

Citació per a la versió publicada

Martínez, C. [Cristina], Feliu, A. [Ariadna], Torres, N. [Núria], Nieva, G. [Gemma], Pinet, C. [Cristina], Raich, A. [Antònia], Mondon, S. [Sílvia], Barrio, P. [Pablo], Andreu, M. [Magalí], Hernández-Ribas, R. [Rosa], Vicens, J. [Jordi], Costa, S. [Sílvia], Suelves Joanxich, J.M. [Josep Maria], Vilaplana, J. [Jordi], Enríquez, M. [Marta], Alaustre, L. [Laura], Vilalta, E. [Eva], Subirà, S. [Susana], Bruguera, E. [Eugeni], Castellano, Y. [Yolanda], Saura, J. [Judith], Guydish, J. [Joseph], Fernández, E. [Esteve] & Ballbè, M. [Montse]. (2022). Acceptability and participation predictors for a pragmatic randomized controlled trial to test a smoking cessation intervention after discharge from mental health wards. *Drug and Alcohol Dependence*, 234, 109390. doi: 10.1016/j.drugalcdep.2022.109390

DOI

<http://doi.org/10.1016/j.drugalcdep.2022.109390>

Handle O2

<http://hdl.handle.net/10609/147052>

Versió del document

Aquesta és una versió acceptada del manuscrit.

La versió en el Repositori O2 de la Universitat Oberta de Catalunya pot ser diferent de la versió final publicada.

Drets d'ús i reutilització

Aquesta versió del manuscrit es fa disponible amb una llicència Creative Commons del tipus Atribució No Comercial No Derivades (CC BY-NC-ND) <http://creativecommons.org/licenses/by-nc-nd/4.0>, que permet baixar-la i compartir-la sempre que se'n citi l'autoria, però sense modificar-la ni utilitzar-la amb finalitats comercials.

Consultes

Si creieu que aquest document infringeix els drets d'autor, contacteu amb l'equip de recerca: repositori@uoc.edu

Acceptability and participation predictors for a pragmatic randomized controlled trial to test a smoking cessation intervention after discharge from mental health wards

Running ahead: Participation in a quit-smoking trial after psychiatric ward discharge

Cristina Martínez^{1,2,3,4,5}, Ariadna Feliu^{1,2,3,5}, Núria Torres⁶, Gemma Nieva⁷, Cristina Pinet⁸, Antònia Raich⁹, Sílvia Mondon¹⁰, Pablo Barrio¹⁰, Magalí Andreu¹⁰, Rosa Hernández-Ribas¹¹, Jordi Vicens¹², Sílvia Costa^{8,13}, Josep Maria Suelves^{14,15}, Jordi Vilaplana¹⁶, Marta Enríquez^{1,2}, Laura Alaustre⁶, Eva Vilalta⁶, Susana Subirà¹², Eugeni Bruguera⁷, Yolanda Castellano^{1,2}, Judith Saura^{1,2,17}, Joseph Guldish⁴, Esteve Fernández^{1,2,5,17*} and Montse Ballbè^{1,2,5,10*}

¹Tobacco Control Unit, Cancer Control and Prevention Program, Institut Català d'Oncologia-ICO, Av. Gran Via de L'Hospitalet 199-203, 08908 L'Hospitalet de Llobregat (Barcelona), Spain

²Cancer Control and Prevention Group, Institut d'Investigació Biomèdica de Bellvitge-IDIBELL, Av. Gran Via de L'Hospitalet 199-203, 08908 L'Hospitalet de Llobregat (Barcelona), Spain

³Department of Public Health, Maternal Health and Mental Health, School of Medicine and Health Sciences, Universitat de Barcelona, C. Feixa Llarga s/n, 08907 L'Hospitalet del Llobregat (Barcelona), Spain

⁴Philip R. Lee Institute for Health Policy Studies, University of California San Francisco, 490 Illinois St., 7th floor, San Francisco, CA 94158, United States

⁵Center for Biomedical Research in Respiratory Diseases (CIBER en Enfermedades Respiratorias, CIBERES), Madrid, Spain

⁶061 CatSalut Respon, Sistema d'Emergències Mèdiques. C. Pablo Iglesias 115, 08908 L'Hospitalet de Llobregat (Barcelona), Spain

⁷Smoking Cessation Unit, Addictive Behaviors Unit, Psychiatry Department, Hospital Universitari Vall d'Hebron, Vall d'Hebron Institute of Research, CIBERSAM, Universitat Autònoma de Barcelona, Passeig de la Vall d'Hebron 119-129, 08035 Barcelona, Spain

⁸Addictive Behaviors Unit, Psychiatry Department, Hospital de la Santa Creu i Sant Pau, C. San Antoni M^a Claret 167, 08025 Barcelona, Spain

⁹Mental Health Department, Althaia Xarxa Assistencial Universitària, C. Dr. Llatjós s/n, 08243 Manresa (Barcelona), Spain

¹⁰Addictions Unit, Psychiatry Department, Institute of Neurosciences, Hospital Clínic de Barcelona. C. Villarroel 170, 08036 Barcelona, Spain

¹¹Alcohol Program, Psychiatry Department, Hospital Universitari de Bellvitge. Institut Català d'Oncologia. IDIBELL. CIBERSAM. Feixa Llarga s/n, 08907 L'Hospitalet de Llobregat (Barcelona), Spain

¹²Psychiatry Department, Hestia Duran i Reynals, Av. Gran Via de L'Hospitalet 199-203, 08908 L'Hospitalet de Llobregat (Barcelona), Spain

¹³Institut d'Investigació Biomèdica Sant Pau. C. San Antoni M^a Claret 167, 08025 Barcelona, Spain

¹⁴Public Health Agency of Catalonia, Health Department, Government of Catalonia, C. Roc Boronat 81-95, 08005 Barcelona, Spain

¹⁵Universitat Oberta de Catalunya, Rambla del Poblenou, 156. 08018 (Barcelona),

¹⁶Serra Húnter Fellow / Computer Science Department, University of Lleida, Jaume II, 69, 25001, Lleida, Spain

¹⁷Department of Clinical Sciences. Faculty of Medicine and Health Sciences, Universitat de Barcelona, C. Feixa Llarga s/n, 08907 L'Hospitalet del Llobregat (Barcelona), Spain

*Both authors should be considered senior authors

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60
61
62
63
64
65

Corresponding author:

Esteve Fernández MD, MPH, PhD
Tobacco Control Unit
Institut Català d'Oncologia
Av. Gran Via de L'Hospitalet, 199-203
08908 L'Hospitalet de Llobregat (Barcelona), Spain
Tel.: +34 - 932607357
E-mail: cmartinez@iconcologia.net

Running head: Acceptability of a quitline after discharge

Word count: 249 Abstract // 1999 Body

Declaration of competing interest: All authors declare no conflicts of interests.

Clinical Trial Registration Details: ClinicalTrials.gov Identifier: NCT03230955

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60
61
62
63
64
65

HIGHLIGHTS

- 50% of smokers with mental health disorders accepted a quit-smoking intervention.
- Smokers that had attempted to quit were more likely to participate in the trial.
- Hospital tobacco control policies mediated participation rates.
- A quitline program may promote cessation benefits introduced during hospitalization.

1
2
3
4
5 **ABSTRACT**
6
7

8 **Background and Aim:** Hospitalization is an ideal time to promote smoking cessation, but
9 interventions are limited for supporting cessation maintenance after discharge. This study aimed
10 to evaluate the acceptability of participating in a trial that tested the efficacy of an intensive
11 telephone-based intervention for smokers after discharge.
12
13
14

15 **Methods:** Adult smokers admitted to mental health wards of six hospitals were invited to
16 participate in the trial. We studied the study acceptance/decline rates by analyzing the
17 characteristics of participants (e.g., sex, age, psychiatric disorder, smoking pattern) and
18 hospitals (e.g., size, tobacco control implementation). We calculated adjusted odds ratios (aOR)
19 to assess predictors of non-participation.
20
21
22
23

24 **Results:** Of 530 smokers that met the study inclusion criteria, 55.5% (n=294) agreed to
25 participate. Participant and non-participants were not different in sex, age, or psychiatric
26 diagnosis. Compared to non-participants, participants had made more attempts to quit in the past
27 year (66.1% vs 33.9%; $p<0.001$) and reported higher abstinence rates during the hospital stay
28 (66.7% vs. 33.3%; $p=0.05$). Participation rates by hospital varied from 30.9% to 82.0%
29 ($p<0.001$). Predictors of non-participation were not having attempted to quit in the last year
30 (aOR=2.42; 95%CI: 1.66–3.53) and low level of tobacco control in the hospital (aOR range:
31 1.79 to 6.39, $p<0.05$).
32
33
34
35
36
37
38

39 **Conclusions:** A telephone-based intervention to promote smoking cessation after discharge was
40 accepted by half of the smokers with mental health disorders. Smokers that had attempted to
41 quit previously and those that stayed in hospitals with a strong tobacco control policy were more
42 likely to participate in the trial.
43
44
45

46 **Keywords:** smoking, hospitalization, mental health, acceptance, telephone, quitline
47
48
49
50
51
52
53
54
55
56
57
58
59
60
61
62
63
64
65

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47

1. INTRODUCTION

Tobacco use is responsible for 16% of deaths in the European region (WHO, 2019). In Spain, 24.5% of adults are smokers (PNsD, 2020). The prevalence is two to four fold higher among people with mental health disorders (Ballbè et al., 2015; Guydish et al., 2016). The high prevalence of smoking in this vulnerable group substantially impairs both quality of life and life expectancy (Bandiera et al., 2015). Thus, smoking among individuals with mental health disorders represents an important health inequality that needs evidence-based solutions.

Hospitalization in smoke-free centers provide a unique opportunity to break the cycle of addiction (Hickman III et al., 2015; Metse et al., 2017). However, supportive follow-up interventions are needed to prolong smoking cessation after discharge (Prochaska et al., 2017). Tobacco quitlines are programs that offer individuals evidence-based psychosocial interventions over the phone –and sometimes free nicotine replacement therapy (NRT). These interventions previously shown to be effective in the general population (Stead et al., 2013).

Testing innovative interventions in Randomized Control Trials (RCTs) provides evidence on their effectiveness (Fitzpatrick et al., 2017). The Consolidated Standards of Reporting Trials (CONSORT) guidelines (Zwarenstein et al., 2008) suggest reporting information about individuals that decide to decline participation in the trial. Few community interventions for promoting smoking cessation have been tested among mentally ill populations after a hospital discharge (Kagabo et al., 2020). Hence, little is known about the acceptability rates and the reasons for declining participation when offered this type of cessation services.

This study aimed to evaluate the acceptability of participating in a RCT for testing the effectiveness of an intensive telephone-based intervention for smokers after discharge from a mental health ward.

2. METHODS

2.1. Design

48
49
50
51
52
53
54
55
56
57
58
59
60
61
62
63
64
65

This study was part of a pragmatic RCT called 061 Quit-Mental trial. It was designed to assess the effectiveness of a telephone-based intervention for smokers with severe mental health disorders to promote smoking cessation after discharge. The study protocol was described previously (Ballbe et al., 2019).

1 This multi-center, cross-sectional study included inpatients of mental health wards in six acute-
2 care hospitals located in the province area of Barcelona (hospital feature described in
3 Supplementary _Table 1).
4

5 **2.2. Study population**

6
7
8 All participants had mental health disorders and were inpatients in the psychiatric wards of each
9 participating hospital. Eligible participants were both sexes, age 18–76 years, and smokers, who
10 had stayed in an acute or detoxification mental health units for at least 24 h, had access to a
11 telephone (landline or mobile), and reside in the province area of Barcelona. Participants were
12 excluded when they were discharged from a psychiatric emergency room; had dementia or brain
13 damage; did not speak or read Spanish or Catalan; were pregnant; had a hearing and/or speech
14 deficit; were attempting to quit smoking in another center or with another intervention; had
15 voluntarily requested discharge; were transferred to another inpatient unit after discharge; or
16 had planned to move their household outside the Barcelona metropolitan area within the
17 following 24 months.
18
19
20
21
22
23
24

25 **2.3. Procedure**

26
27
28 Study clinicians approached eligible patients and invited them to participate in the 061Quit-
29 Mental study, the day before or the same day of discharge, regardless of their willingness to quit
30 smoking. Clinicians first informed the patients about the 12-month pro-active intervention
31 through a smoking quitline. Clinicians explained the intervention as a strategy for helping them
32 quit smoking by enhancing their motivation to quit, to reduce smoking until they quit, or to
33 maintain the abstinence already achieved during their hospital stay. Clinicians also provided an
34 informative leaflet with the details of the study. The recruitment took place between May 2017
35 and July 2019. All participants signed a written informed consent form.
36
37
38
39
40
41
42

43 **2.4. Data collection**

44
45 This data were recorded with a tablet-specific application, designed for the purposes of this
46 study.
47
48

49 For all patients that met the eligibility criteria, we gathered data about sex, age, and the main
50 psychiatric disorder. Additionally, inpatients were asked about their smoking patterns (daily or
51 occasional); the type of tobacco used (manufactured, roll-your-own [RYO], or both
52 (manufactured and RYO), and cannabis use (alone or in combination with tobacco)); the
53 number of cigarettes smoked per day; the age at initiation; their self-assessed Heaviness of
54 Smoking Index (HSI) (low, medium, high) (Chabrol et al., 2005); attempts to quit in the last 12
55
56
57
58
59
60
61
62
63
64
65

1 months (yes/no); attempts to quit during hospitalization (yes/no); and use of NRT during
2 hospitalization (yes/no).
3

4 The main outcome variable was the **patient acceptance to participate in the trial** (yes/no).
5 Inpatients that declined to participate, were asked about their reason/s for declining. The
6 individual selected a specific reason from the following choices: “not interested”, “reluctant to
7 provide a telephone number”, “reluctant to be contacted”, and “Other”.
8
9

10 We also collected information about the **hospitals and psychiatric** units, including: the number
11 of beds; type of patients; total staff; staff-patient ratio; percentage of staff turn-over; available
12 smoking cessation service for patients (yes/no); whether they conducted psycho-educational
13 groups during hospitalization (yes/no), whether patients were permitted to go outside the ward;
14 and their Self-Audit Questionnaire score in 2017 (SAQ). The SAQ provided an indication of the
15 extent to which tobacco control measures were fulfilled in the hospital (maximum score: 144
16 points) (Martinez et al., 2009).
17
18
19
20
21
22

23 **2.5. Statistical analysis**

24 Differences between groups that accepted and declined were assessed using with Chi-squared
25 and U-Mann Whitney tests. To assess the predictors of declining participation, we fitted a
26 logistic regression model. Variables that were assessed with a significance of $p < 0.25$ in the
27 univariate tests were included in the multivariate model. Results are presented as adjusted odds
28 ratios (aOR). Statistical significance was set to $p < 0.05$.
29
30
31
32
33
34
35
36
37

38 **3. RESULTS**

39 Among 530 smokers invited to participate, 294 (55.5%) accepted. The group that accepted
40 participation showed no socioeconomic differences from the group that declined participation
41 (Supplementary_Table 1).
42
43
44
45
46

47 Hospitals with SAQ scores ≥ 100 points had higher participation (62.0%) than hospitals with
48 SAQ scores < 100 points (37.0%, $p < 0.001$).
49
50

51 Smokers that agreed to participate started smoking at an older age than to those that declined
52 participation (mean \pm SD: 17.4 ± 5.5 vs. 16.3 ± 4.4 ; $p = 0.002$). Moreover, participation was
53 significantly higher among smoker that had attempted to quit in the last 12 months ($p < 0.001$),
54 and those that had maintained abstinence during hospitalization ($p = 0.050$), compared to their
55 counterparts (Table 1).
56
57
58
59
60
61
62
63
64
65

1 The main reason for declining participation was “not interested” (78.8%; Table 2). We observed
2 that individuals in different hospitals had different reasons for declining participation ($p<0.001$).
3 Individuals in hospitals 3 and 6 tended to report “reluctant to be contacted” and “other” more
4 often than individuals in the other hospitals. Furthermore, patients that had not attempted
5 quitting declined due to lack of interest more often than those who had attempted quitting
6 (82.7% vs. 73.2%; $p=0.045$). Similarly, smokers that had not abstained during hospitalization
7 declined due to lack of interest more often than those that had abstained during hospitalization
8 (81.8%; vs. 50.0%; $p<0.001$).
9

10
11
12
13
14 Significant predictors for non-participation included: stays in hospitals 2, 3, 4 and 5 compared
15 to stays in hospital 6 (aOR ranging from 1.79 to 6.39; $p<0.05$) and no attempt to quit in the last
16 12 months (aOR=2.42; 95% CI: 1.66–3.53).
17
18

19 **4. DISCUSSION**

20
21
22 Our findings showed that more than half of the smokers approached in acute-care psychiatric
23 hospital units agreed to participate in an intervention to quit smoking. Our results demonstrated
24 that smokers that had been staying in a smoke-free hospital were willing to receive over-the-
25 phone counseling support to either maintain abstinence or continue reduced smoking after
26 hospitalization. Acceptance rates were not associated with patient sociodemographic
27 characteristics or smoking patterns. However, patients that had attempted to quit during the last
28 year and patients that had remained abstinent during their hospital stay were more willing to
29 participate. In addition, patients admitted to hospitals with high levels of tobacco control were
30 more willing to participate than those in hospitals with low level of tobacco control.
31
32
33
34
35
36
37
38
39

40 Although the current trend among psychiatric hospitals is to maintain a completely smoke-free
41 policy, (Kagabo et al., 2020; Soyster et al., 2016; Stockings et al., 2015) smoking cessation
42 follow-up plans after discharge are not typically well-coordinated. Only a few studies have
43 tested the feasibility of continuing tobacco cessation support after discharge. Those studies,
44 showed that the support had a modest effect on abstinence rates (Metse et al., 2017; Stockings et
45 al., 2014). Nevertheless, those studies also demonstrated that patients with cessation support had
46 attempted to quit more frequently, had a lower daily cigarette consumption, and had lower
47 levels of nicotine dependence than patients without cessation support (Stockings et al., 2014).
48
49
50
51
52
53
54
55
56

57 To our knowledge, this study was the first to assess how likely smokers were to accept support
58 for improving their smoking behavior after discharge from a smoke-free, acute-treatment
59 psychiatry ward. Participation rates are not frequently reported in trials (Brown et al., 2021).
60
61
62
63
64
65

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60
61
62
63
64
65

Currently, there is no recommendation for an acceptable participation rate in a RCT (West et al., 2005). In the general population, low participation rates are associated with an insufficient sample size, low statistical power, and selection biases (Heijmans et al., 2015). In studies conducted among vulnerable populations, it is vitally important to report study participation. First, it is important because study participation was reported to be lower in vulnerable populations than in the general population (Naidoo et al., 2020). Second, it is important because these data might encourage clinicians and researchers to facilitate patient engagement in interventions that are especially designed for that population (Zwarenstein et al., 2008). However, the few studies that have studied participation, had a small sample size, showed high variability in participation from 29% (Rogers et al., 2017) to 61% (Metse et al., 2018), and did not explore the reasons for nonparticipation. Our findings, with more than 500 participants, suggested that more than half of the smokers included were interested in receiving support by phone after discharge to help them reduce or quit smoking. We found that less than 10% of those that declined did so because they did not want to be contacted. Most of those that declined to participate had stayed in hospitals with low-level tobacco control policies, and abstinence was rarely promoted. This result led us to conclude that hospital tobacco control policy was a mediator in participation rates. This finding highlighted the need to strengthen the tobacco cessation services offered in psychiatric units to promote abstinence during and after hospitalization.

4.1. Study limitations

The main limitation of this study was the introduction of selection bias. Smokers in acute-care mental health wards that showed a strong desire to quit were referred to an intensive smoking cessation intervention (Antón L, et.al 2019); thus, those patients were excluded from the present 061 Quit-Mental study. Consequently, the present study had a selection bias, and our cohort comprised participants that were more reluctant to quit smoking.

Moreover, we selected hospitals by convenience, which were members of the Smoke-free Hospitals Network (Martinez, 2009). This choice could also have led to a selection bias. However, the included hospitals showed a high level of variability in tobacco control implementation. Furthermore, we explored participation rates and the characteristics of both patients and hospitals that participated. This approach offered the opportunity to explore the reasons underlying the variability among patients and among hospitals.

Another limitation was that we did not conduct a qualitative analysis of the reasons for refusing to participate in our study. Future studies on smokers, regardless of their motivation to quit,

1 should incorporate potential participants' personal insight in the study design to gain a better
2 understanding of the reasons for non-participation. Those results could provide clues to how we
3 might engage patients, or at least increase their motivation level as part of an expected
4 intervention outcome.
5
6
7
8

9 **4.2. Conclusions**

10
11
12
13
14 This study showed that half of the smokers were interested in participating in a smoking
15 cessation quitline intervention after discharge from a mental health ward. We identified two
16 main variables that predicted whether a patient would accept the intervention: a) patients that
17 had abstained from smoking during hospitalization, and b) patients that were admitted to a
18 hospital with a high-level of tobacco control. We observed that the latter variable acted as a
19 mediator in the acceptance rates. Hence, it is important to promote a strong tobacco control
20 culture within the institution. This culture should include providing smoking cessation services
21 to trigger abstinence among the group of smokers. Quitlines could become a community-level
22 solution to continue the benefits of smoking abstinence introduced during hospitalization.
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60
61
62
63
64
65

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60
61
62
63
64
65

REFERENCES

- Antón L, Ballbè M, Gual A, Pinet C, Costa S, Carcolé B, Palau N, F.I., González AI, Hernández-Ribas R, Morchón S, Mondon S, Martí C, Piñas E, Rubio L, B.J., Gómez O, Cano M, Nieva G, Bruguera E, de Maria I, Sanz M, Abella F, Vilarassau A, V.A., Suelves JM, and F.E., 2019. No Title, in: 19th SRNT Europe conference (Ed.), Impact of a Program to Promote Smoking Intervention. Oslo.
- Ballbe, M., Martinez, C., Feliu, A., Torres, N., Nieva, G., Pinet, C., Raich, A., Mondon, S., Barrio, P., Hernandez-Ribas, R., Vicens, J., Costa, S., Vilaplana, J., Alaustre, L., Vilalta, E., Blanch, R., Subira, S., Bruguera, E., Suelves, J.M., Guydish, J., Fernandez, E., 2019. Effectiveness of a telephone-based intervention for smoking cessation in patients with severe mental disorders: study protocol for a randomized controlled trial. *Trials* 20, 38. <https://doi.org/10.1186/s13063-018-3106-5>
- Ballbè, M., Sureda, X., Martínez-Sánchez, J.M., Fu, M., Saltó, E., Gual, A., Fernández, E., 2015. Secondhand smoke in psychiatric units: patient and staff misperceptions. *Tob. Control* 24, e212-20. <https://doi.org/10.1136/tobaccocontrol-2014-051585>
- Bandiera, F.C., Anteneh, B., Le, T., Delucchi, K., Guydish, J., 2015. Tobacco-related mortality among persons with mental health and substance abuse problems. *PLoS One* 10, e0120581. <https://doi.org/10.1371/journal.pone.0120581> [doi]
- Brown, R.A., Minami, H., Hecht, J., Kahler, C.W., Price, L.H., Kjome, K.L., Bloom, E.L., Levy, D.E., Carpenter, K.M., Smith, A., Smits, J.A.J., Rigotti, N.A., 2021. Sustained Care Smoking Cessation Intervention for Individuals Hospitalized for Psychiatric Disorders: The Helping HAND 3 Randomized Clinical Trial. *JAMA Psychiatry*. <https://doi.org/10.1001/jamapsychiatry.2021.0707>
- Chabrol, H., Niezborala, M., Chastan, E., de Leon, J., 2005. Comparison of the Heavy Smoking Index and of the Fagerstrom Test for Nicotine Dependence in a sample of 749 cigarette smokers. *Addict. Behav.* 30, 1474–1477. [https://doi.org/S0306-4603\(05\)00031-6](https://doi.org/S0306-4603(05)00031-6) [pii]
- Delegación del Gobierno para el Plan Nacional sobre Drogas, 2020. Informe 2020 Alcohol, tabaco y drogas ilegales en España. Madrid.
- Fitzpatrick, T., Perrier, L., Tricco, A.C., Straus, S.E., Jüni, P., Zwarenstein, M., Lix, L.M., Smith, M., Rosella, L.C., Henry, D.A., 2017. Protocol for a scoping review of post-trial extensions of randomised controlled trials using individually linked administrative and registry data. *BMJ Open* 7, 1–5. <https://doi.org/10.1136/bmjopen-2016-013770>

- 1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60
61
62
63
64
65
- Guydish, J., Passalacqua, E., Pagano, A., Martinez, C., Le, T., Chun, J., Tajima, B., Docto, L., Garina, D., Delucchi, K., 2016. An international systematic review of smoking prevalence in addiction treatment. *Addiction* 111, 220–230. <https://doi.org/10.1111/add.13099> [doi]
- Heijmans, N., Van Lieshout, J., Wensing, M., 2015. Improving participation rates by providing choice of participation mode: Two randomized controlled trials. *BMC Med. Res. Methodol.* 15, 1–10. <https://doi.org/10.1186/s12874-015-0021-2>
- Hickman III, N.J., Delucchi, K.L., Prochaska, J.J., 2015. Treating Tobacco Dependence at the Intersection of Diversity, Poverty, and Mental Illness: A Randomized Feasibility and Replication Trial. *Nicotine Tob. Res.* 17, 1012–1021. <https://doi.org/10.1093/ntr/ntv034>
- Kagabo, R., Gordon, A.J., Okuyemi, K., 2020. Smoking cessation in inpatient psychiatry treatment facilities: A review. *Addict. Behav. Reports* 11, 100255. <https://doi.org/10.1016/j.abrep.2020.100255>
- Martinez, C., 2009. Barriers and challenges of implementing tobacco control policies in hospitals: applying the institutional analysis and development framework to the Catalan Network of Smoke-Free Hospitals. *Policy. Polit. Nurs. Pract.* 10, 224–232. <https://doi.org/10.1177/1527154409346736> [doi]
- Martinez, C., Fu, M., Martinez-Sanchez, J.M., Ballbe, M., Puig, M., Garcia, M., Carabasa, E., Salto, E., Fernandez, E., 2009. Tobacco control policies in hospitals before and after the implementation of a national smoking ban in Catalonia, Spain. *BMC Public Health* 9, 160. <https://doi.org/10.1186/1471-2458-9-160>
- Metse, A.P., Hizam, N.A.N., Wiggers, J., Wye, P., Bowman, J.A., 2018. Factors associated with retention in a smoking cessation trial for persons with a mental illness: A descriptive study. *BMC Med. Res. Methodol.* 18, 1–8. <https://doi.org/10.1186/s12874-018-0640-5>
- Metse, A.P., Wiggers, J., Wye, P., Wolfenden, L., Freund, M., Clancy, R., Stockings, E., Terry, M., Allan, J., Colyvas, K., Prochaska, J.J., Bowman, J.A., 2017. Efficacy of a universal smoking cessation intervention initiated in inpatient psychiatry and continued post-discharge: A randomised controlled trial. *Aust. N. Z. J. Psychiatry* 51, 366–381. <https://doi.org/10.1177/0004867417692424> [doi]
- Naidoo, N., Nguyen, V.T., Ravaud, P., Young, B., Amiel, P., Schanté, D., Clarke, M., Boutron, I., 2020. The research burden of randomized controlled trial participation: A systematic thematic synthesis of qualitative evidence. *BMC Med.* 18, 1–11. <https://doi.org/10.1186/s12916-019-1476-5>
- Prochaska, J.J., Das, S., Young-Wolff, K.C., 2017. Smoking, Mental Illness, and Public Health. *Annu. Rev. Public Health* 38, 165–185. <https://doi.org/10.1146/annurev-publhealth->

- 1
2 Rogers, E.S., Friedes, R., Jakes, A., Grossman, E., Link, A., Sherman, S.E., 2017. Long-term
3 abstinence and predictors of tobacco treatment uptake among hospitalized smokers with
4 serious mental illness enrolled in a smoking cessation trial. *J. Behav. Med.* 40, 750–759.
5 <https://doi.org/10.1007/s10865-017-9844-0>
6
7
8
9 Soyster, P., Anzai, N.E., Fromont, S.C., Prochaska, J.J., 2016. Correlates of nicotine withdrawal
10 severity in smokers during a smoke-free psychiatric hospitalization. *Prev. Med. (Baltim.)*
11 92, 176–182. <https://doi.org/10.1016/j.ypmed.2016.01.026>
12
13
14 Stead, L.F., Hartmann-Boyce, J., Perera, R., Lancaster, T., 2013. Telephone counselling for
15 smoking cessation. *Cochrane database Syst. Rev.* 8, CD002850.
16 <https://doi.org/10.1002/14651858.CD002850.pub3> [doi]
17
18
19
20 Stockings, E.A., Bowman, J.A., Baker, A.L., Terry, M., Clancy, R., Wye, P.M., Knight, J.,
21 Moore, L.H., Adams, M.F., Colyvas, K., Wiggers, J.H., 2014. Impact of a postdischarge
22 smoking cessation intervention for smokers admitted to an inpatient psychiatric facility: a
23 randomized controlled trial. *Nicotine Tob. Res.* 16, 1417–1428.
24 <https://doi.org/10.1093/ntr/ntu097> [doi]
25
26
27
28
29 Stockings, E.A.L., Bowman, J.A., Bartlem, K.M., Mcelwaine, K.M., Baker, A.L., Terry, M.,
30 Clancy, R., Knight, J., Wye, P.M., Colyvas, K., Wiggers, J.H., 2015. Implementation of a
31 smoke-free policy in an inpatient psychiatric facility: Patient-reported adherence, support,
32 and receipt of nicotine-dependence treatment. *Int. J. Ment. Health Nurs.* 24, 342–349.
33 <https://doi.org/10.1111/inm.12128>
34
35
36
37
38 West, R., Hajek, P., Stead, L., Stapleton, J., 2005. Outcome criteria in smoking cessation trials:
39 Proposal for a common standard. *Addiction* 100, 299–303. [https://doi.org/10.1111/j.1360-](https://doi.org/10.1111/j.1360-0443.2004.00995.x)
40 [0443.2004.00995.x](https://doi.org/10.1111/j.1360-0443.2004.00995.x)
41
42
43
44 WHO, 2019. WHO report on the global tobacco epidemic, 2019: offer help to quit tobacco use:
45 executive summary. *World Heal. Organ.* 1–8.
46
47
48 Zwarenstein, M., Treweek, S., Gagnier, J.J., Altman, D.G., Tunis, S., Haynes, B., Oxman, A.D.,
49 Moher, D., 2008. Improving the reporting of pragmatic trials: an extension of the
50 CONSORT statement. *BMJ* 337.
51
52
53
54
55
56
57
58
59
60
61
62
63
64
65

Supplementary Table 1. Characteristics of the psychiatric units in six participating centers

Characteristics	Healthcare centers					
	Hospital 1	Hospital 2	Hospital 3	Hospital 4	Hospital 5	Hospital 6
Number of beds	8	36	29	38	39	24
Type of treatment						
Acute	x	x	x	x	x	x
Subacute				x	x	
Detoxification	x		x			x
Total staff (in all shifts), n	24	25	34	21	36	23
Staff in morning shift, n*	4-5	13	13	7	12	14
Staff to patient ratio in morning shift	2	0.36	0.5	0.2	1.01	0.95
Staff involved in recruitment, n	2	2	1	1	2	3
Staff turnover, %	16.7%	0.1%	10.0%	5.0%	11.0%	40.0%
SAQ score	129	109	92	73	120	125
Having a professional of reference in smoking cessation						
Yes	x		x	x	x	x
Psychoeducational groups during hospitalization						
Yes	x	x		x	x	x
Approach of smoking intervention						
Behavioral	x		x	x	x	x
Pharmacological	x	x	x	x	x	x
Therapeutic permits to go outside the ward						
Yes	In the last admission phase, inpatients could leave the ward in pajamas, accompanied by professionals or family, at a certain time	Once the patient was stable, he/she was permitted out during the day and on weekends with his/her family	Weekends Group permission to go out to the garden without smoking; Monday to Friday evenings permission (a "pass") to go with family (3 h approx.)	30 min in the mornings and 3h in the afternoons, depending on the patient. Weekends and holidays allowed outside from morning to afternoon, and	Afternoon and day permits	Permission to leave the ward but remain on hospital premises (where smoking was forbidden), permits to leave the hospital for 16 to 20h and on weekend for 10–20h.

15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60
61
62
63
64
65

might be allowed to
spend the weekend at
home, depending on
each case

*Morning shift was the one when participants were mostly
recruited.
SAQ: Self-Audit Questionnaire

Table 1. Sociodemographic, clinical, smoking, and organizational characteristics of patients that participated versus those that declined to participate in the 061 Quit-Mental Study.

Characteristics	Category	Participation					
		Overall	Acceptance		Decline		<i>p</i> -value
		n	n	%	n	%	
	Total	530	294	[55.5]*	236	[44.5]*	
Sociodemographic and clinical characteristics							
Sex	Male	281	155	55.2	126	44.8	0.878
	Female	249	139	55.8	110	44.2	
Age, years (mean, SD)		530	42.6 (12.5)		42.0 (12.0)		0.620
Psychiatric disorder	Bipolar	87	44	50.6	43	49.4	0.306
	Depression	48	29	60.4	19	39.6	
	Schizophrenia	220	116	52.7	104	47.3	
	Substance abuse disorder	119	75	63.0	44	37.0	
	Other	56	30	53.6	26	46.4	
Smoking							
Smoking pattern	Daily	516	285	55.2	231	44.8	0.496
	Occasional	5	2	40.0	3	60.0	
Type of tobacco	Manufactured	361	192	53.2	169	46.8	0.589
	Roll-your-own (RYO)	77	48	62.3	29	37.7	
	Dual use (RYO & Manufactured)	40	24	60.0	16	40.0	
	Tobacco (any type) with cannabis	41	24	58.5	17	41.5	
	Other	8	4	50.0	4	50.0	
Number of cigarettes per day** (mean, SD)		530	21.5 (14.5)		20.2 (12.4)		0.591
Age of initiation (years) (mean, SD)		530	17.4 (5.5)		16.3 (4.4)		0.002
Heaviness Smoker Index	Low	148	87	58.8	61	41.2	0.885
	Medium	204	121	59.3	83	40.7	
	High	102	63	61.8	39	38.2	
Quit attempts (last 12-months)	Yes	286	189	66.1	97	33.9	<0.001
	No	244	105	43.0	139	57.0	
Abstinent during hospitalization	Yes	66	44	66.7	22	33.3	0.050
	No	464	250	53.9	214	46.1	
Nicotine replacement Therapy during hospitalization	Yes	359	205	57.1	154	42.9	0.274
	No	171	89	52.0	82	48.0	
Organizational							
Hospital	Hospital 1	89	53	59.6	36	40.4	<0.001
	Hospital 2	146	78	53.4	68	46.6	
	Hospital 3	41	21	51.2	20	48.8	
	Hospital 4	97	30	30.9	67	69.1	
	Hospital 5	50	30	60.0	20	40.0	
	Hospital 6	107	82	76.6	25	23.4	
Self-Audit Questionnaire	<100	138	51	37.0	87	63.0	<0.001

≥ 100 | 392 | 243 62.0 | 149 38.0 |

*Row percentage; ** All type of tobacco

Table 2. Sociodemographic, clinical, smoking and organizational characteristics of patients that declined to participate in smoking cessation intervention for different reasons.

Characteristics	Category	Reasons for declining							
		Overall	Not interested		Reluctant to be contacted		Other		p-value
		n	n	%	n	%	n	%	
		236	186	78.8	23	9.7	27	11.4	
Sociodemographic and clinical									
Sex	Male	126	100	79.4	10	7.9	16	12.7	0.524
	Female	110	86	78.2	13	11.8	11	10.0	
Age years; (mean, SD)		236	41.6 (11.7)		45.5 (15.6)		41.3 (10.9)		0.329
Psychiatric disorder	Bipolar	43	30	69.8	7	16.3	6	14.0	0.428
	Depression	19	18	94.7	0	0.0	1	5.3	
	Schizophrenia	104	83	79.8	11	10.6	10	9.6	
	Substance use	44	36	81.8	2	4.5	6	13.6	
	Other	26	19	73.1	3	11.5	4	15.4	
Smoking									
Pattern	Daily	231	182	78.8	23	10.0	26	11.3	0.669
	Occasional	3	3	100.0	0	0.0	0	0.0	
Type of tobacco	Manufactured	169	133	78.7	18	10.7	18	10.7	0.269
	Roll-your-own	29	23	79.3	3	10.3	3	10.3	
	RYO & Manufactured	16	11	68.8	2	12.5	3	18.8	
	Tobacco & cannabis	17	16	94.1	0	0.0	1	5.9	
	Other	4	2	50.0	0	0.0	2	50.0	
Cigarettes per day* (mean, SD)		224	20.6 (12.7)		16.9 (11.1)		20.5 (11.0)		0.397
Age of initiation (mean, SD)		235	16.1 (4.2)		17.7 (5.2)		16.3 (4.5)		0.258
Heaviness Smoker Index	Low	61	48	78.7	8	13.1	5	8.2	0.701
	Medium	83	62	74.7	8	9.6	13	15.7	
	High	39	29	74.4	4	10.3	6	15.4	
Quit attempts (last 12-months)	Yes	97	71	73.2	15	15.5	11	11.3	0.045
	No	139	115	82.7	8	5.8	16	11.5	
Abstinent during hospitalization	Yes	22	11	50.0	7	31.8	4	18.2	<0.001
	No	214	175	81.8	16	7.5	23	10.7	
NRT during hospitalization	Yes	154	120	77.9	15	9.7	19	12.3	0.581
	No	82	66	80.5	8	9.8	8	9.8	
Organizational									
Hospital	Hospital 1	36	31	86.1	1	2.8	4	11.1	<0.001
	Hospital 2	68	55	80.9	4	5.9	9	13.2	
	Hospital 3	20	6	30.0	5	25.0	9	45.0	
	Hospital 4	67	65	97.0	1	1.5	1	1.5	
	Hospital 5	20	18	90.0	2	10.0	0	0.0	
	Hospital 6	25	11	44.0	10	40.0	4	16.0	

1 Self-Audit	>100	87	71	81.6	6	6.9	10	11.5	0.526
2 Questionnaire	≥ 100	149	115	77.2	17	11.4	17	11.4	

Acknowledgements

The authors would like to thank the participants and the participating hospitals for contributing to the study.

Ethical approval

The intervention protocol was approved by the Ethics Committee for Clinical Research (CEIC) from the Bellvitge Biomedical Research Institute (IDIBELL) (reference: PR276/16), and the Ethics Committee of each of the six participating hospitals. The study protocol was registered under Clinicaltrials.gov (NCT03230955 approved the 24th of July 2017)

Funding This project was financed by the Instituto Carlos III (ISCIII) (Grant: PI15/00875) Fondo Europeo de Desarrollo Regional (FEDER) “Una manera de hacer Europa. The Tobacco Control Research Group is partly supported by the Ministry of Universities and Research from the Government of Catalonia [2017SGR319] and by the Instituto de Salud Carlos III, Government of Spain (CIBERES CB19/06/00004). EF was also supported by the Instituto de Salud Carlos III, Government of Spain, co-funded by the European Regional Development Fund (FEDER) [INT16/00211 and INT17/00103]. CM was also supported by the Instituto de Salud Carlos III, Government of Spain, co-funded by the European Regional Development Fund (FEDER) [INT17/00116] and Ministry of Health from the Government of Catalonia [PERIS No 9015-586920/2017]. We thank CERCA Programme/Generalitat de Catalunya for institutional support.

Contributions following CRediT standards:

Cristina Martínez: Conceptualization, Methodology, Investigation, Data Curation, Writing – Original Draft, Supervision, Funding acquisition

Ariadna Feliu: Conceptualization, Software, Formal analysis, Writing- Original Draft, Visualization, Project administrator.

Núria Torres: Project administrator, Investigation, Writing-Review & Editing.

Gemma Nieva: Investigation, Writing-Review & Editing.

Cristina Pinet: Investigation, Writing-Review & Editing.

Antònia Raich: Investigation, Writing-Review & Editing.

Sílvia Mondon: Investigation, Writing-Review & Editing.

Pablo Barrio: Investigation, Writing-Review & Editing.

Magalí Andreu: Investigation, Writing-Review & Editing.

Rosa Hernández-Ribas: Investigation, Writing-Review & Editing.

Jordi Vicens: Investigation, Writing-Review & Editing.

Sílvia Costa: Investigation, Writing-Review & Editing.

Josep Maria Suelves: Investigation, Writing-Review & Editing.

Jordi Vilaplana: Software, Investigation, Writing-Review & Editing.

Marta Enríquez: Investigation, Writing-Review & Editing.

Laura Alaustre: Investigation, Writing-Review & Editing.

Eva Vilalta: Investigation, Writing-Review & Editing.

Susana Subirà: Investigation, Writing-Review & Editing.

Eugeni Bruguera: Investigation, Writing-Review & Editing.

Yolanda Castellano: Formal analysis, Writing-Review & Editing.

Judith Saura: Formal analysis, Writing-Review & Editing.

Joseph Guldish: Writing-Review & Editing.

Esteve Fernández: Conceptualization, Methodology, Investigation, Data Curation, Writing-Review & Editing, Funding acquisition.

Montse Ballbè: Conceptualization, Methodology, Investigation, Data Curation, Writing-Review & Editing, Funding acquisition.

The authors of the manuscript were directly involved in the planning, analysis, and writing of the paper. All approve of the final version being submitted and accept full responsibility for the content of the paper. This manuscript has not been submitted to another journal for review. There are no conflicts of interest regarding this investigation.

The authors whose names are listed immediately below certify that they have NO affiliations with or involvement in any organization or entity with any financial interest (such as honoraria; educational grants; participation in speakers' bureaus; membership, employment, consultancies, stock ownership, or other equity interest; and expert testimony or patent-licensing arrangements), or non-financial interest (such as personal or professional relationships, affiliations, knowledge or beliefs) in the subject matter or materials discussed in this manuscript.

They authors have listed their work affiliations:

Cristina Martínez^{1,2,3,4,5}, Ariadna Feliu^{1,2,3,5}, Núria Torres⁶, Gemma Nieva⁷, Cristina Pinet⁸, Antònia Raich⁹, Sílvia Mondon¹⁰, Pablo Barrio¹⁰, Magalí Andreu¹⁰, Rosa Hernández-Ribas¹¹, Jordi Vicens¹², Sílvia Costa^{8,13}, Josep Maria Suelves¹⁴, Jordi Vilaplana¹⁵, Marta Enríquez^{1,2}, Laura Alaustre⁶, Eva Vilalta⁶, Susana Subirà¹², Eugeni Bruguera⁷, Yolanda Castellano^{1,2}, Judith Saura^{1,2,16}, Joseph Guldish⁴, Esteve Fernández^{1,2,5,16*} and Montse Ballbè^{1,2,5,10*}

¹Tobacco Control Unit, Cancer Control and Prevention Program, Institut Català d'Oncologia-ICO, Av. Gran Via de L'Hospitalet 199-203, 08908 L'Hospitalet de Llobregat (Barcelona), Spain

²Cancer Control and Prevention Group, Institut d'Investigació Biomèdica de Bellvitge-IDIBELL, Av. Gran Via de L'Hospitalet 199-203, 08908 L'Hospitalet de Llobregat (Barcelona), Spain

³Department of Public Health, Maternal Health and Mental Health, School of Medicine and Health Sciences, Universitat de Barcelona, C. Feixa Llarga s/n, 08907 L'Hospitalet del Llobregat (Barcelona), Spain

⁴Philip R. Lee Institute for Health Policy Studies, University of California San Francisco, 490 Illinois St., 7th floor, San Francisco, CA 94158, United States

⁵Consortium for Biomedical Research in Respiratory Diseases (CIBER en Enfermedades Respiratorias, CIBERES), Madrid, Spain

⁶061 CatSalut Respon, Sistema d'Emergències Mèdiques. C. Pablo Iglesias 115, 08908 L'Hospitalet de Llobregat (Barcelona), Spain

⁷Smoking Cessation Unit, Addictive Behaviors Unit, Psychiatry Department, Hospital Universitari Vall d'Hebron, Vall d'Hebron Institute of Research, CIBERSAM, Universitat Autònoma de Barcelona, Passeig de la Vall d'Hebron 119-129, 08035 Barcelona, Spain

⁸Addictive Behaviors Unit, Psychiatry Department, Hospital de la Santa Creu i Sant Pau, C. San Antoni M^a Claret 167, 08025 Barcelona, Spain

⁹Mental Health Department, Althaia Xarxa Assistencial Universitària, C. Dr. Llatjós s/n, 08243 Manresa (Barcelona), Spain

¹⁰Addictions Unit, Psychiatry Department, Institute of Neurosciences, Hospital Clínic de Barcelona. C. Villarroya 170, 08036 Barcelona, Spain

¹¹Alcohol Program, Psychiatry Department, Hospital Universitari de Bellvitge. Institut Català d'Oncologia. IDIBELL. CIBERSAM. Feixa Llarga s/n, 08907 L'Hospitalet de Llobregat (Barcelona), Spain

¹²Psychiatry Department, Hestia Duran i Reynals, Av. Gran Via de L'Hospitalet 199-203, 08908 L'Hospitalet de Llobregat (Barcelona), Spain

¹³Institut d'Investigació Biomèdica Sant Pau. C. San Antoni M^a Claret 167, 08025 Barcelona, Spain

¹⁴Public Health Agency of Catalonia, Health Department, Government of Catalonia, C. Roc Boronat 81-95, 08005 Barcelona, Spain

¹⁵Serra Húnter Fellow / Computer Science Department, University of Lleida, Jaume II, 69, 25001, Lleida, Spain

¹⁶Department of Clinical Sciences. Faculty of Medicine and Health Sciences, Universitat de Barcelona, C. Feixa Llarga s/n, 08907 L'Hospitalet del Llobregat (Barcelona), Spain

*Both authors should be considered senior authors