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Impact of the intensified follow-up procedure of patients lost to 6-month follow-up after an intensive smoking and nicotine cessation intervention in practice: a cohort study

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ABSTRACT

Background Post-intervention follow-up is challenging in research and practice. In tobacco reports, patients with missing follow-up were considered smokers. Based on patient and staff preferences, an add-on intensified follow-up procedure after intensive tobacco and nicotine cessation interventions was developed. This study examined the impact of the new procedure on patients lost to follow-up and compared their cessation status with that of those who completed routine follow-up.

Methods Between January and February 2023, 2114 patients participated in the Danish STOPbase for Tobacco and Nicotine after providing informed consent. Overall, 1529 (72%) patients completed routine 6-month follow-up interviews, 136 (6%) patients rejected follow-up participation and 449 (21%) patients were lost to follow-up. Of the 449 patients, 225 patients were randomly selected to undergo the new follow-up procedure with repeated information, up to four extra calls, texts and voice messages from known telephone numbers.

Results Using the new procedure, 143/225 (64%; 95% CI: 61% to 67%) patients completed the follow-up, with a continuous quit rate of 54/225 (24%; 21% to 27%). The lost to follow-up group had a significantly lower continuous cessation rate than the group that completed the routine follow-up: 54/143 (38%; 34% to 42%) and 703/1529 (46%; 45% to 47%), respectively, (p<0.01).

Conclusion Almost two-thirds of the patients lost to 6-month follow-up completed the intensified follow-up procedure and had substantially lower cessation rates than those completing routine follow-up. However, this finding is clinically relevant, as a high follow-up rate impacts the reliability of outcomes, with loss to follow-up reported on continuous use.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Many patients are lost to long-term follow-up after smoking cessation interventions and are considered to have relapsed according to the general guidelines on reporting. A recent study on patients' and therapists' preferences on how to increase the follow-up rate recommended intensifying the follow-up procedure.

WHAT THIS STUDY ADDS

⇒ The intensified procedure could reach almost two-thirds of the group lost to the 6-month follow-up after intensive tobacco and nicotine cessation intervention. Approximately one in four patients had continuously quit smoking or nicotine use.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ Obtaining a high follow-up rate in relation to smoking and nicotine cessation interventions increases the reliability of outcomes in research and practice. This is important for patients, healthcare providers and policymakers. An intensified follow-up procedure has been implemented in Denmark.

INTRODUCTION

The effectiveness of smoking and nicotine cessation interventions (SNCI) is an important part of most national strategies to prevent and control tobacco and nicotine pandemics.[1] Intensive smoking cessation interventions have been associated with substantially higher success in quitting than briefer programmes,[2] particularly when defined by a combination of individual-based or group-based counselling, pharmaceutical support and patient education taking place in at least four sessions of at least 10 min each, as well as follow-up.[3 4]

However, follow-up after SNCI is rarely a part of the clinical routine, and achieving high follow-up rates can be challenging. Achieving the recommended high follow-up rates for better certainty and reliability of outcomes is also a typical hurdle.[5] For research on smoking, specific criteria have been developed to avoid overestimating successful quitting. According to these criteria, participants who were lost to follow-up were deemed continuous smokers,[6] which may have underestimated the smoking cessation rate.

Similar to other countries, Denmark has well-established national health registries and clinical databases. In 2001, a national database was established to document face-to-face smoking cessation interventions and the impact of informed consent. Within the last few years, intensive interventions have also included new nicotine products. Currently, STOPbase for Tobacco and Nicotine collects data to monitor outcomes and ensure high-quality effects of intensive SNCI delivered in approximately 100 stop units distributed across the country.[4] At present, 94 of the 98 Danish municipalities report to STOPbase, which includes more than 200 000 participants. About 9 of the 10 patients agree to

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undergo the 6-month follow-up, which is performed manually and includes a structured telephone interview with up to four call rounds. Despite a follow-up calling rate of approximately 90%, the overall response rate was only 66% (ranging from 25% to ~100%) in 2022.[7]

Accordingly, there is substantial room for improvement. Using a semistructured interview guide, we investigated possible preferences and barriers to achieving improved follow-up rates among 20 patients lost to follow-up after intensive cessation intervention and their 11 therapists.[8] Overall, both patients and therapists preferred to intensify the follow-up procedures by adding additional attempts and means of contact while avoiding the use of unknown telephone numbers. Furthermore, the patients and staff preferred different days or times of the day for the follow-up interviews, and these recommendations were implemented in the STOPbase from 2024. Interestingly, some patients reported successful quitting in relation to the interviews, warranting further evaluation in a larger study.[8]

The objective of this study was to evaluate the effect of the new intensified follow-up procedure (additional calls text, and voice messages from known telephone numbers) as an add-on for patients lost to 6-month follow-up interview after intensive SNCI and to compare their smoking status with the group that responded to the routine follow-up.

The main hypothesis was that the new follow-up procedure would increase the follow-up rate in the group lost to routine follow-up from zero to one-third. The follow-up rate was based on clinical experience, as it is often possible to follow-up with one-third of the patients.

METHODS

Study population

In January and February 2023, 2114 patients (94% smokers and 6% users of other nicotine products) participated in the 6-week standardised Danish intensive SNCI and consented to registration in STOPbase, including the planned early follow-up interview at the end of the intervention. While 136 (6%) said 'no thank you' to further follow-up in advance, the other 1978 consented to follow-up. Overall, 1529/2114 (72%) patients completed the 6-month follow-up interview (±1 month) before the end of September of the same year. The last 449 patients who provided informed consent were lost to follow-up; 379 did not respond at the calling rounds,[4 9] while no contact was attempted for 70 (3%) patients. Half of these 449 patients (n=225) were randomly selected to undergo a new intensified follow-up procedure (project flow in figure 1 and characteristics in table 1). The data were reported in accordance with the Strengthening the Reporting of Observational Studies in Epidemiology guidelines[10] for cohort studies.

Outcomes and data collection

An intensified follow-up procedure was conducted from November to December 2023, the same year as the intervention. The primary outcome was the rate of completed follow-up, followed by continuous successful quitting at the time, obtained using the same interview form as that for the routine follow-up. This consisted of up to four calling rounds for the 6-month follow-up (5–7 months) after the intervention.

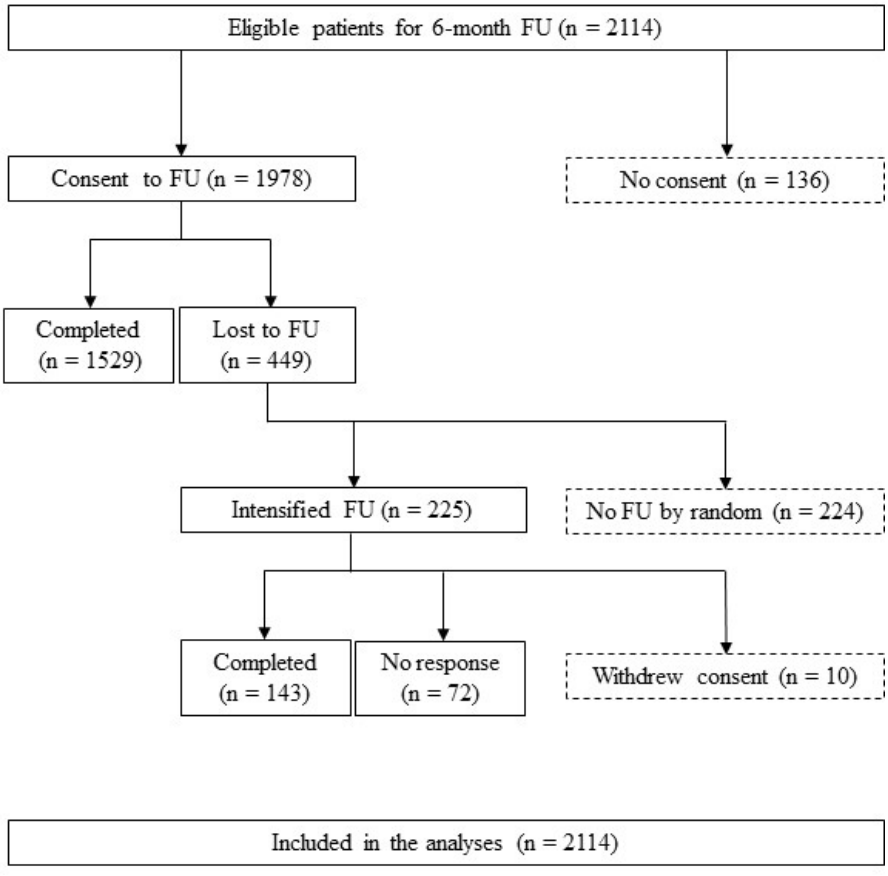

Figure 1 Flow chart: 6-month follow-up (FU) interviews by routine and intensified procedures after the 6-week intensive tobacco and nicotine cessation intervention.

Table 1 Characteristics of all 2114 eligible patients, the 225 patients lost to follow-up (FU), and the 1529 patients completed the routine 6-month FU interview, presented as median (IQR) or %.

	Eligible patients, n=2114	Lost to FU, n=225	Completed FU, n=1529
Age (years), median (IQR) (no unknown)	55 (42–64)	52 (39–62)	56 (43–65)
Males (no unknown)	48%	43%	49%
Education (3% unknown)			
No education	30%	26%	30%
Short	47%	42%	48%
Medium long	16%	24%	15%
Long	5%	6%	5%
Being employed (5% unknown)	56%	48%	57%
Being disadvantaged* (3% unknown)	66%	56%	68%
Smoking (94%) and nicotine (6%) history			
Heavy smoking† (1% unknown)	71%	70%	70%
Pack-years, median (IQR) (11% unknown)	28 (14–43)	24 (12–38)	28 (15–44)
Fagerström nicotine dependency (scale 0–10) median (IQR) (1% unknown)	5 (4–7)	5 (4–7)	5 (4–7)
≥20 g of tobacco per day (1% unknown)	22%	19%	22%
Previous quit attempts (2% unknown)	57%	63%	57%
Living with smoker (3% unknown)	27%	29%	26%
Smoking cessation intervention			
Encouraged by healthcare personal (2% unknown)	68%	60%	68%
Group format (1% unknown)	70%	79%	69%
Nicotine replacement therapy (1% unknown)	60%	57%	60%
Compliance with programme (1% unknown)‡	61%	55%	66%
Successful quitting after intervention (12% unknown)	51%	55%	53%

*Disadvantaged: unemployed and/or no education (except primary to high schooling and/or short work-related courses).
†Heavy smokers: smoking≥20 pack-years, Fagerström Score 7–10 and/or daily smoking≥20 cigarettes.
‡Compliance: attended≥75% of the scheduled sessions.

A new intensified follow-up procedure was developed based on a previous interview study of individuals lost to follow-up and their therapists.[8] The newly developed follow-up procedure included up to four more calling rounds in a month, preceded by supportive text and voice messages with information on the reason for calling, telephone number and name of the interviewers.

For all individuals in STOPbase, consent for participation, smoking and nicotine profile over time, sociodemographics, type, duration (approximately 6 weeks) and compliance with the intervention, as well as the status at the end of the intervention, were collected at the beginning and during the intervention (table 1).[4 9 11] Therapists reported this information after the programme. Data at the routine 6-month follow-up were collected via structured interviews by trained therapists from the national quit line (Stoplinien) or by local therapists according to local decisions.

Statistical analyses

The power calculation was based on the expectation that approximately 25%–30% of included patients completed the intensified procedure among those lost to follow-up, necessitating approximately 21–30 patients, and that their successful quit rate would be half the level (23%) of the group that completed routine follow-up (46%), necessitating 66 patients in each group for a 2α at 0.05 and β at 0.20. Overall, this warranted the inclusion of two groups of 200–250 patients each. Given the limited available literature, these estimates were based on the inclusion of the 20 first responders among 48 patients and their cessation rate of 7/20 in our previous qualitative study[8] while also considering the wide variety of follow-up and cessation rates across stop units nationally.[7]

Descriptive statistics were used for statistical analysis. Characteristics are presented as medians and ranges for continuous data and as numbers and percentages for categorised data. The follow-up rates and successful quit rates are presented as numbers and percentages, including the 95% CI, and compared using the χ^2 test as intention-to-treat for all participants; the Russell standard[6] was applied for those lost to follow-up and for completers of the follow-up as per protocol. Because it was not possible to include zero patients in the χ^2 analyses, it was replaced by a value of 1 for the analysis. Adjustments for confounders were not performed owing to the small number of participants representing each variable. The number of patients who used other nicotine products was markedly small to perform a detailed analysis. Statistical significance was set at $p<0.05$.

Additionally, the impact of the intensified follow-up procedure on the total follow-up and cessation rates was estimated using the Russell standard.[6]

Data analyses were performed using R statistical software V.4.1.0, 18 May 2021.

RESULTS

Among the 225 patients lost to 6-month follow-up, 153 were reached; however, 10 withdrew their consent during the interview. Thus, the follow-up rate in the lost-to-follow-up group increased significantly from 0 to 143 completers, or 64%

Table 2 Number of the 225 patients responding in each calling round of the intensified 6-month follow-up (FU), given in %, numbers and 95% CI

Calling round	Completed FU	n (95% CI)
1	40%	91 (77 to 104)
2	17%	38 (27 to 50)
3	6%	13 (7 to 20)
4	0%	1 (0 to 2)
Total	64%	143 (128 to 158)

(95% CI: 61% to 67%) (p<0.001), which was higher than the 25%–30% expected.

Of the 225 patients, 54 had successfully quit the SNCI by the 6-month follow-up, determined as 24% (95% CI: 21% to 27%) in the intention-to-treat analysis and 54/143 or 38% (34% to 42%) in the per-protocol analysis. The number of completers in the intensifies follow-up group was significantly lower than the 46% (45% to 47%) completers in the group responding to routine 6-month follow-up: 54/143 and 703/1529 (p<0.001).

In the intensified follow-up group, most patients completed the follow-up procedure after the first two attempts, with only a few responding at later attempts (table 2).

The potential impact of adding the intensified follow-up procedure follow-up was estimated by extrapolating the results of the 225 patients to the other 224 patients, constituting the group of 449 patients lost to follow-up, with those neither completing the routine nor the new follow-up procedures considered smokers.[12] This resulted in a follow-up rate of 86% (85%–87%) or (143+142+1529)/2114 for the total group.

Likewise, the success rate after 6 months was 38% (37%–39%) or (54+53+703)/2114.

DISCUSSION

The findings of the current study revealed that the intensified follow-up procedure could substantially increase successful follow-up in almost two-thirds of the group lost to the 6-month follow-up interview after intensive SNCI. Notably, only one of four patients had continuously quit smoking after the intervention, which was approximately half the level and substantially lower than that of the group that completed the routine follow-up. These results could impact the outcomes of the total group of eligible patients, given that the estimated follow-up rate would increase from 72% to 86% and the successful quitting rate from 32% to 38% for the period of this study.

Low follow-up rates after SNCI are generally problematic, and literature on strategies to improve these rates remains sparse. Although a follow-up rate exceeding 80% is generally expected, achieving this rate is often challenging.[5] In tobacco research, this challenge has been addressed by the simple imputation of a worst-case scenario, where patients lost to follow-up are considered smokers to avoid overestimation.[6] This standard has also been applied to the reporting of other nicotine products. However, if this consideration is incorrect, the possible effect could be underestimated or overlooked. Alternatively, missing data could be handled by using multiple imputations,[12] which may introduce bias, especially if the data are not randomly missed.[13] In the present study, successful quitting was highest in the group that completed the routine follow-up and approximately half the level in the group lost to follow-up, which may add to the running optimisation of models for imputation in practice and research within the area of tobacco and nicotine. This may also be relevant in other fields, given that smoking has been associated with a lower response rate to follow-up in relation to respiratory conditions.[14 15]

The relatively high response rate to the intensified follow-up procedure could be, at least in part, because the newly developed follow-up procedure was based on the preferences of a group lost to follow-up, which is similar to the group investigated in the present study. No other studies have identified the involvement of patient preferences in developing a better follow-up procedure in tobacco and nicotine projects. Several studies have evaluated strategies to increase follow-up rates, particularly for postal and electronic questionnaires, as previously reviewed.[16] Recent studies have evaluated intensified contact via combined telephone calls and letters of patients lost to follow-up; however, the results have been contradictory.[15 17 18]

This study has several limitations. First, it was based on intervention data collected in a real-life setting at tobacco and nicotine stop units across the country. The intensified follow-up procedure evaluated in the present study was based on an interview study conducted in a similar patient group and setting; this is also a limitation, and generalisation to other patient groups, settings and cultures should be performed only after careful consideration.

Overall, successful quitting was not validated biochemically, which may have introduced an overestimation of the effect; however, as a strength of this study, the data were collected by performing a structured interview via telephone calls by interviewers trained in follow-up and SNCI instead of patients filling in a questionnaire alone.[19] The intensified follow-up procedure was evaluated only among patients undergoing a 6-week intensive SNCI free of charge, and outcomes may differ for brief SNCI.

Intensified follow-up constitutes a time-consuming add-on to an already manual procedure that includes at least four calls, potentially reducing practical applicability. However, the present results demonstrated the major effect of the first two extra calls, and further use of mail, text and voice messages could easily be digitalised.

In Denmark, the costs for routine follow-ups conducted by the national quit line is approximately €10–12. Adding the intensified follow-up to the already functioning routine is estimated to be an extra €2–5, depending on the number of calls. The average cost of the 6-week intensive SNCI (the gold standard programme) is estimated to be €500, including therapist resources and nicotine replacement therapy.

The results of this study are important for future patients, who can be provided more reliable information regarding the expected effect before undertaking the intensive SNCI, as well as better possibilities to share their outcomes afterwards. This may affect clinical practice by increasing the overall expectation of quitting and avoiding judging all those lost to follow-up as continued users. Furthermore, healthcare planners and policymakers need to have more reliable estimates on intensive SNCI. Although predictors of successful follow-up should be explored, this determination is outside the scope of this study and would be relevant in future investigations. From a research perspective, future studies should also evaluate the intensified 6-month procedure and other interventions in alternate settings, countries and cultures to improve the certainty of the outcomes of tobacco and nicotine interventions.

In conclusion, almost two-thirds of the patients who were lost to the 6-month follow-up interview completed the intensified follow-up procedure. Their cessation rate was approximately half that of those who completed the routine follow-up. However,

the clinical relevance of this finding should be considered, as the high follow-up rate can impact the reliability of outcomes, and the group lost to follow-up could no longer be judged as continuous users of tobacco or other nicotine products.

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Competing interests None declared.

Patient consent for publication Not applicable.

Ethics approval This study involves human participants. All persons were registered in STOPbase and followed up after informed consent was obtained, which could be withdrawn at any time and without explanation, and withdrawal had no impact on the intervention taking place in the stop units. The STOPbase Secretariat and interviewers did not participate in the smoking and nicotine cessation intervention. The STOPbase was approved by the Danish Data Protection Agency (P-2021-900) and further considered by the Scientific Ethical Committee of the Capital Region (685 27), which did not have further comments. Participants repeated the consent to participate in the intensive follow-up study before taking part.

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement Data are available upon reasonable request. All data relevant to the study are included in the article or uploaded as supplementary information.

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