HOW EFFECTIVE ARE BRIEF INTERVENTIONS IN SMOKING CESSATION:

Project of a Cohort Study in a Family Health Care Unit.

Edmundo José Bragança de Sá

Master in Clinical Investigation

Universidade Nova de Lisboa – Northeastern University

Tutor: Isabel Santos,MD,MEd,Phd

September 2012

Acknowledgments:

We thank Bruno Heleno for the review of the project and the manuscript

INDEX

ABSTRACT

Tobacco use remains the most significant modifiable cause of disability, death and illness[1]. In Portugal, 19,6% of the population aged ten years or more smoke[3]. A Cochrane review of 2008[7] concluded that *a brief advice intervention* (compared to usual care) *can increase the likelihood of a smoker to quit and remain nonsmoker 12 months later by a further 1 to 3 %.* Several studies have shown that Primary Care Physicians can play a key role in these interventions[8,9,10]. However we did not find studies about the effectiveness of brief interventions in routine consultations of Family Doctors in Portugal. For this reason we designed a Cohort Study to make an exploratory study about the effectiveness of brief interventions of less than three minutes in comparison with usual care in routine consultations. The study will be implemented in a Family Healthcare Unit in Beja, during six months. Family Doctors of the intervention group should be submitted for an educational and training program before the study begin. Quit smoking sustained rates will be estimated one year after the first intervention in each smoker. If, as we expect, quit smoking rates will be higher in the intervention group than in the control group, this may change Portuguese Family Doctors attitudes and increase the provision of brief interventions in routine consultations in Primary Healthcare Centers.

1. THE STATE OF THE ART

1.1. Burden of disease

According to the World Health Organization (WHO) tobacco use remains the most significant modifiable cause of disability, death and illness, in particular cardiovascular and respiratory disease, in high income countries. Some key facts from the WHO Media Centre reveal that tobacco kills up to 50% of its users and nearly six million people each year[1].

In Portugal, tobacco use has globally diminished along the last twenty years[2]. This reduction has been consistent in men while in women it is growing, particularly in youngest ages. Nearly twenty per cent of the Portuguese population aged ten years or more smokes[3] and 8100 deaths in the year 2000 were attributed to smoking, most of them by cancer(3400) and cardiovascular diseases(1800)[4].

The delivery of timely and effective tobacco dependence interventions can help to curb this highly significant health threat and reduce the disease burden and mortality of smokers[5,6].

Among smokers who are aware about the risks of tobacco use (e.g. public health messages, policy changes, cessation marketing messages, family members), nearly 60% to 70% want to quit smoking and the majority of these individuals have done at least an attempt to quit in any time of their lives[4,8,10]. A Cochrane review of 2008[7] concluded that, assuming an unassisted quit rate of 2 to 3%, *a brief advice intervention can increase the likelihood of a smoker to quit and remain nonsmoker 12 months later by a further 1 to 3 %.*

1.2. What is the role of Primary Health Care?

In 1979, Russell et al.[9], have shown that Primary Care Physicians or Family Doctors can play a key role in this strategy[9] . Further studies [10,11,12,13] have also shown that smoking cessation interventions in Primary Health Care are simple, efficient and effective. In Portugal, the National Healthcare Service has a universal coverage of the population where the Family Doctors working in Healthcare Centers or Family Healthcare Units are the first point of care. This represents a mix of unique conditions which may increase the success of brief advice interventions aimed at increasing quit rates:

- Multiple encounters face-to-face with tobacco users where brief interventions may fit, given time constraints of each encounter
- Family Doctors have a deep knowledge of their patients, their family and social environment
- More than 70% of tobacco users visit their family doctor at least one time a year[5, 10]
- Family Doctors have a life cycle continuous relationship and many different opportunities for clinical encounters.

1.3. Which are the barriers to smoking cessation interventions in primary care?

Many barriers have been identified against smoking cessation interventions in routine consultations by Family Doctors[12]. Time constraints for each consultation (about 15 minutes in Portugal) with many "competing" preventive interventions to address in the same visit[25]. Another barrier is an inadequate training[14,16] of the physicians, the perceived lack of effectiveness and negative attitudes toward smoking cessation interventions[15,17,18]. One recent review[16] from the Cochrane Tobacco Addiction Review Group examined the evidence on training healthcare professionals to help people quit smoking. They found that training programs can influence attitudes and beliefs of physicians and warrant further attention to identify smokers and increase the number to who advice is offered and given support for quitting tobacco.

In Portugal, the National Program for Prevention and Control of Tobacco Use aims that at least 50% of tobacco users with a consultation in the last 24 months have a brief intervention[19]. National guidelines include recommendations for the education and training of Healthcare Professionals in brief and intensive interventions for smoking cessation and the inclusion of clinical support systems in the usual medical electronic record software.

1.4. Why is it important to do this study?

Despite all the advantages cited above, smoking cessation interventions are not yet widely part of routine care [12] and various reasons are given for Family Doctors not providing smoking advice[15,17,18] . Also, actual data of these interventions in routine consultations are unknown in Portugal. In the reviewed literature, no studies about the efficacy of a brief intervention in routine consultations of Family Doctors in Portugal were found, specifically if it has the same or different quit rates than found in other countries[7,9,10,22].

With this study we will pursue some of the aims of the National Program for Prevention and Control of Tobacco use (to educate and train healthcare professionals in smoking cessation interventions and to make a brief intervention in most of smokers) and at the same time we will evaluate the effectiveness of brief interventions in routine primary healthcare for the Portuguese population.

2. OBJECTIVES

2.1. Primary Objective:

To make an exploratory study to evaluate the effectiveness of brief interventions during routine consultations by Family Doctors in Portugal, compared to usual care. The effectiveness will be measured by the Relative Risk of sustained abstinence rate for at least one year after the first intervention.

2.2. Secondary Objectives:

1- To determine the effectiveness of training Family Doctors in brief interventions for smoking cessation. The effectiveness will be deducted from the results of the first objective.

2- To explore the effectiveness of a brief intervention by Family Doctors in specific populations (e.g. pregnant women, teenagers, high cardiovascular risk patients, patients with diabetes mellitus, psychiatric patients and patients with chronic obstructive lung disease.).The decision to make a statistical analysis will depend on co-morbidities and number of patients in each sub group.

3. METHODS

3.1. Study Design: Cohort Study

We have aimed to conduct a randomized trial to address this research question. However preliminary contacts with possible participants suggested that most physicians would decline to be randomized. Reasons to decline are basically the same found in other studies[12,15,17]: lack of time, difficulty to impress on smokers the importance of quitting, low perceived effectiveness of brief smoking cessation interventions and lack of training. We have thus decided for a cohort study design, controlling for confounders in the analysis.

We plan to use this study as a feasibility study, allowing for the development of an educational package and to assess the use of resources that can later inform a cluster randomized trial.

3.2. Setting: Primary Healthcare – Family Doctors Consultations at the USF AlfaBeja.

The USF AlfaBeja it is a healthcare unit integrated in the Local Healthcare Unit of Baixo Alentejo (ULSBA), with nine Family Doctors working and delivering primary healthcare to 16277 individuals. The ULSBA, belonging to the National Healthcare Service, it is responsible for delivering primary and secondary healthcare services to all population in Baixo Alentejo, a region in the south of Portugal.

3.3. Study population: All individuals between 15 and 84 years old (13451 individuals) who attended the Family Doctors belonging to the Family Healthcare Unit AlfaBeja (USF AlfaBeja).

For ethical reasons, people suffering from terminal illnesses or those unwilling to participate will be excluded from the study. Also severe psychiatric disorders or addiction to other psychoactive substances will be not included in the study as they need more intensive interventions beyond the scope of this study.

Although guidelines[5,6] state that smokers over the age of 65 can benefit greatly from abstinence reducing their risk of death from coronary heart disease, Chronic Obstructive Lung Disease and lung cancer we did not find studies in very old people over the age of 84. We think that in this sub set of aged population the announced benefits of reduced mortality will not be significant enough to include them in the intervention group. That's why we prefer to limit the study to individuals until 84 years of age.

In July of 2012 the total prevalence of smokers between 15 and 84 years of age in the USF AlfaBeja was of 10,7% ranging between Family Doctors from 4,5% to 18% (Table 1). This prevalence was obtained through the electronic records summary statistics for the nine Family Doctors with possibly under registers of smokers[13].

3.4. Description of the intervention: The intervention consists in the delivering of the recommendations of evidence-based guidelines[4,5,6,19] according to the algorithm presented ahead.

Although there is a wide variety in the definition of brief interventions (simple advice or minimal interventions), for the purpose of this study we define a **brief intervention as a minimal counseling of less than 3 minutes**, **taking place during a consultation** for any other motivation problem or complain[5]. The main purpose of this brief intervention is to identify tobacco users and to make a **stepped intervention**[6,8,18] based on the transtheoretical model of behaviour change developed by Prochaska and DiClemente in 1982 and **using the strategy of the five "A"**[19]: **A**sk about tobacco use, **A**dvise to Quit, **A**ssess willingness to make a quit attempt, **A**ssist in quit attempt and **A**rrange follow up.

We have already asked all the nine Family Doctors of the USF AlfaBeja if they would like to participate in the study as intervention group and consequently in the training program. Only four of the nine Family Doctors accepted to participate as intervention group and to make a training program on the brief intervention protocol (Family Doctors A, B, D and I). These four Family Doctors will have a two days three hours course in which the importance and expected effectiveness of the intervention will be presented, as well as the protocol will be explained and trained some practical aspects with the use of pedagogic techniques such as role playing.**(ANNEX I) .** The other five Family Doctors (C,E,F,G and H) will be the control group and their patients who smoke will receive the usual care.

Table 1: Identified smokers prevalence by Family Doctor

Family Doctor **USF AlfaBeja**	**Identified Smokers Prevalence (%) between 15-84 years**
A	**255(16,6%)**
B	**217(13,8%)**
C	74 (4,8%)
D	**210(14,2%)**
E	112(7,5%)
F	158(11,9%)
G	78(5,3%)
H	70(4,5%)
I	**267(18%)**
TOTAL	**1441 (10,7%)**

The basic steps of the intervention are (see algorithm in page 12) :

1) All patients within 15 to 84 years of age who have a consultation for any motive and for any Family Doctor of the USF AlfaBeja will be asked by the administrative support staff about tobacco consumption. If they are tobacco users a written informed consent**(ANNEX II)** will be provided for them by nurses to read and sign and a questionnaire about characteristics of tobacco consumption will be delivered to be completed while waiting for the consultation by Family Doctor **(ANNEX III)**.

2) The tobacco users from Family Doctors of the control group will receive usual care. The patient's filled questionnaire will not be available for the Family Doctors of this control group.

3) The Family Doctors of the intervention group will have access to the questionnaire filled by their patients and once the motivating problem of the consultation has been resolved, they will give a *clear, strong and personalized advice* to quit smoking and will *assess about the willingness of the patient to make a quit attempt* at this time. This brief intervention must be registered by the Family Doctor in a data collection sheet **(ANNEX IV)**

4) If the tobacco user is not ready to quit, the family doctor will assure a follow-up contact or reassessment in the next consultation. If the tobacco user is willing or ready to quit *assist the patient in quitting* providing counseling and medication or referring him to a specialized consultation in the ULSBA. In any case *arrange a follow-up contact* either in person or via telephone and write all the information in the data collection sheet.

5) If the tobacco user has already quitted and he or she is in the maintenance stage, a reinforcement advice should be done in every consultation and registered in the data collection sheet.

3.5. Intervention period: This intervention will be applied for a period of six months.

3.6. Outcomes assessment:

1) Self reported abstinence via telephone one year after the first consultation for each smoker of the two groups (intervention and control) within the intervention period.

The investigator will contact the smokers through one of telephone numbers registered in the patients' questionnaire. The investigator will be unaware of smoker allocation during data collection.

2) Additional number of tobacco users recorded in the intervention period of six months.

3.7. Data Collection:

From the Patient´s questionnaire (ANNEX III):

1) Socio-demographic characteristics (age, gender, educational level, family and cohabitation with smokers)

2) Characteristics of individual's tobacco consumption (daily consumption in number of cigarettes/day, age at the start, nicotine dependence measured by the Brief Fagerström test, motivation level measured by the Richmond test.

From the physician's data collection sheet (ANNEX IV) and clinical electronic records:

3) Physician perception of the stage of behavior change according to the transtheoretical model of Prochaska and Diclemente, specifically the readiness and willingness to quit.

4) Morbidity or specific status of the patient: pregnant woman, teenager, diabetics patients, high cardio-vascular risk patients, psychiatric patients and patients with chronic obstructive lung disease.

5) Subsequent consultations in the intervention period of six months and possible alterations of the stage of behavior change.

3.8. Potential confounders:

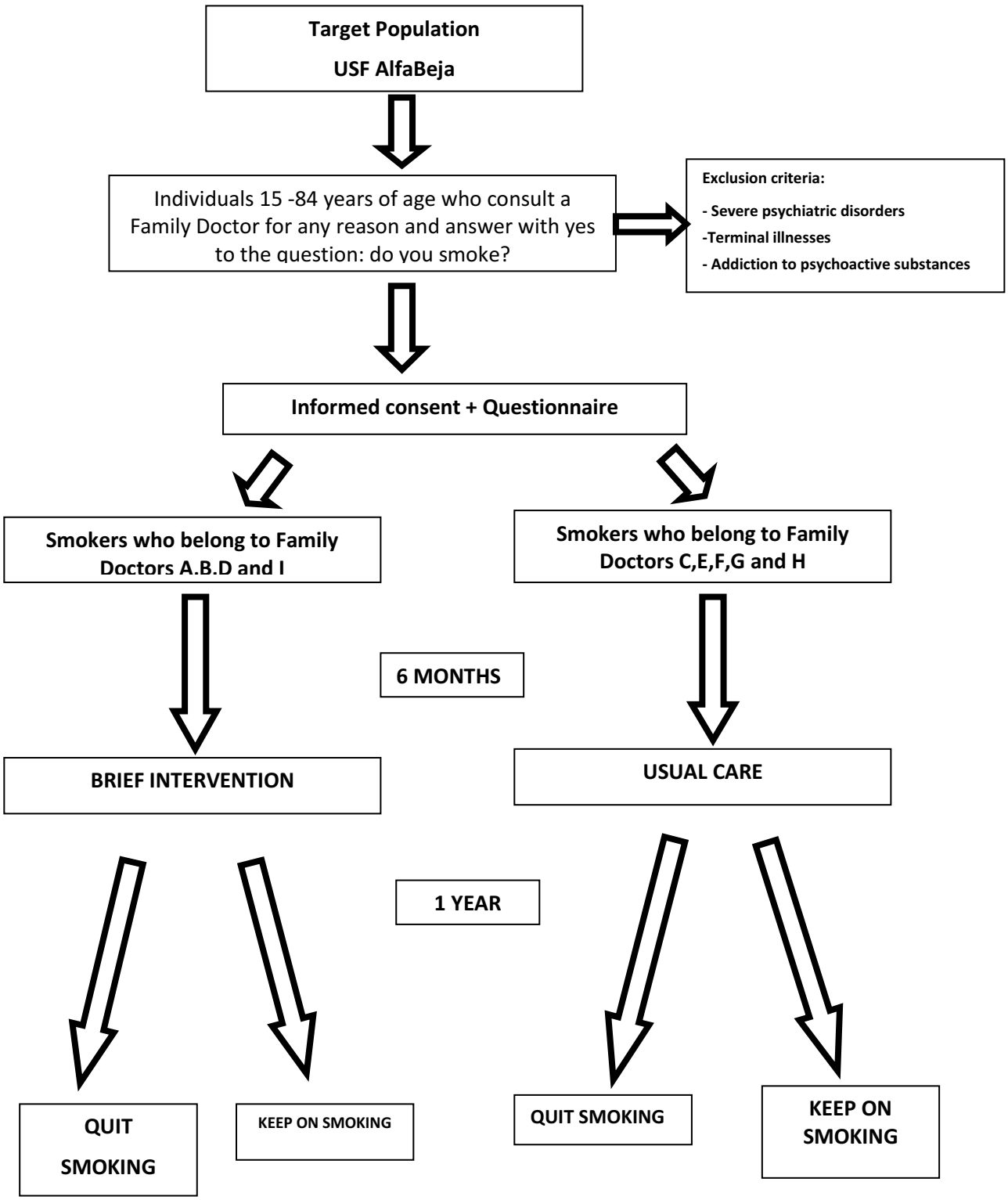
1) Tobacco dependence, measured by a Brief Fagerström Test with three dependence levels: mild (0-2 points), moderate (3-4 points) and high(5-6 points).

2) Motivation level measured by the Richmond Test with three levels: low motivation (0-6 points), moderate motivation (7-9 points), high motivation (10 points)

3) Self-reported educational level, measured in an ordinal scale with five levels: uneducated, primary school, middle-school, high school, higher education.

4) Self-reported cohabitation with another smoker as a binary outcome.

3.9. Cohort Study's algorithm



4. STATISTICAL ANALYSIS :

	Quit Smoking	Keep on smoking	Total	Quit smoking rates
Brief Intervention	**A**	**B**	**a+b**	**a/a+b**
Usual Care	**C**	**D**	**c+d**	**c/c+d**

1) Estimation of quit smoking rates in intervention and control groups.

2) Estimation of Relative Risk (RR) of smokers to quit and maintain smoking cessation one year after have been exposed to the brief intervention, in comparison with smokers of the control group:

$$RR\ 1 = \frac{\text{Quit smoking rate with brief intervention}}{\text{Quit smoking rate with usual care}}$$

3) Estimation of a crude odds ratio (OR) of smokers to quit and maintain smoking cessation one year after have been exposed to the brief intervention, in comparison with smokers of the control group (A*D/B*C)

4) Using a logistic regression model, provide an estimate of OR adjusted for tobacco dependence, Richmond motivation level, self-reported education level and cohabitation with another smoker.

5. ETHICAL ASPECTS:

The study will respect the Helsinki's Declaration and successive revisions as well as the norms of good clinical practice, specifically:

1) Privacy and confidentiality of data will be assured by the investigator.

2) Informed consent will be provided in verbal and written forms to participants of the two groups and all subjects will have opportunity to see in detail any item of the study or to give up in any moment.

The protocol will be submitted for appreciation by the Ethical Committee of the ULSBA and by the National Data Protection Committee (CNPD)

6. POTENTIAL BIAS:

6.1. Follow up losses Bias: because of follow-up loss one year after the intervention period in both intervention and control groups. To prevent this bias at least two phone numbers are asked to the subject in the initial questionnaire. Also an "intention-to-treat" analysis will be used, analyzing all subjects according to the group which they were originally allocated.

6.2. Selection Bias: The family doctors that accepted to be included in the intervention group are also those who have already the highest prevalence smoking rates, denoting more interest and sensibility for this problem.

6.3. Performance Bias: it may occur differences in care provided by each family doctor in both groups. Education and training programs for family doctors before the study begins can be useful to reduce the occurrence of this kind of bias in the intervention group.

6.4. Evaluation Bias: this can occur when evaluating by phone the smoking status of the subject one year later. To prevent this bias the phone evaluation will be blind.

6. TASKS AND TIMELINE

7.1. PERMISSION TO IMPLEMENT THE STUDY

When: July 2012

How: Ask authorization of the USF AlfaBeja Coordinator to implement the study in his healthcare unit and explain to him the main objectives. Ask the Family Doctors of the USF AlfaBeja if they accept to participate as intervention group or control group.

7.2. PREPARATION OF THE STUDY PROJECT DOSSIER

When: September 2012

How: Preparation of a dossier with the project, educational and training programs for healthcare professionals (family doctors, nurses and administrative support staff), questionnaires and informed consent form and data collection sheets.

.

7.3. SUBMISSION TO ETHIC COMMITTEE:

When: October 2012

How: presentation of the project dossier to the Ethic Committee of ULSBA for appreciation and approval.

7.4. SUBMISSION TO THE NATIONAL DATA PROTECTION COMMITTEE:

When: November 2012

How: Submission for approval of the project dossier to the CNPD.

7.5. PRESENTATION TO HEALTHCARE PROFESSIONALS OF USF ALFABEJA:

When: December 2012

How: One hour meeting with all healthcare professionals of the USF AlfaBeja with presentation of the project and definition of tasks for each professional class: administrative support staff, nurses and family doctors.

7.6. EDUCATIONAL AND TRAINING PROGRAMS:

When: From 15 December 2012 to 31 January 2013

How: 1) Educational and training program of one hour/one day for support staff (how to ask with privacy if a patient smokes)

2) Educational and training program of two hours/one day for nurses (how to present the informed consent form and the questionnaire to the patient and how to answer all possible questions the patient may ask).

3) Educational and training program of three hours/two days for Family Doctors of the intervention group **(ANNEX I)**

7.7. INTERVENTION PERIOD

When: From 1 st February 2013 to 31 July 2013

How: Weekly make sure all smokers involved have their informed consent forms signed. Verify if the patients questionnaires are completed, namely if there is at least two phone numbers registered. Follow-up of records and data collected by all healthcare professionals of the intervention group. Regular meetings and mailings to the healthcare professionals involved whenever it will be necessary and specially if there are protocol violations..

7.8. FOLLOW-UP AND FINAL ASSESSMENT

When: From February to July 2014

How: Evaluation via telephone of tobacco use or smoking cessation of all subjects recruited during the intervention period in the two groups. This evaluation is with occultation whether the subject belongs to the intervention group or to the control group.

7.9. DATA COLLECTION

When: From February 2013 to September 2014

How: Excel database of socio-demographic characteristics of each subject, characteristics of individual's tobacco consumption, co-morbidities, physician perception of the stage of behavior change, type of brief intervention, subsequent consultations and final telephone evaluation.

7.10. STATISTICAL ANALYSIS

When: September and October 2014

How: Estimation of quitting rates and relative risk

7.11. STUDY CONCLUSION AND PUBLIC PRESENTATION

When: From November 2014 to January 2015

How: Discussion of results and investigator conclusions. Peer review and final manuscript. Submission of final manuscript to a peer reviewed medical journal for publication.

REFERENCES:

1. **Tobacco – fact sheet** nº 339,(May 2012) [disponível in http://who.int/mediacentre/factsheets/fs339/en/index.html]

2. Nogueira PJ, Dias CM, Gomes CO, Nunes E, Ramos M, Carreira M, Santos NS, et al. **Infotabac Relatório. Avaliação da lei do tabaco em Portugal 2008-2010**. Direcção Geral da Saúde - Instituto Nacional de Saúde Dr.Ricardo Jorge, 2011

3. **4º Inquérito Nacional de Saúde 2005/2006**. Instituto Nacional de Estatistica – Instituto Nacional de Saúde Dr. Ricardo Jorge.

4. Nunes E, Candeias A, Mendes B, Pardal C, Fonseca J, Oliveira L, et al.**Programa tipo de Actuação em Cessação Tabágica**, Circular Normativa nº 26/DSPPS Direcção Geral da Saúde, 2007

5. Fiore MC, Jaen CR, Baker TB, Bailey WC , Benowitz NL, Curry Sj, e tal.2008: **Treating Tobacco use and dependence:2008 update.** Clinical Practice Guideline. Rockville,MD:US Department of Health and Human Services.Public Health Service;2008

6. Reis I, Fortuna P, Ascenção R, Bugalho A, Costa J, Carneiro AV**. Norma de Orientação Clínica para a Cessação Tabágica.** CEMBE.Faculdade Medicina Lisboa, 2008

7. Stead LF, Bergson G, Lancaster T. **Physician advice for smoking cessation**. Cochrane Database of Systematic Reviews2008, Issue2.Art.No.:CD000165.DOI:10.1002/14651858.CD000165.pub3.

8. Cabezas C,Martin C, Granollers S, Morera C, Ballve JL, Zarza E, Blade J, Borras M, Serra A, Puente D. **Effectiveness of a Stepped Primary Care Smoking Cessation Intervention (ISTAPS): design of a cluster randomized trial**. BMC Public Health 2009, 9:48. DOI:10.1186/1471-2458-9-48. Published: 4 February 2009

9. Russell MA, Wilson C, Taylor C, Baker CD. **Effect of General Practitioner's advice against smoking.** BMJ 1979;2:231-5

10. Ferrero MB. **Tres minutos de atención al paciente fumador.Diagnostico y tratamiento no farmacológico del tabaquismo: utilidad del consejo médico y de la intervención mínima sistematizada**. Semergen 2002;28(9):471-3

11. Espinosa EO, Pardo BM, Sanz ES, Aramburu EA. **Intervención Minima en Tabaquismo? El protocolo de atención al paciente fumador en Atención Primaria**. Aten Primaria.2005;36(9): 510-4

12. Coleman T.**Cessation interventions in routine health care**. BMJ 2004;328:631-3

13. Szatkowski L, Lewis S, McNell A, Huang Y, Coleman T. **Can data from primary care medical records be used to monitor national smoking prevalence?** J Epidemiol Community Health 2012;66:791-5

14. Twardella D, Brenner H. **Lack of training as a central barrier to the promotion of smoking cessation: a survey among general practitioners in Germany**. European Journal Public Health, April 2005;15(2):140-5

15. Blumenthal DS. **Barriers to the provision of smoking cessation services reported by clinicians in underserved communities**. J Am Board Fam Med;20(3):272-9

16. Carson KV, Verbiest MEA, Crone MR,Brinn MP, Esterman AJ, Assendelft WJJ, Smith BJ. **Training health professionals in smoking cessation**. Cochrane Database of Systematic Reviews 2012,Issue 5.Art nº CD000214.DOI:10.1002/14651858.CD000214.pub2

17. Steinberg MB, Delnevo CD. **Physician beliefs regarding effectiveness of tobacco dependence treatments: results from the NJ Health Care Provider Tobacco Survey**. Journal Gen Intern Med. Oct 2007;22(10):1459-62

18. Meredith LS, Yano EM, Hickey SC, Sherman SE. **Primary Care Provider attitudes are associated with smoking cessation counseling and referral**. Med Care. Sep 2005;43(9):929-34

19. **Programa Nacional para a Prevenção e Controlo do Tabagismo – Orientações Programáticas**. Direção-Geral da Saúde. (disponível em http://www.coppt.pt/attachments/242_201206_Orientacoes-programaticas-PNPCT.pdf)

20. Cahill K, Lancaster T, Green N. **Stage-based interventions for smoking cessation**. Cochrane Database of Systematic Reviews 2010, Issue 11.Art. Nº CD004492. DOI10.1002/14651858.CD004492.pub4.

21. Rebelo L. **Intervenção breve no paciente fumador: Aplicação prática dos "5 As" e dos "5 Rs"**. Rev Port Clin Geral 2011;27:356-61

22. Bredesen H, Lous J. **Smoking Cessation with special focus on Primary Health Care**. Ugeskr Laeger. Feb 2008; 171(9); 683-8

23. Lancaster T, Stead LF. **Individual Behavioural counseling for smoking cessation** (Review). Cochrane Database of Systematic Reviews 2005, Issue 2.Art.No.:CD00192. DOI:10.1002/14651858.CD001292.pub2.

24. Grimshaw G, Stanton A. **Tobacco Cessation Interventions for young people**. Cochrane Database of Systematic Reviews 2006, Issue 4.Art.Nº CD003289.DOI:10.1002/14651858.CD003289.pub4.

25. McWhinney IR, Freeman T. Textbook of Family Medicine. 3rd ed. Oxford University Press Inc, New York 2009

ANNEXES