

# Exploratory analyses of the popularity and efficacy of four behavioral methods of gradual smoking cessation

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## Implications

There is evidence that people who would like to quit smoking gradually should be supported to do so. However, as this is relatively new thinking and there is large potential for variation in methods, guidance on the best way to offer support is sparse. This paper is an exploratory analysis of the popularity and efficacy of various methods in an attempt to move the topic forward and inform the implementation of gradual smoking cessation methods in practice. The identified popularity of some methods over others signposts directions for future research.

## Abstract

### Introduction

Around half of smokers attempt to stop by cutting-down first. Evidence suggests this results in similar quit rates to abrupt quitting. Evidence for the effectiveness and popularity of different gradual cessation methods is sparse.

### Method

Secondary, exploratory, analyses of a randomized trial of gradual versus abrupt smoking cessation. Gradual participants (N=342) chose between four methods of cutting-down over two weeks: cutting-out the easiest cigarettes first (HR-E); cutting-out the most difficult cigarettes first (HR-D); smoking on an increasing time schedule (SR); and not smoking during particular periods (SFP). Nicotine replacement therapy and behavioral support were provided before and after quit day. We used logistic and linear regression modelling to test whether method chosen was associated with smoking reduction, quit attempts, and abstinence, whilst adjusting for potential confounders.

### Results

Participants were on average 49 years old, smoked 20 cigarettes per day, and had an FTCD of 6. 14.9% (51/342) chose HR-E, 2.1% (7/342) HR-D, 46.2% (158/342) SFP, and 36.8% (126/342) SR. We found no evidence of adjusted or unadjusted associations between method and successful 75% reduction in cigarette consumption, reduction in percentage cigarettes per day or exhaled carbon monoxide, quit attempts, or abstinence at four-week or six-month follow-up.

### Conclusions

Future research and practice could focus more heavily on the SR and SFP methods as these appeared notably more popular than HR. There was substantial imprecision in the efficacy data, which should be treated with caution; however none of the gradual cessation methods showed clear evidence of being more efficacious than others.

## Introduction

Approximately half of smokers attempting to stop choose to gradually cut-down the amount they smoke before quitting completely.<sup>1,2</sup> However, healthcare guidance generally only advises that patients are supported to quit abruptly, by stopping all at once, on a 'quit date'. A recent Cochrane Review meta-analysed 22 studies (9219 participants) comparing gradual with abrupt cessation, and found moderate certainty evidence that neither approach resulted in superior quit rates.<sup>3</sup> This suggests that smokers could be supported to quit gradually, particularly if they have failed to quit abruptly in the past, or do not feel confident enough to do so. This support could encourage people who would not otherwise have attempted quitting to make an attempt, boosting population quit rates.

Evidence on the best ways to operationalize gradual cessation is sparse. The Cochrane Review provided a summary of gradual cessation methods implemented in randomized controlled trials (RCTs).<sup>3</sup> In some cases participants were simply asked to reduce before quitting with no specific guidance. More structured methods included setting a quit date to work towards, with advice to reduce over a period varying between one week and 18 months. Some participants were advised to reduce until they were smoking no cigarettes, whereas others were advised to reduce by a certain amount (e.g. 75%) before stopping altogether. Structured methods could be split into two types; those that focused on reducing the number of cigarettes smoked per day, and those that identified particular situations to stop smoking in, such as at home or at work. This approach focused on reducing time in the day when a person could smoke, and is sometimes known as smoke-free periods reduction. Some studies in the review advised participants to replace their cigarettes with a form of smoking cessation pharmacotherapy (e.g. nicotine replacement therapy, varenicline, bupropion) whilst trying to reduce, and there was some evidence that using fast-acting nicotine replacement therapy (NRT), such as gum or lozenges, or varenicline, whilst reducing consumption resulted in higher quit rates than other types of cessation medications or no medication. There was also evidence that providing smokers with behavioral support for gradual cessation was more effective than providing them with self-help materials only. The evidence comparing the use of any particular behavioral gradual cessation method over another was not sufficiently strong to draw firm conclusions,<sup>3</sup> however some individual studies have provided indications that different reduction methods may result in different rates of efficacy.<sup>4</sup> As successful smoking reduction has been found to predict subsequent cessation, it is possible that if the method of reduction used influences the success of smoking reduction this may also influence subsequent quitting success.<sup>5,6</sup>

This paper presents data from the Rapid Reduction Trial (RRT), a large RCT of abrupt versus gradual smoking cessation methods.<sup>7,8</sup> Unlike the Cochrane Review<sup>3</sup>, this trial found that abrupt was superior to gradual cessation<sup>7</sup> and the differences between the results of this trial and others is explored elsewhere.<sup>9</sup> Participants randomized to gradual cessation were provided with a choice of four different behavioral reduction methods. This paper provides a secondary analysis of data from this trial to explore the popularity and efficacy of these four methods of gradual cessation. This information could be beneficial when deciding which gradual cessation methods to pursue in future empirical testing and healthcare implementation. The data could also be used to inform the design of further related research.

## Methods

RRT recruited adult tobacco smokers willing to make a quit attempt in two weeks' time, who smoked at least 15 cigarettes or 12.5 grams of loose-leaf tobacco daily or who had an expired carbon monoxide (CO) concentration of at least 15 parts per million (ppm), and had no

contraindications to the use of NRT. Participants were recruited through primary care in Birmingham, Bristol, London and Nottingham, UK, and randomized to either a gradual (N=342) or abrupt trial arm (N=355). Participants set a quit day two weeks after enrolment, and the intervention differed between groups only during those first two weeks. Participants were provided with regular face-to-face behavioural support throughout the study, until eight weeks after their quit day. The pharmacotherapy offered was identical in both groups from quit day onward and consisted of 21 milligram per day nicotine patches, plus fast-acting NRT of the participant's choice (e.g. nicotine gum or lozenge). Further methodological details are published elsewhere.<sup>8</sup>

Participants randomised to gradual cessation were able to choose between four different behavioural, reduction methods: hierarchical reduction-difficult (HR-D); hierarchical reduction-easy (HR-E); scheduled reduction (SR); or smoke-free periods (SFP). Each approach was described to participants by the nurse at their baseline appointment and they specified which one they would like to choose at that point. All participants were asked to reduce their baseline smoking consumption by 50% in week one, and by a total of 75% by the end of week two, before quitting completely. During those two weeks participants were provided with nicotine patches and fast-acting NRT to use whilst still smoking.

Participants using both hierarchical reduction method were asked to classify each of the cigarettes they would usually smoke in a day as either habitual or particularly rewarding. HR-D participants were then advised to stop smoking their most rewarding cigarettes first, and HR-E participants to stop smoking their least rewarding cigarettes first. Participants using the SR method were provided with an individualised baseline inter-cigarette interval, which was calculated by dividing a participant's waking hours by their average number of cigarettes per day (cpd); for example, where a person had 16 waking hours in a day and smoked 16 cpd the resulting inter-cigarette interval was one hour. To achieve a 50% reduction in consumption in week one, inter-cigarette intervals were doubled (e.g. to two hours). Participants were advised to smoke at each inter-cigarette interval whether or not they wanted to. If they could not smoke at that time the cigarette was missed and the next opportunity to smoke took place at the next inter-cigarette interval. Unlike the other methods, participants using the SFP method did not focus on reducing cpd and instead identified the times during the day when they would typically smoke (their smoking periods), and then concentrated on gradually eradicating 75% of these. In their remaining smoking periods participants could smoke as much as they wanted, but committed to not smoking outside these periods. All participants worked with a nurse to plan an individualised schedule designed to reduce their smoking (See Supplementary Material).

For this analysis we categorised participants in the gradual cessation arm according to which of the four reduction methods they chose. We used this data to establish the popularity of each method. We then compared participant baseline characteristics across the four groups. We used logistic and linear regression modelling (for categorical and continuous variables respectively), using IBM SPSS Statistics 25,<sup>10</sup> to examine whether the following efficacy outcomes differed by reduction method:

- CO-validated (<10 ppm), prolonged smoking abstinence at four-week follow-up (primary outcome)
- CO-validated (<10 ppm), prolonged smoking abstinence at six-month follow-up
- quit attempts lasting 24 hours or more
- achievement of reduction target (75% reduction in cpd)

- percentage pre-quit cpd reduction;
- percentage pre-quit CO reduction

Abstinence was defined according to the Russell Standard,<sup>11</sup> allowing a two-week grace period and assuming those lost to follow-up were continuing smokers. For all other outcomes those lost to follow-up were also assumed to have not made the desired behaviour change, i.e. no quit attempt, less than 75% reduction in cpd, or 0% change in cpd or CO. As well as the predictor variable – reduction method – the following potential confounding baseline variables were entered into the model: age, gender, ethnicity, education level, employment status, age started smoking, cohabitation with another smoker, number of previous serious quit attempts, cpd, exhaled CO, Fagerstrom Test for Cigarette Dependence (FTCD),<sup>12</sup> preference for abrupt versus gradual quitting, confidence in quitting.

## Results

The least popular reduction method was HR-D (7/342; 2.1%), followed by HR-E (51/342; 14.9%), SR (126/342; 36.8%), and SFP (158/342; 46.2%).

Participants were equally split between males and females, on average 49 years old, smoked 20 cpd, had made two previous serious quit attempts and had an FTCD score of 6, indicating high dependence. Most participants (93.5%) described their ethnicity as "white." (Table 1). Baseline characteristics were similar across the self-selected groups, with only level of education differing substantially; a lower percentage of participants in the HR-D group had a post-secondary school educational qualification.

No association between chosen reduction method and any of the outcome measures was found, both before and after adjusting for potential confounders (Table 2). Absolute rates gave some indication of fewer quit attempts and less abstinence in participants who chose HR-D but these trends were non-significant.

## Discussion

HR-D was by far the least popular reduction method, and SFP the most popular, closely followed by SR. For this group of participants, who were asked to use NRT as a cessation aid and to reduce their smoking to gradually quit within two weeks, there was no evidence of an association between reduction method and adherence to the 75% reduction target, percentage reduction in pre-quit cigarette consumption and CO levels, the number of quit attempts made or short- or long-term smoking abstinence. The point estimates suggested little evidence of a difference between the three most popular methods, but there was imprecision so that modest differences could not be excluded.

Evidence from interviews with RRT participants randomised to gradual cessation suggested that participants chose their reduction method based on how well it would fit-in with their lifestyle.<sup>9</sup> Participants who chose the SR and SFP methods reported doing so because they seemed simplest. Participants who chose HR-E over HR-D said that they had done so because cutting-out the harder cigarettes first seemed daunting. One participant suggested that eliminating the easier cigarettes first got the *“mind and body working to get rid of the harder ones”*. Some participants questioned whether the SFP method was actually a reduction method, as they felt it may still be possible to smoke their usual amount in the available smoking periods. This may be why it was such a popular method. However, even though some participants did say that they smoked more than usual in their remaining

periods, they recognised this issue and tried not to do so. This was reflected in the average cpd reduction in the SFP group (37.9%, sd 37.2), which was the greatest reduction observed across groups.

The average reduction rates across methods presented in this paper differ from those reported in the paper reporting the primary analyses from this trial.<sup>7</sup> This is because in this case we assumed those missing at follow-up had not changed their behaviour and had reduced by 0 cpd (a common approach in smoking cessation research<sup>11</sup>), whereas in the aforementioned primary paper we carried out a complete case analysis. These two different approaches were adopted to best suit the needs of the different analyses.

Our findings support evidence from the Cochrane Review examining smoking reduction for smoking cessation,<sup>3</sup> which found no evidence that gradual cessation methods aimed at reducing cpd resulted in superior quit rates to methods aimed at reducing smoke-free periods. However, these findings were limited substantially by indirectness, imprecision and risk of bias. The results of this analysis should also be treated with caution. First, the methods offered to participants had very specific design elements, such as the relatively short two-week reduction period and the 50% and 75% recommended reduction thresholds. Variations on these design features may influence the replication of these results. Similarly, any variation in participants' NRT use across groups could have been a confounding factor. NRT adherence was not controlled for in this analysis as it would be impossible to know whether variations in NRT use were as a result of differing participant characteristics or because participants abandoned their quit attempt and NRT use as a result of an unpopular or ineffective method. It is also possible that participants did not actually follow the method that they originally chose throughout the duration of the pre-quit programme and that they chose to attempt to quit in a different way. However, the support provided to participants in this study was intensive and participants developed their reduction strategy with a nurse using study specific materials tailored to each reduction approach (See Supplementary material). At each weekly visit they discussed the plan going forward, and in weeks -1 and 0 how well the plan had gone the previous week. We believe that this will have minimised the likelihood of participants switching between quitting methods during the pre-quit period, but this is not impossible.

In addition, participants were not randomly allocated, and instead chose their reduction method. Analysis suggests that this choice was random with respect to other predictors of achieving abstinence such as dependence measures, and we adjusted for these differences in any case. Nevertheless, lack of balance of unknown predictors cannot be excluded. There was some imprecision in the estimates, meaning that modest differences in effectiveness could have been missed. As HR-D was chosen by so few people, estimates for this method were very imprecise. However, the fact that participants could choose their preferred method could also be seen as a positive aspect of this research, as it has allowed us to assess which gradual cessation approaches may be the most useful to test and adopt in the future.

Although our analysis suggests that there is no difference in the efficacy of the four smoking reduction to quit methods, and thus does not provide evidence that any method should be offered in favour of the others on these grounds, issues with statistical power limit our confidence in this result. However, the lack of popularity of the HR methods suggest that future research and implementation could focus more heavily on the SR and SFP methods as these are more appealing to smokers. These findings are particularly important in focusing research and practice in healthcare systems where there are limited health professional

training resources available. The relative efficacy and mechanisms of action of the SR and SFP methods should be tested in an adequately powered, well-designed RCT, taking into account interim outcomes, such as attendance for quit day support and making a quit attempt. The efficacy of other characteristics of gradual cessation methods should also be investigated further to inform healthcare training and guidance.

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### Declarations of Interest

NL, SM, and PA report no known conflicts of interest.

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Table 1: Baseline characteristics and pre-quit NRT use split by group

Participant characteristic	Total (N=342) <sup>a</sup>	HR-D (N=7) <sup>a</sup>	HR-E (N=51) <sup>a</sup>	SFP (N=158) <sup>a</sup>	SR (N=126) <sup>a</sup>
Age, median (IQR)	49.0 (17.3)	56.0 (32.8)	53.0 (15.5)	49.0 (17.0)	48.0 (20.0)
Male gender, n/N (%)	175/342 (51.2)	4/7 (57.1)	26/51 (51.0)	77/158 (48.7)	68/126 (54.0)
White ethnicity, n/N (%)	319/341 (93.5)	7/7 (100.0)	49/51 (96.1)	142/158 (89.9)	121/125 (96.8)
Post-secondary school (15/16y) educational qualification, n/N (%)	159/330 (48.2)	1/7 (14.3)	32/50 (64.0)	72/153 (47.1)	54/120 (45.0)
In paid employment, n/N (%)	190/340 (55.9)	4/7 (57.1)	31/51 (60.8)	93/157 (59.2)	62/125 (49.6)
Age started smoking (y), median (IQR)	16.0 (3.0)	18.5 (4.0)	17.0 (4.0)	16.0 (4.0)	16.0 (3.0)
Lives with smoker, n/N (%)	116/335 (34.6)	2/7 (28.6)	15/51 (29.4)	58/156 (37.2)	41/121 (33.9)
Number of previous quit attempts, median (IQR)	2.0 (2.0)	2.0 (1.0)	2.0 (2.0)	2.0 (2.0)	2.0 (2.0)
Number of cpd, median (IQR)	20.0 (10.0)	20.0 (3.0)	20.0 (9.0)	20.0 (9.0)	20.0 (10.0)
Expired CO (ppm), median (IQR)	24.0 (14.0)	23.5 (16.0)	26.0 (16.0)	24.0 (15.0)	25.0 (13.0)
FTCD score, median (IQR) <sup>c</sup>	6.0 (3.0)	5.5 (3.0)	6.0 (3.0)	6.0 (3.0)	6.0 (3.0)
Preference for abrupt treatment arm, n/N (%)	107/342 (31.3)	4/7 (57.1)	17/51 (33.3)	44/158 (27.8)	42/126 (33.3)
Preference for gradual treatment arm, n/N (%)	179/342 (52.3)	2/7 (28.6)	24/51 (49.6)	90/158 (57.0)	63/126 (50.0)
No trial arm preference, n/N (%)	56/342 (16.4)	1/7 (14.3)	10/51 (19.6)	24/158 (15.2)	21/126 (16.7)
Confidence in quitting, median (IQR) <sup>d</sup>	4.0 (1.0)	4.0 (1.0)	4.0 (1.0)	4.0 (1.0)	4.0 (1.0)

<sup>a</sup>Numbers of participants used to calculate statistics for each variable vary due to missing data; <sup>b</sup>For continuous variables significance tests were carried out using chi<sup>2</sup> tests and for continuous variables using Kruskal Wallis tests; <sup>c</sup>Range from 0 to 10, where 10=highest level of dependence; <sup>d</sup>Measured on a scale from 1 to 6, where 1=Very low and 6=Extremely high cpd: cigarettes per day; CO: carbon monoxide; FTCD: Fagerstrom Test for Cigarette Dependence; HR-D: hierarchical-difficult; HR-E: hierarchical-easy; IQR: inter-quartile range; n: numerator; N: denominator; p: probability; ppm: parts per million; SFP: smoke-free periods; SR: scheduled reduction; y: years

Table 2: Unadjusted and adjusted associations between chosen reduction methods and smoking outcomes

Outcome	Reduction method	n/N (%)	Mean (sd) % reduction	Unadjusted OR/regression coefficient (95% CI)	Unadjusted p-value	Adjusted OR/regression coefficient (95% CI) <sup>a</sup>	Adjusted p-value
<b>Four week abstinence</b>	SR <sup>b</sup>	51/126 (40.5)	n/a	n/a	n/a	n/a	n/a
	HR-D	1/7 (14.3)	n/a	0.31 (0.03 to 2.70)	.285	0.26 (0.03 to 2.48)	.242
	HR-E	19/51 (37.3)	n/a	0.91 (0.46 to 1.84)	.800	0.82 (0.39 to 1.73)	.816
	SFP	63/158 (39.9)	n/a	1.06 (0.64 to 1.75)	.830	1.13 (0.66 to 1.94)	.665
<b>Six month abstinence</b>	SR <sup>b</sup>	18/126 (14.3)	n/a	n/a	n/a	n/a	n/a
	HR-D	0/7 (0.0)	n/a	incalculable	n/a	incalculable	n/a
	HR-E	10/51 (19.6)	n/a	1.56 (0.65 to 3.75)	.318	1.39 (0.53 to 3.63)	.498
	SFP	25/158 (15.8)	n/a	1.19 (0.60 to 2.37)	.624	1.44 (0.68 to 3.02)	.342
<b>Quit attempts</b>	SR <sup>b</sup>	77/126 (61.1)	n/a	n/a	n/a	n/a	n/a
	HR-D	2/7 (28.6)	n/a	0.32 (0.56 to 1.80)	.195	0.26 (0.04 to 1.73)	.164
	HR-E	28/51 (54.9)	n/a	0.81 (0.41 to 1.62)	.554	0.76 (0.35 to 1.64)	.489
	SFP	103/158 (65.2)	n/a	1.23 (0.73 to 2.05)	.438	1.57 (0.88 to 2.79)	.127
<b>Achievement of reduction target</b>	SR <sup>b</sup>	22/126 (17.5)	n/a	n/a	n/a	n/a	n/a
	HR-D	2/7(28.6)	n/a	0.91 (0.10 to 8.22)	.933	0.99 (0.10 to 10.25)	.991
	HR-E	10/51 (19.6)	n/a	1.05 (0.44 to 2.51)	.913	1.45 (0.55 to 3.85)	.453
	SFP	31/158 (19.6)	n/a	1.20 (0.64 to 2.25)	.575	1.69 (0.84 to 3.41)	.143
<b>Cpd reduction<sup>c</sup></b>	SR <sup>b</sup>	n/a	35 (36)	n/a	n/a	n/a	n/a
	HR-D	n/a	32 (43)	-11 (-42 to 20)	.479	-14 (-44 to 16)	.368
	HR-E	n/a	37 (36)	1 (-12 to 13)	.937	1 (-12 to 14)	.848
	SFP	n/a	37 (37)	3 (-6 to 12)	.527	5 (-4 to 14)	.278
<b>CO reduction<sup>c</sup></b>	SR <sup>b</sup>	n/a	30 (74)	n/a	n/a	n/a	n/a
	HR-D	n/a	23 (40)	-20 (-52 to 12)	.209	-24 (-56 to 8)	.135
	HR-E	n/a	35 (34)	-1 (-15 to 12)	.838	-2 (-15 to 12)	.786
	SFP	n/a	31 (43)	-5 (-15 to 5)	.308	-3 (-13 to 7)	.560

<sup>a</sup>adjusted for potential confounders: baseline age, gender, ethnicity, education level, employment status, age started smoking, cohabitation with another smoker, number of previous serious quit attempts, cpd, expired CO, Fagerstrom Test for Cigarette Dependence (FTCD), preference for abrupt/gradual quitting, confidence in quitting; <sup>b</sup>reference category;

<sup>c</sup>linear regression coefficients

CI: confidence intervals; cpd: cigarettes per day; CO: carbon monoxide; HR-D: hierarchical-difficult; HR-E: hierarchical-easy; n: numerator; N: denominator; n/a: not applicable; OR: odds ratio; p: probability; sd: standard deviation; SFP: smoke-free periods; SR: scheduled reduction