%)	.85 (.70, 1.03; p = 0.09)	0.85 (.70, 1.04; p = 0.13)	0.85 (0.67-1.07; p = 0.17)
CO Validated cessation for >= 7 days	200 (7.7%)	119 (9.2%)	81 (6.2%)	.66 (.49, .88; p = 0.006)	0.64 (0.47, 0.87; P = 0.004)	0.62 (0.45-0.86; p = 0.004)
Reported cessation for >= 3 months	401 (15.5%)	216 (16.6%)	185 (14.3%)	.83 (.67, 1.03; p = 0.09)	0.84 (0.67, 1.05; P = 0.14)	0.86 (0.66-1.10; p=0.23)
Reports one or more quit attempts lasting > 24 hrs**	594 (22.9%)	289 (22.3%)	305 (23.5%)	1.07 (0.88-1.28; p=0.49)	1.05 (0.86-1.27; p=0.60)	1.15 (0.88-1.50; p = 0.30)
Median (IQR) no. quit attempts reported	2 (1-3)	2 (1-4)	2 (1-3)	n/a	n/a	n/a
<b>Outcomes at 1 month</b>						
Prolonged cessation since quit date	1040 (40.1%)	520 (40.1%)	520 (40.1%)	0.99 (.85, 1.16; p = 0.93)	1.01 (0.86, 1.19; P = 0.88)	1.00 (0.80-1.26; p = 0.96)
Reported cessation for >= 7 days	831 (32.0%)	417 (32.2%)	414 (32.0%)	.98 (.83, 1.16; p = 0.85)	0.99 (0.84, 1.18; P = 0.97)	0.97 (0.77-1.22; p=0.80)

\*Adjusted for age, gender, educational level and heaviness of smoking index; 2397 cases included in adjusted analyses.

\*\* Additionally adjusted for all forms of non-trial support.

