Enhanced smoking cessation support for newly abstinent smokers discharged from hospital (The Hospital to Home trial): A randomised controlled trial

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Abstract

Background and aims

The United Kingdom's National Institute for Health and Care Excellence guidance (NICE PH48) recommends that pharmacotherapy combined with behavioural support be provided for all smokers admitted to hospital; however, relapse to smoking after discharge remains common. This study aimed to assess the effect of adding home support for newly-abstinent smokers to conventional NICE-recommended support in smokers discharged from hospital.

Design

individually-randomised parallel group trial.

Setting

One UK acute hospital.

Participants

404 smokers aged >18 admitted to acute medical wards between June 2016 and July 2017 were randomised in equal numbers to each treatment group.

Interventions and comparators

The intervention provided 12 weeks of at-home cessation support which included help in maintaining a smoke-free home, help in accessing and using medication, further behavioural support and personalised feedback on home air quality. The comparator was NICE PH48 care as usual.

Measures

The primary outcome was self-reported continuous abstinence from smoking validated by an exhaled carbon monoxide level <6ppm four-weeks after discharge from hospital.

Findings

In an intention-to-treat analysis at the four-week primary endpoint, 38 participants (18.8%) in the usual care group and 43 (21.3%) in the intervention group reported continuous abstinence from smoking (odds ratio 1.17, 95% confidence interval 0.72 to 1.90, Bayes factor 0.33). There were no significant differences in any secondary outcomes, including self-reported cessation at 3 months, having a smoke-free home, or number of cigarettes smoked per day in those who did not quit.

Conclusions

Provision of a home visit and continued support to prevent relapse to smoking after hospital discharge did not appear to increase subsequent abstinence rate above usual care in accordance with UK guidance from the National Institute of Health and Care Excellence.

Introduction

Tobacco smoking is the largest avoidable cause of premature death and disability in the UK(1). Half of all lifelong smokers die as a consequence of their smoking, typically from lung cancer, chronic obstructive pulmonary disease or cardiovascular disease (2). Average life expectancy among smokers is 10 years less than in never-smokers, equivalent to nearly 3 months of life lost for every year smoked after the age of 35 (2, 3). Quitting smoking at almost any age significantly increases both expectancy and quality of life (2). Helping as many as possible of the more than 7 million current smokers in the UK (4) to quit smoking is therefore one of the highest public health priorities, and also one of the most cost effective of medical interventions(5). Doing so would also help save the UK National Health Service around £1 billion in health care costs each year(6).

Every year an estimated 1.1 million smokers are admitted to English hospitals (7) and every one of these admissions represents a prime opportunity to intervene to promote smoking cessation, particularly since most smokers abstain from smoking while in hospital (8). Recent NICE guidance (PH48)(9) recommends that smoking cessation interventions should be provided in routine care pathways for all smokers admitted to hospital, and our earlier work has demonstrated that default delivery of cessation support to all smokers significantly increases uptake of support and doubles the proportion of smokers who quit long term (10).

Smoking cessation interventions are well established and usually consist of behavioural support delivered either face-to-face or over the telephone, and pharmacotherapies (11-19). A systematic review of 50 studies by Rigotti and colleagues found that high intensity behavioural interventions that are initiated during hospital admission and include at least one month of supportive contacts increases smoking quit rates at six months of beyond, and adding NRT increased quit rates further (20), though the authors did not find any effect for less intensive interventions, or for adding varenicline or bupropion to behavioural support. In our study, among smokers who received care similar to that now recommended by NICE, 62% of those who were abstinent at discharge had relapsed by four weeks, and 81% by 6 months (10). Two studies in the US tested a post-discharge smoking cessation support package which included automated interactive voice telephone calls and stop smoking medications for three months after discharge. The first study allowed participants the option of a telephone call from a live tobacco counsellor, and reported that quit rates were significantly higher in the intervention group at one month and six months (though not at three months)(21). The latter study utilised a telephone quitline in place of a live counsellor and found that quit rates were significantly

higher in the intervention group for the duration of treatment (one and three months) but this effect was no longer significant after six months (22).

Evidence suggests that intensive interventions to support smoking cessation after discharge from hospital have potential to increase quit long term quit rates, but there is still potential to increase these further. To our knowledge, no study to date has investigated providing a home visit after discharge from hospital to support the transition from temporary abstinence to the home environment. We therefore aimed to test, as an extension to our hospital inpatients study (10), the effectiveness of an intensive home support intervention for newly-abstinent smokers delivered within 24 hrs of hospital discharge and maintained for up to 12 weeks post discharge.

Methods

Trial design and participants

We used a parallel group individually randomised study design. Eligible participants comprised all patients aged over 18 years admitted for at least 24 hours to one of the 18 acute medical wards at a large UK teaching hospital (Nottingham City Hospital) who were ascertained to be current smokers, lived within a 40 mile radius of the hospital, were able to provide informed consent and were not pregnant. Recruitment ran from 28 June 2016 to 28 July 2017. The trial was registered with ISRCTN 31 May 2016 (ISRCTN10774163) and activated with the National Institute for Health Research in April 2016.

Procedures

All patients admitted to acute medical wards

Smoking cessation practitioners (SCPs) visited each participating hospital ward on every weekday to ascertain the smoking status of all newly admitted patients, either from a checklist completed on the paper admission proforma for each patient or, in absence of clear documentation, by questioning the patient directly. Specialisms of wards included cardiac (n=4), respiratory (n=4), oncology (n=2), stroke (n=2), thoracic (n=1), renal (n=1), infectious disease (n=1), pre-operative (n=1); the remaining two wards were 'overspill' wards for the above specialisms that opened at times of increased capacity. Enforcement of hospital smoke free policy was variable across wards. Patients were categorised as current smokers if they answered 'yes' to the question 'Do you smoke?' or if they answered 'no', but reported that they had smoked in the seven days before admission. Regardless of desire to quit smoking after discharge, all current smokers were offered smoking cessation pharmacotherapy and behavioural support as recommended for secondary care settings in NICE

PH48 guidelines (9), which in brief comprised: one-to-one behavioural counselling delivered at the bedside by SCPs trained to National Centre for Smoking Cessation and Training standards (23); and either dual nicotine replacement therapy comprising a long-acting transdermal nicotine patch in conjunction with a short-acting preparation (inhalator, gum or lozenge) or therapy with varenicline or buproprion. Further daily behavioural support was offered to each patient by the SCP and delivered as often as accepted by the patient throughout admission. Current smokers who were eligible for inclusion in the trial were also given a patient information sheet describing the trial, and visited 24 hours later by a researcher who provided further information as required and requested written consent. All consenting participants completed a baseline questionnaire and where possible provided an exhaled Carbon Monoxide (CO) measurement, and for the remainder of their admission received cessation support in accordance with NICE PH48 guidelines (9). SCPs and other members of the research team liaised with patients and clinical staff to ascertain likely discharge dates so that all participants could, where possible, be visited on the day of discharge or on the Friday immediately before a planned weekend discharge, ensuring that smokers in both groups had received NICE PH48 care (including two weeks' supply of NRT or pharmacotherapy to take home on discharge). In order to be enrolled in the trial, patients must have been attempting to remain abstinent throughout their admission (though lapses did not preclude participation) and be willing to attempt continued abstinence after discharge.

Randomisation and masking

Consenting participants were individually randomised, using concealed allocation, to receive either usual care or the intervention. The randomisation sequence (1:1 in permuted blocks of random size up to size six) was generated using a computer random number generator and patients were allocated sequentially. Randomisation was conducted independently by the University of Nottingham Clinical Trials Unit and delivered by the research team. The trial interventions were necessarily open in design, so research staff delivering the interventions and collecting follow up data were not blind to participant allocation. However all analysis and work of the trial steering group were carried out blind to treatment allocation. According to the randomisation, participants then received usual care or the intervention package described below.

Data collection

In both treatment groups, baseline demographic data including smoking behaviour (which included information about who smoked in the home), advice delivered and /or NRT received in hospital were collected face to face at the bedside by the researcher during the initial admission to

hospital. Follow up data were collected at 4 and 12 weeks after discharge from hospital either in face to face or telephone contact by the research team and included information on hospital readmissions, quit attempts and general smoking behaviour including smoking behaviour at home, type of help used to support quit attempt. Participants were contacted a maximum of three times by telephone at various times in the 'working-day' then by text and finally by letter in an attempt to collect follow up data. All members of the research team were trained in Good Clinical Practice and informed consent.

Usual Care

On the day of or the day before discharge, or on the first working day after unplanned discharge, the research team referred those participants to usual care directly to their local stop smoking service (LSSS) for further cessation support after discharge. The support provided varied between LSSS but typically comprised behavioural support from a NCSCT-trained community SCP either face-to-face or in a group in a health or community setting, or delivered by telephone, and continued pharmacotherapy provided, on request, by the LSSS or participants' general practitioner (GP) (23, 24). Participants were not offered electronic cigarettes but were free to use their own e-cigarette to support their quit attempt alongside or instead of prescribed pharmacotherapy. Participants were contacted by telephone by the research team at 4 and 12 weeks after discharge and asked to complete a short questionnaire describing their quit experience (products used, support received and number of other smokers in the household) and report their smoking status. If patients reported abstinence from smoking in line with the Russell Standard (25) a researcher visited the patient at home, work or in a convenient community setting to validate smoking status by measuring exhaled CO.

Intervention

On the day of or the day before discharge, or on the first working day after unplanned discharge, the SCP arranged to visit the patient at home, where possible between 24 and 48 hours after discharge. Those patients who did not want to be visited within this timescale were offered further telephone support with arrangements made to visit the home as soon as acceptable to the participant. The SCP offered one-to-one counselling, delivered at the discretion of the patient and usually weekly, but not less than once a fortnight, which included discussing the benefits of removing smoking paraphernalia from the home, discussions around feelings about smoking, managing high risk situations and maintaining changes to smoking habits for up to 12 weeks. During the home visits, SCPs also discussed quitting with other family members who were present, identified themselves as

smokers and expressed a desire to quit; provided an explanation and (if appropriate) a demonstration of how to use cessation pharmacotherapy; and, if accepted, referred the person to the LSSS or directed towards smoke-free websites and mobile phone apps which may have been helpful. Personalised feedback on home air quality was provided through 24 hour sampling using a Sidepak Aerosol Monitor AM510 (TSI Instruments Ltd, High Wycombe, UK), positioned in the main living area to measure concentrations of $PM_{2.5}$. The research team converted data collected during the three periods of air quality measurement (baseline, week 7 and week 12) into a graphical format that could be easily explained to the participant immediately after each measurement period, relating the information to the WHO recommended 24 hours of $PM_{2.5}$ concentrations below 25 $\mu g/m^3$ per 24-hour period(26). Participants were shown the graphs with attention drawn to periods of time that showed particularly high or low SHS exposure in the home, supported by the discussion of reasons for high or low values and of strategies to reduce exposure both in general and during periods when levels were particularly high.

Participants who experienced problems with or for any reason were not using their cessation pharmacotherapy were offered alternatives. SCPs also provided text and telephone support to participants at times of relapse risk, or in the event of relapse, were available for contact at any time during office hours. Patients were directed towards to websites and smart phone apps designed to support quitting. Any participant who relapsed to smoking during the 12-week intervention period was encouraged to make another quit attempt with support of the SCPs.

E-cigarettes were not provided as part of the trial, but patients who wished to purchase or use their own e-cigarette were advised to do so in line with the NCSCT guidelines for e-cigarettes (27), and their use was incorporated into the patients' quit plan. Air monitoring as a marker for second hand smoke, supplemented with discussions of the dangers of second-hand smoke (28, 29) was offered at the initial home visit and again after four weeks to those patients who admitted to smoking indoors or who had cohabitees who smoked indoors. Cessation support was offered for a total of 12 weeks. Cessation outcome data, with CO validation if appropriate, were collected as in the usual care group, but intervention participants were also asked questions about the components of the intervention as part of the 12 week questionnaire.

Outcome measures:

The primary outcome was self-reported continuous abstinence from smoking validated by an exhaled carbon monoxide level <6ppm at four weeks after discharge from hospital. Secondary outcomes included self-reported and validated continuous abstinence from smoking at three months after discharge from hospital, self-reported reduction in cigarette consumption at four weeks after discharge smoking, self-reported presence of a smoke free home baseline four weeks and three months post-discharge from hospital, changes in maximum concentrations of $PM_{2.5}$ in indoor air and the proportion of time PM2.5 concentrations exceed WHO recommended safe levels of maximum exposure of 25 µg/m3 per 24-hour period at 24-48 hours, four weeks and three months post-discharge from hospital, and utilisation of each component of the complex intervention measured through participant self-report at four weeks and three months after discharge from hospital.

Statistical analysis

The primary analysis was by intention to treat and included all participants randomised to usual care or intervention. For smoking cessation outcomes it was assumed that participants who did not provide data at four weeks or three months, or those who did not provide an exhaled CO reading for validation of cessation, continued to smoke (25). It was also assumed that there was no change in the number of cigarettes smoked per day by these participants. A descriptive comparison of baseline characteristics was made between those randomised to intervention and usual care, and comparison of baseline characteristics of those who provided outcome data and those who did not was used to explore the pattern of missingness.

We estimated the effect of the intervention on our primary outcome by comparing CO-validated four-week cessation between the intervention and the usual care groups using unadjusted logistic regression, stating the odds ratios and risk differences (estimated using the adjRR post-estimation command in Stata) with their 95% confidence intervals. Logistic regression was also used for binary secondary outcomes. Linear regression was used to determine the effect of the intervention on the self-reported number of cigarettes smoked per day by participants who were not abstinent from smoking four weeks after discharge, with adjustment for baseline cigarette consumption. This outcome variable was log transformed with results presented as the ratio of cigarettes smoked in the intervention group compared to usual care. For the primary and secondary outcomes, we carried out sensitivity analyses adjusting for baseline covariates of prognostic importance including cohabitation with a smoker, deprivation index, heaviness of smoking index as these have been identified as the most important factors for cessation in previous literature (30-32).

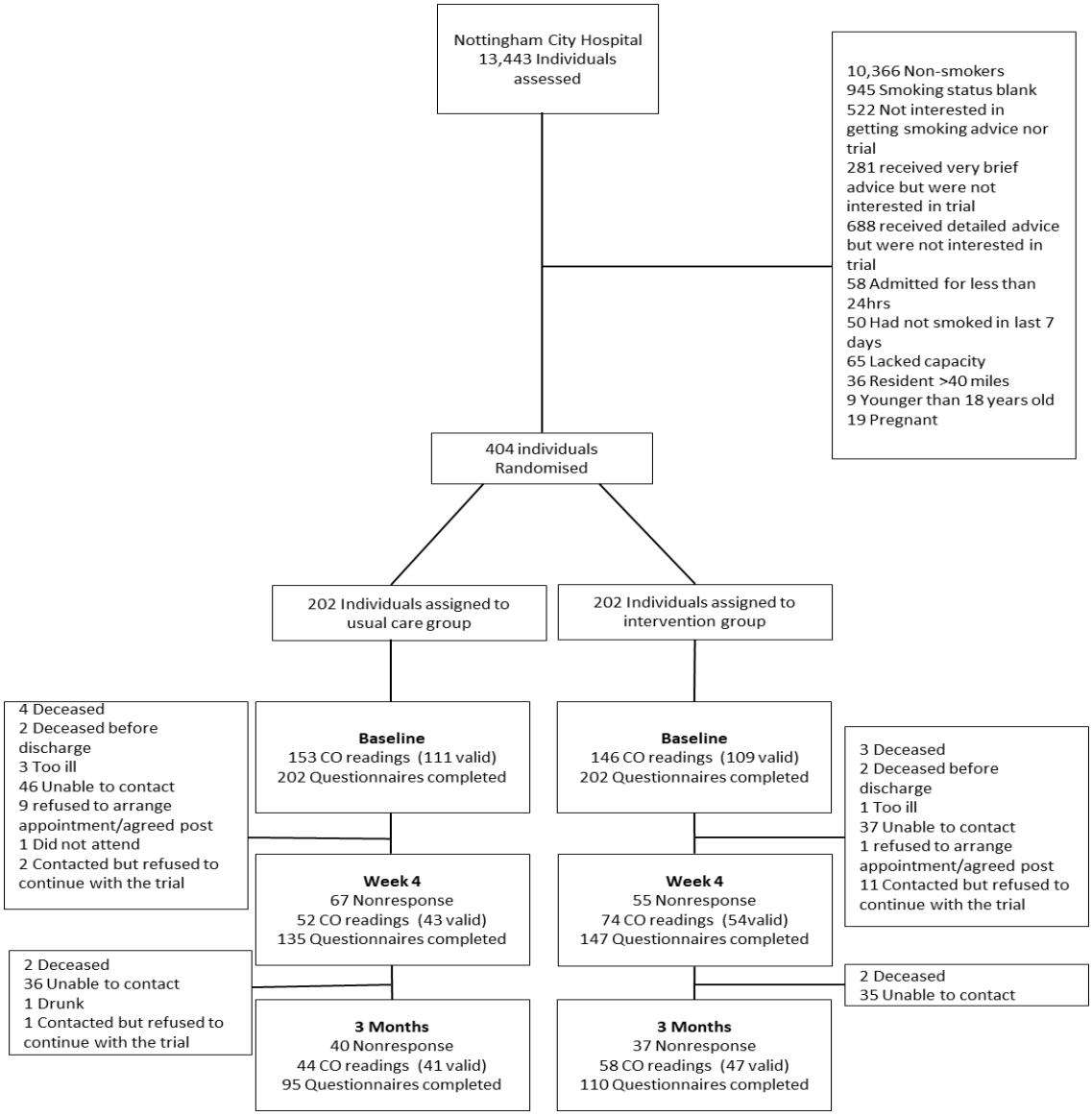
In a further sensitivity analyses, we additionally adjusted for whether the participant had been readmitted to hospital during the four weeks after the primary discharge. We explored whether allowing for clustering by hospital ward affected the results for our primary outcome by fitting hospital ward as a random effect into our primary analysis. We also imputed missing values for CO readings using predictive mean matching imputation (drawing from the 5 closest observations) and we imputed missing values for smoking status using logistic regression imputation. This was repeated 20 times. Unadjusted logistic regression was carried out on each of the 20 observations and the results were combined using MI procedures in Stata. We also compared self-reported smoking at four weeks between participants who did and did not take part in the trial to determine which group was more or less likely to quit. All analyses were conducted in STATA 14. The study sample size of 400 participants was calculated *a priori* to provide 90% power to detect a 16 percentage point increase (from 38% to 54%) in CO-validated cessation at four weeks in the intervention group relative to the usual care group.

Results

Recruitment and participant flow during trial

We assessed a total of 13 443 patients admitted to Nottingham City Hospital between 28 June 2016 and 28 July 2017 (Figure 1). Of these, 10,366 (77%) ascertained to be non-smokers and 945 (7%) in whom we were unable to ascertain smoking status were excluded. A further 237 patients (2%) who did not meet other study entry criteria were also excluded (Figure 1). A total of 969 patients (7%) accepted advice to quit but declined to participate in the trial, while 522 (4%) declined advice and participation. A total of 404 patients (3% of all screened admissions and 19% of all ascertained smokers) were randomised, 202 to the intervention and 202 to usual care (Figure 1).

Figure 1: CONSORT diagram of study recruitment and participation (33)



Characteristics of participants

Participants were of mean (Standard Deviation (SD)) age 55 (15) years; 60% were male and over 60% were in the two most deprived quintiles of the general population (Table 1). Most (85%) were emergency (unplanned) admissions. Participants in both groups smoked a median of 15 (range 10 to 20) cigarettes per day, and more than half had less than moderate scores on the Heaviness of Smoking Index. There were no marked differences in baseline characteristics between participants randomised to intervention or usual care groups, though the usual care arm had a higher proportion of people who were more heavily smoking dependent and lower proportion of smokers who had smoked for more than 41 years (Table1).

Table 1: Participant Characteristics and Background summary table

Characteristic	Total	Usual Care	Intervention
	404	202	202
Age (Years)			
Mean (SD)	54.77 (14.50)	55.58 (13.82)	53.96 (15.11)
Gender			
Female N (%)	158 (39.11)	86 (42.57)	72 (35.64)
Male N (%)	246 (60.89)	116 (57.43)	130 (64.36)
Ethnic group			
White British (%)	372 (92.08)	189 (93.56)	183 (90.59)
White Other* (%)	15 (3.71)	6 (2.98)	9 (4.46)
Other† (%)	11 (2.72)	3 (1.50)	8 (3.96)
Unknown (%)	6 (1.49)	4 (1.96)	2 (0.99)
Multiple deprivation index rank			
1 – most deprived(%)	168 (42.00)	82 (41.21)	86 (42.79)
2 (%)	85 (21.25)	47 (24.62)	38 (18.91)
3 (%)	60 (15.00)	31 (15.58)	29 (14.43)
4 (%)	42 (10.50)	19 (9.55)	23 (11.44)
5 – least deprived (%)	45 (11.25)	20 (10.05)	25 (12.44)
Reason admitted to hospital			
Elective surgery N (%)	58 (14.36)	26 (12.87)	32 (15.84)
Emergency N (%)	340 (84.16)	172 (85.15)	168 (83.17)
Routine care N (%)	3 (0.74)	3 (1.47)	0
Other N (%)	3 (0.74)	1 (0.49)	2 (0.99)
Number of other people living in the house			
Adults			
Mean (SD)	0.88 (0.92)	0.86 (0.89)	0.90 (0.95
Children			
Mean (SD)	0.44 (0.99)	0.41 (0.93)	0.47 (1.05)
Qualification			
None N (%)	163 (40.35)	84 (41.58)	79 (39.11)
GCSEs N (%)	117 (28.96)	45 (22.28)	72 (35.64)
A-levels/AS-levels N (%)	44 (10.89)	23 (11.39)	21 (10.40)
Degree N (%)	38 (9.41)	23 (11.39)	15 (7.43)
Other (%)	42 (10.40)	27 (13.37)	15 (7.43)
No of cigs daily before admission			
Median (IQR)	15 (10-20)	15 (10 - 20)	15 (9–20)
Heaviness of smoking index			
Very low dependence (%)	139 (35.10)	60 (30.30)	79 (39.90)
Low to moderate dependence (%)	119 (30.05)	59 (29.80)	60 (30.30)
Moderate dependence	94 (23.74)	48 (24.24)	46 (23.23)
High dependence	44 (11.11)	31 (15.66)	13 (6.57)
Years smoking			
<1	1 (0.26)	0	1 (0.52)
1 - 10	25 (6.53)	8 (4.19)	17 (8.85)
11 - 20	53 (13.84)	23 (12.04)	30 (15.63)
21 -40	146 (38.12)	76 (39.79)	70 (36.46)
41 +	158 (41.25)	84 (43.98)	74 (38.54)
Live with other smokers			
Yes	144 (37.11)	77 (40.10)	67 (34.18)
No	244 (62.89)	115 (59.90)	129 (65.82)
Readmission status			
Readmitted to hospital between baseline and 4 weeks post discharge	43 (10.64)	18 (8.91)	25 (12.38)
Readmitted to hospital between baseline and 3 months post discharge	69 (17.08)	31 (15.35)	38 (18.81)

* White – Irish and European
†Mixed White and Black Carribean, Mixed White and Black African, Asian/Asian British Indian, Asian/Asian British Pakistani, Black/Black British Carribean, Black/Black British African, Any Other Ethnic Group

Participants in the Intervention group were more likely to accept behavioural support (OR 10.87, 95% CI 4.21 to 28.08 (P<0.001)) in comparison to those in the usual care arm. An offer of NRT was more common in the intervention arm(P=0.02), though there was a higher instance of missing data (whereby there was no clear description of whether NRT was offered or not in the clinical notes). Acceptance of NRT did not vary between the two groups (OR 1.13, 95%CI 0.67 to 1.93). (Table 2).

Table 2: Acceptance of smoking cessation support

	Total	**Usual Care**	**Intervention**	**Unadjusted OR (95% CI) [P-value]**
Accept behavioural support	**404**	**202**	**202**	
Yes n (%)	351 (86.88)	157 (77.72)	194 (96.04)	10.87 (4.21,28.08) [p<0.01]
No n (%)	49 (12.13)	44 (21.78)	5 (2.48)	**1**
Unknown n (%)	4 (0.99)	1 (0.50)	3 (1.49)	
Offered NRT	**351**	**157**	**194**	
Yes n (%)	323 (92.02)	148 (94.27)	175 (90.21)	[p=0.02]
No n (%)	5 (1.42)	5 (3.18)	0	
Unknown n (%)	23 (6.55)	4 (2.55)	19 (9.79)	
Accepted NRT		**148**	**175**	
Yes n (%)	244 (75.54)	109 (73.65)	135 (77.14)	1.13 (0.67,1.93) [p=0.63]
No n (%)	71 (21.98)	34 (22.97)	37 (21.14)	
Unknown n (%)	8 (2.48)	5 (3.38)	3 (1.72)	

Primary outcome

At four weeks after discharge from hospital, 68 participants in the usual care group and 54 in the intervention group did not provide outcome data, for reasons including withdrawal from the study, non-response to contact, and death (Figure 1). Of all randomised participants, 38 (18.8%) in the usual care group and 43 (21.3%) in the intervention group reported continuous abstinence from smoking which was validated by an exhaled CO of less than 6 ppm (Table 2). The relative odds of cessation at four weeks did not differ between groups either before (Odds Ratio (OR) 1.17, 95% Confidence Interval (CI) 0.72 to 1.90) or after (OR 0.95, 95% CI 0.56 to 1.62) adjustment for baseline covariates and additionally readmission to hospital during these four weeks, which occurred in 18 (8.9%) usual care and 25 (12.4%) intervention group participants (Table 2). There was also no

substantial change in the odds of validated abstinence after allowing for potential clustering by ward (OR 1.19, 95% CI 0.72 – 1.98). One hundred and forty seven participants in the intervention group accepted a home visit, of which 67 were visited within 24-48 hours and 80 were seen outside of this time; there was no difference in quit rates between these groups (p=0.31).

Secondary outcomes

There was no significant difference between treatment groups for secondary outcomes (Table 3). Self-reported abstinence at one and three months, and self-reported establishment of a smoke-free home were all slightly but not significantly higher in the intervention group, but for three months abstinence the CO-validated proportions were almost identical (14.4% in the usual care and 13.9% in the intervention group). Adjustment for baseline covariates and additionally for readmission to hospital during the three-month period (which occurred in 31 (15.4%) usual care and 38 (18.8%) intervention participants) had no appreciable effect on these differences.

A higher proportion of self-reported quitters failed to validate their quit status in the intervention group than usual care at three months. Of 14 participants in the intervention group who were not CO validated quitters, three did not provide a CO reading and 11 had CO readings above 6ppm (26% of self reported quitters). In contrast, of three participants in the usual care group who were not CO validated quitters, two did not provide a CO reading and one had CO readings above 6ppm (3% of self reported quitters).

Table 3: Trial effectiveness summaries: Four week and three month comparison by treatment arm (Odds Ratio)

	Usual Care Group	Intervention Group	Unadjusted	Adjusted model 1†	Adjusted model 2 ‡
			Odds ratio (95% CI) [P-value]	Odds ratio (95% CI) [P-value]	Odds ratio (95% CI) [P-value]
Total	202	202	404	392	277
Continuous smoking cessation, validated at 4 weeks*	38 (18.81%)	43 (21.29%)	1.17 (0.72, 1.90) [0.53]	1.05 (0.64, 1.73) [0.84]	0.95 (0.56, 1.62) [0.85]
Self-reported continuous smoking cessation (4 weeks)	50 (24.75%)	55 (27.23%)	1.14 (0.73, 1.78) [0.57]	1.11 (0.70, 1.75) [0.66]	0.99 (0.60, 1.63) [0.97]
Self-report having a smoke-free home (4 weeks)	92 (45.54%)	102 (50.50%)	1.22 (0.83, 1.80) [0.32]	1.11 (0.72, 1.70) [0.64]	1.06 (0.69, 1.64) [0.78]

Self-reported continuous smoking cessation (3 months)	32 (15.84%)	42 (20.79%)	1.39 (0.84, 2.32) [0.17]	1.32 (0.78, 2.22) [0.30]	1.31 (0.74, 2.32) [0.35]
Continuous smoking cessation, validated at 3 months *	29 (14.36%)	28 (13.86%)	0.96 (0.55, 1.68) [0.89]	0.86 (0.49, 1.53) [0.67]	0.81 (0.44, 1.50) [0.51]

** Validated by exhaled CO less than 6ppm*
† Adjusted for co-habitation with a smoker status, deprivation index & heaviness of smoking index
‡ Adjusted for readmission status, cohabitation with a smoker status, deprivation index & heaviness of smoking index

The self-reported number of cigarettes smoked by participants who were not abstinent at four week decreased in both usual care and intervention from a median of 15 (range 10-20) to 6.5 (range 0-15) and from a median of 15 (range 9-20) to 3 (range 0-10) respectively, but again, this difference was not significant either before or after adjustment for baseline covariates.

An average of 10 behavioural support sessions (SD 4.64) per participant were arranged by the research team, of which an average of 4.69 (SD 1.99) and 7.43 (SD 4.39) sessions were attended within the first four weeks after discharge and in total, respectively. The choice of home visit or telephone contact was dictated by the participant. Participants received, on average, 3.84 (SD 3.30) weeks' supply of NRT and 30 (14.85%) received at least four weeks of NRT. Contact with participants lasted for a median of 5.86 weeks (IQR 2.86-9.71 weeks) and 134 participants (66.3%) received more than the recommended four weeks of smoking cessation support. All advisors adhered to the NCSCT standard treatment programme as a guideline for the 12-week duration (34). Measures of uptake and perceived helpfulness of trial components among intervention group participants are summarised in Table 4. Both home visits and follow-up behavioural support (face-to-face or telephone) were accepted by and delivered to over 70% of participants, and supportive phone call texts and nicotine replacement therapy by over 50%. These components were considered helpful by a majority of participants. Uptake of referral to LSSS was very low at less than 2%.

Table 4: Adherence to and helpfulness of intervention components at three months (intervention group only)

	Used at least once during trial(%)	Participants reporting the component as useful* (%)
Received behavioural support	97 (79.51%)	61 (62.89%)
Home visit	89 (72.95%)	64 (71.91%)
Nicotine Replacement Therapy	69 (56.56%)	47 (68.12%)

Supportive phone calls texts	69 (56.56%)	37 (53.62%)
Support to make home Smoke-Free	25 (20.49%)	13 (52.00%)
Air quality feedback	20 (16.39%)	14 (70.00%)
Information on E-Cigarettes	16 (13.11%)	7 (43.75%)
Advice given to other smokers about quitting**	12(9.84%)	4 (33.33%)
Signposting to websites	12 (9.84%)	2 (16.67%)
Signposting to phone apps	12 (9.84%)	2 (16.67%)
Referral to local SSS	2 (1.64%)	0 (0%)

*In those using the component

** *To family, carers, others.*

Comparison of self-reported smoking status at week four between trial participants and patients who consented to provide follow-up data but declined trial participation indicates that the non-participants were more likely to quit (45 of 114 (39.5%) reported they had quit at four weeks) than trial participants (105 of 404 (26.0%) had quit) This difference was evident both before and after adjustment for Heaviness of Smoking Index (adjusted OR 1.94 (95% CI 1.12 to 3.34), p=0.019).

Discussion

This study demonstrates that smoking cessation treatment delivered in accordance with NICE PH48 guidance (9) to inpatients in an acute UK hospital is not enhanced by adding a package involving a home visit after discharge to encourage compliance, assist in creating a smoke-free home or other initiatives intended to enhance treatment compliance and support sustained cessation after discharge. The study builds on our own (10) and others' (35) work demonstrating that systematic intervention to support cessation in hospital inpatients is effective, and this approach was incorporated into current NICE guidance recommending that all in-patient smokers receive behavioural support and pharmacotherapy while in hospital, and receive follow up, for at least four weeks, after discharge (9). Our aim was to reduce the proportion of smokers who relapse to smoking within the first month after discharge, which even in those receiving the systematic cessation intervention exceeded 60% (10).

The relapse rate in both our trial groups was similar, and at around 80% was markedly higher than in the intervention group in our earlier study (10) and also higher than that achieved at six months in the observational evaluation of the Ottawa smoking cessation model (35). In contrast, the approximately 60% relapse rate among patients who received the usual care (NICE PH48) intervention and provided follow-up data without participating in the trial was similar to that observed in the group receiving an equivalent intervention in our earlier work (10). There are no obvious explanations for these discrepancies, but their existence suggests that quit rates differ markedly between patients with different levels of motivation to participate in formal trials. It may

be the case that those who declined support and participation in the study had higher quit motivation and/or confidence in their ability to maintain abstinence during and after discharge without the support offered as part of our intervention. The failure of the present study to identify an effect of the enhanced intervention does not appear to be attributable to random differences in participant characteristics between the two treatment groups, as the two groups were closely matched on most variables, the only exception being a modest difference in Heaviness of Smoking Index which should, if anything, have favoured the intervention.

Our findings are however consistent with the results of other attempts, in a wide range of settings, to prevent relapse among smokers who have quit (36). A Cochrane review of studies of relapse prevention found no evidence that interventions involving the delivery of behavioural support or pharmacotherapy were effective, though extending the period for which pharmacotherapy was used had some effect (36). The review included three studies of hospital inpatients (37-39) and involved adding support to cessation interventions less intensive than those used in the present study. It does not therefore follow that the relatively comprehensive intervention we used, as recommended by NICE, is responsible for the lack of effect of the relapse prevention package; rather, it appears that relapse prevention using the methods we tested, delivered once a smoker has commenced a quit attempt in hospital, is no more effective than existing support systems. In contrast to a number of previous studies, the present study ensured that all willing participants were discharged with a supply of NRT regardless of treatment group and thus the difference was largely in the delivery of additional behavioural support only, which may partly explain the lack of difference between groups.

This study is subject to a number of limitations. The recruitment rate was low, which limits the representativeness and generalisability of findings, although each group was demographically similar. There was also a large loss to follow up which may have underestimated the effect of our intervention, however this rate was similar in both groups and so is unlikely to have biased the effect size achieved. All components of the intervention were offered to all participants in the intervention arm. However, some of the participants did not have access to the internet or a smart phone which ruled out them being able to view websites or apps. The majority did not smoke indoors and so were not able to take-up the air monitoring component of the intervention. We cannot, therefore, be certain that intervention components would not be useful if fully implemented by smokers although stop smoking websites and apps were not rated as useful by the vast majority of participants who used them.

We did not collect data on abstinence from smoking whilst in hospital as participants may have felt obliged to deny smoking given the hospital smoke free policy, however smoking abstinence did not form part of our study eligibility criteria. The power calculation was based on an anticipated quit rate in the control group of 38%, which was achieved in our previous, similar study (10), and a potential increase in quit rate of 16% was calculated based on time and resource availability rather than an anticipated increase. At 19%, the actual quit rate was lower than our estimate so power to detect a 16% increase would have been lower than expected. As there was actually only a 2% difference between groups for our primary outcome, a lack of power is unlikely to explain our findings.

Partcipants attended an average of 7.43 behavioural support sessions, lasting a median of 5.86 weeks, however participants received an average of 3.84 weeks of NRT which is less than the minimum 4-weeks shown to be effective and may have contributed to the findings of this study. Given that two thirds of participants received more than 4-weeks of smoking cessation support, and around three quarters accepted the home visit we believe that the intervention was delivered largely as anticipated. However, only 46% of home visits were made within the 24-48 hour target time period specified in our protocol. Despite this, there was no difference in quit rates between those that were seen within 48 hours and those who were not and thus we cannot be sure where the failure of the intervention occurred. Adherence to the intervention appears to have been good and is unlikely to account for the lack of effect seen in this study. We did not conduct a process evaluation and so cannot guarantee intervention fidelity and this should be a priority in future studies.

Given the importance of smoking cessation to individual and public health, and the opportunity presented by admission to hospital to deliver effective interventions, it is essential that further research continues to address the intervention components and designs used to maximise their efficacy. For now however, our study indicates that cessation is more likely to be improved by working on measures to increase the currently low uptake of cessation support and retention in treatment by smokers admitted to hospital (40) than bespoke packages intended to prevent relapse; and therefore that wider implementation of the NICE PH48 recommendations, rather than new developments in those recommendations, are the immediate healthcare priority in helping smokers who are admitted to hospital to quit.

References

1. Peto R & Pan H. Mortality from smoking in developed countries 1950-2010. https://wwwctsuoxacuk/research/mortality-from-smoking-in-developed-countries-1950-2005-or-later. 2012:pp 512-23.
2. Doll R, Peto R, Boreham J, Sutherland I. Mortality in relation to smoking: 50 years' observations on male British doctors. Bmj. 2004;328(7455):1519.
3. Pirie K, Peto R, Reeves GK, Green J, Beral V. The 21st century hazards of smoking and benefits of stopping: a prospective study of one million women in the UK. Lancet (London, England). 2013;381(9861):133-41.
4. Office for National Statistics. Adult smoking habits in the UK: 2017 On-line2018 [Available from: https://www.ons.gov.uk/peoplepopulationandcommunity/healthandsocialcare/healthandlifeexpectancies/bulletins/adultsmokinghabitsingreatbritain/2017. .
5. Godfrey C, Parrott S, Coleman T, Pound E. The cost-effectiveness of the English smoking treatment services: evidence from practice. Addiction. 2005;100(s2):70-83.
6. Royal College of Physicians. Hiding in plain sight: treating tobacco dependency in the NHS. London; 2018.
7. Szatkowski L, Murray R, Hubbard R, Agrawal S, Huang Y, Britton J. Prevalence of smoking among patients treated in NHS hospitals in England in 2010/2011: a national audit. Thorax. 2015;70(5):498-500.
8. Rigotti NA, Munafo MR, Stead LF. Interventions for smoking cessation in hospitalised patients. The Cochrane database of systematic reviews. 2007(3):CD001837.
9. National Institute for Health and Care Excellence (NICE). Smoking: acute, maternity and mental health services (ph48). nice.org.uk/guidance/ph48 (accessed 18 Jan 2018); 27 November 2013.
10. Murray R, Leonardi-Bee J, Marsh J, Jayes L, Li J, Parrott S, et al. Systematic identification and treatment of smokers by hospital based cessation practitioners in a secondary care setting: cluster randomised controlled trial. BMJ. 2013;347:f4004.
11. Civljak M, Stead LF, Hartmann-Boyce J, Sheikh A, Car J. Internet-based interventions for smoking cessation. The Cochrane database of systematic reviews. 2013(7):Cd007078.
12. Hajek P, Stead LF, West R, Jarvis M, Hartmann-Boyce J, Lancaster T. Relapse prevention interventions for smoking cessation. The Cochrane database of systematic reviews. 2013(8):Cd003999.
13. Hartmann-Boyce J, Lancaster T, Stead LF. Print-based self-help interventions for smoking cessation. The Cochrane database of systematic reviews. 2014(6):Cd001118.
14. McRobbie H, Bullen C, Hartmann-Boyce J, Hajek P. Electronic cigarettes for smoking cessation and reduction. The Cochrane database of systematic reviews. 2014(12):Cd010216.
15. Stead LF, Lancaster T. Combined pharmacotherapy and behavioural interventions for smoking cessation. The Cochrane database of systematic reviews. 2012;10:Cd008286.
16. Stead LF, Perera R, Bullen C, Mant D, Hartmann-Boyce J, Cahill K, et al. Nicotine replacement therapy for smoking cessation. The Cochrane database of systematic reviews. 2012;11:Cd000146.
17. Stead LF, Hartmann-Boyce J, Perera R, Lancaster T. Telephone counselling for smoking cessation. The Cochrane database of systematic reviews. 2013(8):Cd002850.
18. Thomas D, Abramson MJ, Bonevski B, George J. System change interventions for smoking cessation. Cochrane Database of Systematic Reviews. 2017(2).
19. Whittaker R, McRobbie H, Bullen C, Rodgers A, Gu Y. Mobile phone-based interventions for smoking cessation. The Cochrane database of systematic reviews. 2016;4:Cd006611.
20. Rigotti NA, Clair C, Munafo MR, Stead LF. Interventions for smoking cessation in hospitalised patients. The Cochrane database of systematic reviews. 2012(5):Cd001837.

21. Rigotti NA, Regan S, Levy DE, Japuntich S, Chang Y, Park ER, et al. Sustained Care Intervention and Postdischarge Smoking Cessation Among Hospitalized Adults: A Randomized Clinical TrialPostdischarge Smoking Cessation Among AdultsPostdischarge Smoking Cessation Among Adults. JAMA. 2014;312(7):719-28.
22. Rigotti NA, Tindle HA, Regan S, Levy DE, Chang Y, Carpenter KM, et al. A Post-Discharge Smoking-Cessation Intervention for Hospital Patients: Helping Hand 2 Randomized Clinical Trial. American journal of preventive medicine. 2016;51(4):597-608.
23. National Centre for Smoking Cessation and Training. NCSCT Training Standard. Learning Outcomes for Training Stop Smoking Practitioners 2010 [Available from: http://www.ncsct.co.uk/usr/pub/NCSCT_training_standard.pdf.
24. National Centre for Smoking Cessation and Training (NCSCT). Local Stop Smoking Services Service and delivery guidance 2014. www.ncsct.co.uk (accessed 18/01/2018); 2014.
25. West R, Hajek P, Stead L, Stapleton J. Outcome criteria in smoking cessation trials: proposal for a common standard. Addiction (Abingdon, England). 2005;100(3):299-303.
26. World Health Organization. Air quality guidelines: global update 2005: particulate matter, ozone, nitrogen dioxide, and sulfur dioxide. http://www.who.int/phe/health_topics/outdoorair/outdoorair_aqg/en/; 2006.
27. National Centre for Smoking Cessation and Training (NCSCT). Electronic cigarettes. www.ncsct.co.uk; 2014.
28. Wilson I, Semple S, Mills LM, Ritchie D, Shaw A, Donnell R, et al. REFRESH—reducing families' exposure to secondhand smoke in the home: a feasibility study. Tobacco Control. 2012.
29. Ratschen E, Thorley R, Jones L, Opazo Breton M, Cook J, McNeill A, et al. A randomised controlled trial of a complex intervention to reduce children's exposure to secondhand smoke in the home. Tobacco Control. 2017.
30. GOV.UK. Department for communities and local government. English indices of deprivation. 2015.
31. for the GMESG, Bolte G, Fromme H. Socioeconomic determinants of children's environmental tobacco smoke exposure and family's home smoking policy. European Journal of Public Health. 2008;19(1):52-8.
32. Braubach M, Fairburn J. Social inequities in environmental risks associated with housing and residential location--a review of evidence. Eur J Public Health. 2010;20(1):36-42.
33. CONSORT Transparent Reporting of Trials. The CONSORT Flow Diagram.
34. National Centre for Smoking Cessation and Training (NCSCT). Standard Treatment Programme, A guide to providing behavioural support for smoking cessation. www.ncsct.co.uk (accessed 18 jan 2018); 2014.
35. Reid RD, Mullen KA, Slovinec D'Angelo ME, Aitken DA, Papadakis S, Haley PM, et al. Smoking cessation for hospitalized smokers: an evaluation of the "Ottawa Model". Nicotine Tob Res. 2010;12(1):11-8.
36. Hajek P, Stead LF, West R, Jarvis M, Hartmann-Boyce J, Lancaster T. Relapse prevention interventions for smoking cessation. Cochrane Database of Systematic Reviews. 2013(8).
37. Hajek P, Taylor TZ, Mills P. Brief intervention during hospital admission to help patients to give up smoking after myocardial infarction and bypass surgery: randomised controlled trial. Brit Med J. 2002;324(7329):87-9.
38. Schmitz JM, Spiga R, Rhoades HM, Fuentes F, Grabowski J. Smoking cessation in women with cardiac risk: a comparative study of two theoretically based therapies. Nicotine & tobacco research : official journal of the Society for Research on Nicotine and Tobacco. 1999;1(1):87-94.
39. Hasuo S, Tanaka H, Oshima A. [Efficacy of a smoking relapse prevention program by postdischarge telephone contacts: a randomized trial]. [Nihon koshu eisei zasshi] Japanese journal of public health. 2004;51(6):403-12.

40. Hutchinson J, Mangera Z, Searle L, Lewis A, Agrawal S. Treatment of tobacco dependence in UK hospitals: an observational study. Clinical medicine (London, England). 2018;18(1):35-40.