

# Mesura de l'exposició al fum ambiental del tabac i avaluació de les polítiques preventives en la població infantil

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# Tesi doctoral

# Programa de Doctorat en Medicina

Universitat de Barcelona

# MESURA DE L'EXPOSICIÓ AL FUM AMBIENTAL DEL TABAC I AVALUACIÓ DE LES POLÍTIQUES PREVENTIVES EN LA POBLACIÓ INFANTIL

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A la Marta, la Vinyet i l'Arola, el vertader motor pel qual em llevo cada matí.

# Reconeixements:

A la meva vida professional, que ja comença a ser un xic llarga pel que se suposa que hauria de ser un doctorant, he tingut l'oportunitat de contactar amb moltes persones. Grans professionals, grans investigadors, grans professors, grans alumnes. I tot ells m'han influenciat. N'hi ha amb el quals m'he emmirallat per la seva actuació, per la seva manera de pensar, d'afrontar els reptes, de proposar relacions, d'investigar, de tractar les persones. I també n'hi ha que, veient com actuaven, he pensat que no volia assemblar-m'hi. Tots ells, en qualsevol cas, m'han influenciat de manera positiva ja que m'han permès conformar la meva personalitat i la meva actuació professional. Bé per imitació, bé per reflexió. A tots ells, doncs, vull fer un reconeixement, en aquest moment important de la meva carrera professional. Com comentem a vegades amb el Jose: "un petit pas per a la humanitat, però un gran pas per a mi".

Penso ara en fer un reconeixement al Jordi Casabona. Va ser el primer que va confiar en mi -allà per l'any 1991- i em va donar l'oportunitat de dedicar-me a la Salut Pública i l'Epidemiologia quan jo no en sabia res i només tenia ganes d'entrar en aquest món. Recordaré sempre una frase seva i que he repetit milers de vegades als meus alumnes: "la recerca no és una metodologia, la recerca és una actitud".

Ara bé, és de justícia fer un parell de reconeixements especials. En primer lloc a l'Esteve Fernández, director d'aquesta tesi. No sé quants anys fa que conec l'Esteve i podria dir que la nostra relació s'ha convertit en alguna cosa més que professional. No hi ha hagut dia en que no hagi après alguna cosa de l'Esteve. Del seu esperit perfeccionista, de la capacitat de fer possible les coses més inversemblants. Del seu neguit per posar-se al davant de reptes dificilíssims i d'establir vincles més enllà que professionals amb la gent que professionalment aprecia. La seva bondat el va fer respondre positivament a la meva petició de lideratge del meu projecte de tesi. I en tot moment he sentit que confiava en mi. Cada vegada que hem agut de recomençar, hem recomençat amb un somriure, amb una paraula d'escalf i deixant de banda tot el que ens pogués distreure de tirar endavant. Sempre amb mirada cap el futur. A més a més, l'Esteve ha sabut crear un entorn de treball, la Unitat de Control del Tabaquisme, que, format per un munt de persones que ara venen, que ara van, funciona com una autèntica unitat. També un agraïment especial a totes les persones d'aquest a unitat amb les qui he tingut l'oportunitat de treballar com l'Anna, la Xisca, la Marcela, l'Ester, el Jose i la Montse. Ha sigut un autèntic luxe sentir-me part d'aquest equip. Els he vist treballar sense descans, superant els reptes del finançament escàs,

superar els entrebancs administratius per aconseguir tirar endavant una sol·licitud, de no defallir buscant mostres amunt i avall i tantes altres situacions complexes, que han resolt, majoritàriament, amb un somriure. En el seu acolliment he trobat el que tantes vegades havia buscat fora.

Un altre reconeixement específic per al Jose. Ell ha co-dirigit el projecte. Ell va ser el primer que va veure en el projecte una oportunitat. El Jose ha sigut el vertader motor d'aquesta tesi. Sempre ha confiat en les meves possibilitats i sempre m'ha estat animant a tirar endavant el projecte, fins i tot en els moments en que semblava que mai no veuria la llum. El Jose ha actuat com un autèntic "coach". Com la persona que constantment ha buscat la manera de motivar-me, de facilitar el camí. La seva generositat ha estat immensa. Crec que en el Jose es combinen algunes característiques difícils de trobar, com són una ment privilegiada per a la recerca, una capacitat inacabable pel treball i una generositat sense fi. Diria, que trobar el Jose ha estat el millor de tot aquest projecte professional. Estic segur que tenim per davant grans coses per fer junts. Jose, a partir d'ara ens podrem centrar en reptes personals i esportius. Tenim molt quilòmetres per fer junts.

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Moltes gràcies a tots. Anem per feina!.

# Resum

Antecedents: El tabaquisme passiu o exposició al fum ambiental del tabac (FAT) és responsable de 603.000 defuncions l'any en el món (1% de la mortalitat global). L'exposició passiva al fum del tabac també té efectes en els nens, atès que aquests tenen un sistema respiratori més immadur, respiren més ràpidament i inhalen més contaminants per quilogram de pes corporal, comparat amb els adults. S'ha de destacar que les actuacions de salut pública sobre el control del tabaquisme en els diferents països occidentals, han estat centrades en la prohibició de fumar en espais públics i centres de treballs, a més d'implementar activitats destinades a prevenir el tabaquisme entre els adolescents o els seus pares. L'exposició al FAT pot ocórrer en ambients privats (com el propi lloc de residència o cotxes), en llocs públics (restaurants, bars, espais d'oci) o en lloc de treball. Les xifres d'exposició en cada un d'aquests espais varien àmpliament en funció del país, les normatives i el lloc concret de l'exposició

**Objectius:** 1) Avaluar els efectes d'una intervenció comunitària sobre prevenció del tabaquisme i exposició al FAT en una població escolar de Catalunya. 2) Analitzar la correlació entre la implantació d'espais lliures de fum en diversos països europeus i la prevalença de tabaquisme actiu i passiu en espais privats.

**Metodologia**: Per poder respondre aquests dos objectius s'han realitzat dos estudis. Un primer estudi d'intervenció en escolars de Terrassa (Programa Respir-net), per avaluar l'impacte d'una intervenció a diferents nivells (alumnes, escola, pares) en la disminució de l'exposició al FAT. I un segon estudi ecològic a nivell europeu.

**Resultats:** El programa Respir-net va aconseguir que entre els alumnes intervinguts la prevalença d'exposició al FAT disminuís un 14% a l'escola, un 19,9% l'exposició al FAT a casa i un 21,8% al transport. Els alumnes de les escoles que van informar d'un bon acompliment de les activitats dissenyades en el programa, van reportar unes disminucions més elevades de la prevalença d'exposició al FAT. Es va poder observar que el bon acompliment de les activitats dissenyades en el programa d'intervenció va generar unes disminucions més elevades de l'exposició al FAT en tots els àmbits mesurats d'entre 3 i 10 punts percentuals.

A nivell ecològic no s'ha pogut observar una correlació entre la implementació de polítiques públiques lliures de fum i prevalences altes de tabaquisme en espais privats, com ara la casa o el cotxe particular.

Conclusions: Les actuacions preventives encaminades a disminuir l'exposició del fum ambiental del tabac han de ser multinivell i l'èxit d'aquestes intervencions depèn molt del grau d'acompliment de les activitats plantejades així com de la qualitat de cada intervenció. Les intervencions preventives tenen un efecte menys notable sobre aquells adolescents que ja es declaren com a fumadors. La prohibició de fumar en espais públics no implica un increment de la prevalença de consum en espais privats. Els països amb polítiques més clares i concretes de prohibició de fumar en espais públics són els que tenen una proporció més elevada de cases lliures de fum.

# **Abstract**

Introduction: Passive smoking or secondhand smoking (SHS) is responsible of 603.000 deaths yearly in the World (about 1% of overall mortality). Passive smoking has also effect on child, since they have a more immature respiratory system, they breath faster and they inhale more pollutants per kilogram of weight, as adults do. Public Health activities to control smoking in western countries have been focused in banning smoking in public places and working places. Also many activities have been put in place in order to prevent smoking in adolescents and their parents. SHS may occur in private venues (house or cars), public places (restaurants, bar, or leisure places) or in work places. Figures of SHS exposure in those places vary widely among different countries, due to different specific laws and also depending on different places.

**Obective:** 1) To evaluate impact of community intervention to prevent active smoking and secondhand smoke in a School population in Catalonia. 2) To analyze possible correlation between smoke free places in different European Countries and prevalence of active and passive smoking in private venues.

**Methods:** Two different studies were designed. To answer the first objective, an intervention study (Respir-net) was carried out in Terrassa (Spain). It was a multi-level intervention at schools, teachers, students and their parents in order to decrease SHS. To answer the second objective we carried out an ecologic study at European level.

**Results:** Respir-net program got a decrease of 14% of SHS at School, 19,9% of SHS at home and 21,8% in transport. Pupils from schools were the program was well implemented and developed reported slightly higher decreases of the prevalence at SHS. The best accomplishment of all activities designed in Respir-net program achieved higher decreases (between 3 and 10 points less) of SHS measured in all settings.

At an ecologic level we could not stablish any correlation between the implementation of policies of free smoke places and the increase of the prevalence of active smoking in private venues, as home or car.

**Conclusions:** Preventive activities designed to decrease exposure to SHS must be designed as multilevel actions and its success is mainly related with its best development and the quality of each of these activities. Preventive actions have less effect in those adolescents who already

started to be active smokers. Smoking bans in public places do not generate increase of smoking in private venues. Countries with well-defined policies against tobacco consumption are those with higher proportion of smoke-free houses.

# Índex

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# 1. Introducció

# 1.1. Tabaquisme actiu i passiu. L'epidèmia del tabac

Les conseqüències del consum de tabac són ben conegudes tant entre la població fumadora con la no fumadora. El consum de tabac és el principal factor de risc de molts càncers com el de boca, llavi laringe, bufeta, esòfag, pàncrees, ronyó i, especialment del càncer de pulmó. A més a més, el tabac també s'ha revelat com un clar factor de risc de l a cardiopatia coronària, malalties vasculars perifèriques i malaltia pulmonar obstructiva crònica<sup>1</sup>. El consum de tabac ja és la primera causa de mort evitable i de morbi-mortalitat als països desenvolupats. Segons l'informe MPOWER de l'Organització Mundial de la Salut (OMS) 5,4 milions de morts anuals arreu del món són conseqüència del tabac i s'estima que l'any 2030 es podrien atribuir a l'epidèmia del tabaquisme més de 8 milions de morts<sup>2</sup>. A Espanya s'atribueixen al tabac més de 53.000 defuncions anuals, de les quals el 45% són càncers<sup>3</sup>.

L'epidèmia del tabaquisme té un mode de difusió general arreu del món<sup>4</sup>. L'epidèmia té quatre fases ben definides. A la primera fase, la prevalença entre els homes és menor del 15% i entre les dones pràcticament no hi ha consum. El consum individual dels adults és inferior a 500 cigarretes i pràcticament no s'aprecia l'impacte del tabaquisme a la mortalitat. Aquesta primera fase sol durar un parell de dècades. La segona fase té una durada d'entre dues i tres dècades i en aquesta fase la prevalença entre els homes arriba al seu nivell màxim (50-80%) i en les dones el consum augmenta molt ràpidament. El consum mitjà anual pot ser d'entre 1000 i 3000 cigarretes, però entre els homes pot arribar fins els 4000. Al final d'aquesta segona fase, fins el 10% de les morts totals entre el homes ja es poden relacionar amb el consum de tabac. La fase III es caracteritza perquè la prevalença entre els homes comença a disminuir i se situa, al final de d'aquesta fase, al voltant del 40%. El consum de tabac entre les dones s'estabilitza i mai no arriba als nivells dels homes. El consum anual de cigarretes se situa, tant per homes com per dones, entre 3000 i 4000. La mortalitat associada al tabaquisme pot arribar fins el 25-30% entre els homes i al voltant del 5% en les dones. Aquesta tercera fase pot durar al voltant de tres dècades. En la fase IV, la prevalença d'homes i dones s'acosta molt i se situa, en les dones al voltant del 30% i en el homes prop del 35%. En aquesta fase, la mortalitat per causes relacionades amb el consum de tabac pot arribar a ser del 30-35% en els homes i del 20-25% en les dones. El pas d'una fase a l'altra ve determinat per tres grans factors. Primer la prevalença de consum (expressada com a percentatge de fumadors diaris), segon la quantitat de tabac consumit i tercer l'impacte de la mortalitat atribuïble al tabac. Actualment a Espanya s'observa una tendència descendent a la prevalença de consum entre la població general, que es va iniciar unes dècades abans entre els homes que entre les dones <sup>5, 6, 7</sup> pel qual podríem dir que Espanya pot estar ja a la etapa IV de l'epidèmia de tabaquisme.

Un cop va quedar clara la importància del tabaquisme actiu com a factor de risc de les malalties cardiovasculars i respiratòries, així com dels principals càncers -no només el de pulmó- s'ha pogut comprovar com el tabaquisme passiu o altrament dit exposició al Fum Ambiental del Tabac (FAT) també té un paper important en el desenvolupament d'aquestes malalties. El concepte de fumador passiu es va introduir a la dècada de 1970 i fa referència a les persones que respiren el fum del tabac consumit per altres persones<sup>8</sup>. L'informe del Departament de Salut Americà de l'any 1972 ja agrupava els efectes del fum ambiental del tabac (FAT) en quatre punts<sup>9</sup>:

- a. les molèsties ocasionades als altres;
- b. les consequències sobre el nadó nascut de mare fumadora (reducció del pes al néixer i augment de les complicacions perinatals);
- c. les repercussions en persones amb malalties coronàries o asma en les quals s'accentuen els símptomes i
- d. l'augment de la incidència de bronquitis i pneumònia en fills de pares fumadors.

L'exposició al FAT és una mescla complexa de contaminants que inclouen tòxics i irritants i també substàncies carcinogèniques, i l'Agència Internacional per a la Recerca en Càncer (IARC) considera l'exposició al FAT com un carcinogen de tipus I<sup>10</sup>. El FAT el formen dues corrents d'aire, la que es deriva de la pròpia cigarreta (puro o pipa) en combustió i que s'anomena corrent lateral, i també la corrent provinent del fum que exhala el fumador i que s'anomena corrent principal. S'estima que el FAT està compost per més de 8000 substàncies, entre les quals hi ha tòxics i irritants com ara l'àcid cianhídric, diòxid de sofre, monòxid de carboni, amoníac i formaldehid a més de fins a 53 substàncies cancerígenes i mutàgenes som l'arsènic, el corm, nitrosamines i benzopirè<sup>11, 12, 13</sup>.

El tabaquisme passiu o exposició al FAT és responsable de 603.000 defuncions l'any en el món (1% de la mortalitat global)<sup>14</sup>. A la Unió Europea (UE) s'estima que cada any moren unes 79.000 persones degut a alguna de les quatre principals causes relacionades amb el Tabaquisme passiu<sup>15</sup>. A Espanya, l'any 2011 aquestes morts s'han quantificat en 1028 de les quals 124 degudes a càncer de pulmó i la resta (904) a malalties isquèmiques del cor<sup>16</sup>.

# 1.2. Tabaquisme actiu i passiu en població infantil

El tabaquisme entre els adolescents i els joves té els mateixos efectes que en la població adulta. Ara bé, hi ha algunes consideracions conductuals que són específiques per aquests grups d'edat. L'adolescència és una etapa de canvis constants tant físics com emocionals i els adolescents són, per tant, particularment vulnerables. Aquesta vulnerabilitat fa que puguin començar a tenir contactes amb conductes arriscades, incloent el consum de tabac. L'assumpció d'aquestes conductes té a veure amb la sensació de pertinença a un grup, el sentiment d'independència de la família, la maduració personal i la sensació de tenir una imatge social positiva entre els seus amics. S'ha observat que els nois i noies que comencen a fumar, abans tenien una baixa consideració personal o baixa autoestima<sup>17</sup>.

Les dades americanes sobre tabaquisme actiu mostren que l'any 2015 la prevalença d'adolescents d'ensenyança secundària que declaraven haver fumat durant l'últim mes, era al voltant del 2,3% <sup>18</sup>, mentre que l'any 2011 era del 4,3% <sup>19</sup>. Tanmateix, les dades per als joves de batxillerat també han experimentat un descens l'any 2015 front les dades de l'any 2011 (9,3% front a 11,1% respectivament), el que representa una disminució del 15,8% <sup>18,19</sup>. Al nostre entorn, en adolescents de 12 i 13 anys de Terrassa, es va poder mesurar l'any 2006 una prevalença del 2,5% de fumadors, d'aquests un 1,5% van declarar que havien experimentat alguna vegada amb el tabac i l'altre 1% es declaraven fumadors habituals <sup>20</sup>.

L'exposició passiva al fum del tabac també té efectes en els nens, atès que aquests tenen un sistema respiratori més immadur, respiren més ràpidament i inhalen més contaminants per quilogram de pes corporal, comparat amb els adults<sup>21</sup>. En nens i adolescents, l'exposició al FAT també s'ha assenyalat com una factor que augmenta el risc de malalties respiratòries i cardiovasculars<sup>22</sup>. Un estudi als Estats Units d'Amèrica (EUA) en nens de 4 a 16 anys va concloure que l'exposició al FAT augmentava la freqüència de símptomes respiratoris i l'absentisme escolar, suggerint, a més, que l'exposició al FAT podia provocar restriccions de la funció pulmonar<sup>23</sup>. També s'ha observat que en adolescents amb infeccions recurrents de l'oïda, hi havia un 60% més de risc de ser fills de pares fumadors que fumaven a dins de casa<sup>24</sup>. Tant l'exposició al FAT com el tabaquisme són factors de risc evitables per la salut respiratòria dels infants i adolescents<sup>25, 26</sup>. La iniciació al tabaquisme sol començar en l'adolescència, quan hi ha també els primers contactes amb l'alcohol o altres drogues il·legals<sup>27,28</sup>. Així, a l'estat de Maryland (EUA) es va poder mesurar que els factors que més influenciaven l'inici del consum regular de tabac eren la influència dels companys, els anuncis de tabac i l'exposició al FAT<sup>29</sup>. Un estudi a

Nova Zelanda demostrava que els nens que començaven a fumar més joves, eren nens fills de pares fumadors que havien estat exposats al FAT dins els cotxes<sup>30</sup>. Tot i que als EUA i la UE el tabaquisme entre adolescents ha disminuït en l'última dècada<sup>18, 19</sup>, concretament a Espanya la prevalença de fumadors era del 14,7% entre els joves de 14 i 16 anys l'any 2006<sup>31</sup>, encara s'estima necessari desenvolupar programes i intervencions de salut pública per prevenir tant el tabaquisme com l'exposició al FAT en els nens i els adolescents <sup>32, 33</sup>.

S'ha de destacar que les actuacions de salut pública sobre el control del tabaquisme en els diferents països occidentals, han estat centrades en la prohibició de fumar en espais públics i centres de treballs, a més d'implementar activitats destinades a prevenir el tabaquisme entre els adolescents o els seus pares<sup>18,19</sup>. Un estudi per prevenir el tabaquisme en escolars italians va comprovar que el programa preventiu només tenia efecte en els nens més petits i no tant en els adolescents<sup>34</sup>. L'establiment d'un programa preventiu a un grup d'escoles Anglaterra i Gal·les va mostrar efecte a llarg termini en la prevenció del tabaquisme, tot i que no en van poder demostrar l'efecte en el moment en que els nois i noies abandonaven l'escola<sup>35</sup>. De la mateixa manera, a Holanda es va poder comprovar que un programa educatiu a escoles de primària tenia efecte preventiu del tabaquisme quan els alumnes ja estaven cursant secundària i era més efectiu en les noies que no en els nois<sup>36</sup>. A Escòcia, un programa de prevenció del tabaquisme en adolescents, liderat pels propis companys de classe, va mostrar també un efecte reduït en la prevenció final del tabaquisme, que s'anava perdent a mesura que passava el temps des de la intervenció<sup>37</sup>. Ara bé, la majoria d'intervencions encaminades a prevenir el tabaquisme han mostrat efectes moderats que es van diluint al llarg del temps<sup>38</sup>.

# 1.3. Mesures de control del tabaquisme i control de tabaquisme a Espanya

L'any 2003 es va formular el Conveni Marc de l'OMS per al Control del Tabaquisme (CMCT)<sup>39</sup>. Aquest CMCT es va elaborar en resposta a la globalització de l'epidèmia de tabaquisme i reafirma el dret de totes les persones a disposar el màxim grau d salut que es pugui tenir. L'article 8è del CMCT fa referència específica a la protecció contra el FAT en els llocs de treball interior, els mitjans de transport públic i els espais públics tancats. El CMCT recollia que els Estats signants s'havien de comprometre a: eliminar tota la publicitat, promoció i patrocini del tabac en un plaço de 5 anys; requerir l'ús d'etiquetes amb advertències que ocupin al menys un 30% dels envasos del tabac; prohibir l'ús de descriptors com ara "light" o "suaus" que poguessin ser mal interpretats;

i protegir les persones no fumadores del HAT a tots els espais públics i lloc de treball. L'Estat Espanyol va signar-lo l'any 2003 i el va ratificar l'any 2005<sup>39</sup>.

Una altra iniciativa mundial en la prevenció i control del tabaquisme és la del Banc Mundial. L'any 2003 el Banc Mundial es van promulgar les mesures més cost-efectives per reduir l'impacte del tabaquisme <sup>40</sup>. Les sis mesures específiques van ser:

- Augment dels impostos sobre les cigarretes i altres productes del tabac
- Creació d'espais lliures de fum a la feina i en espais públics (escoles, centres sanitaris, transports, cinemes, restaurants, etc)
- Ampliació de les prohibicions de la publicitat i la promoció de tots els productes, logotips i marques de tabac.
- Millora de la informació al consumidor
- Etiquetats amb advertències sanitàries directes i grans als paquets de cigarretes i altres productes del tabac
- Ajuts perquè els fumadors que vulguin deixar de fumar puguin fer-ho

L'evidència científica indica que els millors resultats s'han obtingut quan les sis mesures s'han aplicat de manera conjunta i integral<sup>41</sup> i que l'augment del preu és la mesura més eficaç per reduir la prevalença del consum<sup>42</sup>, especialment entre els joves i els grups socials amb baixos ingressos econòmics.

Basant-se en aquestes mesures del Banc Mundial, s'ha proposat una escala de puntuació per classificar l'aplicació de les mesures de control i prevenció als diferents països<sup>43</sup>. Aquesta "Escala de control del tabaquisme" té un rang entre 0 i 100 punts en funció de les mesures que s'hagin implementat.

La puntuació d'aquestes sis mesures són:

- Augment del preu del tabac, fins a 30 punts
- Restricció de fumar als llocs de treball i espais públics, fins a 22 punts
- Millora de la informació al consumidor sobre els efectes del tabac, fins a 15 punts
- Ampliació de les prohibicions de la publicitat i la promoció de tots els productes, logotips i marques de tabac, fins a 13 punts
- Etiquetat amb advertències sanitàries directes i grans, als paquets de cigarretes i altres productes del tabac, fins a 10 punts

• Ajut mitjançant tractament per als fumadors per deixar de fumar, fins a 10 punts.

Un altre eina cabdal per a la prevenció i el control del tabaquisme ha estat l'estratègia MPOWER, publicada per l'OMS l'any 2008<sup>2</sup> que es basa en les 6 següents mesures:

- Monitorització del consum de tabac (Monitor)
- Protecció de la població del FAT (Protect)
- Oferta d'ajut als fumadors per deixar el tabaquisme (Offer)
- Advertència dels perills del tabac (Warn)
- Fer complir les restriccions de publicitat, promoció i patrocini (Enforce)
- Augment dels impostos sobre el tabac (Raise)

Just després del llançament d'aquestes iniciatives (CMCT de l'OMS i estratègies MPOWER), diversos països europeus, amb Irlanda al capdavant, van promulgar lleis d'espais sense fum per a millorar el control del tabac i protegir a la població no fumadora, tot produint-se una verdadera "epidèmia" de lleis de control del tabac al continent<sup>44</sup>. A Espanya, l'1 de Gener de 2006 va entrar en vigor la llei 28/2005 de mesures sanitàries front el tabaquisme i reguladora de la venda, el proveïment i el consum i publicitat dels productes del tabac<sup>45</sup>. Aquesta llei regulava tres aspectes fonamentals del control del tabaquisme: augment de l'edat legal per comprar tabac (de 16 a 18 anys), prohibició de la publicitat i el patrocini i establiment de certes restriccions del consum. Aquesta llei va suposar un gran avenç per a la salut pública, tot i que va ser una llei incompleta ja que no vetllava prou per la salut d'un col·lectiu important de treballadors, com ara els treballadors de l'hostaleria i l'hostalatge 46, 47. La llei prohibia fumar als llocs de treball, però els bars i restaurants, i l'hostaleria en general, van ser una gran excepció. La llei també permetia que els propietaris de locals més petits de 100 m<sup>2</sup> podessin escollir si al seu establiment s'hi podia fumar o no. En canvi, per als locals més grans de 100m² la llei sí que feia efectiva la prohibició de fumar, ara bé, el propietari podia habilitat un zona per a fumadors, convenientment aïllada i que no podia superar el 30% de la superfície del local<sup>45</sup>. Aquestes excepcions de la llei espanyola aplicables a locals d'hostaleria és el que es coneix com a "modelo español" 48. Aquest "modelo español" ha sigut utilitzat per part de la indústria del tabac i per patronals de l'hostaleria de països com Grècia, Portugal o Àustria, per dificultar l'aplicació de polítiques de prohibició total en aquests països<sup>49</sup>.

És remarcable que, davant aquesta situació, diversos estudis van avaluar l'impacte de la llei i del "modelo español" referent a l'exposició declarada al FAT, que van mostrar una reducció de l'exposició al FAT a la població general, però, en canvi, no es va poder observar la mateixa reducció en els treballadors de l'hostaleria<sup>50</sup>. Aquest fet va generar una revisió de la llei 28/2005 i la posterior aprovació de la llei 42/2010 que modificava l'anterior<sup>51</sup>. A la nova llei, entre les principals modificacions s'hi va incloure la prohibició de fumar a tots els establiments d'hostaleria, independentment de les característiques del local, així com la prohibició de fumar ens alguns espais exteriors com ara hospitals i centres educatius.

Darrerament, s'ha pogut mesurar l'impacte de les lleis de 2005 i 2010<sup>52</sup> i es va observar que s'havia produït un important augment de la prevalença de cases lliures de fum, que van passar a ser del 55,6% abans de les lleis fins al 72,6% després de la llei de 2011. Amb la qual cosa sembla que el consum de tabac, que s'ha prohibit en els espais públics, no s'ha desplaçat automàticament cap als espais privats, com la casa.

# 1.4. Exposició passiva en ambients privats (cases i cotxes): principal font d'exposició per als nens

L'exposició al FAT pot ocórrer en ambients privats (com el propi lloc de residència o cotxes), en llocs públics (restaurants, bars, espais d'oci) o en el lloc de treball. Les xifres d'exposició en cada un d'aquests espais varien àmpliament en funció del país, les normatives i el lloc concret de l'exposició. En aquest sentit, encara que l'exposició passiva al FAT està regulada a l'interior dels espais públics i llocs de treball, l'exposició passiva al FAT pot ocórrer, també, en ambient privats. Al Canadà es va poder mesurar l'any 2006 que un 22,1% dels joves i adolescents estaven exposats al fum del tabac a casa i que un 28,1% hi estaven al cotxe mentre anaven cap a l'escola<sup>53</sup>. A Carolina del Nord (EUA) la proporció d'escolars que van declarar haver estat exposats al FAT la setmana prèvia a l'enquesta va ser del 40%, i d'aquests, un 85% van declarar haver-hi estat al cotxe<sup>54</sup>. A Grècia es va estimar que un 79,3% de nens i adolescents no fumadors, estaven exposats al FAT a casa i un 38,2% deien estar-ho també fora de casa<sup>55</sup>. Un estudi realitzat a Sud Àfrica va poder assenyalar que un 25,7% dels adolescents estaven exposats al FAT a casa i un 34.2% a fora de casa<sup>56</sup>.

La manca de bons resultats en les intervencions directes sobre el tabaquisme en escolars així com l'aparició de les lleis de prohibició del consum de tabac en els llocs públics i la por de que

aquestes lleis desviessin el consum cap a espais privats que, per tant, podrien suposar possible augment de l'exposició al FAT, van generar, fa uns anys, la necessitat de fer una aproximació al problema d'una manera més amplia, amb actuacions a diferents nivells, en diferents llocs i tenint en compte els diferents actors del problema<sup>57</sup>. Les actuacions haurien de dissenyar-se amb activitats continuades i progressives a les escoles, també a casa, basades en la teoria social cognitiva, amb principis de modificació de conductes i mirant d'incrementar l'autoeficàcia i les expectatives de resultats<sup>57</sup>.

Por tot això, es proposa en aquesta tesi per compendi d'articles avaluar l'impacte i viabilitat de realitzar una intervenció en adolescents a diferents nivells, en diferents entorns i d'una manera coordinada per tal de valorar l'eficàcia d'un programa preventiu de l'exposició al FAT i també l'inici del tabaquisme. A més a més d'avaluar el possible desplaçament de la exposició al FAT a l'ambient privat després de la implementació de polítiques de espais lliure de fum.

# 2. Hipòtesis i objectius:

# 2.1 Hipòtesis

- 1. Les intervencions preventives del tabaquisme, especialment en població vulnerable, com ara els adolescents, poden disminuir la incorporació al consum actiu de tabac i a l'exposició al FAT.
- 2. Les polítiques que promouen els espais lliures de fum no fan augmentar l'exposició al FAT en l'àmbit privat (casa i cotxes).

# 2.2 Objectius

- 1. Avaluar els efectes d'una intervenció comunitària sobre prevenció del tabaquisme i exposició al FAT en una població escolar de Catalunya.
- 2. Analitzar la correlació entre la implantació d'espais lliures de fum en diversos països europeus i la prevalença de tabaquisme actiu i passiu en espais privats.

# 3. Articles

Pere respondre els objectius de la tesi, es van desenvolupar dos estudis separats, amb les metodologies apropiades per a cada un. Aquests dos estudis es van publicar en dos articles científics. Per tant aquesta tesi es un compendi de dos articles científics publicats i acceptats a revistes indexades del primer quartil. A més a més, a l'annex I es posa un altre article derivat de l'estudi Respir-net on el doctorant ha participat i que es va publicar a la revista Acta Paediatrica (segon quartil del seu grup). Per altre banda, a l'annex II i annex III es posa el procés editorial dels dos articles de la tesi fins la seva acceptació (Preventive Medicine i Tobacco Control).

# Article 1:

**Blanch C**, Fernández E, Martínez-Sánchez JM, Ariza C, López MJ, Moncada A, Schiaffino A, Rajmil L, Saltó E, Pascual JA, Nebot M; RESPIR·NET research group. Impact of a multi-level intervention to prevent secondhand smoke exposure in schoolchildren: a randomized cluster community trial. Prev Med. 2013 Nov;57(5):585-90.

Objectiu: Mesurar l'efectivitat d'una intervenció multinivell (individu, família i escoles) per prevenir l'exposició al fum ambiental del tabac en una població escolar d'ensenyança secundària obligatòria entre els 12 i els 14 anys.

La revista Preventive Medicine (*Prev Med*) està inclosa en el Journal Citation Report de ISI-Web of Knowledge amb un factor d'impacte l'any 2015 de 2,893 (posició 34 de 173, primer quartil, del grup Public, Environmental, and Occupational Health).

# Resum dels resultats:

La intervenció preventiva de l'exposició al fum ambiental en escolars d'ensenyança secundària obligatòria de Terrassa va aconseguir un seguiment del 88%.

El programa va aconseguir que entre els alumnes intervinguts la prevalença d'exposició al FAT disminuís un 14% a l'escola, un 19,9% l'exposició al FAT a casa i un 21,8% al transport. En canvi, entre els alumnes que estaven a les escoles control, la disminució de la prevalença al FAT només es va notar a casa; concretament amb una disminució del 16,9% de la prevalença. L'exposició al

FAT en els espais públics durant el temps lliure no va mostrar cap disminució ni en el grup d'intervenció ni en el grup de control.

Els alumnes de les escoles que van informar d'un bon acompliment de les activitats dissenyades en el programa, van reportar unes disminucions més elevades de la prevalença d'exposició al FAT. Així, la disminució de la prevalença d'exposició al FAT a casa va ser -27,6% front a -15,7% en els alumnes de les escoles control; la disminució de l'exposició al FAT al transport -25,6% front a -19,9%; la disminució de l'exposició FAT durant el temps lliure -10,1% front a +9,7% i a la disminució de l'exposició al FAT l'escola -6,9% front a -16,3%.

Es va poder observar que el bon acompliment de les activitats dissenyades en el programa d'intervenció va generar unes disminucions més elevades de l'exposició al FAT en tots els àmbits mesurats d'entre 3 i 10 punts percentuals. En canvi la intervenció no va tenir cap efecte preventiu front el tabaquisme actiu. Tant a les escoles del grup d'intervenció com a les escoles control es va observar un increment significatiu de la prevalença d'alumnes fumadors abans del programa i un cop finalitzat aquest.

#### Article 2:

Martínez-Sánchez JM, **Blanch C**, Fu M, Gallus S, La Vecchia C, Fernández E. Do smoke-free policies in work and public places increase smoking in private venues?. Tob Control. 2014 May;23(3):204-7.

Objectiu: Avaluar la correlació entre la implementació de les polítiques de control del tabaquisme, particularment les prohibicions de fumar en espais públics i als llocs de treball, i la prevalença de fumar en espai privats, en els 27 països de la Unió Europea.

La revista Tobacco Control (*Tob Control*) està inclosa en el Journal Citation Report de ISI-Web of Knowledge amb un factor d'impacte el 2015 de 6,321 (posició 8 de 173, primer decil, del grup Public, Environmental, and Occupational Health).

# Resum de resultats:

La proporció de ciutadans Europeus que no permeten fumar a dins de casa seva va ser del 61%, amb diferències entre països, essent la més baixa Grècia (39%) i la més alta Finlàndia (95%). El

país que té una puntuació més baixa de l'Escala de Control del Tabaquisme (TCS) que mesura la implementació de les sis polítiques és Àustria amb 35/100, mentre que el país amb una puntuació més alta és el Regne Unit amb 93/100. Països amb prevalences altes de cases i cotxes lliures de fum com ara Finlàndia i Suècia, tenen puntuacions de la banda alta a l'escala de TCS (58 i 61 respectivament). Els països amb puntuacions relativament baixes a la TCS (Àustria i Grècia) tenen prevalences també relativament baixes de persones que fumen a casa i al cotxe.

A nivell ecològic no s'ha pogut observar una correlació entre la implementació de polítiques públiques lliures de fum i prevalences altes de tabaquisme en espais privats, com ara la casa o el cotxe particular.

# Article 1 de la tesi

Blanch C, Fernández E, Martínez-Sánchez JM, Ariza C, López MJ, Moncada A, Schiaffino A, Rajmil L, Saltó E, Pascual JA, Nebot M; RESPIR·NET research group. Impact of a multi-level intervention to prevent secondhand smoke exposure in schoolchildren: a randomized cluster community trial. Prev Med. 2013 Nov;57(5):585-90.

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# Impact of a multi-level intervention to prevent secondhand smoke exposure schoolchildren: A randomized cluster community trial



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#### ABSTRACT

Objective. To assess the effectiveness of a multi-level (individual, family, and school) school-based intervention to prevent the exposure to secondhand smoke (SHS) in a population of schoolchildren (12–14 years old).

Method. This was a community trial with cluster randomization of schools to an intervention and comparison group (ClinicalTrials.Gov identifier NCT01881607). The intervention targeted schoolchildren in Terrassa (Catalonia, Spain). We assessed SHS exposure in different settings and tobacco consumption by means of a questionnaire before and one year after the intervention.

Results. We analyzed data from 1734 students with both baseline and follow-up data. The crude analysis showed that SHS exposure among students in the intervention group significantly decreased at school (-14.0%), at home (-19.9%), and on transportation (-21.8%). In the comparison group, SHS exposure significantly decreased only at home (-16.9%). After adjustment for potential confounders, the good accomplishment of the activities showed a possible trend towards a non-significant reduction in exposure at home, transportation,

Conclusion. While this school-based multi-level intervention had no overall effect in SHS exposure, the improvement of the activities focused on preventing SHS would be needed in order to achieve a significant decrease in the proportion of children exposed to SHS.

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#### Introduction

Secondhand smoke (SHS) is a complex mixture of pollutants that include toxic and irritant compounds as well as carcinogenic substances (IARC, 2004). SHS has been classified by the International Agency for Research on Cancer as a type I carcinogen to humans (IARC, 2004). Moreover, children are inevitably more vulnerable to the effects of SHS exposure because they are still physically developing (Bearer, 1995); preventing exposure of this age group to SHS is thus an important issue for public health.

Exposure to SHS and tobacco smoking is an avoidable risk factor for childhood respiratory diseases (Bloch et al., 2008; Hawthorne et al., 2008). Respiratory symptoms related to asthma are among the most frequent diseases during childhood (Sears, 1997), and more severe symptoms can be present in children exposed to SHS (Gergen, 2001). A study in the US of children aged 4-16 years concluded that SHS

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exposure increased the frequency of respiratory symptoms and school absenteeism, and suggested that SHS exposure may provoke restricted pulmonary function (Mannino et al., 2002).

Smoking initiation occurs during adolescence, as does the first contact with alcohol and other illegal drugs (Sutherland and Willner, 1998). Every day, nearly 3900 children less than 18 years of age in the US alone try their first cigarette, and more than 950 children will become new, regular, daily smokers (American Lung Association, 2011). In European countries, tobacco smoking among adolescents has decreased in the last decade. In Spain, the prevalence of smokers among pupils aged 14–16 was 14.7% in 2006 (Villalbi et al., 2012). It is necessary to develop and implement public health interventions to prevent both smoking initiation and SHS exposure in children (Sussman et al., 2006).

There have been multiple educative interventions to prevent tobacco consumption, but few interventions use a comprehensive approach to focus on preventing SHS exposure among children and adolescents (Gehrman and Hovell, 2003). Most studies have addressed parental smoking cessation exclusively, with the obvious implication that if the parent will quit smoking, the child's exposure would be reduced or eliminated. A Cochrane review focused on interventions among parents attending clinical pediatric or child health services has provided no evidence of a positive effect of such interventions, although it is possible that the reviewed studies had little power to detect small effects (Roseby et al., 2008). Hence, interventions to prevent SHS exposure in children and adolescents should incorporate a stepped approach from the school setting to the household, based on social cognitive theory, behavior-modification principles, and self-efficacy and outcome expectations (Gehrman and Hovell, 2003). The objective of this study was to assess the impact of a multi-level (individual, family, and school) intervention to reduce SHS exposure and smoking initiation among a population of schoolchildren 12-14 years old.

# Methods

Study design

This community trial (ClinicalTrials,Gov with identifier NCT01881607) randomized schools to intervention and comparison groups to assess the effectiveness of the intervention (cluster randomization). The intervention was designed to target schoolchildren aged 12–14 years in the first and second years of Compulsory Secondary Education (Enseñanza Secundaria Obligatoria in the Spanish educational system) in Terrassa, a city in the Metropolitan Area of Barcelona with more than 200,000 inhabitants. These children were attending the secondary school for an entire cycle of 4 years. Participation in the study was offered in May 2006 to the 25 secondary schools of the city; all of them agreed to participate, beginning in September 2006 (2006–2007 academic year).

Ethics

The study protocol was approved by the Research Ethics Committee of the "Hospital Universitari de Bellvitge". Parents and school staff provided written informed consent for the children to participate in the study and for all measurements to be performed. The deans and responsible health education personnel were informed about the main study objective and the planned intervention.

Participants and field-work development

Schools were allocated at random to the comparison group (13 schools) or the intervention group (12 schools). All pupils in the first year of Compulsory Secondary Education in these schools were included in the study. During October–November 2006, a field-work team visited all schools for baseline (pre-intervention) data collection (questionnaire on SHS exposure and smoking); these data included 1779 pupils of the 1888 pupils enrolled in the schools (94.2% participation). One year later, during October–November 2007, the field-work team revisited the schools to obtain post-intervention data from the same pupils (now in the second year of Compulsory Secondary Education). The post-intervention participation rate was 92.4% (1818 of 1968 pupils

enrolled). As expected, some of the 1779 pupils included in 2006 were lost to follow-up because they had changed to a school outside Terrassa (n=24) or because they were not present at school or refused to participate in the follow-up survey (n=21). Moreover, in 2007 we surveyed children who did not participate in the 2006 baseline data collection. These pupils were already in the second year of Compulsory Secondary Education in 2006 or had arrived at the schools from outside Terrassa in 2007 (typical of migrants, who arrive once the academic course has started). Thus, after linkage via a unique confidential code, our study included a total of 1734 pupils (977 in the comparison group and 757 in the experimental group) with baseline and follow-up data (follow-up rate of 97.5%).

# Information collected

We administered a questionnaire at baseline and one year later to gather sociodemographic data and data on self-perceived SHS exposure and smoking behavior. The questionnaire was prepared from previously validated questionnaires on SHS and smoking (Ariza et al., 2008; Ariza et al., 2009; Tomas et al., 2002).

Exposure to SHS was investigated at home, at school, on transportation (private or public), and during leisure time. SHS exposure at home was assessed by asking "How many people living with you at home usually smoke at home (not including balcony, terrace, or gallery)?" Those who answered "nobody" were considered to be non-exposed. SHS exposure at school was assessed in the classroom, corridor, main door entrance, teachers' room, playground, and restroom. Respondents who answered "nowhere at school" were considered to be non-exposed. SHS exposure on transportation was differentiated between public and private transportation; participants who were rated as "exposed" answered that somebody smoked near him/her. SHS exposure during leisure time was assessed with the question, "Have you been in indoor places – neither at home nor at school – where somebody smokes (so close to you that you can smell the smoke)?" This question had four possible answers (often exposed, sometimes, seldom, never), and weekdays and weekends were considered separately. Exposed subjects answered "often exposed" or "sometimes."

To gain information about the participants' behaviors related to tobacco smoking, we asked, in accordance with previous research (De Vries et al., 2003), "Which one of these situations better describes your behavior?" We considered "regular smokers," who declared that they smoke every day or at least once per week; "experimental smokers," who reported that they smoke once per month, at least once per month, or were self-declared ex-smokers; and "non-smokers," who said that they had never smoked or had smoked just once

We determined socioeconomic status by means of the Family Affluence Scale (von Rueden et al., 2006), a socioeconomic indicator designed to be answered by children and adolescents. The scale includes information about family car ownership, bedroom occupancy, family holidays in the past 12 months, and computer ownership. A composite score was calculated for each subject based on the sum of the responses for the preceding four items, producing an ordinal scale from 0 to 7 that was coded into three categories: low (0–3), intermediate (4–5), and high affluence (6–7). The scale has been translated and adapted to Spanish for previous research in Spain (Martin-Pujol et al., 2013).

#### Intervention

Based on a previously evaluated intervention to prevent smoking initiation (PASE/ESFA Program) (Ariza et al., 2008) we designed a new intervention (the RESPIR · NET Program) including two new activities to prevent passive smoking to be applied at three levels: in the classroom (pupils), at the school (pupils, teachers, and parents), and in the family (pupils and parents). The intervention at the classroom consisted of six sessions with the pupils of 1 h each that were conducted by the teacher/tutor. The specific objectives, contents, and activities of these sessions are summarized in Table 1. We provided the teachers with a training session and a teachers' guide, and we gave each pupil a workbook with the activities, including space to record personal notes. Each pupil received a pen and a sticker with the logo of the program. At the school level, the intervention consisted of four types of posters with specific messages directed to students, teachers, and parents, and the fourth poster type advertised the new smoking laws. Moreover, we gave teachers and school managers the guide "Towards a Smoke-Free School" (Ariza and Lopez, 2006) to facilitate the prevention and control of smoking (active and passive) in the school environment. The intervention at the family level included several activities. Parents were required to complete the "My risk thermometer" activity at home with

**Table 1**Intervention sessions in the classroom (RESPIR·NET Program).

Session title	Objectives	Contents	Activity
Session 1 "Don't bet your health"	Sensitize against the consequences of active and passive smoking, analyzing self-environment.	Self-evaluation of attitude toward smoking. Identify situations of passive smoking.	Simulation role-playing for sensitizing and assessing exposure to SHS. Self-evaluation of motivation toward the program.
Session 2 "Tobacco and alcohol today"	Inform about the addictive substances most currently used during these ages (tobacco & alcohol).	Knowledge about the drug and the dependency, active and passive smoking, alcohol and other drugs.	Brief talk and debate on addictions.
Session 3 "Do I feel pressure? Who is pressing me?"	Identify the role of social pressure in behaviors, especially for becoming a smoker.	Skills to recognize peer pressure for becoming a smoker or alcohol drinker (social influences).  Assertive communication skills and development.	View and debate about the DVD "La Festa" ("The Party").
Session 4 "Money first"	Explain how marketing tries to influence people.	Tobacco, alcohol, and social media. External pressure to smoke and drink alcohol (focus on the publicity) and how to resist.	Seminar on analysis/creation of advertisements.
Session 5 "My risk thermometer"	Know the burden of SHS in the community. Identify places where one can be exposed to SHS and how to protect against SHS.	Sources of exposure to SHS. Consequences of SHS. How to protect against SHS.	Awareness of self-exposure to SHS to estimate everyone's level of SHS. Small groups complete a task and debate.
Session 6 "Let's do it!"	Develop skills for resisting peer pressure. Definition of attitudes and expectations toward the future.	Training on social skills and communication for resisting peer pressure in front of active and passive smoking. Expectations toward future behaviors.	Role-playing, assertiveness, debate, and self-declaration of future behaviors.

their children. Parents received a brochure with information on the risks of SHS exposure and recommendations to prevent SHS exposure (who is a passive smoker, basic data on exposure and risk, current legislation, alternatives to protect the family, and where to find more information), and a refrigerator magnet with the logo of the program. Finally, we measured the quality of the intervention according to the actual number of

sessions accomplished and self-evaluation of the teachers who administered the intervention. Based on these data, the intervention was classified as very good/good and fair/poor.

The comparison schools did not follow any alternative or special program of lessons, but simply the usual practice, and no changes in the protocol were made after commencement of the trial.

**Table 2**Demographic characteristics of participating schoolchildren aged 12–14 years with baseline and follow-up data, RESPIR·NET Program, Terrassa (Spain) 2006–2007.

	Group							
	Intervention (n	= 757)	Comparison (n =	= 977)				
Variable	N	%	N	%	p-Value*			
Age in years ( $n = 1620$ )								
11	89	12.6	114	12.5				
12	542	76.9	716	78.3				
13	72	10.2	79	8.6				
14	2	0.3	6	0.7				
Sex $(n = 1734)$					0.780			
Male	378	49.9	533	54.6				
Female	379	50.1	4444	45.9				
	3,0	5011		1010	0.056			
Origin ( $n = 1725$ )								
Catalunya	601	79.9	776	79.8				
Rest of Spain	16	2.1	17	1.7				
Other	93	12.4	137	14.1	0.551			
Smoker ( $n = 1631$ )					0.551			
No	693	98.0	902	97.6				
Occasional	9	1.3	14	1.5				
Regular	5	0.7	8	0.9				
Secondhand smoke exposure					0.860			
At home	336	44.7	410	42.2				
At school	345	45.6	398	40.7				
On public transportation	121	17.3	146	14.9				
On private transportation	216	28.5	273	27.9				
Leisure time	379	50.1	508	52.0				
					0.520			
School (n = $1734$ )	0.44	4= 0						
Public	341	45.0	341	34.9				
Subsidized	416	55.0	636	65.1	< 0.001			
Socioeconomic status (n = 1621)					\0.001			
Low	89	12.6	100	10.9				
Medium	324	46.0	374	40.8				
High	291	41.3	443	48.3				
					0.020			

<sup>\*</sup> McNemar's  $\chi^2$  test.

**Table 3**Exposure to secondhand smoke in different settings and tobacco consumption at baseline and after one year in schoolchildren aged 12–14 years after the multi-level intervention (intervention and comparison groups), RESPIR·NET Program, Terrassa (Spain) 2006–2007.

	Group											
	Intervention (n = 757)					Comparison (n = 977)						
	Before		After		Difference%	p-Value*	Before		After		Difference %	p-Value*
Secondhand smoke exposure	Secondhand smoke exposure $(n = 757)$		(n = 757)				(n = 977) $(n = 974)$		974)			
	n	(%)	n	(%)			n	(%)	n	(%)		
Home	336	(44.7)	271	(35.8)	-19.9	< 0.01	410	(42.4)	344	(35.2)	-16.9	< 0.01
School	345	(45.6)	297	(39.2)	-14.0	< 0.01	398	(40.7)	405	(41.6)	2.2	0.739
Transportation	288	(38.0)	225	(29.7)	-21.8	< 0.01	338	(34.6)	307	(31.4)	-9.2	0.082
Leisure time	379	(50.1)	388	(51.3)	2.4	0.633	508	(52.0)	502	(51.4)	-1.1	0.787
Active smokers	(n = 1)	707)	(n = 700)			(n = 944)		(n = 934)				
	n	(%)	n	(%)			n	(%)	n	(%)		
No	693	(98.0)	643	(91.9)	-8.9	< 0.01	902	(97.6)	861	(92.3)	-5.4	< 0.01
Occasional	9	(1.3)	25	(3.6)	177.0	0.010	14	(1.5)	35	(3.8)	153.3	< 0.01
Regular	5	(0.7)	32	(4.6)	557.1	< 0.01	8	(0.9)	37	(4.0)	344.4	< 0.01

The figures do not sum up the total due to some missing values.

#### Statistical analysis

Given the paired nature of the data (pre-post comparisons), analyses were restricted to schoolchildren with complete information at baseline and 12month follow-up (after intervention) who continued to study at the same school as when the baseline data were obtained. We calculated the prevalence of SHS exposure in the various settings and assessed the various smoking behaviors. For paired comparisons we used McNemar's  $\chi^2$  test to compare the prevalence of SHS exposure and smoking behaviors before and after the intervention. To report the magnitude of the changes observed, we calculated the average percentages of change (before and after intervention) and the 95% confidence intervals for prevalence of SHS exposure and smoking behaviors. We used logistic regression with random effects (schools as unit of randomization) to adjust for potential clustering effects to account for unit of analysis errors. Thus, we computed the relative impact of the intervention in the prevalence of SHS exposure and smoking behaviors taking into account potential confounders. Multivariate analyses were performed with Stata 9 (StataCorp, College Station, TX, USA).

#### Results

The initial sample of 1968 students was well balanced, but after one year of follow-up there was some attrition. Among the final sample of 1734 pupils with both baseline and follow-up, data was slightly

**Table 4**Multivariate logistic regression models with random effects of the changes in prevalence of SHS exposure in different settings and tobacco consumption among schoolchildren aged 12–14 years after the multi-level intervention, RESPIR·NET Program, Terrassa (Spain) 2006–2007.

		Overall		Good accomplishment of the intervention	
		OR	95% CI	OR	95% CI
Model for SHS exposur	re				
At school	Comparison	1		1	
	Intervention	1.37	0.61-3.07	1.23	0.46 - 3.25
At home	Comparison	1		1	
	Intervention	1.02	0.74-1.41	0.85	0.54-1.35
On transportation	Comparison	1		1	
	Intervention	0.84	0.66-1.07	0.82	0.57-1.18
During leisure time	Comparison	1		1	
	Intervention	1.089	0.83-1.40	0.93	0.64-1.36
Model for smoking					
Current/occasional smoker	Comparison	1		1	
	Intervention	1.20	0.69-2.09	1.53	0.78-3.02

OR = Odds ratio derived from logistic regression models with random effects (schools as unit of randomization) to adjust for potential clustering effects, sex, socioeconomic status, and origin. CI = Confidence Interval.

unbalanced for age, gender, origin, prevalence of SHS, and smoking behavior. The only significant differences between the intervention and comparison groups were related to school type (some overrepresentation of subsidized schools in the comparison group) and socioeconomic status (slight over representation of intermediate and high affluence levels in the comparison group; Table 2).

Changes in the prevalence of SHS exposure in different settings and active smoking for the intervention group and the comparison group before and after the intervention are reported in Table 3. SHS exposure among students in the intervention group significantly decreased at school (-14.0%), at home (-19.9%), and on transportation (-21.8%). For the comparison group, a significant decrease was detected for SHS exposure at home (-16.9%), with no significant changes in the other settings. Exposure to SHS during leisure time did not decrease in the intervention or comparison groups. The percentage of students who became occasional or current smokers increased significantly in both groups (p < 0.01). We observed a greater reduction in SHS exposure at home (-27.6%), transportation (-25.6%) and leisure time (-10.1%), but not at school (-6.9%), among pupils in the schools with good accomplishment of the intervention as compared with pupils in schools with a poor intervention (home -15.7%, transportation -19.9%, leisure time +9.7%, and school -16.3%).

The percentage of non-exposed pupils in the intervention group that remained non-exposed at the end of the trial was 90.8% at home, 71.8% at school, 81.7% in transportation, and 61.6% during leisure time. The corresponding figures for the control group were 89.1%, 71.3%, 79.2%, and 64.0%. We found that among pupils in schools with a good accomplishment of the intervention the percentage remaining non-exposed was slightly higher in all setting (3–10 points of percentage).

We observed that the intervention had no effect on SHS exposure in any setting after adjusting for age, sex, socioeconomic level, origin and the clustering among schools (Table 4). The good accomplishment of the activities showed a possible trend towards a non-significant reduction in exposure at home, transportation, and leisure time. After a one-year follow-up, the intervention exerted no preventive effect on becoming a smoker (Table 4).

#### Discussion

This study represents the first experience in Spain of developing a school-based multi-level intervention to prevent exposure to SHS among schoolchildren. The results of this study showed a possible trend on how this type of educational program can contribute to decrease SHS exposure at home, on transportation and leisure time. The effect of the intervention, however, relies mostly on the degree of accomplishment of the activities proposed. The quality of intervention was an important issue of the RESPIR·NET Program. Therefore, we

<sup>\*</sup> McNemar's  $\chi^2$  test for paired data.

monitored the adherence to the program and completeness of activities both in the intervention and comparison schools. We cannot discard that this monitoring had exerted a "positive" effect in the comparison schools, thus reducing the magnitude of the true effect of the intervention.

We detected a decrease in the crude prevalence of SHS exposure among schoolchildren at home (approximately 20%) and on transportation (approximately 22%, mainly due to a reduction of exposure in private cars) after our intervention. Similarly, a pre-test and post-test intervention in Portugal showed that the proportion of children exposed to SHS at home decreased significantly, by approximately 10%, after an intervention for "smoke-free homes" (Precioso et al., 2010). Furthermore, a study conducted in the United States among young people who had never smoked demonstrated that participants living in families with soft rules prohibiting smoking at home or in a car had a 48% higher prevalence of SHS exposure than participants living in families with strict rules. For those living in families with no rules, the prevalence of SHS exposure was greater (Cartmell et al., 2011). However, there were no significant changes in children exposed to SHS at home after smokefree legislation was implemented in 2007 in Wales; the percentage of exposed children was approximately 20%, but the proportion of children exposed in cafeterias, restaurants, busses, trains, and during indoor leisure time fell significantly (Holliday et al., 2009).

The reduction of SHS exposure among schoolchildren is an important issue of public health. Although smoke-free legislation around the world has banned smoking in public places (indoor workplaces, offices, bars, restaurants, etc), consumption in private venues such as the home and the car is not regulated, and thus constitutes the main source of SHS exposure among schoolchildren. Data from the Global Youth Tobacco Survey indicated that among schoolchildren worldwide, the prevalence of SHS exposure at home was 42.5%, with the highest prevalence in Eastern European countries (77.8%) and the lowest prevalence in African countries (27.6%) (Warren et al, 2008). A study in New Zealand of children 10-13 years old reported that 39.3% were exposed at home and 30.8% were exposed in the car (Glover et al., 2011). In the United States, 29% of children aged 0-17 years were exposed to SHS at home, according to the National Survey of Children's Health (Hawthorne et al., 2008). In Canada in 2006, 22.1% of youth in grades 5-12 were exposed to smoking in their home on a daily basis, and 28.1% were exposed to smoke while riding in a car (Leatherdale and Ahmed, 2009). In Europe, exposure to SHS at home ranged from 76.8% for Greek adolescents in 2004-2005 (Rachiotis et al., 2010) to 42% of households in North England, where smoking took place in the presence of children (Alwan et al., 2010).

Several studies have revealed a decrease in the proportion of children exposed to SHS in recent years. When reported, this decrease was more significant for those exposed to SHS in cars (Cartmell et al., 2011; Holliday et al., 2009; Leatherdale and Ahmed, 2009), although the proportion of smoking behavior in private cars is still quite high in several countries. The observed point prevalence of smoking in cars in Wellington, New Zealand was 4.1%; of these cars, 23.7% had other occupants exposed to SHS (Martin et al., 2006). Another study in Italy found that the proportion of people smoking in cars was 6.9% in private cars and 12% in commercial cars; and only 0.9% of these vehicles contained children less than 7 years of age who could be considered to be exposed to SHS (Sbrogio et al., 2010). In Spain, a study found a prevalence of smoking in cars of 5.5%, with 9.8% in commercial vehicles (Curto et al., 2011); 5.2% and 2.2%, respectively, of passengers less than 14 years of age were exposed to SHS in these vehicles. Discrepancies in these overall data may represent the impact of different national laws and recommendations that have changed dramatically during recent years across countries. Nonetheless, these data show that SHS exposure continues to occur in private cars with child passengers, and there is still room for more educative and public health interventions. Since cars are places of reduced dimensions in which SHS concentrations can be much higher than in other environments (home, workplace, or leisure settings such as discos and bars) (Jones et al., 2009), it is necessary to encourage educative interventions to prevent SHS exposure. Interventions aimed at reducing SHS exposure at home or in other private settings, such as cars, are of paramount importance because these settings are generally out of the scope of smoke-free legislation (IARC, 2009).

The proportion of schoolchildren in the intervention group who became active smokers was not impacted by the activities performed in this study. This observation is not surprising; at these ages, adolescents usually have their first experiences with tobacco consumption (Pierce et al., 2012). With only one year of follow-up, we were not able to measure the long-term impact of our intervention. Other European school-based programs such as the European Smoking Prevention Framework Approach have been effective, but they employed longer follow-ups after the intervention (De Vries et al., 2006). In our study, after the first contact with tobacco smoking, the adolescent may have had the opportunity to reflect on the choice of becoming a daily smoker or just giving up smoking. Nonetheless, the large increases in the percentages of smokers in our study must be interpreted with caution. The baseline numbers of smokers in both groups were extremely small, and thus any minimal increase in the absolute frequency exerted a large influence on the final percentage of change. Moreover, we did not identify any variables that were predictive of change or of the success of the intervention. Although all of our analyses were adjusted for age, gender, socioeconomic status, and origin, we believe that the low numbers of smoking children at baseline may have influenced the final results.

Among the limitations of our study, we have to consider the use of a questionnaire to measure SHS exposure and tobacco consumption. However, to minimize possible recall bias, we used a validated questionnaire and trained interviewers (Ariza et al., 2009; Tomas et al., 2002). The lack of significant effect of the intervention could be also related to other factors. First, some months before the beginning of the trial, a comprehensive smoke-free legislation was passed in Spain (Fernandez, 2006) that could have attenuated the net effect of the intervention. Thus, both the comparison and control group could have decreased the baseline exposure to SHS prior to the intervention. This reflects the real conditions in which these community interventions are implemented. Second, contamination of the comparison group cannot be excluded since there was no geographical restriction between schools in the study groups. However the schools are distributed across the city without a clustering between them. Third, given the paired nature of the data, we opted not to perform an "intention to treat" analysis since the number of pupils excluded was low (2.5% of the sample: 21 lost-to-follow up and 24 switchers between groups). Thus, our results should not differ substantially from the actual effects. Fourth, the inclusion of the effect of the cluster randomization in the analysis also yields estimates with wider confidence intervals. Fifth, this was a multi-level intervention in which we were unable to measure the impact of each educational activity, because we only measured the effect at the end of the program; the number of schools precluded further stratification. Finally, even allocation was done at random, the comparison and intervention groups were slightly unbalanced for some sociodemographic characteristics. The multivariate analyses, including the pupils clustering, have allowed us to control for this potential source of bias.

While attrition is a common source of bias in intervention studies with follow-up of participants we obtained a very high follow up rate (97.5%). New studies using a multi-level strategy and several activities should incorporate mechanisms of evaluation to disentangle the potential differential effects of the various activities.

In conclusion, our multi-level intervention to prevent SHS exposure among schoolchildren could modestly reduce SHS exposure at home, on transportation and leisure time, when the interventions had a good accomplishment. These reductions can be important, because the main sources of SHS exposure among children are private venues such as home and cars. Moreover, we found that most studies dealing with SHS exposure drew their populations from different settings, but none

used interventions at school to include activities related to avoidance of SHS. The improvement of the activities focused on preventing SHS would be needed in order to achieve a significant decrease in the proportion of children exposed to SHS. These activities should be added to more traditional intervention programs targeting the prevention of active to-bacco smoking in young people.

# The RESPIR · NET Group

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#### **Contributorship statement**

EF, AS, MN, CA, JAP and ES designed the present study, which was reviewed and approved by all authors. AS and AMP coordinated the field work. CB, JMMS, and EF designed the current analysis, with the support of MN and CA. All authors had full access to the raw data and interpreted the results. CB wrote the first draft of the manuscript, and all authors contributed to its successive versions. All authors read and approved the final manuscript. EF is the guarantor.

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### Conflict of interest statement

The authors declare that there are no conflicts of interests.

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#### Appendix A. Supplementary data

Supplementary data to this article can be found online at http://dx.doi.org/10.1016/j.ypmed.2013.07.018.

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# Article 2 de la tesi Martínez-Sánchez JM, Blanch C, Fu M, Gallus S, La Vecchia C, Fernández E. Do smoke-free policies in work and public places increase smoking in private venues?. Tob Control. 2014 May;23(3):204-7.

# Do smoke-free policies in work and public places increase smoking in private venues?

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## **ABSTRACT**

**Objective** To evaluate the correlation between the implementation of tobacco control policies, particularly smoke-free bans at work and in public places, and smoking prevalence in private venues in the 27 countries of the European Union.

**Design** Ecological study with the country as the unit of analysis.

**Data sources** Data analysis of tobacco control activities in European countries in 2007 as compiled in the Tobacco Control Scale (TCS) and information on the level of smoking permissiveness in houses and cars from the Special Eurobarometer on Tobacco conducted in 2009.

**Analysis** Spearman rank-correlation coefficients ( $r_{sp}$ ) and their 95% confidence intervals (CIs) were calculated. **Results** The correlation between the TCS score and the prevalence of smoking in private venues (houses and cars) where smoking inside was always allowed was close to zero. A similar lack of association was observed between the TCS score of specific bans at work and in public places and smoking rules inside houses and cars. There was a non-significant direct correlation between the TCS score and the prevalence of smoke-free houses ( $r_{sp}$ =0.21, 95% CI -0.19 to 0.55) and a non-significant inverse correlation with smoking allowed in certain rooms inside the house ( $r_{sp}$ =-0.34; 95% CI -0.64 to 0.05)

**Conclusions** Smoke-free legislation in workplaces and public places is not correlated with increased smoking prevalence in private venues (houses and cars) at an ecological level.

# INTRODUCTION

Once the Framework Convention on Tobacco Control was ratified, several European countries implemented smoke-free bans in workplaces and in other public places to protect the non-smoking population from the harmful effects of secondhand smoke (SHS) exposure. Comprehensive smoke-free policies decreases SHS exposure and associated health hazards in both non-smokers and smokers, and increase the likelihood among smokers of quitting or reducing cigarette consumption.<sup>2-8</sup> However, the tobacco industry and the hospitality sector, during the debate about implementation of smoke-free policies in different countries, argued that the restriction of smoking in public places would displace tobacco consumption private venues, particularly Theoretically, according to this argument, exposure to SHS among children would have increased after the implementation of smoke-free legislation. To our knowledge, only one study,9 conducted in the USA, supports this hypothesis, while other studies show no displacement of smoking prevalence toward private house after the implementation of smoking bans.<sup>2</sup> <sup>10</sup> <sup>11</sup> Moreover, the increase of the overall tobacco control measures may improve the support to smoking bans in public venues and to the denormalisation of tobacco consumption<sup>4</sup> <sup>5</sup> <sup>7</sup> <sup>8</sup>; this could encourage the adoption of voluntary smoke-free homes and cars.

The objective of this study was to evaluate the correlation between the implementation of tobacco control policies, particularly smoke-free bans in work and public places, and smoking prevalence in private venues (inside houses and cars) in the 27 countries of the European Union.

#### **METHODS**

This ecological study was based on data obtained from different sources, with the country as the unit of analysis. We used data on tobacco control activities in European countries in 2007 as compiled in the Tobacco Control Scale (TCS). The TCS provides a score for each country reflecting the level of implementation of smoke-free rules according to six selected cost-effective policies. An expert working group from the European Network for Smoking Prevention (ENSP) developed the TCS by means of a questionnaire sent to ENSP correspondents within each country. The score for each policy was weighted by its reported effectiveness based on existing research and the discussion of a panel of experts on tobacco control.

We also obtained information on smoking rules inside homes and cars from the Special Eurobarometer 332) on Tobacco (Eurobarometer 72.3).<sup>14</sup> The Eurobarometer is a cross-sectional study conducted for the European Commission by TNS Opinion & Social in the 27 countries of the European Union plus the three additional candidate countries in 2009 (Croatia, Turkey and the Republic of Macedonia). The fieldwork was performed in October 2009. In each country, interviews were conducted face-to-face at people's houses, and in the appropriate national language. The sample was weighted for socio-demographic variables. The final sample (n=30 292) was representative of the population ages 15 years and above in each country (about 1000 participants in each country, except in Cyprus, Luxemburg, and Malta, which had approximately 500 respondents each). 14

# **Variables**

Tobacco use inside the houses

Data on smoking inside the houses were obtained using the Eurobarometer question: 'Which

**To cite:** Martínez-Sánchez JM, Blanch C, Fu M, et al. Tob Control 2014;**23**:204–207. statement best describes smoking situation inside your house?' The possible answers were: 'smoking is not allowed at all inside the house,' 'smoking is allowed only in certain rooms inside the house' and 'smoking is allowed everywhere inside the house'.

#### Tobacco use inside the cars

Information about smoking rules inside private cars was obtained using the Eurobarometer question: 'Do you allow smoking in your car?'. The possible answers were 'smoking is never allowed in my car'; 'smoking is allowed sometimes in my car' and 'smoking is allowed all the time in my car'.

# Tobacco control policies

To quantify the grade and effort of implementation of tobacco control policies in European countries, we used data from the 2007 TCS. 12 The six policies considered in the TCS and their corresponding scores are as follows: price increases through higher taxes on tobacco products (maximum 30 points); bans/ restrictions on smoking in public and workplaces (maximum 22 points); better consumer information, including public information campaigns, media coverage and publicising of research findings (maximum 15 points); comprehensive bans on the advertising and promotion of all tobacco products, logos and brand names (maximum 13 points); large, direct health-warning labels on cigarette boxes and other products (maximum 10 points); and treatment to help dependent smokers to quit, including increased access to medications (maximum 10 points). The maximum score of the TCS is 100 points, indicating full implementation of all strategies considered.

## Statistical analysis

We analysed the correlation between the TCS score and smoking rules inside the houses and cars by means of Spearman rank-correlation coefficients ( $r_{\rm sp}$ ) and calculated the 95% confidence intervals (CIs) of the Spearman coefficients. We also analysed the correlation between the score of bans/restrictions on smoking in workplaces and public places and smoking rules inside houses and cars.

# **RESULTS**

The overall prevalence of Europeans who did not allow smoking at all inside the homes was 61%. The lowest prevalence was observed in Greece (39%) and the highest one in Finland (95%). The prevalence of Europeans who never allowed smoking in their cars was 52%, ranging from 17% in Bulgaria to 78% in Finland.

The TCS score substantially varied among countries, with Austria having the lowest (35/100) and UK the highest country

score (93/100). The countries with a higher prevalence of smoke-free houses and cars (Finland and Sweden) showed reasonably high TCS scores (58 and 61 points, respectively). In the countries with lower TCS scores (Greece and Austria; scores ≤36), the prevalence of smoke-free houses and cars was relatively low (39% and 54% in houses, respectively, and 24% and 54% in cars, respectively).

There was a direct non-significant correlation between the overall TCS score and the prevalence of smoke-free houses  $(r_{sp}=0.21, 95\%\text{CI}-0.19 \text{ to } 0.55)$  and an inverse non-significant correlation with the norm of allowing smoking in certain rooms inside the houses  $(r_{sp}=-0.34; 95\% \text{ CI} -0.64 \text{ to } 0.05)$ . The correlations were close to zero between the overall TCS score and the prevalence of houses where smoking was allowed everywhere inside the houses and the prevalence of cars where smoking was allowed all the time in the cars. A similar lack of correlation was observed between the TCS score of specific bans at work and in public places and smoking rules inside houses and cars, with no pattern according to the degree of rules about smoking inside the house or car (table 1).

## **DISCUSSION**

At an ecological level, there is no correlation between the implementation of smoke-free legislation at work and in public places and an increase in prevalence of smoking in private venues (houses and cars) in the European countries. If the hypothesis argued by the tobacco industry and hospitality sector were true, we would have expected to find a positive correlation. Moreover, more developed smoke-free policies (as measured by the TCS), particularly at work and in public places, were positively correlated, although non-significantly, with a high prevalence of smoke-free houses.

The results from this ecological analysis are in line with those of other studies based on data at the individual level before and after national smoke-free bans at workplaces and in public places. A study conducted in the USA based on individual data<sup>15</sup> showed that living in a county with smoke-free legislation in public places was associated with smoke-free houses for smokers and non-smokers (ORs=7.76 and 4.16, respectively), with a dose-response relationship with the level of the smoking ban of the county. Another study conducted in England among children (4-15 years old) with reported data and salivary cotinine as a biomarker of SHS exposure 16 showed that the English smoke-free law did not produce a shift in SHS exposure to homes. The same study also found an increase in the proportion of children living in smoke-free houses between 1998 and 2008 (from 64% to 80%).<sup>16</sup> Similarly, in Scotland, among primary schoolchildren (around 11 years old), there was a reduction in

**Table 1** Correlation (r<sub>sp</sub>) and 95% confidence intervals (CIs) between the overall Tobacco Control Scale (TCS) score or the specific score of bans/restrictions on smoking in workplaces and public places and smoking rules inside houses and cars

	TCS	p Value	Public places bans	p Value
Tobacco rules inside the house				
Smoking is not allowed at all inside the house	0.21 (-0.19 to 0.55)	0.295	0.20 (-0.20 to 0.54)	0.322
Smoking is allowed in certain rooms inside the house	-0.34 (-0.64 to 0.05)	0.083	-0.27 (-0.59 to 0.12)	0.174
Smoking is allowed everywhere inside the house	-0.01 (-0.38 to 0.38)	0.979	0.06 (-0.32 to 0.43)	0.749
Tobacco rules in cars				
Smoking is never allowed in my car	0.07 (-0.32 to 0.44)	0.729	-0.05 (-0.42 to 0.34)	0.822
Smoking is allowed sometimes in my car	-0.20 (-0.54 to 0.20)	0.322	0.01 (-0.37 to 0.39)	0.977
Smoking is allowed all the time in my car	0.07 (-0.32 to 0.44)	0.745	0.09 (-0.30 to 0.45)	0.674

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salivary cotinine concentration<sup>10</sup> and an increase in the proportion of children reporting a completely smoke-free house<sup>17</sup> after passage of the Scottish smoke-free legislation. This finding likely reflects the impact of smoke-free legislation on both increased smoking cessation of parents and reduced acceptability of smoking at home.

The main limitation of our study derives from its ecological design. 18 We have no information about the intensity of SHS exposure<sup>19</sup> at the individual level in the houses where smoking continues to be allowed. However, even though we do not infer any relationship at the individual level, our results are in agreement with other studies with data at the individual level. 15 16 17 Also, some discrepancies exist in the prevalence estimates between data from Eurobarometer and data from representative surveys.<sup>20</sup> Nevertheless, the design Eurobarometer was the same for all countries, which increases comparability across countries at the ecological level. Moreover, the sample size was satisfactorily large and representative by country, and the interviews were face-to-face. Another potential limitation is derived from the lack of information about the stage of the tobacco epidemic among different countries.<sup>21</sup> Countries at late stages have low prevalence of smokers, and hence, the likelihood of smoke-free homes is higher, even in the absence of strong tobacco control policies. Data from Finland and Sweden illustrate this possible paradox. The time interval between the TCS (from 2007) and the Eurobarometer survey (from the end of 2009) is a strength of our study because it provides an adequate time frame (2 years) for observing the potential effects of tobacco control policies on smoking behaviour (potential displacement of smoking to private venues). Moreover, the score of the policy on smoking bans in public and workplaces of the TCS in the period of our study, between 2007 and 2010, did not show appreciable changes: the scores increased in 14 countries, did not change in nine countries, and decreased in five countries.<sup>22</sup>

Current evidence at the ecological and individual levels indicates no increase in the prevalence of smoking in private venues (houses and cars) following the enactment of comprehensive smoke-free legislation, in particular comprehensive smoking bans in work and public places. However, promotion of smoke-free houses and cars should be a priority for public health interventions. Such private venues, particularly homes, <sup>23–25</sup> are the main settings where children are exposed to SHS and children are the most vulnerable to the harmful effects of SHS exposure.

# What is already known on this topic

► The tobacco industry and the hospitality sector have hypothesised that legislation for smoke-free public places will displace the tobacco consumption to private venues, particularly the homes.

# What this paper adds

- ▶ Our findings confirm that smoke-free legislation in work and public places is not correlated with increased smoking in private venues (houses and cars) at the ecological level.
- ► Promotion of smoke-free houses and cars remains a priority for public health interventions because the main sources of SHS exposure among children are private venues.

**Contributors** JMMS conceived the study, prepared the database, analysed the data and drafted the manuscript. JMMS, EF, CB, MF, SG, and CLV contributed substantially to the conception, design, and interpretation of data. All authors contributed to the manuscript and approved its final version.

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Competing interests All authors have completed the Unified Competing Interest form at http://www.icmje.org/coi\_disclosure.pdf (available on request from the corresponding author) and declare: no financial relationships with any organisations that might have an interest in the submitted work in the previous 3 years; no other relationships or activities that could appear to have influenced the submitted work.

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# 4. Discussió conjunta dels articles

Els principals resultats d'aquesta tesi són que els programes educatius preventius del tabaquisme actiu així com de l'exposició al fum ambiental del tabac, han de ser programes extensius, amb intervencions a molts nivells i que tinguin en compte tots els actors implicats. A més a més, s'observa que un seguiment acurat de totes les activitats és probablement el factor que millor pot predir l'èxit del programa. Per altra banda, les lleis encaminades a prohibir el consum del tabac en espais públics no han generat un major consum en l'àmbit privat.

Sembla ser que la implicació i conscienciació familiar en la prevenció del tabaquisme pot tenir un paper rellevant a l'hora protegir els adolescents de l'exposició al FAT. Uns quants estudis han reportat aquest fet i, com a exemple, en la majoria d'estudis s'ha observat una disminució de l'exposició al FAT en els vehicles privats<sup>53, 58, 59</sup>. En aquest sentit, l'estudi d'intervenció a Terrassa (primer article de la tesi doctoral), entre els nens que van acomplir millor el programa educatiu es mostra una disminució de l'exposició al FAT al transport gairebé 5 punts superior als nens de les escoles on la intervenció no es va fer d'una manera tant acurada. Aquesta dada aniria en la línia de que el major compromís i conscienciació de les famílies pot ajudar a reduir l'exposició al FAT dels nens en l'àmbit del vehicle privat. Ara bé, les dades internacionals sobre exposició al FAT al transport privat mostren gran variabilitat entre països<sup>60, 61, 62, 63</sup> la qual cosa pot ser reflex de les diferents polítiques i legislacions i del moment en el temps en què cada país ha promulgat aquestes legislacions. En qualsevol cas, queda clar que el vehicle privat és un potencial espai on l'exposició al FAT pot ser elevada i que les actuacions encaminades a prevenir que els pares fumin al cotxe és una de les intervencions de salut pública importants a fer, ja que normalment aquest espais privats queden fora de les polítiques d'espais lliures de fum¹².

En quan a l'exposició al FAT en altres àmbits, el primer estudi d'aquesta tesi doctoral fet amb adolescents de Terrassa, s'observava un descens semblant de l'exposició al FAT a casa tant en el grup d'intervenció com en el grup control. Això podria ser degut a la sensibilització general respecte al tabaquisme. Ara bé, en les escoles on la intervenció s'havia fet de manera més intensa amb millor acompliment de les activitats, el descens va ser de gairebé 10 punts percentuals superior que a les escoles control. Un fet semblant s'havia observat a un estudi americà que mostrava com els adolescents de famílies que tenien regles poc definides respecte sobre els llocs on es podia fumar, tenien un 48% més de prevalença d'exposició al FAT que els

fills de les famílies amb regles clares<sup>54</sup>. Per tant, novament, la intensitat de la intervenció es revela com un factor important a tenir en compte en el desenvolupament d'un programa preventiu.

És necessari remarcar el fet de que el seguiment acurat del programa d'intervenció (Respir-net) va tenir un major impacte en la disminució de l'exposició al FAT. S'ha d'assenyalar que el programa Respir-net era una intervenció exhaustiva. Es van dissenyar materials de treball i materials de suport per a educadors, els alumnes i els pares. A l'aula es van preparar 6 activitats encaminades a sensibilitzar, informar, identificar pressions i comportaments socials, així com poder avaluar el risc personal i desenvolupar activitats per no cedir a la pressió del grup i saber definir les pròpies actituds. Aquestes sessions a l'aula es desenvolupaven amb diferents activitats que anaven des del "role-playing", a xerrades, visualització de continguts, declaracions, compromisos etc. Com es pot veure, es tracta d'una intervenció complexa i d'aquí que el seu seguiment correcte no fos del tot senzill. És possible que alguns centres, per la implicació del professorat, els seguiment dels alumnes, o bé la interferència amb el ritme habitual de les assignatures de l'ESO, el programa Respir-net no es pogués desenvolupar amb tota la intensitat necessària. Així, un cop acabat el programa es va passar als centres un güestionari per tal que n'avaluessin el seu seguiment i la valoració de les activitats individuals i la valoració final de la utilitat del programa. Atès que l'avaluació dels efectes del programa no es van mesurar fins al final de totes les activitats, no es pot saber quina de les activitats va resultar més efectiva en la prevenció de l'exposició al FAT. Tot i això, en l'anàlisi de resultats es va poder observar que els alumnes de les escoles que havien declarat un millor seguiment i utilitat del programa, van ser els alumnes que van experimentar unes reduccions més elevades en la seva exposició al FAT en diferents àmbits.

És remarcable indicar que el programa Respir-net va tenir impacte en disminuir l'exposició al FAT en els diferent àmbits d'anàlisis, excepte en el temps de lleure. Cal recordar que en aquell moment a Espanya just havia entrat en vigor a llei 28/2005 que establia la prohibició només parcial de fumar en espais de lleure<sup>45</sup>.

És remarcable que el programa no va tenir cap efecte en la prevenció del inici del tabaquisme actiu entre alumnes de les escoles intervingudes. Hi ha alguns motius pels quals això pugui ser així. D'entrada la prevalença de fumadors en començar l'estudi era molt baixa i està ben descrit que en aquestes edats és quan els adolescents comencen a tenir les seves primeres experiències amb el tabac<sup>64</sup>, així doncs era de preveure que just al cap d'un any de seguiment, la proporció d'alumnes fumadors pogués incrementar-se.

Segons el que s'observa en el segon article d'aquesta tesi (article 2), sembla clar que la prohibició de fumar en espais públics és una mesura amb un èxit important per evitar l'exposició al FAT i que a l'hora podria estar aconseguint una disminució individual del consum del tabac i no pas un desplaçament cap a l'àmbit privat. Aquest segon article assenyalava, a nivell ecològic, com fins i tot els països amb legislacions més desenvolupades -mesurat com a puntuacions més altes en la TCS- eren els que presentaven prevalences més altes de cases lliure de fum.

Aquest fet s'havia observat prèviament en estudis fets a nivell de país, per exemple US<sup>65</sup>, a UK<sup>66</sup>, Escòcia<sup>67</sup>, Irlanda, França Alemanya i Holanda<sup>68</sup>. També a l'estudi fet a Gal·les després de la prohibició de fumar als bars, restaurants, autobusos i resta d'espais públics va disminuir clarament el FAT dels adolescents durant el temps lliure, però en canvi no va suposar cap canvi en la proporció d'adolescents que estaven exposats al FAT a casa<sup>59</sup>. A la ciutat de Barcelona es va poder analitzar l'impacte de les dues lleis espanyoles de 2005 i 2010 sobre la prohibició de fumar en espais públics<sup>69</sup>. La proporció de persones que es declaraven exposades al FAT va caure del 75,7% l'any 2004-05 fins el 56,7% a l'any 2011-12. Aquest descens es va observar en tots els àmbits pels quals es mesurava (casa, lloc de treball/estudi, temps lliure i transport públic). Darrerament la publicació d'un estudi fet a Espanya<sup>52</sup> ha posat de relleu que l'impacte de les dues lleis de 2005 i 2010, també han comportat un increment significatiu de cases lliures de fum (+11%) o totalment lliures fum (+57%).

Així doncs pràcticament tots els estudis fets després de les successives implementacions de lleis, han pogut desmentir la temença que havia aparegut durant els debats previs a les lleis – majoritàriament entre la indústria del tabac i els sector de l'hostaleria<sup>70</sup>- de que aquestes desplaçarien el consum dels espais públics cap els espais privats, amb el conseqüent increment de l'exposició al FAT, especialment en els infants.

# 5. Limitacions i fortaleses de la tesi

Els resultats dels estudis d'aquesta tesi doctoral tenen les següents limitacions:

En l'Article 1 de la tesi, els nivells d'exposició dels alumnes al transport públic semblen massa elevats, tenint en compte que a Espanya ja hi havia una prohibició de fumar al transport públic des de l'any 1988<sup>71</sup>. Creiem que al qüestionari no va quedar clara la definició d'exposició al transport públic. Molt probablement si persones que contestaven el qüestionari estaven exposades al FAT durant l'espera de l'autobús a la parada, podien considerar que s'havien exposat al FAT al transport públic. La intenció de la pregunta era saber si l'exposició ocorria dins de l'autobús.

Una altra limitació de l'Article 1 va ser que no es va poder avaluar per separat l'impacte de cada una de les activitats de la intervenció. La mesura de l'exposició al FAT es va fer només al final del programa i per tant hi ha un únic valor. Tampoc no es va mesurar l'opinió dels pares dels alumnes que havien estat intervinguts i no es va poder saber l'impacte global que el programa podia haver tingut sobre la família. I per tant, si s'havia produït algun canvi a nivell del consum a la llar o al cotxe particular.

Finalment, la limitació principal de l'Article 2 és el seu caràcter ecològic. Es van trobar algunes diferències entre les dades de l'Eurobarometer i les dades de prevalença reportades individualment en estudis concrets d'alguns dels països que conformen aquest Eurobarometer. Ara bé, el període de temps entre la mesura de les dades de la TCS (referents a 2007) i les dades de l'Eurobarometer (any 2009) és un període correcte ja que permet veure com les dades de prohibicions de l'2007 han impactat, al cap de dos anys, en les prevalences de tabaquisme i d'exposició al FAT.

Per altra banda, les fortaleses de la present tesi doctoral son les següents:

A l'estudi d'intervenció (Article 1) les principals fortaleses són la gran representativitat de la mostra, ja que fa referència a totes les escoles d'ensenyança secundària de Terrassa i també que la distribució aleatòria al grup d'intervenció o control, va permetre prevenir la possible formació de clusters. L'estudi va tenir, a més, una taxa de participació i seguiment molt alta entre la primera mesura i la segona mesura (97,5%).

A part, l'estudi va aprofitar estratègies d'intervenció que s'havien fet amb anterioritat al territori per tal d'avaluar intervencions preventives del tabaquisme actiu com el programa PASE/ESFA<sup>72</sup> i també materials utilitzats prèviament en la campanya "Vers una escola lliure de fum" <sup>73</sup>

En l'estudi ecològic (Article 2), el període de temps entre la mesura de les dades de la TCS (referents a 2007) i les dades de l'Eurobarometer (any 2009) és una fortalesa important. Aquests dos anys de decalatge permeten veure com les estratègies de prohibicions de l'2007 han impactat, al cap de dos anys, en les prevalences de tabaquisme i d'exposició al FAT.

# 6. Conclusions

- Les actuacions preventives encaminades a disminuir l'exposició del fum ambiental del tabac han de ser multinivell i l'èxit d'aquestes intervencions depèn molt del grau d'acompliment de les activitats plantejades així com de la qualitat de cada intervenció.
- Les intervencions poden ser més efectives en l'entorn familiar (a casa) i en els àmbits públics (transport públic) en els quals quedi clara la prohibició de fumar i per tant, disminueixi molt la possible exposició al FAT. En aquest sentit, cal estudiar els motius pels quals un programa que disminueixi l'exposició al FAT en l'àmbit familiar, no disminueix aquesta exposició al cotxe privat.
- Les intervencions preventives tenen un efecte menys notable sobre aquells adolescents que ja es declaren com a fumadors.
- La prohibició de fumar en espais públics no implica un increment de la prevalença de consum en espais privats.
- Els països amb polítiques més clares i concretes de prohibició de fumar en espais públics són els que tenen una proporció més elevada de cases lliures de fum.

# 7. Implicacions en salut pública

Els resultats d'aquesta tesi poden tenir una interessant aplicabilitat en salut pública ja que s'han identificat possibilitats de millora tant de les activitats preventives com del desenvolupament de polítiques i programes de control del tabaquisme:

- Cal dissenyar les activitats preventives tenint en compte actuacions a diferents nivells i considerant els diferents actors implicats.
- La intensitat de les activitats així com el seu bon acompliment són factors predictors de l'èxit final de l'objectiu fixat en el programa preventiu.
- Les actuacions preventives s'han de començar aviat ja que, un cop els adolescents han començat a ser consumidors actius, són més refractaris a les intervencions.
- Les legislacions clares i extenses són les que tenen un impacte més gran en la cessació de consum de tabac en públics.
- Les intervencions encaminades a prohibir el consum de tabac en públic no desplacen el consum de tabac cap a llocs privats.
- S'ha de promoure espais lliures de fum, especialment a les cases i als cotxes particulars ha de ser una prioritat de salut pública.

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# 9. Annexes

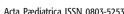
**Annex I:** Article derivat de l'estudi Respir-net: Martín-Pujol A, Fernández E, Schiaffino A, Moncada A, Ariza C, Blanch C, Martínez-Sánchez JM; RESPIR·NET research group.. Tobacco smoking, exposure to secondhand smoke, and asthma and wheezing in schoolchildren: a cross-sectional study. Acta Paediatr. 2013;102(7):e305-9.

**Annex II:** Procés editorial de l'article de la tesi publicat a la revista Preventive Medicine

**Annex III:** Procés editorial de l'article de la tesi publicat a la revista Tobacco Control

# Annex I

Article derivat de l'estudi Respir-net: Martín-Pujol A, Fernández E, Schiaffino A, Moncada A, Ariza C, Blanch C, Martínez-Sánchez JM; RESPIR·NET research group.. Tobacco smoking, exposure to second-hand smoke, and asthma and wheezing in schoolchildren: a cross-sectional study. Acta Paediatr. 2013;102(7):e305-9.



# **REGULAR ARTICLE**

# Tobacco smoking, exposure to second-hand smoke, and asthma and wheezing in schoolchildren: a cross-sectional study

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#### Keywords

Adolescents health, Asthma, Cross-sectional survey, Tobacco smoke pollution, Wheezing

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#### **ABSTRACT**

**Aim:** To analyse the association between tobacco smoking, exposure to second-hand smoke (SHS) and reports of wheezing and asthma in a sample of schoolchildren.

Methods: A structured questionnaire was administered to 1766 students (7th grade, aged

12–13 years) at 25 schools in Terrassa, Spain (2006). We determined the prevalence of active smoking, exposure to SHS and reports of wheezing and asthma, and their association by means of prevalence odds ratios (OR) and 95% confidence intervals (CI). **Results:** 97.5% of children were nonsmokers, 1.5% were experimental smokers and 1% were regular smokers. 41.1% of children reported exposure to SHS at home, 40.0% at school, 53.9% in their leisure time and 33.2% while using private or public transportation. Wheezing was reported by 9.2% of children, and 9.2% reported asthma. A significant association was found between smoking tobacco and wheezing: OR in experimental smokers = 3.0 (95% CI 1.2–7.7), and OR in active smokers = 4.2 (95% CI 1.4–12.5). Exposure to SHS while using transportation was associated with wheezing (OR = 1.4; 95% CI 1.0–2.0). Tobacco smoking and exposure to SHS were not associated with asthma.

**Conclusion:** Active and experimental smokers, and those who reported exposure to SHS while using public or private transportation, had higher likelihood of reporting wheezing. No association between active or passive smoking and asthma was observed.

# INTRODUCTION

Smoking tobacco and exposure to second-hand smoke (SHS) are avoidable risk factors for respiratory diseases in childhood (1). Exposure to SHS is associated with an increased risk of foetal damage, intrauterine growth restriction, neonatal sudden death syndrome, acute respiratory diseases, chronic and acute otitis, atopy and asthma (2,3,4). Respiratory symptoms related to asthma are among the most frequent conditions during childhood (5,6), and more severe symptoms can be present in children exposed to SHS (7). A study of children aged 4–16 years old in the USA concluded that exposure to SHS increased the frequency of respiratory symptoms and school absenteeism and also restricted pulmonary function (8).

Since the first contact with tobacco, alcohol and other illegal drugs is usually during secondary school (9), it is desirable to actively prevent exposure to SHS and active tobacco smoking in this age group (10).

The objective of the present study was to estimate the association between tobacco smoking and exposure to SHS with wheezing and asthma in schoolchildren in the seventh grade, which is the first year of compulsory secondary

## **Key notes**

- The prevalence of exposure to second-hand smoke in this population (year 2006) was high (79.5%) and varied according to the settings of exposure.
- The prevalence of tobacco smoking in this population (year 2006) was very low (1.0% current smokers and 1.5% experimental smokers).
- There is a significant association between tobacco smoking and exposure to SHS and wheezing, but not with asthma.

education in the Spanish educational system, in schools in Terrassa (near Barcelona, Spain).

## **METHODS**

# Study design

This study was part of a larger study that included the design and evaluation of a school-based program focused on SHS exposure prevention (the RESPIR.NET study). The target population was schoolchildren aged 12–13 years old in their first year of compulsory secondary education in Terrassa, Spain, a city of 213 000 inhabitants in the metropolitan area of Barcelona. All 25 schools in the city agreed to participate in this study. This report presents the results of the pre-intervention cross-sectional study, which was conducted from October to November, 2006.

#### **SUBJECTS**

The study population included 1888 schoolchildren. Of these, 109 (5.8%) did not attend school on the day that the questionnaire was administered, and another 13 (0.7%) did not respond to the questionnaire for other reasons (mainly language problems). The final sample thus included 1766 schoolchildren (93.5% of the original study population).

#### **Ouestionnaire and variables**

Data were collected using a self-administered questionnaire that included items on tobacco smoking, exposure to SHS and respiratory symptoms. Information on respiratory symptoms was collected using the Spanish version of the self-administered ISAAC questionnaire (International Study of Asthma and Allergy in Childhood) (5,11).

# Tobacco smoking

To determine the children's behaviour related to tobacco smoking, the following question was asked: 'Which one of these situations best describes your behaviour?'. We considered 'regular smokers' those who stated that they smoked every day or at least once a week; 'experimental smokers' those who stated that they smoked once a month or at least once a month or who identified themselves as exsmokers; and 'nonsmokers' those who had never smoked or who had just smoked once.

# Exposure to SHS

Exposure to SHS was investigated in different settings, namely at home, at school, while using private or public transportation, during leisure time and in general. Exposure to SHS at home was assessed by asking, 'How many people living with you at home usually smoke at home (not including smoking on the balcony or terrace)?'. Those who answered 'nobody' were considered 'not exposed' to SHS. Exposure to SHS at school was determined by asking separately about exposure in classrooms, corridors, main door entrances, teacher's rooms, playgrounds and bathrooms with the question, 'At school, do you smell tobacco smoke in any of the following places?'. Those who

responded that they smelled tobacco smoke 'nowhere at school' were considered 'not exposed' to SHS at school. Exposure during transportation differentiated between public and private transportation, and those who responded that somebody smoked nearby during transportation were considered exposed. SHS exposure during leisure time was assessed by the question, 'Do you usually spend time in indoor places – not at home nor at school – where somebody smokes (so close to you that you can smell the smoke)?'. This question had four possible responses, that is often exposed, sometimes, seldom or never, and weekdays and weekends were considered separately. We considered schoolchildren who answered 'often exposed' or 'sometimes' to be exposed. Thus, for general exposure to SHS, a child was considered 'exposed' when he/she reported being exposed to SHS in any of these four settings (school, home, transportation or leisure time).

# Respiratory symptoms

The Spanish ISAAC questionnaire was used to measure wheezing (5,11). Two trained nurses performed spirometry tests (three pulmonary function tests) with a portable spirometer (Datospir 120-C; Sibelmed, Barcelona, Spain). All spirometry results were reviewed by a pneumologist, and the best value of the three tests was used. Results were considered normal if the Forced Vital capacity (FVC) or Forced Expiratory Volume in 1 sec (FEV1) ≥80% and were considered altered if FVC or FEV1 <80%.

# Socioeconomic status (SES)

We used the family affluence scale, a socio-economic indicator designed for use with children and adolescents (12), which includes information about family car ownership, bedroom occupancy, family holidays in the past 12 months and computer ownership. A composite score was calculated for each child based on the sum of responses to these four items, producing an ordinal scale from 0 to 7, which was recorded into three categories: low (score 0–3), intermediate (score 4–5) and high affluence (score 6–7) levels (13).

## Statistical analysis

We estimated the prevalence and 95% confidence intervals (CI) of tobacco smoking, exposure to SHS, wheezing and asthma. The prevalence odds ratios (OR) and 95% CI for the association between wheezing and asthma with SHS were assessed by logistic regression models adjusted for age, sex, birthplace, type of school (public/private) and SES. All statistical analyses were carried out with SPSS 13.0 for Windows (SPSS Inc., Chicago, IL, USA).

#### **Ethics**

The study protocol was approved by the Research Ethics Committee of the 'Hospital Universitari de Bellvitge'. Parents and school staff provided informed consent for the children to participate in the study and for all measurements to be performed.

#### **RESULTS**

A total of 1766 schoolchildren were interviewed. Fifty-three per cent were boys, and the median age for both boys and girls was 12 years old. Most children (82.9%) were born in Catalonia (Spain), about 2% were born in other regions of Spain and 15% were born in other countries, mainly Morocco and Ecuador. Overall, 12.1% of children were in the lowest affluence category (low SES), and 60% were from subsidized schools (private schools which receive state subsidies) (Table S1, electronic supplementary material). Wheezing was reported by 9.2% (95% CI 7.9–10.6%) of the children, and another 9.2% (95% CI 7.9–10.6%) reported asthma; altered spirometry values were present in 8.8% (95% CI 7.3–10.3%) of all of the spirometry tests performed (1431 children) (Table S2).

There were no differences in tobacco smoking and exposure to SHS between boys and girls (Table S3). Most children (97.5%) did not smoke, 1.0% (95% CI 0.5–1.4%) were current smokers and 1.5% (95% CI 1.0–2.1%) were experimental smokers. SHS exposure was reported at home by 41.1%, at school by 40.0%, while using transportation by 33.2% and during leisure time by 53.9%. The prevalence of exposure to SHS while using private transportation was significantly higher than while using public transportation (29.7% vs. 17.3%, respectively, p < 0.05). Overall, 79.5% (95% CI 77.6–81.4%) were exposed to SHS in at least one of the four settings considered in the study.

The association between smoking tobacco, exposure to SHS and wheezing and asthma is shown in Table 1. After adjusting for sex, age, birthplace, SES and type of school, only wheezing was associated with being an experimental or regular smoker (OR = 3.0, 95% CI 1.2–7.7 and OR = 4.2, 95% CI 1.5–12.5, respectively) and with exposure to SHS during leisure time (OR = 1.5, 95% CI 1.0–2.0). Reports of asthma or altered spirometry did not show any significant associations with tobacco consumption or SHS exposure (Table 1).

# **DISCUSSION**

We found a high prevalence of exposure to SHS in this population of schoolchildren, who were in the first year of compulsory secondary education in Terrassa (Barcelona). Notably, there was a significant association between tobacco smoking or exposure to SHS and wheezing, but no such association with asthma. The high prevalence of (self-reported) SHS exposure was somewhat surprising, considering that there has been a complete ban on smoking at schools since January 2006. While it is possible that the ban is weakly enforced at schools, this difference may be explained, in part, by the inclusion in our study of a detailed list of places at school where exposure to SHS might occur; this could have prompted the students' recall.

One-third of the schoolchildren reported exposure to SHS while using transportation. There is some evidence that recommendations about avoiding smoking in cars are effective in preventing children's exposure to SHS (14). It is

surprising that participants reported being exposed to SHS while using public transportation, as smoking is currently forbidden on buses and on metro and passenger trains. However, exposure to SHS might occur while the children wait for transportation, for example at bus stops or metro or train stations, as people sometimes smoke in the open air before getting on the transport. A study of adults in Spain in 2006 also showed a perception of exposure to SHS in such places, with 40% reporting exposure (15) and 30% reporting exposure at bus stops. Thus, banning tobacco smoking in these open-air public areas should be considered (1,16).

Among our participants, whose mean age was 12 years old, the proportion that reported exposure to SHS at home was lower than in the other settings. Although smoking at

**Table 1** Association between tobacco consumption and exposure to second-hand smoke (SHS) with wheezing, asthma and altered spirometry in schoolchildren in the first year of compulsory secondary education in Terrassa (Barcelona, Spain), 2006

	n	%	Adjusted OR <sup>†</sup>	95% CI
Models for wheezing				
Tobacco consumption				
Nonsmoker	145	8.6	1	
Experimental smoker	6	22.2	3.0	1.27.7
Current smoker	5	29.4	4.2	1.512.5
Exposure to SHS				
Not exposed	478	27.1	1	
Home	75	10.5	1.2	0.91.8
School	76	10.9	1.2	0.91.7
Transportation	97	10.3	1.3	0.91.8
Leisure time	66	11.3	1.5	1.02.0
General	135	9.8	1.3	0.82.0
Models for asthma				
Tobacco consumption				
Nonsmoker	155	9.2	1	
Experimental smoker	3	11.1	1.2	0.34.0
Current smoker	2	12.5	1.3	0.35.9
Exposure to SHS				
Not exposed	478	27.1	1	
Home	68	9.5	1.1	0.81.5
School	64	9.2	0.9	0.61.3
Transportation	95	10.1	1.3	0.91.8
Leisure time	60	10.3	1.3	0.91.8
General	133	9.5	1.1	0.71.7
Models for altered spirometr	ry			
Tobacco consumption				
Nonsmoker	122	10.0	1	
Experimental smoker	2	11.8	1.0	0.24.3
Current smoker	0	0		
Exposure to SHS				
Not exposed	478	27.1	1	
Home	52	10.3	1.1	0.71.6
School	46	9.3	0.9	0.61.3
Transportation	66	9.6	1.0	0.71.4
Leisure time	48	11.4	1.3	0.92.0
General	100	10.1	1.1	0.71.8

\*Odds Ratio adjusted for sex, age, birthplace, socioeconomic status and type of school.

home by parents is the main source of childhood exposure to SHS (17), exposure tends to diminish as children grow up and spend more time out of their homes and with friends.

The Global Youth Tobacco Survey (GYTS), conducted between 2000 and 2007, found that overall exposure of European adolescents aged 13- to 15-year-old to SHS was around 68% (65.0–70.8%) (18). The prevalence in our study was slightly higher than that found in the GYTS, but the GYTS study included only two very general questions about SHS exposure at home or in other settings, which possibly underestimates the true prevalence. Furthermore, in the countries included in the GYTS, the smoking epidemic is not as widespread as in the countries of the European Union, such as Spain.

The prevalence of regular smokers and experimental smokers in our study, 2.5%, is within the range from 1.1% to 5.8% found in previous studies of children of similar ages (19,20). Although these prevalence rates are quite low, it is still important to implement preventive interventions for children in this age range. A study from 2001 that was also conducted in Terrassa but that involved schoolchildren aged 14- to 15-years-old found a 15.5% prevalence of daily smokers (21), probably due to increases in tobacco smoking at the end of secondary school (22).

The ISAAC study performed in Spain in 1999, which involved children aged 13- to 14-years-old, found wheezing prevalence rates of 7.8% in boys and 7.0% in girls (5). A study in Tenerife (Spain) in young people aged 14- to 21years-old found a prevalence of asthma of 10.5% (23). There are no big differences between the findings of these studies and ours, as we found that the prevalence of both asthma and wheezing was 9.2%. Similarly, our findings of the prevalence of altered spirometry values were not very different than those reported by another study in 12- to 17year-olds (24) and also concur with previous studies showing a clear relationship between wheezing and smoking and, to a lesser extent, with wheezing and exposure to SHS (25–27). Notably, these studies, as well as our study, found no significant relationship between SHS and asthma. Our results for the association between smoking, wheezing and asthma are, however, based on a very low number of current or experimental smoker children, and hence, the results have to be cautiously interpreted.

One possible limitation of our study might be information bias, as most data were self-reported using self-administered questionnaires. However, the ISAAC questionnaire was adapted and validated previously in our setting (28), spirometry was conducted by two experienced nurses and both smoking and exposure to SHS via self-reporting are considered valid epidemiological data (29). We conducted a pilot study in 92 secondary and high school students in Barcelona that showed a good correlation between self-declared SHS exposure and salivary cotinine concentrations (30). Secondly, most nonresponse (109 schoolchildren, 5.8% of the sample) was due to absenteeism. This might be considered a study limitation if student absenteeism was related to some of the analyzed variables. A study in

California found that exposure to SHS was associated with and increased school absenteeism due to respiratory diseases, especially among students with asthma (8). If this were the case in our study, assuming that the prevalence of asthma and wheezing might be higher in the absentee students than in the studied sample (for example, twofold higher), the prevalence of exposure to SHS would be underestimated only by about 0.2–0.4%. In the worst-case (and unlikely) scenario, in which all absences were due to SHS exposure, our prevalence rates would be underestimated by about 3% at the most. Thus, we think that the presence of these nonresponders probably did not affect our final estimations.

Among the study strengths, noting that all the secondary schools in the city agreed to participate and that pupils participation was almost complete (93.5%). We included information on SHS exposure in several settings, while most published studies only consider exposure to SHS at home or outside of the home. Finally, as this study was conducted in October and November, our data should not have been affected by seasonal increases in respiratory symptoms due to flu (typically highest in January and February) or allergenic agents (highest in March and April).

In conclusion, smoking and exposure to SHS in adolescent schoolchildren remain high, and both are associated with wheezing. Effective school-based interventions should be designed and implemented to prevent both active and passive smoking among schoolchildren.

# **ACKNOWLEDGMENTS**

We acknowledge the skilled efforts of Pepi del Bas, Ester Teixidó, Ana Villegas and Ester Basart in collecting data and appreciate the schools and parents who allowed us to conduct this study.

# **CONFLICT OF INTERESTS**

The authors have no competing interests.

# **FUNDING**

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## **SUPPORTING INFORMATION**

Additional Supporting Information may be found in the online version of this article:

**Table S1** Sociodemographic characteristics of schoolchildren in the first year of compulsory secondary education (n = 1766) in Terrassa (Barcelona, Spain), 2006.

**Table S2** Prevalence (%) and 95% confidence interval (CI) of wheezing and asthma in schoolchildren in the first year of compulsory secondary education in Terrassa (Barcelona, Spain), 2006.

**Table S3** Prevalence (%) and 95% confidence interval (CI) of tobacco consumption and exposure to secondhand smoke in schoolchildren in their first year of compulsory secondary education in Terrassa (Barcelona, Spain), 2006.

Annex II
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Procés editorial de l'article de la tesi publicat a la revista Preventive Medicine

# Carta de presentació de l'article del Preventive Medicine

L'Hospitalet de Llobregat, October 24th, 2012.

Prof. Alfredo Morabia Editor-in-Chief Preventive Medicine

Dear Prof. Morabia:

Please find enclosed our manuscript "Impact of a multi-level intervention to prevent secondhand smoke exposure in schoolchildren (12-14 years old)" for your consideration in Preventive Medicine as an Original Research Paper.

Our study provides information about the results of several educational activities to prevent secondhand smoke in schoolchildren in the city of Terrassa (Barcelona, Spain). The main interest of our research is that for the first time in Spain, a multilevel intervention to prevent SHS has been developed at schools. The results of this multilevel intervention showed some impact on decreasing SHS at school, at homes, and also in transportation. The effect the program was better in those schools with the higher accomplishment of all the proposed activities. Our study also showed the need of including this type of activities to prevent secondhand smoke to the more traditional programs designed to prevent tobacco smoking in the young people.

All the authors carefully read the manuscript and fully approve of it. In their name I also declare that the manuscript is original and it is not submitted anywhere other than your journal. The authors declare there are no conflicts of interest.

We would of course be ready to provide further information about our data and methods you desire. Correspondence about the manuscript should be addressed to me as indicated in the first page of the manuscript.

Thank you very much for your kind attention.

Yours sincerely,

Esteve Fernández, MD, PhD

E-mail: efernandez@iconcologia.net

#### Resposta a la primera revisió de l'article del Preventive Medicine

L'Hospitalet de Llobregat, November 5, 2012.

Prof. Alfredo Morabia Editor-in-Chief Preventive Medicine

RE: Please find enclosed our manuscript "Impact of a multi-level intervention to prevent secondhand smoke exposure in schoolchildren (12-14 years old): a community trial" PM-12-765

Dear Prof. Morabia:

Thank you very much for your email of October 31<sup>st</sup> and the opportunity to continue with the submission of the manuscript.

We have used the CONSORT statement and have introduced some modifications in the manuscript according to the checklist. Now the title includes the design (we have added ": a community trial"), we provide details on sample size computation, and have included the flowchart in addition with the paragraph already present in the Methods section.

All the authors carefully read the manuscript and fully approve of it. In their name I also declare that the manuscript is original and it is not submitted anywhere other than your journal. The authors declare there are no conflicts of interest.

We would of course be ready to provide further information about our data and methods you desire. Correspondence about the manuscript should be addressed to me as indicated in the first page of the manuscript.

Thank you very much for your kind attention.

Yours sincerely,

Esteve Fernández, MD, PhD

E-mail: efernandez@iconcologia.net

## PREVENTIVE MEDICINE-12-765R1 Impact of a multi-level intervention to prevent secondhand smoke exposure in schoolchildren (12-14 years old): a community trial

#### Reviewer #1:

This community trial to prevent second hand smoke exposure appears to be a well written manuscript with sound methodological quality, although this is somewhat difficult to determine in the absence of a pre-specified published protocol. The authors should be commended for attempting to address an area of research that is currently lacking in evidence and will certainly benefit from this evaluation once published.

We thank all reviewers' comments and we appreciate the opportunity to improve the presentation of our results. Also this revision of the manuscript has allowed us to clarify some of the methodological issues which were not clear enough in our previous version.

1. Pages 4 to 6: A description of what the comparison group actually consisted of is required, be it alternative health lessons or simply usual practice.

The schools in the control group did not follow any alternative or special programme of lessons, but simply the usual practice. Thus, according to the reviewer comment, we provide this information at the end of the section devoted to the intervention:

"The comparison schools did not follow any alternative or special programme of lessons, but simply the usual practice."

2. Page 4 and tables 3 and 4: An adjustment should be made to the results reported to take into account clustering effects. Randomisation occurred at the school whilst the data has been analysed at the individual participant level, which will produce a unit of analysis error. This can result in overestimation of the statistical significance of the results by not taking into account clustering of the individuals in the data (see Rooney 1996 and Ukoumunne 1999 below). Some useful references for this include Rao 1992 and Gail 1992.

We appreciate the reviewer's comment and have re-analyzed the data incorporating the clustering effect into the models. As shown in the new table 4, the only change is the OR for SHS at school for the intervention group (for all schools and restricted to "good accomplishment" schools). Accordingly, we have changed some sentences in the results and discussion sections, to accommodate to this result (please see the tracked changes copy of the manuscript).

3. Page 4: You should state in your study design section that no important changes to study methodology were made after trial commencement, to reassure the reader in the absence of a prespecified protocol. Also include the method of allocation concealment if this occurred (i.e. exactly how were the schools allocated to intervention and control). If it did not occur you will need to include this as a limitation.

Although we did not register nor publish the protocol of the trial, we strictly followed the protocol as approved by our Research and Ethics Committee. No changes occurred after the commencement of the trial. We have added a sentence including this information in the Methods section.

As explained in the Methods section, we allocated the schools at random to the intervention or comparison group. We used the "random sampling" command in SPSS. We however believe that it is not necessary to include this detail in the text, but we are open to include it if the Editor considers it necessary.

4. Page 5 or 7: Under information collected or statistical analyses you need to mention if you had any missing data from student questionnaires and if so, how it was addressed (e.g., random imputation of numbers) if not, please state this.

For the statistical analysis, we only used data from those pupils with questionnaires filled-out at the first round in 2006 and in the posterior assessment in 2007. Pupils with either missing data in 2007 (lost to follow-up for any reason) or missing data in 2006 (i.e. new comers) were excluded from the analysis. There was some missing information for some variables in a small proportion of these participants, but no random imputation was done. We have indicated in the tables when that missing values were present.

5. Pages 7 to 8 and table 3: When doing a direct (provisional) comparison between intervention and control at final follow-up none of the results appear to be significant, which should be reported in this manuscript and I believe should be considered as the primary outcome of the study (home OR 1.02 95%CI 0.84 to 1.25; school OR 0.91 95%CI 0.75 to 1.10, transportation OR 0.92 95%CI 0.75 to 1.13, leisure time OR 0.99 95%CI 0.82 to 1.20). Despite the intervention producing no demonstrable evidence of effect, this in its self is still publishable and adds important information to the evidence base as it highlights that a different approach is needed.

The OR provided by Reviewer #1 seemed to come just from the comparison of the answers to the "after" questionnaire in both groups. In our opinion this approach does not consider the status of the participants "before" the intervention, being this one of the strengths of the design. For this reason we used the McNemar's Chi-square test for paired data.

6. Table 3: As the primary objective is to determine the ability of the intervention to prevent second hand smoke exposure, it would be logical that an assessment would be done to determine if students who were' not exposed' at baseline were indeed prevented from exposure during the study

period, otherwise the aim of the study would be to reduce second hand smoke exposure as is currently reported in this manuscript.

In agreement with these observations, we have analyzed the data to understand how the intervention affects the proportion of "non- exposed" pupils before and after the intervention. Thus it is possible to compare the crude effect of the intervention versus the control group, and also compare it related to the quality of the intervention.

The percentage of non-exposed pupils in the intervention group that remained non-exposed at the end of the trial was 90.8% at home, 71.8% at school, 81.7% in transportation, and 61.6% during leisure time. The corresponding figures for the control group were 89.1%, 71.3%, 79.2%, and 64.0%. We found that among pupils in schools with a good accomplishment of the intervention the percentage remaining non-exposed was slightly higher in all setting (3-10 points of percentage). Thus, we have included these figures in the text.

7. Page 7 lines 5 to 7 and table 3 The degree of implementation, which authors report was collected page 7 ".we measured the quality of the intervention according to the actual number of sessions accomplished." should be reported in table 3. For example, separate out by the number of students who received greater than 75% of the planned intervention. If this is what you have presented on page 8 and table 4, then it is not very clear and needs revision (p-values should also be provided in table 4). Perhaps consider presenting dichotomous data instead, with the number of students (and %) who received: session 1, session 2 up to session 6 etc. This would give the reader a better understanding about the degree of implementation.

As suggested by the reviewer, we have computed with the crude effect observed depending on the quality of the intervention:

GOOD					
	Before		After		Diff. %
Secondhand smoke					
exposure	N=251		N=251		
	n	%	n	%	dif %
Home	118	47.4	86	34.3	-27,6
School	87	34.7	81	32.3	-6,9
Transportation	97	38.6	72	28.7	-25,6
Leisure Time	139	55.4	125	49.8	-10,1
POOR					
	Before		After		Diff. %
Secondhand smoke					
exposure	N=506		N=506		
	n	%	n	%	dif %
Home	218	43.4	185	36.6	-15,7
School	258	51	216	42.7	-16,3
Transportation	191	37.7	153	30.2	-19,9
Leisure Time	240	47.4	263	52	9,7

We have introduced the main results of this table within the text:

"We observed a greater reduction in SHS exposure at home (-27.6%), transportation (-25.6%) and leisure time (-10.1%), but not at school (-6.9%), among pupils in the schools with good accomplishment of the intervention as compared with pupils in schools with a poor intervention (home -15.7%, transportation - 19.9%, leisure time +9.7%, and school -16.3%)."

8. Page 7 and table 3: Potential confounders are reported as being taken into account, the actual variables should be listed in brackets next to this sentence. If the results in table 3 have been adjusted for these confounders, they should also be added in a key below the table. Also, the key for table 3 should state exactly how data is presented (i.e., I assume that results are reported as 'n(%)', this needs to be clear.

Table 3 shows the crude bivariate analysis without any type of adjustment. It is just the "before-after" comparison of the proportion of pupils according to SHS and smoking. We have added the "subheadings" "N" and "(%)" to the Table. We are inclined to maintain this Table without any other modification, in order to show the crude data before showing the adjusted estimates in Table 4.

9. All pages: Some proof reading is required as there are very minor grammatical errors and spelling mistakes e.g.,
pg 3 line 54 ".if the parent quits smoking.";

Done.
pg 8 line 19 ".preventive effect on becoming a smoker.";

Done.
pg 8 line 35 ".study show (instead of showed) how this type of educational."

We have not changed it because we wrote all the discussion in past tense.

table 3 heading 'Group';

Done.
pg 12 "EF is the guarantor.";

Done.
pg 14 Hawthorne reference ".Geneva' (not Geneve).

10. Pg 7 line 32: First time USA is mentioned it should be written in full.

Done.

11. Pages 8 to 11: The discussion needs some restructuring and should consolidate the sections outlining limitations, currently part of it is in the first paragraph under discussion on page 8, some on page 10 in the second paragraph and the primary section resides on page 11. The first paragraph typically provides a brief summary of the results, followed by the completeness of the evidence and applicability in addressing your original aim, then a discussion about the studies strengths followed by its limitations and whether you consider these limitations to be significant or not and why, then finally you would compare your results to other literature and provide a concluding statement. As it currently stands, there is too much discussion comparing these results to the available evidence/literature and not enough reporting the strengths and limitations.

We appreciate the comment of the reviewer. Our Discussion section already followed the traditional structure outlined by the reviewer. We have accommodated the Discussion to the changes in the Results due to the incorporation of the clustering to the analysis (see revised version of the text). Moreover, we have expanded the paragraph devoted to the strengths and limitations, including some of the comments in reviewer's point 12 (see below).

- 12. Page 11: Other limitations to consider include:
- the potential of concurrent initiatives such as public policy and government legislation to impact the outcome of the study - in particular you mention the implementation of new smoking laws on page 6

We agree and have included a sentence in the Discussion (see text)

possibility of contamination where the intervention can be implemented in control schools due
to teachers sharing information for class programs if adequate geographical separation has
not occurred. Also, did any of your 'matched' students switch schools between baseline and
follow-up? This needs to be stated. If you do not believe there is a possibility for
contamination please state that it is unlikely

We have included a sentence in the Discussion (see text)

• Clustering effects see point 2 above

We agree and have included a sentence in the Discussion (see text)

Allocation concealment if this didn't occur - see point 3

See response to point 3.

• Lack of blinding for outcome assessors, investigators, participants and people delivering the intervention (e.g., teachers) (not reported as occurring in your consort checklist)

It is known that blinding in community trials is very complicated and, given the intervention implemented in our study, we should say almost impossible. This is not a clinical trial where researchers can control this factor. Hence, we are inclined not to include this point in the Discussion.

13. Abstract conclusion, Highlights and pg 11 conclusion: Given points 2, 5 and 6 above, I don't agree with your conclusion that the intervention is responsible for prevention of SHS exposure. This data needs to be re-analysed and conclusions re-written to reflect the evidence. In addition, you can't conclude from your study that adding the SHS intervention to traditional intervention programs for to prevent tobacco smoking in young people will indeed produce an additional benefit above that of the traditional program, as this was not assessed in your study. When combining similar interventions such as SHS exposure prevention and tobacco smoking prevention any potential effect of the 'standalone' initiative will be diminished, thus you could conclude only that a combined 'traditional' and SHS exposure prevention initiative should be considered in the next phase of tobacco research in youth.

We have re-written these sentences according to the reviewer's comments (see text)

14. Pg 12: Please provide a statement regarding ethics approval. Was ethics approval sought or obtained? If not, please state this and why it did not occur.

Ethical approval was obtained. We have included the following statement:

"The study protocol was approved by the Research Ethics Committee of the "Hospital Universitari de Bellvitge". Parents and school staff provided written informed consent for the children to participate in the study and for all measurements to be performed."

15. Table 2 and pg 7: P-values are not recommended in characteristic tables. What you have reported on page 7 is the appropriate place to mention significant differences

In our opinion the P-values in this table allows an easier reading of the characteristics and comparison between both groups. Thus, we prefer to keep P-values in the table.

16. Table 3: Why are the n-values for the comparison before (n=977) and after different (n=974)? This needs to be explained or if a typo corrected.

This is not a typo, actually the only category were the groups before and after matched in the number of respondents was that in the intervention group. All other categories reported in former Table 3 showed discrepancies among the number of pupils who answered that specific question in the questionnaire before and after. In Table 3 this has been commented in a footnote.

"The figures does not sum up the total because of some missing values."

17. Table 3: You should also consider an 'intention to treat' analysis, which is usually recommended for tobacco related research (i.e., subject results will be included regardless of whether they received the intervention or not). It is not clear if you have done this as it has not been reported in the statistical analysis section or tables.

We appreciate the comment. Given the paired nature of the data, we opted to restrict the analyses to those pupils with complete data before and after the intervention. Moreover, the number of pupils not include in the analyses was 21 who were lost to follow-up and 24 switchers (from control to intervention group [n=12] or viceversa [n=12]). This restriction allows us to adjust the multivariate model with random effects to quantify the effect of the intervention. We believe that the exclusion of the 2% of the sample would only have a residual impact on the estimates presented. We have included a sentence about this limitation in the Discussion section (see text).

#### Reviewer #3:

The paper is an interesting one, overall well written and analyzed.

Thank you very much for your kind comments.

Abstract: the results section should say "analyze DATA from X students"

Done

text: In methods section, should state how many pupils lost to follow up?

Done (see text)

Intervention section, should state why two new activities were included in addition to the previous evaluated intervention. what is your rationale for this?

Our goal was to evaluate whether SHS could be prevented by means of multi-level intervention offered from the schools. Since an intervention on tobacco smoking was already available, we decided to modify that intervention by adding the new activities on SHS. This is explained in the first sentence of the "intervention" subheading within the Methods section.

Do you have any data on the compliance with the intervention materials/sessions? how many teachers participated?

Teachers evaluated the number of sessions given at each school and also reported their self- impression. Not any other formal partial analysis were performed a part of the final assessment. Interventions were classified as good, fair or poor, as explained in the subheading "intervention" in Methods.

### Is there a reason the authors speculate behind the "unbalanced" between the intervention and control groups"?

We appreciate the reviewer's comment and the opportunity to clarify this point. There were different schools included in the study –public and private/subsidized- with differing socioeconomic characteristics of the attendants and also possible gender differences. Although the allocation to intervention or control school was done randomly, due to the small number of schools participating, there were still some chances to get unbalanced populations. Since this was not the case, the authors wanted to comment that both samples were well balanced. This is clear from the Results, and the potential confounding effect due to this slight unbalance between the groups is controlled for by means of the multivariate analysis. Thus, we have included two sentences in the Discussion section (see text).

#### Resposta a la segona revisió de l'article del Preventive Medicine

L'Hospitalet de Llobregat, April 12th, 2013.

Prof. Eduardo L. Franco Editor-in-Chief Preventive Medicine

Dear Prof. Franco:

Please find enclosed our revised manuscript "Impact of a multi-level intervention to prevent secondhand smoke exposure in schoolchildren (12-14 years old): a randomized cluster community essay" for your consideration in Preventive Medicine as an Original Research Paper.

We appreciate very much the reviewers' and Editor's thoughtful comments and the opportunity to revise the manuscript. We have incorporated most of them into the new version of the manuscript. Please find enclosed our point-by-point response together with a clean copy of the new version. Given the major changes introduced, we are also attaching a marked (highlighted in yellow) copy as "supplementary material".

All the authors carefully read the manuscript and fully approve of it. In their name I also declare that the manuscript is original and it is not submitted anywhere other than your journal. The authors declare there are no conflicts of interest.

We would of course be ready to provide further information about our data and methods you desire. Correspondence about the manuscript should be addressed to me as indicated in the first page of the manuscript.

Thank you very much for your kind attention.

Yours sincerely,

Esteve Fernández, MD, PhD

E-mail: efernandez@iconcologia.net

# PREVENTIVE MEDICINE-12-765R2 Impact of a multi-level intervention to prevent secondhand smoke exposure in schoolchildren: a randomized cluster community trial

#### **Editor:**

1) Change the manuscript title to "Impact of a multi-level intervention to prevent second-hand smoke exposure in school children: a cluster randomized community trial"

We have changed the title.

2) Change the word "essay" to "trial" throughout the text, as applicable.

We have changed "essay" to "trial" throughout the text.

3) Register your RCT in an accredited trial register. Once your protocol receives a registration number, indicate it in the abstract and in the Methods section.

We have registered the study and included the ID in the abstract and Methods section. Please find attached the registration receipt.

4) Address the final concerns from reviewer #1 (see below).

We have addressed the reviewer's comments.

#### Reviewer #1:

Once again I would like to congratulate all the authors on a well written manuscript with methodologically sound and interesting findings. I look forward to seeing the published version. Thank you for addressing the questions I raised regarding your study. I believe you have addressed all the points well and where you decided not to follow the advice I understand your reasoning and am happy with the outcomes.

If I could make a couple more minor suggestions being to add one sentence in your methods stating that you have adjusted your data for potential clustering effects to account for unit of analysis errors, as this will make your methodology around this point clearer.

We have indicated it.

Your response to point 16 where you have added a footnote to table 3 needs some grammatical revision, perhaps... "The figures do not sum up to the total due to some missing values."

We have changed the footnote.

I don't understand why you would change your title to include 'essay' instead of 'trial' but I assume this has been amended based on feedback from one of the other peer reviewers and as such will leave it be.

As also asked by the Editor, we have changed "essay" to "trial" throughout the text.

#### Resposta al comentari de l'Editor de l'article del Preventive Medicine

L'Hospitalet de Llobregat, June 21st, 2013.

Prof. Eduardo L. Franco Editor-in-Chief Preventive Medicine

Dear Prof. Franco:

Please find enclosed our revised manuscript "Impact of a multi-level intervention to prevent secondhand smoke exposure in schoolchildren: a randomized cluster community trial" for your consideration in Preventive Medicine as an Original Research Paper.

We appreciate very much the reviewers' and Editor's response to our previous review and the acceptance provided our revision. We have incorporated the Editor's comments and Reviewer's #1 comment into the new version of the manuscript. The trial is now registered in ClinicalTrials.Gov with identifier NCT01881607. Please find the changes highlighted in yellow in the manuscript.

I have also incorporated a note in the first page, indicating that Dr. Manel Nebot, co-IP of the project, co-author of the paper and good friend, passed away past October. I would wish to include the note as a small tribute to him.

Thank you very much for your kind attention.

Yours sincerely,

Esteve Fernández, MD, PhD

E-mail: efernandez@iconcologia.net

#### Acceptació de l'article de Preventive Medicine

Ms. No.: PM-12-765R3

Title: Impact of a multi-level intervention to prevent secondhand smoke exposure in schoolchildren (12-14 years old): a randomized cluster community trial Corresponding Author: Dr. Esteve Fernandez Authors: Carles Blanch; Jose M Martínez-Sánchez; Carles Ariza; María J López; Albert Moncada; Anna Schiaffino; Luis Rajmil; Esteve Saltó; José A Pascual; Manel Nebot

Dear Dr. Fernandez,

We are pleased to inform you that your newly revised manuscript, referenced above, has been accepted for publication in Preventive Medicine. Your manuscript has been forwarded to Elsevier's Production Department. You will be contacted by them in the near future regarding the proofs of your article.

Thank you for submitting your paper to Preventive Medicine.

Respectfully,

Eduardo L. Franco, DrPH, FRSC, FCAHS Editor-in-Chief

Gayle A. Shinder, PhD Deputy Editor

Preventive Medicine pm@elsevier.com

Annex III
Procés editorial de l'article de la tesi publicat a la revista Tobacco Control

#### Carta de presentació de l'article publicat a Tobacco Control

L'Hospitalet de Llobregat, November 5, 2012.

Prof. Ruth Malone Editor Tobacco Control

Dear Prof. Ruth Malone:

Please find enclosed our manuscript "Do smoke-free policies in work and public places increase smoking in private venues?" for your consideration in Tobacco Control as a *Brief Research*.

The tobacco industry and the hospitality sector have hypothesized that smoke-free legislation in public places will displace tobacco consumption to private venues, particularly the home. However, our findings based on data of 27 European countries confirm that smoke-free legislation in work and public places is not associated with increased smoking in private venues (houses and cars). This result also calls attention that smoke-free houses and cars are a priority for public health interventions.

All the authors carefully read the manuscript and fully approve of it. In their name I also declare that the manuscript is original and it is not submitted anywhere other than your journal. The authors declare there are no conflicts of interest.

We would of course be ready to provide further information about our data and methods you desire. Correspondence about the manuscript should be addressed to me as indicated in the first page of the manuscript.

Thank you very much for your kind attention.

Yours sincerely,

Jose M Martínez-Sánchez, PhD, MPH, BSc

E-mail: jmmartinez@iconcologia.net

### Tobaccocontrol-2012-050877 Do smoke-free policies in work and public places increase smoking in private venues?

#### Response to the Reviewers' comments

We thank the editor and the reviewers' comments for the useful comments.

#### Reviewer #1

This is an important topic and the regional size of the study (Europe) is great. However, I believe the conclusion of the paper is not reflective of what the study measured. As I read the paper, the variable used was strength of tobacco control (tobacco control score) and not passage of smoking bans. In addition, the data on smoking behavior is taken at one time so it is impossible to know if changes in work and public place bans lead to increases in private venues.

We agree with the reviewer that TCS covers more than smoking bans –it is a scale including several components of tobacco control. We had already explained this in the "Tobacco control policies" section of the Methods. Moreover, the TCS also includes the level of implementation of smoke-free bans at work and public places (score between 0 and 22). Then, we focused mainly in this policy because this is the most relevant one to answer the debate raised about whether banning smoking in public places can move tobacco consumption to private settings.

According to this comment we have included the following sentence in the results of the abstract:

"A similar lack of association was observed between the TCS score of specific bans at work and in public places and smoking rules inside houses and cars."

The objective of our study was not to measure changes in smoking behavior. We aimed to evaluate the correlation between the level of tobacco control (as measured by the TCS) and prevalence of smoking behavior in private venues after the policies were implemented. We also tried to measure any possible correlation between level of smoke-free bans and tobacco consumption in private settings. Consequently, the ecological design of our study allowed us to analyze this correlation.

Instead, the study showed that in those countries with strong tobacco control, non-smoking behaviors extended to private locations. Problem is that in countries with weaker overall tobacco control - did these same benefits not transfer or perhaps was there increasing private exposure in those countries. You still a valuable brief but the overall claim of what the data shows could be sharpened.

Our results showed there is no correlation between TCS, smoke-free bans, and smoking in private venues. If the restriction of smoking in public places would displace tobacco consumption to private venues, as the tobacco industry and the hospitality sector argued, this correlation would have been positive.

Moreover, our data also showed a positive correlation, although statistically non significant, between TCS and the prevalence of smoke-free houses.

We have included the following sentence in the discussion to clarify our results:

"If the hypothesis argued by the tobacco industry and hospitality sector were true this relationship would have been positive."

#### Reviewer #2

1. Page 2 line 48. Conclusion of abstract. 'and thus is not increasing the prevalence of second-hand smoke exposure...' The data do not tell us anything about the intensity of exposure - it is entirely possible that in those houses and cars where people continue to smoke that they are now smoking more (due to their inability to smoke in public spaces). So while the prevalence is not increasing, those smokers who continue could, possibly be smoking more.

We agree with the reviewer's comment. We deleted this sentence in the conclusion of the abstract.

2. Page 3 Line 32. it would be useful to mention the Akhtar study in the introduction. This study showed no evidence of displacement of smoking activity to homes after the introduction of smoke-free legislation in Scotland in 2006.

We included in the Introduction a sentence on the Akhtar and other studies, providing the relevant reference:

"To our knowledge, only one study,<sup>9</sup> conducted in US, supports this hypothesis, whilst other studies show no displacement of smoking prevalence to home after the implementation of smoking ban. <sup>2;10;11</sup>"

3. Page 3 line 39. Again in the study objective I would recommend making it clear that it is to look at smoking prevalence in private venues.

We have changed the sentence according to the suggestion of the reviewer.

4. Page 4. Line 41 and 53. 'Tobacco consumption'. The data do not provide information aout consumption (i.e. there is no consideration of volume or frequency of smoking) and so I would recommend calling these two variables 'Tobacco use inside the house/car'.

Done.

5. Page 5. Line 29. Typo '...indicating full implementation...'

Done.

6. Results. I think it would be useful to give a table with data including the TCS scores and public ban scores for each country.

We agree with the reviewer on the utility of such a table. However, we do not have the possibility to include it; given the rules of the journal for brief reports (only one table is allowed). This information, moreover, is available in the TCS report (references 12 and 13, which can be accessed on the internet).

7. Page 6. Line 53. The first sentence of the discussion again makes the mistake of saying that there is no relationship between smoke-free laws and exposure to SHS in private venues. What it should say is prevalence - we have no data on intensity of exposure among those who continue to be exposed.

We changed it.

8. Page 7/8. the discussion acknowledges the weakness of an ecological study. It may be useful here to explicitly acknowledge that at an individual level those who continue to be exposed may be exposed more often.

We agree with the reviewer's comment and we have included this limitation in the discussion section as follows:

"We have no information about the intensity of SHS exposure<sup>19</sup> at the individual level in the house where smoking continues to be allowed."

9. Page 8. Line 13. Wrong use of the word 'exposure' again: suggest correct with 'the prevalence of exposure'

Done.

10. The authors may wish to consider that this evidence may suggest that TC policies have little effect on private space prevalence of exposure and so have little effect on the de-normalisation of smoking. Some consideration of why Finland has 95% smoke-free homes (and yet only a 58 point TCS score) may be useful.

We agree with the reviewer's comment. It is true that there is a sort of paradox with the Finnish data: high prevalence of smoke-free homes (and cars) whilst a "relatively" low TCS score (Finland ranks sixth among the 27 EU states). Perhaps there are other non-controlled factors, in addition to our primary focus – the TCS. Actually, Finland stands in the 4<sup>th</sup> stage (final stage) of the Lopez's tobacco epidemic model, and has a relatively low smoking prevalence (and the country). This is also related to the prevalence of smoke-free homes.

As suggested by the reviewer we have included a comment on this point:

"Another potential limitation derives of the lack of information about the stage of the tobacco epidemic among different countries<sup>21</sup>. Countries at late stages have low prevalence of smokers and hence the likelihood of smoke-free homes is higher, even in the absence of strong tobacco control policies. Data from Finland and Sweden illustrate this possible paradox."

#### Reviewer: 3

• In terms of background information, it would be very useful to document any changes in country-level policies between 2007 and 2009 (your data collection points).

We compared the TCS of 2007 and 2010 to document potential changes in the policy on smoking restriction in our period of data-collection. We did not find substantial changes (average of +2 points in the score) during this period. As suggested by the reviewer, we included a sentence in the discussion section to address this topic:

"Moreover, the score of the policy on smoking bans in public and work places of the TCS in the period of our study, between 2007 and 2010, did not show appreciable changes: the score increased in 14 countries, did not change in 9 countries, and decreased in 5 countries. <sup>22</sup>"

• I would suggest that public place bans do not just protect non-smokers from SHS but also smokers.

We agree with the reviewer's comment as explained in the second sentence in the first paragraph of the introduction section. Moreover, we specified the protection of SHS among smokers as follows:

"The implementation of comprehensive smoke-free policies decreases SHS exposure and associated health hazards for non-smokers and smokers as well"

• You mention "exposure" in both your introduction and discussion section and suggest that your findings can inform us about exposure to SHS, however I do not believe that you can, at the end of the day, the questions from the Eurobarometer survey do not address exposure to SHS but just places where smoking is permitted. I might smoke only in the living room but if that is where everyone is sitting then they will be exposured more to SHS than me smoking only in the kitchen and bedroom that are not used as much. Thus you cannot claim in any way that you are contributing to understand the influence of policy on SHS exposure. You can only see if there is or isn't an association between tobacco control policy and extent to which smoking is restricted in shared private places such as homes and cars. This is less of interest to researchers in the field.

We agree with the reviewer's comment, as also pointed out by reviewer #2 (see comment #3). We have changed "exposure to SHS" by "prevalence of smoking" in the whole manuscript. Moreover, as the example cited by the reviewer illustrates, we have no information about the intensity of exposure from the Eurobarometer (see also comment #8, reviewer #2).

• It makes less sense to me to look at the overall tobacco control score, you don't make a clear case in your introduction, why you would expect total amount of tobacco control to influence where smoking is permitted. I think that these two variables are so distal and it would be unlikely to find any effect even if a case was made.

All the initiatives for tobacco control, particularly smoke-free bans, have generated intense debate in the media among different actors according with their own interests (i.e.: the tobacco industry and hospitality representatives argued that this policy can move tobacco consumption from public to private places). Countries with high level of tobacco control have banned tobacco advertising and launched more frequently media campaigns (TV, radio, newspapers, etc.) about the adverse effects of exposure to SHS on non-smokers health. This information could partially explain the increased support to smoke-free bans

and denormalisation of smoking (Fong et al. Tob Control 2006; Fichtenberg et al. BMJ. 2002; Martinez-Sanchez et al. PLoS ONE. 2010; Willemsen et al. BMC Public Health. 2012). The increased support to smoking bans and the denormalisation of tobacco consumption could influence in the voluntary extension of smoke-free regulation to private venues.

We have included the following sentence in the introduction section:

"Moreover, the increase of the overall tobacco control measures may improve the support to smoking bans in public venues and to the denormalisation of tobacco consumption<sup>4,5,7,8</sup>; this could help the adoption of voluntary smoke-free homes and cars."

• Finally in terms of the prior results mentioned in your discussion, I would not say that your results are consistent as you didn't find any effects and furthermore the studies discussed focus on more specific relationships and thus it is hard to compare your research with the prior research that you discuss.

According to the reviewer comment, we have modified the sentence:

"The results from this ecological analysis are in the line with those of other studies carried out with data at the individual level before and after national smoke-free bans at workplaces and in public places."

## Tobaccocontrol-2012-050877.R1 Do smoke-free policies in work and public places increase smoking in private venues?

#### Response to the Editor's comments

We thank the editor for his useful comments.

1. The limitations can be further noted. The primary limitation is that with the ecologic design the results reported are purely correlational and no causal relationship can be made. However, the correlations observed do not provide evidence that smokefree policies have resulted in an increase in smoking in private venues.

We agree with the editor's comment. We have read the text carefully and we have changed any indication of causality.

2. Soften the 2nd sentence of the Discussion. Failure to find an association here does not imply that the correlation would be significantly positive with this study design.

We have softened the second sentence of the Discussion as suggested by the Editor.

3. Because of the limitations on assessing causality with this design, please review thoroughly the text and remove any indication as such.

Done.

#### Aceptacció de l'article

27-Mar-2013

Dear Dr. Jose Martínez-Sánchez,

Manuscript ID tobaccocontrol-2012-050877.R2 - Do smoke-free policies in work and public places increase smoking in private venues?

We are pleased to accept your article for publication in Tobacco Control.

Your paper will be now sent for editing and typesetting and you will receive a proof to check in about 10 days; please check your junk mail if you have not received your proof within this time, in case the automatic email goes there.

If you wish to have your article published under our Open Access option, please ensure you pay the fee of £1950 (plus applicable VAT) within 48 hours, so that we can process your article. You can pay the fee using our secure online system. For more details on our Open Access option please visit: <a href="http://tobaccocontrol.bmj.com/site/about/unlocked.xhtml">http://tobaccocontrol.bmj.com/site/about/unlocked.xhtml</a>.

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If you have any questions, please contact me, quoting the manuscript ID.

Yours sincerely,

Andrew Hyland, Senior Editor Tobacco Control

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