



Formulaire Rapport final concernant des projets de recherche

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1. Informations générales

Nom du projet

Combining default choices and shared decision making to improve tobacco cessation at 6 months in primary care patients: a pragmatic, cluster-randomized trial

Personne à contacter pour information complémentaire

Kevin Selby

Courriel

kevin.selby@unisante.ch

Remarque importante :

Le rapport sera publié sur le site Internet du FPT. Veuillez décrire les résultats aussi brièvement que possible, dans une langue simple, compréhensible par un public non initié, et en évitant les termes techniques. Le rapport doit obligatoirement être rédigé dans l'une des langues officielles (pas en anglais).

Signature

Nom

Kevin Selby

Signature

Lieu/ Date

Lausanne, 30.04.24

2. Évaluation du projet

2.1 Évaluation du résultat du projet

De manière générale, comment évaluez-vous le déroulement et le résultat du projet ?

Commentez brièvement votre évaluation.

Overall, we were very happy with certain results of the project and less happy with others. We were happy with the creation and use by General practitioners (GPs) of the paper and electronic tools www.howtoquit.ch, as well as the training program. Feedback was positive and we see that GPs in the intervention group continued to report changes to their practice at 12 months follow-up. We also learned a lot by adapting our intervention to the French context. The overall results are promising and support continuing to disseminate our results. Finally, it was important to do a randomized trial to address the lack of rigorous data for a decision aid for smoking cessation. However, there were difficulties with recruitment and retention. Despite multiple reminders, many GPs recruited 4 patients or fewer. We had many problems recontacting patients recruited in France at 6 months follow-up (44% lost to follow-up). Finally, we were disappointed by the lack of signal for an effect on the primary outcome of smoking abstinence at 6 months follow-up.

2. Résumé i

Background: While quitting smoking dramatically decreases overall mortality, general practitioners (GPs) are less likely to prescribe medications for smoking cessation than other risk factors. Guidelines recommend providers first assess patients' "readiness" to quit, an "opt-in" strategy, but only a minority of tobacco users are ready to quit on a given day. An "opt-out" strategy offering treatment as the default choice increased quit attempts in hospital and with pregnant women, but has not been tested in primary care. We assessed the effect of training GPs to offer smoking cessation treatments as the default choice using an encounter decision aid (DA).

Methods: We conducted a pragmatic, cluster-randomized controlled trial with GPs in private practice in Switzerland and France. The intervention was a half-day course teaching GPs the default choice approach using a DA. Control GPs received a 1-hour refresher training on smoking cessation aids. GPs recruited daily smokers seen for routine care. The primary outcome was self-reported, 7-day, point prevalence smoking abstinence collected by telephone at 6 months. Secondary outcomes were quit attempts and use of smoking cessation aids at 3-weeks, 3-months and 6-months, and a patient-reported measure of shared decision making (CollaboRATE scale 1-10, where higher scores = more patient involvement).

Results: 42 GPs completed the training (76% in practice in Switzerland vs 24% in France, 62% women), of whom 34 (81%) recruited 287 current smokers. Among the participating patients, 51% were women, the mean age was 48 years (SD: 2.6), 77% smoked <20 cigarettes/day, and 221 responded at 6 months follow-up (77%). The intervention did not affect self-reported smoking abstinence rate at 6 months (9.5% in the intervention and 10.4% in the control groups, respectively OR 0.88 (95%CI 0.37–2.10). It did, however, increase the number of quit attempts at 3-weeks (OR 2.09, 95%CI 1.04–4.20) and the use of smoking cessation aids at the 3-week and 3-month follow-ups (OR 2.57, 95%CI 1.21-5.45 and OR 2.00, 95%CI 1.11-3.60, respectively). The mean CollaboRATE score was 8.05/10 in the intervention group and 7.28/10 in the control group ($p=0.02$), reflecting more patient involvement in decision-making.

Conclusion: Training GPs to use a decision aid did not improve smoking abstinence rate, despite short-term increases in quit attempts and use of smoking cessation aids. It improved patient involvement in decision making.

3. Étapes restantes i

The scientific abstract describing our randomized trial will be presented as a poster at the Swiss Society of General Internal Medicine conference in Basel in May, 2024, and as an oral presentation at the International Shared Decision Making Society conference in Lausanne in July, 2024. A manuscript detailing the results is currently being reviewed by co-authors and will be submitted by the end of April 2024 to the Journal of General Internal Medicine.

Analyses are still ongoing concerning implementation outcomes, meaning uptake of the intervention by general practitioners. We expect to have an article describing those outcomes by the end of 2024.

4. Résultats du projet

4.1 Questions de recherche i

The full protocol is available here: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9508762/>.

The primary objective was to evaluate the effect of a training program encouraging GPs to offer smoking cessation treatment as a default choice to all current smokers using an interactive, encounter decision aid (electronic or paper version), on the proportion of current smokers seen in primary care who have quit smoking 6 months after a baseline visit to their GP, as compared to enhanced usual care.

Secondary objectives were to: 1) evaluate the effect of the intervention on the proportion of patients who make quit attempts; 2) evaluate the effect of the intervention on the proportion of patients who use a quit aid; 3) evaluate the effect of the intervention on patients' perceived involvement in discussions about smoking cessation; and finally, 4) measure the uptake of key behaviours, notably offering quit aids to all current smokers and use of the DA, by GPs.

4.2 Démarche i

We conducted a pragmatic, cluster-randomized controlled trial with GPs in private practice in Switzerland and France. The intervention was a half-day course teaching GPs the default choice approach using a decision aid, with GPs able to use the paper or electronic version. Control GPs received a 1-hour refresher training on smoking cessation treatments. GPs then recruited among their patients seen for routine care, any adult, daily smokers, regardless of their motivation to quit smoking. The primary outcome was self-reported, 7-day, point prevalence smoking abstinence at 6 months collected by telephone. Secondary outcomes were quit attempts and use of smoking cessation aids at 3-weeks, 3-months and 6-months, and a patient-reported measure of shared decision making (CollaboRATE scale 1-10, higher scores = more involvement).

We also conducted qualitative interviews with both patients (n=20) and GPs (n=12) from Switzerland to explore the acceptability of the default choice approach using a decision aid. We transcribed all interviews and performed thematic coding using the software MAXQDA.

4.3 Résultats i

42 GPs completed the training (76% in practice in Switzerland vs 24% in France, 62% women), of whom 34 (81%) recruited 287 current smokers. Two GPs dropped out and 6 failed to recruit any patients. Among the participating patients, 51% were women, with a mean age of 48 years (SD: 2.6), 77% smoked <20 cigarettes/day, 62% had the intention to try quitting in the next 3 months. A total of 221 responded at 6 months follow-up (77%). Primary and secondary outcomes are in the Table.

Table: Patient-reported smoking abstinence, quit attempts, and use of a smoking cessation aid at 3-weeks, 3-months, and 6-months follow-up, adjusted for clustering by GP (n=34 recruiting GPs and n=287 patients)

| | Intervention (%) | Control (%) | Odds-Ratio (95% CI) |
|--|------------------|----------------|---------------------|
| Primary outcome | | | |
| 7-day, point-prevalence smoking abstinence at 6-month follow-up, intention to treat sample | 10/105 (9.5%) | 19/182 (10.4%) | 0.88 (0.37 – 2.10) |
| 7-day, point-prevalence smoking abstinence at 6-month follow-up, complete case sample | 10/85 (12%) | 19/126 (14%) | 0.78 (0.30 – 1.99) |
| Secondary outcomes | | | |
| 7-day, point-prevalence smoking abstinence | | | |
| 3-week follow-up | 4/89 (4.5%) | 11/156 (7%) | 0.62 (0.18 – 2.17) |
| 3-month follow-up | 12/79 (15%) | 16/134 (12%) | 1.31 (0.57 – 3.02) |
| Quit attempt since last contact | | | |
| 3-week follow-up | 32/85 (38%) | 33/144 (23%) | 2.09 (1.04 – 4.20) |
| 3-month follow-up | 25/66 (38%) | 34/118 (29%) | 1.58 (0.76 – 3.26) |
| 6-month follow-up | 32/70 (46%) | 40/115 (35%) | 1.58 (0.86 – 2.90) |
| Use of a smoking cessation aid since last contact | | | |
| 3-week follow-up | 36/89 (40%) | 36/156 (22%) | 2.57 (1.21 – 5.45) |
| 3-month follow-up | 33/78 (42%) | 36/134 (27%) | 2.00 (1.11 – 3.60) |
| 6-month follow-up | 34/81 (42%) | 40/135 (30%) | 1.73 (0.94 – 3.18) |

*Adjusted for clustering of patients at the level of General Practitioners

Additional secondary outcomes were included at the time of the 3-week follow-up phone call. At that time, 51% of intervention patients recalled using a decision aid versus 9% of control patients ($p<0.001$) and 33% of intervention patients had received a prescription for nicotine replacement therapy versus 19% of control. The proportion of patients prescribed varenicline, bupropion, electronic cigarettes, or

other treatments was similar between groups. The mean CollaboRATE score was 8.05 out of 10 (SD 2.25) in the intervention group and 7.28 (SD 2.35) in the control group ($p=0.02$).

We conducted 20 semi-structured interviews with patient participants (mean age 49 years, 55% female). In the intervention group, 7/12 participants appreciated the DA, saw it as useful, usable, and valuable. 2/12 participants did not find it helpful and 3/12 did not recall having used it. Participants felt their GP provided moral support, more than from a specialist (cardiologist or pulmonologist) because their GP knows them better and has more time during the visit. They felt that the most important factor influencing smoking cessation was their own motivation, not treatment.

The thematic analysis of interviews with GPs is not yet completed.

4.4 Discussion

An intervention training GPs to offer smoking cessation aids as the default choice to current smokers in their consultation using an encounter DA did not increase self-reported abstinence at 6 months follow-up. There were, however, promising improvements in SDM and short-term increases in the number of quit attempts and use of nicotine replacement therapy. Given the limited efficacy and difficulties implementing current approaches to smoking cessation in primary care, these short-term increases and greater patient involvement in discussions should stimulate future research. The encouraging short-term results are still enough to justify including our decision aid and the concept of default choices in the training of GPs in Switzerland.

There are several possible reasons why the intervention didn't increase smoking abstinence. Firstly, fewer patients than expected were recruited as most GPs were too busy and uncomfortable delegating this task. Despite these recruitment issues, our data showed that achieving our target sample size would likely not have changed the outcome, as our results still fell short of the expected effect. Additionally, the control group may have had a stronger intervention than we anticipated, as they received specific training on smoking cessation therapies, unlike previous studies where controls had different or no training. It's also possible that while our approach increased attempts to quit using nicotine replacement therapy, it did not improve the quality of these attempts. More intensive and prolonged interventions for GPs, or better patient follow-up after initial quit advice, might be necessary.

Our intervention contained two related components: encouraging GPs to discuss smoking cessation aids with all current smokers regardless of their level of motivation ('default choice') and a decision aid comparing smoking cessation aids to increase patients' knowledge and involvement in choosing a treatment. Together this approach increased the proportion of patients getting a treatment (principally nicotine replacement), making a quit attempt, and their involvement in discussions. In qualitative interviews, patients did not feel judged or coerced. However, there was no effect on smoking abstinence at 6 months follow-up.

We can thus encourage GPs to be more proactive with patients who smoke and use of the decision aid. But these elements should be one more part of their toolbox, which can also include brief interventions and motivational interviewing.

4.5 Transfert dans la pratique et collaboration

Our paper decision aid is already being distributed as part of the “Vivre sans tabac” curriculum for GPs, which is maintained as part of Pepra of the FMH. The electronic decision aid is soon going to be translated into German and Italian and will also be featured in the “Vivre sans tabac” materials (discussed with Dr Isabelle Jacot Sadowski (Unisanté), responsible for “Vivre sans tabac”). The decision aids will also be used by the project STEN, led by Prof Yasser Khazaal, and financed by the Tobacco Control Fund. They also remain freely available here: <https://www.unisante.ch/fr/consultations-medicale/professionnels-sante/aides-decision>.

The default choice with shared decision making approach is currently taught annually in the University of Paris diploma on smoking cessation. It is taught once a year as part of continuing medical education at Unisanté.

The study results will be presented at a Tobacco colloquium at Unisanté in 2025. I will propose it as a topic for the November 2024 of the *Association suisse pour la prevention du tabagisme* (AT).

4.6 Publications i

Published:

Hempel-Bruder C., Habfast-Robertson I., Durand M.A., Berlin I., Marti J., Khazaal Y., Quinto C., Faouzi M., Selby K. (2022) Combining default choices and an encounter decision aid to improve tobacco cessation in primary care patients: protocol for a cluster-randomized trial. *BMC primary care*. 23 (1) p. 246. [10.1186/s12875-022-01859-9]

Selby K., Marti J., Durand M.A. (2022) We are all choice architects: using behavioral economics to improve smoking cessation in primary care. *Journal of general internal medicine*. 37 (7) pp. 1783-1785. [10.1007/s11606-021-07322-2]

Holland De Sa Neto H., Habfast-Robertson I., Hempel-Bruder C., Durand M.A., Jacot-Sadowski I., Khazaal Y., Berlin I., Selby K. (2022) Formative Provider Testing of a New Encounter Decision Aid for Smoking Cessation: Questionnaire Study. *JMIR formative research*. 6 (4) pp. e32960. [10.2196/32960]

Submitted:

Boesch, A., Durand, M.-A., Habfast-Robertson, I., Jacot-Sadowski, I., Berlin, I., Selby, K. Patient reactions to proactive tobacco cessation counseling using a decision aid in primary care: A qualitative study. Submitted to *Tobacco Use Insights*.

Selby, K., Habfast-Robertson, I., Durand, M.-A., Hempel-Bruder, C., Boesch, A., Marti, J., Kazaal, Y., Faouzi, M., Maisonneuve, H., Berlin, I. Combining default choices and an encounter decision aid to improve tobacco cessation in primary care patients: A pragmatic, cluster-randomized trial. Submitted to the *Journal of General Internal Medicine*.

Planned:

Habfast-Robertson, I., Boesch, A., Durand, M.-A., Berlin, I., Faouzi, M., Maisonneuve, H., Selby, K. The perspective of general practitioners on using shared decision making for smoking cessation: a qualitative study. Target journal *British Journal of General Practitioners* or *BJGP Open*.

5. Annexes i

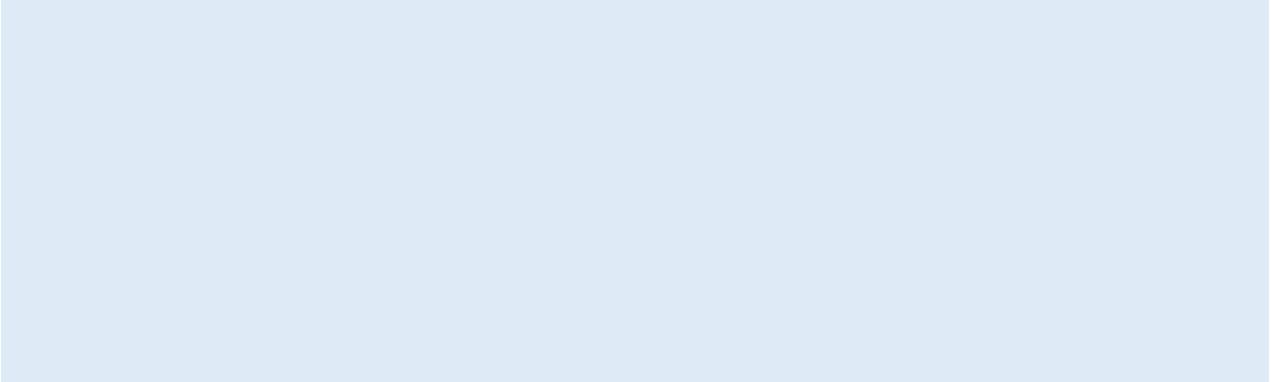
Aperçu du décompte final du budget (voir le [site web FPT](#))

Article submitted to *Tobacco Use Insights*

Article submitted to the *Journal of General Internal Medicine*

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6. Autres remarques

A large, solid light blue rectangular area occupies the center of the page, spanning from approximately y=195 to y=365. It is positioned below the section header and above the explanatory text, likely intended for the user to type or write their remarks.

Veuillez envoyer tous les documents (le formulaire en format PDF et Word) par e-mail directement à la personne responsable de votre dossier au FPT et à info@tpf.admin.ch. Si vous ne disposez pas d'une signature électronique qualifiée, veuillez scanner la première page du formulaire signée à la main et l'envoyer également sous forme de document PDF.

Explications relatives aux différents champs

Signature

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Évaluation du résultat du projet

Utilisez les feux tricolores pour évaluer le déroulement du projet :

- vert = comme prévu
- orange = quelques écarts ou difficultés
- rouge = écarts ou difficultés relativement importants

Commentez brièvement votre évaluation dans le champ prévu à cet effet.

Résumé

Décrivez sur une page au maximum la situation initiale, la ou les hypothèse(s) de départ, les expériences faites, les principaux résultats et la ou les principale(s) conclusion(s) de votre recherche. Relevez en particulier les applications pratiques de ces résultats dans le domaine de la prévention du tabagisme en Suisse.

Le résumé sera traduit dans les autres langues officielles. Il doit être rédigé de manière à ce que des tiers n'ayant pas de connaissances scientifiques approfondies comprennent votre projet et ses conclusions.

Étapes restantes

Veuillez indiquer si/comment les étapes restantes (voir la demande) ont pu être remplies. Veuillez vous référer aux indicateurs définis.

Questions de recherche

Veuillez à nouveau mentionner brièvement quelles ont été les questions de recherche. Indiquez également si elles ont changé en cours de projet, ou si de nouvelles questions sont venues s'y ajouter.

Démarche

Décrivez la démarche concrète mise en œuvre. Comment avez-vous testé vos hypothèses, comment avez-vous collecté vos données ? Quelles étaient les parties prenantes au projet et comment ont-elles été intégrées dans le plan de recherche ? Quels instruments (de collecte) avez-vous utilisés ?

Résultats

Quels sont les principaux résultats de votre recherche ? Présentez-les si possible sous forme de texte ou au moyen de graphiques et de tableaux facilement compréhensibles.

Discussion

Analysez les résultats de votre recherche et les conclusions que vous en tirez. Quelle est leur utilité pour la prévention du tabagisme en Suisse ? Votre recherche apporte-t-elle une contribution nouvelle à la prévention du tabagisme ou éclaire-t-elle un nouvel aspect d'une question déjà étudiée auparavant ? En quoi les résultats de votre recherche contribuent-ils à améliorer le travail des acteurs de la prévention du tabagisme ? Comment vos résultats peuvent-ils être utilisés par les milieux de la science, de la politique ou des médias, que ce soit à des fins d'amélioration ou d'adaptation du travail ou dans le but d'informer ou de s'informer soi-même ?

Transfert dans la pratique et collaboration

Quelles mesures avez-vous prises pour diffuser les enseignements de votre recherche ? Ce transfert dans la pratique s'est-il déroulé avec succès ? Que pouvons-nous en attendre à l'avenir ? Avec quels acteurs de la prévention du tabagisme ou d'un autre domaine avez-vous collaboré à cet effet ?

Publications

Établissez une liste des publications en lien avec votre projet. D'autres publications sont-elles prévues ? Précisez le type (p. ex. article scientifique, rapport) et le statut (p. ex. en préparation, publié) de chaque document. Veuillez faire figurer ici les liens vers les publications en libre accès ou nous en envoyer une version PDF afin que nous puissions la publier sur notre site Internet. Remarque importante : le FPT privilégie la publication dans des revues librement accessibles (open access). Une dérogation à ce principe n'est possible que si vous avez justifié l'impossibilité ou l'inutilité d'une publication en libre accès dans votre demande.

Annexes

Mentionnez toutes les annexes jointes au rapport, telles que les rapports d'évaluation, les publications ou tout autre document utile.