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（出國類別：出國進修）

衛生服務研究與衛生科技評估

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出 國 人 職　　稱：技正
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關鍵詞: 衛生科技評估,實證醫學,菸害防制,尼古丁置換療法,電話諮詢

內容摘要: 本研修課程，具備公共衛生的基本學科，即研究法、統計、流行病學、質性研究，以及本學科的重點，亦即經濟評估（含進階經濟評估）、實證醫學及實證醫學方法學之一-系統性文獻回顧。本人並在本所醫療資訊主任Andrew Booth的指導下，以系統性文獻回顧中的量化方法-統合研究爲方法學，完成一份探討「主動提供電話諮詢服務對已接受尼古丁置換療法者的效益」碩士論文；爲Cochrane Collaboration中該主題既有之統合分析，提前置入新的研究證據（Cochrane Collaboration 中之統合分析會依新證據的出現不定期更新），並對本署在開徵菸酒健康捐之後的新措施，亦即電話諮詢服務提供，以及門診戒菸提供尼古丁置換療法，此兩種服務合併提供對意欲戒菸者所帶來的效益，提出國際社會實證資料，俾爲菸害政策制定參考。

本文電子檔已上傳至出國報告資訊網

目次

目的：

本次研修目的在於藉由參與「衛生服務研究以及衛生科技評估」（Health Services Research and Health Technology Assessment）此一年制碩士課程，探索實證醫學概念，並學習如何對衛生保健及醫療業務進行效益評估。

過程：

(一) 學校簡介

本次研修地點位於英國英格蘭中北部雪菲爾大學，是一所具有三百年悠久歷史的大學，歷年總體排名皆位全英國二十名左右，以教學嚴謹著稱。本人所研修之「衛生服務研究以及衛生科技評估」課程屬醫學院(Medicine Faculty)內醫療照護研究組織(Medical Care Research Unit, MCRU) 內的衛生綜合研究研究所(School of Health and Related Research, ScHARR)所開設，本年共招生十三名，含九名在職生及四位全職生，全職生除本人外，二位來自英國本地，另一位來自中國。

(二) 課業要求

本研究所要求全職學生需於一年內完成 120 修課學分(部分修課學分可依學生需求自行選擇)及 60 論文學分，本人的 120 修課學分含八學程單元（module)，簡述如下：

修習學分

1. 「研究法」(Research Method)

本單元旨在介紹各種研究方法，著重隨機對照試驗（Randomised Controlled Trials, RCTs）

2. 流行病學

著重病例對照與世代研究之危險因子評估

3. 統計及資料分析(statistical analysis)

教授資料統計分析方法，並運用 SPSS 模擬分析實際研究數據

4. 「醫療衛生評估」及「進階醫療衛生評估」(Health Economic Evaluation and Advanced Health Economic Evaluation)

本兩單元旨在教授具體評論(critically appraise)經濟評估研究之方法學，及成本效能(cost-efficacy)、成本效用（cost-utility）及成本效益（cost-benefit）之深入分析，並發展至如何運用馬可夫鏈及決策分析(decision analysis)等方法

5. 質性分析(Qualitative Research)

教授質性研究的架構研究法 (Framework analysis), 以自研究對象所蒐集到的資訊形成主題(themes)來探討研究問題.

6. 實證醫學(Evidence Based Medicine)及系統性文獻回顧 Systematic Review

教授在醫學及公共衛生領域推動實證醫學的策略和實證醫學工具(系統性文獻分析)

碩士論文

本人之碩士論文是以上述系統性文獻回顧爲方法學所完成的一個統合分析（meta-analysis，全文見附錄）。其目的是以本人出國前承辦之菸害防制業務所推出的二項新措施，即尼古丁置換療法及電話諮詢爲研究主題，探討有意願戒菸的民眾在接受尼古丁置換療法（Nicotine Replacement Therapy, NRT）後，若再接受電話戒菸諮詢（Telephone Counselling ），其成本效益爲何。 英國 Cochrane Library 中已有針對本主題所完成之統合分析，嗣後並經加入新的研究成果（總計四篇研究）而更新第一版本；本人之論文則再加入二〇〇三年五月的一份最新研究報告證據。惟以上所有報告皆未改變統合分析之結論，亦即，電話諮詢對已接受 NRT 者未產生明顯效果，已接受 NRT 者若再投以電話諮詢，其效果並不顯著。但要強調的是，這個統合分析所收錄的研究皆來自北美洲（美國和加拿大兩國），是否完全適用於亞洲國家如台灣，仍需有本土的資料佐證。

心得：

(一)此一年之碩士研習課程，與台灣的碩士訓練比較，大體而言，英國學者對於研究架構基礎(亦即研究法)非常重視，也非常注重培養學生閱讀研究報告的批判能力，能教育學生善用學術工具(舉例而言，如 CONSORT ,一種具實證且經過認可的檢查表，協助研究者提升隨機對照研究報告的撰寫品質，也可讓讀者利用這樣的方法來評估一份報告是否符合閱讀者的需求)，以抉擇和運用研究報告成果。

(二)談及研究方面，英國學者發表一份衛生研究報告時，最後一節都一定會闡述如何普及(disseminate)其研究成果，而非只是將成果出版即宣告「完工」，因爲英國衛生界認爲研究者必須先爲其成果的推廣做準備，同時也使研究者在研究的過程中，先考慮到實際推廣層面的問題，方便研究成果爲眾人所

享。建議國內衛生界亦可學習此模式，在合適的委託或補助研究計畫或工作計畫的格式或範本中，加入此部分，以協助各業務單位妥爲運用每年度產出之研究成果，達成資訊共享。

(三)英國的實證醫學風氣非常興盛，並建置有爲數不少之國際知名資料庫(本人論文一共蒐尋九大醫療資料庫方完成，其中含英國所建置的如 Cochrane Collaboration、National Research Register、HealthPromise 以及 Health Education Board for Scotland 等，佔半數左右)，以及便捷的網路資料網絡（本校 ScHARR 的網路資訊網爲本人指導老師 Andrew Booth 所架設，爲英國許多研究者、書藉所推薦）爲臨床及衛生行政人員提供一份資料豐富的蒐尋工具。除了資訊網路的普及外，大學圖書館中亦培養爲數不少的圖書館員（在本所中常可見爲此種人員召開的訓練課程）其功能強大，專職協助資料蒐尋者蒐集世界各地資料，爲研究者或臨床人員省下許多時間，並能及時獲得正確資料。

建議：

(一)實證醫學是醫療改革的一大方向，建議國內衛生政策的制定，能建立從實證醫學角度出發的環境，不流於以辦理一個工作計畫即結束的形式，並培養更多此領域的人員，協助醫院培育領導推行實證醫學的種籽人員，並努力推動國內建立台灣實證醫學資料庫，並和國以縱向及橫向培養各單位人員研擬、執行各項政策時，能具有蒐尋實證及據以判斷的能力。

(二)醫療資源究應如何配置？英美等國近年來較傾向於研究各種醫療保健服務對標的群體所產生的效用，然後綜合成關聯表（League Table），成本/效益比低者，即列爲優先執行的政策。雖不同群體之間的效用仍有許多值得深入探討的議題，但是此指標可顯示民眾對醫療服務的個人效用評價，建議在國

內亦可及早建立此類指標，將民眾的需求納入政策制定的基礎。

(三)國內的相關衛生行政、研究機構在委託文獻回顧研究時，通常並不區分傳統回顧（Traditional Review）或是系統性回顧（Systematic Review or Overview），但其間仍有巨大差別；若是一般傳統的文獻回顧，沒有經由系統性回顧的方法學進行，所得的結果仍然只是回顧者（Reviewer）個人的見解，與實證醫學的理念差距甚遠，故建議應在國內推廣此一方法學。惟，一系統性回顧報告的完成，需要投入甚多的資源和人力，宜鼓勵學界多培養上述人才。

(四)質性研究因需投入龐大的資源、人力、時間，故此方法學往往較少爲行政機關以業務導向所委託或補助之計畫所採行，但因質性研究可與量化研究互補，故需要深入探討的某些健康行爲成因的議題，建議可考量進行質性研究，以突破政策或計畫執行之瓶頸。

(五)建議國內衛生界，於委託或補助研究計畫或工作計畫時，能加入如何普及研究成果的思考，協助各業務單位妥爲運用每年度產出之研究成果，達成資訊共享。

(六)根據本人進行之統合分析結果，本署在開徵菸酒健康捐之後的新措施，亦即電話諮詢服務提供，以及門診戒菸提供尼古丁置換療法，可研究區分此兩種服務對何種群體之戒菸效益最明顯，提供國際社會實證資料，提供協助菸害政策制定之參考。

附錄

Proactive telephone counselling as a support for nicotine replacement therapy: a meta-analysis of randomised controlled trials

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08/02

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Proactive telephone counselling as a support for nicotine replacement therapy: a meta-analysis of randomised controlled trials

Abstract

Background:

Nicotine replacement therapy (NRT) has been widely accepted as effective to help smokers quit smoking, but resumption is common with passage of time. It is suggested that NRT can be augmented with telephone counselling, which seems successful in helping smokers stay in abstinence in several studies.

Objective:

To evaluate the additional effect of proactive telephone counselling as an adjunct to NRT assisted smoking cessation.

Search strategy:

Major electronic databases were comprehensively searched, and references in the selected studies were also hand-searched. Keywords "nicotine replacement (patch, gum, nasal spray, and tablet)" and "telephone" were used. All databases were searched from their inception to June 2003.

Selection criteria:

Randomised controlled trials measuring the effects of proactive telephone counselling added to NRT assisted smoking cessation were selected. In a study with several trial arms, only the two arms which could reveal the additional effects of telephone counselling were compared.

Data collection and analysis:

Selected studies were extracted using a structured extraction form. The definition of outcome was examined in each study, and the main outcome was the abstinence from smoking at 6-months. In each study, outcome analysis was based on an intention-to-treat basis, and those who withdrew or were lost to follow up were considered as smokers. Also, biochemically-validated outcome was used wherever available in the studies.

Main results:

Five studies met the inclusion criteria, and altogether there were one thousand five hundred thirty-seven (in figures please) participants included in the review. Each participant was designated to receiving three to five calls, depending on the protocol, within a time period of four months. They were followed at least to the sixth month. Four studies showed no significant difference between the treatment and control groups, but the most recent trial, the only trial that recruited hospitalised participants, had a significant result. The pooled relative risk was 1.17 (95% CI 0.98 − 1.41), with the test of heterogeneity being not significant (Chi^2 =5.6, df=4, p=0.23). This failed to show a significant effect of telephone counselling added to NRT assisted smoking cessation.

Conclusions:

Our result was similar to the review in the Cochrane Collaboration; therefore, we do not expect much benefit from simply referring patients, who have recently received NRT, to proactive telephone counselling services. Further studies should focus on how to provide other incentives to help smokers using NRT to stay abstinent.

Abbreviations and Definitions

Nicotine replacement therapy (NRT)

According to the American Lung Association, nicotine replacement therapy is to use nicotine-containing products (nicotine gum, transdermal patch, the nicotine nasal spray, and nicotine inhaler and nicotine sublingual tablets/lozenges) to help relieve some of the withdrawal symptoms people experience when they quit smoking. Take nicotine patches for example, they release a constant amount of nicotine in the body; the nicotine dissolves right through the skin to compensate the drop of nicotine in the body.

Proactive telephone counselling

Counselling given on the telephone calls, which was based on a cognitive theory, to help people change their behaviour. Proactive calls indicated here are calls initiated by the counselors, not the counselees.

Randomised controlled trial (RCTs)

An experimental study in which participants recruited in the study are randomly allocated to either arms of the trial, to ensure that they all have the same chance of receiving any particular treatment (1).

Background

Current problem of tobacco use

Evidence of the health hazards of tobacco use, the major preventable cause of mortality, is well established. In 1995, tobacco was responsible for 120,000 deaths of people over 35 years of age in the UK, and rates of tobacco use are increasing, particularly in young people. Around 1 in 4 adults in the UK smoke cigarettes and about two-thirds say they would like to give them up. However, giving up permanently is difficult, and each year, only about 2% of all smokers manage to do so (2).

Current services of smoking cessation

Nowadays there are several types of smoking cessation interventions available to smokers. These services include the non-pharmacological method (physician advices, health education, self-help materials, behavioural-change treatments, acupuncture, exercise, etc.) and the pharmacological method (nicotine replacement therapy, antidepressants, anxiolytics, etc.). Effects of some treatments mentioned above have been investigated; amongst them, the NRT and telephone counselling are considered to be effective, according to the systematic reviews in the Cochrane Collaboration (3,4).

Nicotine replacement therapy

Nicotine replacement therapy (NRT) is frequently used as a component of smoking cessation strategies, except in the presence of special circumstances (such as pregnant or lactating women), and has been shown to significantly improve cessation rates (3). It helps smokers to stay abstinent by minimizing many of the physiological and psychomotor withdrawal symptoms usually experienced following smoking. The review

in the Cochrane collaboration concluded that, all of the commercially available forms of NRT (patches, gums, nasal spray and tablets) are effective, as part of a strategy to promote smoking cessation. They increase quit rates approximately 1.5 to 2 folds, regardless of setting, and the effectiveness of NRT appears to be largely independent of the intensity of additional support provided to the smoker (3).

Telephone counselling

Telephone counselling can be classified into two approaches, reactive or proactive (5). Proactive telephone counselling is outreach calls, made by counsellors, to counselees. In the real world, proactive telephone counselling has been added to several other smoking cessation services such as self-help materials, physician advices, group treatment, or to pharmacotherapy. In one of Lichtenstein's study of proactive phone counseling, he claimed that it appeared most effective when used as the sole intervention modality or when augmenting programmes initiated in hospital settings. (5).

While in the reactive approach, calls are initiated by counselees who call the helpline/ hotline or the call center. This counselee-initiated model has been established in some countries such as in the U.S., Australia and the U.K. Though in some cases smokers may actively request following counseling calls, it is comparatively passive to be called to give counseling, therefore, reactive approach is sometimes considered to attract only a small percentage of eligible smokers (6).

The effectiveness of the telephone counseling has been evaluated, and in some trials it has shown significant short-term effects or substantial long-term effects of telephone

counselling (7,8,9,10,11). One randomised controlled trial found a dose-response relationship between telephone counselling and abstinence from smoking (12).

Cost of counselling service

Smoking cessation is thought to be extremely cost-effective, but unfortunately there is not much evidence of the cost-effectiveness of telephone counselling. According to Song (13), the cost-effectiveness of adding NRT to counselling for smoking cessation is better than many other accepted health care interventions, and Lando (11) further indicated that, the cost of telephone intervention could be relatively low if trained volunteers initiated telephone calls.

Previous systematic review of telephone counseling

Stead and colleagues (4) have systematically reviewed and reported the effect of telephone counselling for smoking cessation in 2001, which was recently updated in Feb 2003. In their review, four main types of telephone counselling assisted intervention were compared with their counterparts, in which the proactive telephone counselling plus nicotine replacement therapy versus nicotine replacement therapy alone was one of them.

Four studies (Ockene 1991, Lando 1997, Reid 1999, Solomon 2000) were included in their review, and they concluded that none of the studies showed a statistically significant effect of adding telephone support. The authors claimed that the possibility of a small benefit was not excluded, based on the pooled OR of 1.08 (95% C.I. 0.82-1.43). In the current review, new evidence will be added, whenever possible, and content of telephone counselling in each trial will be compared.

Objectives

The question addressed in this review is, does proactive telephone counselling increase quit rates significantly in smokers who had previously received NRT, compared with smokers receiving identical NRT treatment without telephone counselling? The result will be used to inform the Department of Health in Taiwan of its newly implemented programmes, the provision of NRT and telephone counselling services to smokers.

Methods of the review

Criteria for considering studies for this review

Types of participants

Smokers who smoked at least a puff of a cigarette per day and were motivated to quit were investigated. Participants could be either from the general population or were patients seen in the clinics and hospitals. Patients at the terminal stage, pregnant or lactating women were excluded (please refer to Appendix 1 for the inclusion and exclusion criteria).

Types of intervention

Studies which at least had two arms to reveal the additional effect of telephone counselling were selected. Namely, there should be one arm of NRT plus telephone counselling, and one arm of NRT alone. Other supplemental interventions, whichever appropriate, should be identically distributed in both arms.

Types of outcome measures

Main outcome was the prevalence of abstinence at six month. Abstinence at other time points will be compared if available.

Types of studies

Only randomised controlled trials (RCTs) were considered in this review.

Types of settings

Studies conducted in either clinical or community setting would be accepted, only if prescription or provision of NRT was part of the programme and was offered free of charge.

Search strategy for identification of studies

All study processes in this review were summarized in Figure 1, due to time and resources constraints, all processes were conducted by the author solely.

Data Sources

Major electronic databases including the Cochrane Controlled Trial Register (CCTR), Medline, EMBASE, PsycINFO, Science Citation Index (SCI), CINAHL, National Research Register (NRR), HealthPromise, and Health Education Board for Scotland (HEBS) were searched. References in the selected studies were also hand-searched. Due to time and resources constraints, evidences from other sources were not searched.

Keywords

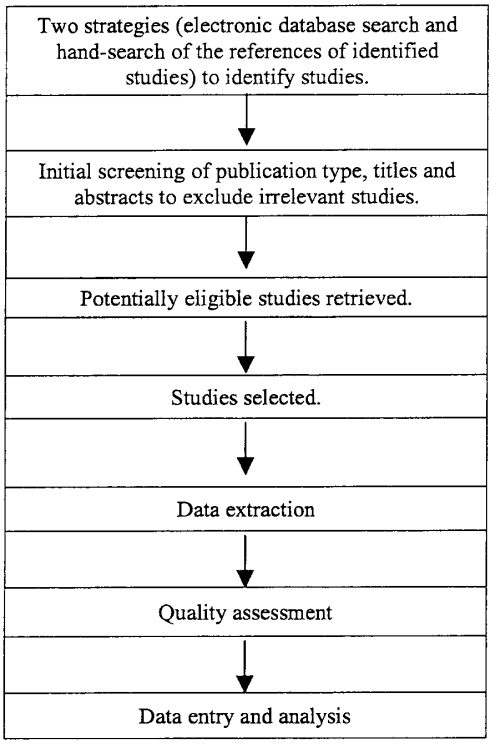
The keywords used to identify relevant studies were "randomised controlled trial", "smoking cessation", "nicotine replacement (patch, gum, nasal spray and tablet)" and "telephone". We have expected a highly sensitive, rather than specific, search result, in order to identify as many potential studies as possible (search strategies used in the Medline were summarized in Appendix 2).

Time of literature search

Every electronic database was searched from its inception till June 2003.

Potentially relevant studies with at least an arm of nicotine replacement therapy alone and another arm of nicotine replacement therapy plus proactive telephone counselling were identified. These studies were further excluded if they did not meet the inclusion criteria or their outcome did not reveal the additional effect of telephone counselling.

Figure 1 Study processes used in the review



Altogether there were one hundred and eighteen studies identified, in which almost half of them (n=58) were not randomised controlled trials (i.e. surveys, reviews, cohort studies or case studies etc.), were first excluded (a highly sensitive search strategy was used by the author to identify as much potential literature as possible). Of the remaining sixty studies, another fifty-four studies were further excluded, either because they lacked NRT, telephone counselling or both (n=37), or the additional effect of telephone counselling was not measured (n=12), or the NRT medication was purchased by the subjects (n=4), or NRT was provided only to some participants (n=1). Six reports

completely fit the predetermined criteria, but two of them have been reported for one trial, therefore, the one published most recently in a peer-reviewed journal was retained. The studies selection process was summarized in the QUOROM flow chart in Figure 2.

Data extraction

Relevant information of the selected studies was then extracted out unmasked using a structured extraction form. From several available data extraction forms, the author chose the one developed by Sally Hollis and Tina Leonard in the Cochrane Skin Group, whose structure and items extracted were considered by the author as more appropriate than others, and modified it to extract important information in this review. Below are the main items extracted, which were classified into several categories (please refer to Appendix 3 for detailed extraction information):

General information

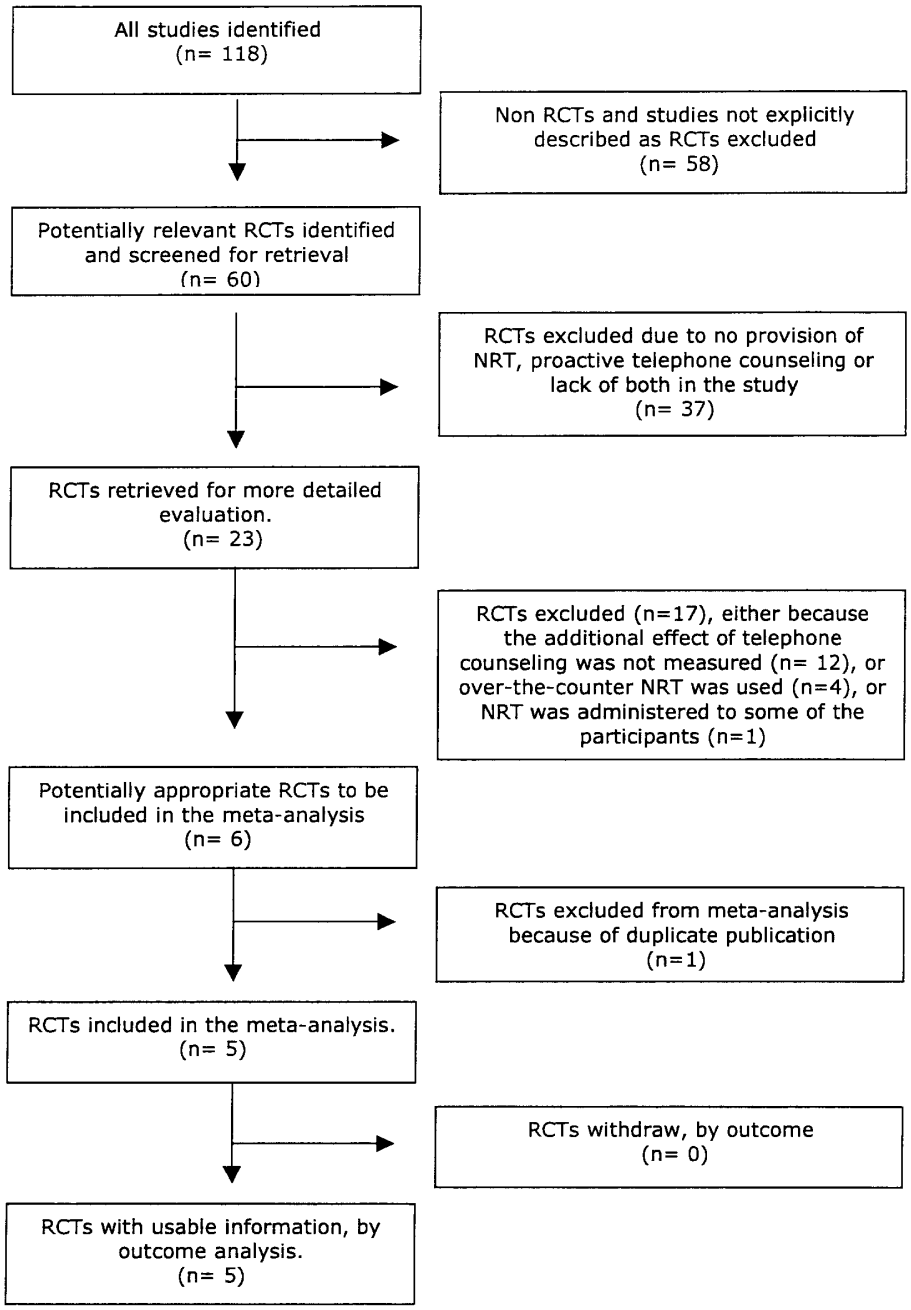
Date of Extraction, authors, titles, journal, year of publication and the country/origin and identification of the reviewer.

Specific information

Study characteristics

1. Study design (The method and randomisation process, description of withdrawals and dropouts, type of trial and the setting of the study.)
2. Participants (Age requirement, baseline cigarette consumption and others.)
3. Intervention/Control (NRT: type, duration and dose; telephone counselling: experience of counsellors, frequency, timing and content of counselling; supplement services to both trial arms.)
4. Outcome (Rates of abstinence from smoking.)

Figure 2 QUOROM Flow Chart



Outcome measures and results

Definition of outcome, baseline health, withdrawals and dropouts, length of follow-up, content of counseling, average calls received by counselees, length of each call, biochemical validation of self-report outcome.

Conclusion (author's note on methodology and outcome)

Quality Assessment

Each study was assessed using a structured quality checklist, established by the author based on the Jadad's quality assessment scale (14) and the framework proposed by Cambell (15). All studies were appraised unmasked. The author examined the internal (selection bias, performance bias, detection bias and attrition bias) and external validity (the patients, treatment regimens, settings and modalities of outcomes) of each trial. For quality assessment checklist please refer to Appendix 4.

To identify if selection bias has been minimized, the author examined the process of randomisation (generation of allocation sequences and concealment of allocation sequences), if these primary evidences were not properly provided, the secondary evidence should be provided by demonstrating comparability from the baseline values of important prognostic factors in both trial arms.

Blinding in this study may not be feasible, but if other principal investigators had been involved, blinding of these investigators might be necessary. This could at the same time reduce the performance bias in the trials. Since in these trials outcome assessors were not blinded, the minimization of detection bias might be reached if a biochemical method

was used to validate the self-reported abstinence. The intention-to-treat analysis will be considered as important in this review, because how withdrawals and losses to follow up were managed would eventually change the effect size.

Data analysis

To avoid the overestimation of the benefits by the odds ratio (16), the risk ratio (RR) was used in the analysis as the summary statistics, and if the number of participants being abstinent in each trial arm was not given in each study, it would be obtained by the percentage multiplied by the number randomised. Statistical pooling of study results was considered as appropriate if both the intervention and control arms were similar. The software used to perform the analysis was the MetaView in RevMan 4.2, provided by the Cochrane Collaboration, and the fixed effect model was adopted to pool the effects of abstinence at six-months.

Description of the studies

Five studies met the inclusion criteria and were included in this review. They were all conducted in the North America, four of them in the United States, one in Canada, and were conducted respectively in the years 2003, 2000, 1999, 1997 and 1991. Three of them recruited participants in the clinical settings (one in a medical center, one in a Home Maintenance Organisation, one in five clinics), two of them recruited participants from the community (one through radio advertisement, the other used posters posted in health care facilities, human services agencies and public bulletin boards). Four trials provided supplemental services such as self-help materials, physician advices and reactive telephone helpline registration, which were equivalently added to both arms.

In four studies participants were required to be at least 18 years of age, but one of the studies, which recruited hospitalized patients, did not specify the age requirement. Range of addiction to nicotine of the participants was wide, from a puff of a cigarette to at least 20 cigarettes per day. Four studies used nicotine patches, while one used nicotine gums, and the numbers of telephone call designated to provide to each subject in the treatment group were from three to five calls. Characteristics of the studies included were summarized in Table 1.

Methodological qualities of included studies

None of these studies adequately reported the process of randomisation (both randomisation sequence and concealment of randomisation), but all claimed that the baseline characteristics of the participants were comparable (assessment of internal validity was summarized in Table 2).

Two trials provided physician advice, yet only one of them mentioned the blinding of physicians. However, most trials did not consider blinding nor did they mention the blinding to the outcome assessors. Four of them used carbon monoxide in the breath sample or salivary cotinine level to validate the self-reported abstinence. Although each study claimed that they analysed results based on the intention-to-treat analysis, yet attrition was unclear. Only two reported withdrawals or losses to follow up, in which one study had a rate of losses to follow up at around 15% in both trial arms.

Table 1 Characteristics of selected trials

Author	Year	Eligibility of Participant			NRT	Number of telephone calls	Setting	Supplement services	Follow-up (Years)
		Age	Cigarette per day required	Motivation to quit					
Simon	2003	Not stated	>=20 The pre-hospitalization week	At the contemplation or at the action stage of quitting	Patch	5	Clinical	Self-help materials	1
Solomon	2000	18 - 50	>=5 (Period not stated)	Readiness to be at least 7 on a 0-10 scale	Patch	3	Community	None	0.5
Reid	1999	>= 18	>=15 The past year	Not cleared if assessed	Patch	3	Community	1. A self-help booklet 2. Physician advises	1
Lando	1997	18 - 65	>=20 The past two year	Not cleared if assessed	Patch	4	Clinical	1. An orientation cessation 2. Reactive telephone support registered 3. Self-help materials	1
Ockene	1991	18 - 75	>=1 puff of cigarette The previous week	Subjects with lowing intention to quit on a 3-point scale were excluded	Gum	3	Clinical	1. Physician advice 2. Physician counselling 3. A self-help booklet	2

NB Numbers in brackets were obtained from the percentage from the original paper.

Table 2 Assessment of internal validity

	Selection Bias			Performance Bias	Detection Bias		Attrition Bias	
	Generation of randomisation sequence	**Concealment of treatment allocation**	**Baseline prognostic factors in both groups**	**Blinding to investigators**	**Blinding to outcome assessor**	**Outcome biochemically Confirmed**	**Withdrawals and losses to follow up**	**Intention-to-treat Analysis**
Simon	Adequate	Not clear	Comparable	Unclear	Unclear	Yes	losses to follow up: 3 in the treatment group and 4 in the control group	Yes
Solomon	Unclear	Unclear	Comparable	Unclear	Unclear	Yes	Unclear	Yes
Reid	Adequate	Unclear	Comparable	Yes	Unclear	Yes	Withdrawals (could not be reached): 15.2% in the treatment group, 14.6 in the control group.	Yes
Lando	Adequate	Unclear	Comparable	Unclear	Unclear	Yes	Unclear	Yes
Ockene	Unclear	No (Patient preference)	Unclear	No	Unclear	No	Unclear	Yes

Results

Five studies were selected out of 118 identified studies, and altogether 1,537 participants were included in these studies, and hence, the review.

Participants joined in these trials were in their thirties to fifties. The sex distribution varied from one study to another, one study include only low-income women; one included almost all male in-patients; two other studies included either slightly more men or women, one did not specify it.

The nicotine dependence was measured by the Fagerstorm score, and these study included participants with different scores, from four to about eight in both treatment and control groups. One study only revealed the average value in both group as a whole, which was five. Two of the studies reported the average years smoking of their participants, which ranged from about twenty-one to twenty-four years, and all these participants smoked around twenty to thirty cigarettes per day. However, baseline prognostic factors were found to be comparable in four studies which provided relevant information. Characteristics of the participants of each study were summarized in table 3.

Patterns of telephone counselling given in these studies can be described in several perspectives: type of counselors, experience of counselors, content of counselling, timing of counselling, etc. Counsellors could be experienced smoking cessation counselors or trained nurses, trained psychologists, trained health educators and

trained ex-smokers. The content of counselling focused on the encouragement and reinforcement of successful abstinence, the strategies and behavioral recommendations to quit, and to ascertain the use of patches or gums. Each telephone counselling session was reported to last about 9 minutes to half and hour, but the average number each counselee received was not properly reported. All calls were made within the fourth month since the quit date. Unfortunately, most researchers did not provide adequate details about the counsellors' experience in giving smoking cessation counselling. Information about telephone counselling was summarized in Table 4.

Point prevalence of abstinence from smoking at 6-months was the main outcome in our review, and these five studies held the same definition for the outcome evaluation (i.e. subjects not smoking during the past seven days). Four out of five studies showed non-significant difference in the effect of helping participants staying abstinent from smoking at 6-month, with the confidence interval of the RR extending through both sides where RR=1. Only the most recent study, which recruited participants while they were hospitalized, showed a statistically significant effect of adding telephone support (RR=1.66, 95% CI 1.06 – 2.59).

The pooled RR, based on the fixed effects model (test for heterogeneity was not significant with Chi^2=5.6, df=4, P=0.23), was 1.17 (95% C.I. 0.98 – 1.41), not significant either (please refer to Figure+ 3). It showed that the participants in the treatment group were not necessarily better off than the control group.

Table 3 Characteristics of the participants in the selected studies

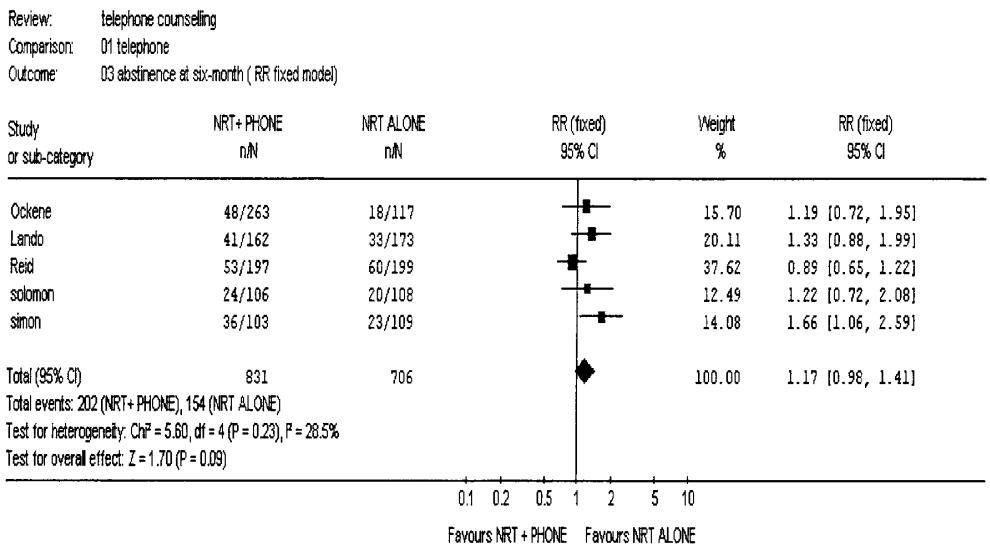
	Mean age (SD)		Sex (% Female)		Mean FTQ Score (SD)		Mean Number of Year Smoking (SD)		Mean Number of Cigarettes per day (SD)	
	Treatment	Control	Treatment	Control	Treatment	Control	Treatment	Control	Treatment	Control
Simon	55 (11)	54 (11)	2%	3%	4 (2)	4 (2)	Not stated	Not stated	25 (12)	24 (14)
Solomon	32.9 (8.0)	33.2 (9.1)	100%	100%	5.7 (23)	5.6 (2.3)	Not stated	Not stated	23.0 (12.0)	24.3 (11.5)
Reid	38.4 (8.2)	37.5 (7.9)	47.2%	47.7%	7.7 (1.9)	7.1 (1.7)	21.9 (8.2)	21.3 (8.1)	24.2 (8.5)	22.8 (6.9)
Lando	41.6 (-)	42.9 (-)	60.5%	61.3%	5.0 (-)	5.1 (-)	23.2 (-)	23.7 (-)	27.4 (-)	28.5 (-)
Ockene	Not stated	Not stated	Not stated	Not stated	Not stated	Not stated	Not stated	Not stated	Not stated	Not stated

Table 4 Characteristics of the telephone counselling and the relative risk

	Type of counsellors	Experience of counsellors	Content of counselling	Timing of counselling	Average Calls Received	Length of Counselling (minutes)	Results Relative risk (95% CI)
Simon	Trained Nurses or public health educators*	Not stated	Base on social learning theory and the stages of change model, to continue the skills training initiated during the initial counselling cession. Participants who had relapsed were encouraged to set new quit days.	Two counselling were occurred t the 1st, 3rd weeks after discharge, and the following 3 calls were occurred in the next three months.	Not stated	10	1.66 (1.06, 2.59)
Solomon	Ex-smokers who had received 7 hours of training for the support role.*	Not stated	To provide encouragement, guidance, much reinforcement for quitting smoking, and helped the woman cope with high risk for smoking situation using semi-structured protocols. (Brief quality control check for counselling was conducted by a research assistant.)	1st call took place before the quit day 2nd call occurred on or shortly after the quit day 3rd call was four days later Subsequent calls were initiated by counselors, on a weekly to biweekly basis for up to 3 months.	7	9	1.22 (0.72, 2.08)
Reid	Trained nurse-counsellors	Not stated	Scripted interventions by Orleans and colleagues.	At the 2nd, 6th and 13th weeks after the target quit day (TQD).	Not stated	Not stated	0.89 (0.65, 1.22)
Lando	Experienced smoking cessation counselors.	Not stated	To ascertain the compliance of patches, reaction to the problems with the patches, aided the relevant coping strategies, reinforce success abstinence.	At the 1st, 4th, 7th to 9th, 12th weeks after the target quit day (TQD).	3.8	10-15	1.33 (0.88, 1.99)
Ockene	Master's degree-level psychologists or health educators.*	Not stated	Open-ended questions similar to those used by physician, provided behavioral recommendations and negotiated a cessation or maintenance plan.	At approximately one, two, three months after initial contact.	Not stated	20	1.19 (0.72, 1.95)

* Counselling was given by the same counsellor

Figure 3 Pooled relative risk of five selected studies



Discussion

Nicotine replacement therapy has been widely accepted to help smokers quit smoking, however, it is suggested that nicotine replacement products should be used in conjunction with a behavior change programme. Amongst several types of behavior change programme, proactive telephone counselling was considered as one of the formats for delivering behavioural counselling, and was recommend by the U.S. smoking cessation practice guidelines (17).

However, based on the five trials conducted in the North America for the past decade, our analysis did not find adequate support for the effectiveness of active telephone

counselling as an adjunct to nicotine replacement therapy; therefore, we did not alter the conclusion of the previous review, after adding new evidences from a trial reported recently.

Due to time and resources constraints, all study processes (data search, extraction, quality assessment and analysis) were conducted by the author. Every effort has been made to comprehensively search the major electronic databases using quite sensitive search strategies. No restriction on language and time was put to the search, still, the author acknowledged that there might be publication bias, although in this review the risk was comparatively low.

The scope of the review was narrowed down to only proactive telephone counselling and free-of-charge nicotine replacement therapy, therefore, it would be inappropriate to apply the results to those whom actively call the helpline, quitline (or any specified numbers) or whom spend their out-of-pocket money to purchase over-the-counter patches or gums. At the same time, this result was not applicable to smokers under 18 years of age, since none of these studies indicated their participants were younger than 18 years old.

Calculation of study power was performed by two studies (Lando 1997, Reid 1999), but other two trials (Solomon 2000, Simon 2003) with smaller population size might have been underpowered. Quality of the included studies varied, most of them managed to provide secondary evidence to ascertain the internal validity (e.g. baseline

comparability instead of generation of randomisation sequence and concealment, or biochemically-validated results instead of blinding of the outcome assessors), except the trial reported by Ockene in 1991. However, if we excluded this poorly reported study in this meta-analysis, the result would nevertheless be unaffected (RR= 1.17, 95% C.I. 0.96 – 1.43), and so was it if the pooled RR was obtained using the more conservative model, the random effects model (RR= 1.19, 95% C.I. 0.95 – 1.49), instead of the fixed effects model.

The study which reported a significant result was the most recent study. When compared with the results from three other studies of similar reporting quality, this trial included different participants, recruited when hospitalized in a veterans medical center, at older age and had lower average nicotine dependence score, and, the large majority of them were men at the contemplation or action stage to quit. It is likely that these patients were more motivated to quit because of being reminded by counsellors their poorer health condition. However participants were averagely better motivated to quit in this review, since some subjects were excluded, being not assessed highly motivated. The issue of motivation to quit might be an important prognostic factor in smoking cessation (18), therefore it should be verified and explored in future studies.

Unfortunately, not enough details about telephone counselling were revealed in these studies. We were not clear the experience the counselors had to give the counselling; moreover, we could not tell that the counseling was more problem-solving or emotion-supporting, in terms of the content of counseling. What were the difficulties

encountered in the interaction during counselling? It would be more valuable if we obtained adequate counselling information, since the intensity or timing of counselling in these studies did not vary much from one another, but the quality of counselling was what that really matters when comparing the effectiveness.

Only one study reported the continuous abstinence at 6-month, and long-term abstinence after one year was not available. Since it was common that the rate of abstinence dropped very quickly after one year in lots of trials, there should be more efficient strategies to implement the nicotine replacement therapy in smoking cessation.

Finally, the author was not able to perform the subgroup analysis and sensitivity analysis because of the scarcity of the trial data. It would be feasible only if we had more trial data to compare at this moment.

Conclusions

Implications for practice

Simply referring smokers who are motivated to receive nicotine replacement therapy to proactive telephone counselling may not yield more effects. We need to provide other incentives in order to help people to stay in abstinence from smoking. Proactive telephone counselling may produce larger effects while it is provided to some specific populations or in combination with other services other than NRT.

Implications for future research

For a lack of relevant researches in other areas, experiences are welcome outside the North America, but the counselling protocol should be with a more clear and defined content about the respect of behaviour-change. Relationship between motivation to quit and abstinence from smoking in subject receiving telephone counselling can be further explored. Review for the effect of telephone counselling provided to those who spent their out-of-pocket money for over-the-counter nicotine patches or gums may reveal a different pattern of smokers' behaviour, otherwise studies as such should be included in the current analysis.

Potential conflict of interest

None

Acknowledgements

Here I would like to thank Andrew Booth, my supervisor, for instructing me the whole process of conducting this review, his experience and ideas have been a great help.

Characteristics of included studies

Simon 2003

Intensive smoking cessation counselling versus minimal counselling among hospitalized smokers treated with transdermal nicotine replacement: A randomised trial. American Journal of Medicine. 114(7):555-62, 2003 May.

Methods：Clinical setting, U.S

Recruitment: Patients who had been hospitalised at least 2 days were assessed to identify smokers.

Randomisation: Computerized algorithm was used, method not stated.

Participants: 107 in the treatment arm, 116 in the control arm. 55 years old in the treatment arm, 54 years old in the control arm. FTQ score was 4 in both treatment arms.

Intervention: 2 months NRT followed by 5 proactive counselling.

Control: NRT only (both arms also received self-help materials).

Outcomes: Abstinence at 6 and 12 months, salivary cotinine concentration Validated, intention-to-treat analysis. 35% (36/103) and 21% (23/109) were abstinent at the 6-months.

Note: Participants were hospitalized patients, who were already at the contemplation or action stage of quitting, almost all male participants.

Solomon 2000

Solomon LJ, Scharoun GM, Flynn BS, Secker-Walker RH, Sepinwall D. Free nicotine patches plus proactive telephone peer support to help low-income women stop smoking. Preventive Medicine 2000;31:68-74.

Methods：Community setting, U.S

Recruitment: Women respond to flyers posted in health care facilities, human service agencies, and public bulletin boards, and called to a local office telephone number to be screened.

Randomisation: Not stated.

Participants: 106 in the treatment arm, 108 in the control arm. 32.9 years old in the treatment arm, 33.2 years old in the control arm. FTQ score was 5.7 in the treatment arm, 5.6 in the control arm.

Intervention: 8-10 weeks NRT followed by 3 proactive counselling.

Control: NRT only (supplement services not stated).

Outcomes: Abstinence at 3 and 6 months, CO concentration Validated, intention-to-treat analysis. 23% (24/106) in the treatment group and 19% (20/108) in the control group were abstinence at the 6-months.

Note: These were low-income women, and they were also screened for the motivation to quit (details not shown), and most calls happened in the quitting stage, not follow-up stage.

Reid 1999

Reid RD, Pipe A, Dafoe WA. Is telephone counselling a useful addition to physician advice and nicotine replacement therapy in helping patients to stop smoking? A randomised controlled trial. CMAJ 1999;160:1577-1581.

Methods：Community setting, Canada

Recruitment: Smokers respond to the radio advertisements.

Randomisation: Random number table and maximization randomisation, handled by a study coordinator.

Participants: 197 in the treatment arm, 199 in the control arm. 38.4 years old in the treatment arm, 37.5 years old in the control arm. FTQ score was 7.2 in the treatment arm, 7.1 in the control arm.

Intervention: 12 weeks NRT followed by 3 proactive counselling.

Control: NRT only (both arms also received a self-help booklet and physician advises).

Outcomes: Abstinence at 6 and 12 months, CO concentration Validated, intention-to-treat analysis. 26.9% and 30.2% were abstinence at the 6-months.

Note: The requirements for health condition were stringent (subjects with abnormal renal and liver function were excluded, and the author have screened and recruited those with higher motivation (details not stated).

Lando 1997

Lando HA, Rolnick S, Klevan D, Roski J, Cherney L, Lauger G. Telephone support as an adjunct to transdermal nicotine in smoking cessation. American Journal of Public Health 1997;87:1670-1674.

Methods : Clinical setting, U.S.

Recruitment: Eligible patient in a home maintenance organization (HMO) were interviewed by study staffs.

Randomisation: A random block design was used in which each sequential set of orientation sessions included all study condition.

Participants: 162 in the treatment arm, 173 in the control arm. 41.6 years old in the treatment arm, 42.9 years old in the control arm. FTQ score was 5 in the treatment arm, 5.1 in the control arm.

Intervention: 8 weeks NRT followed by 4 proactive counselling.

Control: NRT only (both arms also received an orientation cessation, reactive telephone support registered and self-help materials).

Outcomes: Abstinence at 6 and 12 months, CO concentration Validated, intention-to-treat analysis. 25% in the treatment group and 19% in the control group were abstinence at the 6-months.

Note: The requirements for motivation to quit in participants were stringent (readiness was to be at least 7 on a 0 -10 scale).

Ockene 1991

Ockene JK, Kristeller J, Goldberg R, Amick TL, Pekow PS, Hosmer D et al. Increasing the efficacy of physician-delivered smoking interventions: a randomised clinical trial.

Methods：Clinical setting, U.S

Recruitment: Patients were recruited from two internal medicine and three family practice clinics but details of recruitment were not revealed.

Randomisation: Not stated.

Participants: 263 in the treatment arm, 117 in the control arm. Mean age of all subjects was 35.2 years old. Mean FTQ score of all subjects was 5.1.

Intervention: Duration, dose of NRT and intensity of telephone calls not stated (we only select one arm in the 2*3 factorial design, half subjects in this arm received telephone counselling.

Control: NRT only (both arms also received physician advice, physician counselling and a self-help booklet).

Outcomes: Abstinence at 6 months, no biochemical validation used, intention-to-treat analysis mentioned. 18.3% in the treatment group and 15.4% in the control group were abstinent at the 6-months.

Note: This study included a very broad spectrum of addiction of smokers, also, the motivation to quit is not necessarily high. This programme involves a large amount of work of physicians providing patient-centered counselling, and should be considered should heterogeneity appear.

Reasons to exclude studies

(A) Studies that were not RCTs (i.e. reviews, surveys, census, case studies, case serious, cohort studies, decision-tree analysis, non-randomised controlled trials) or were not explicitly described as RCTs

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Impact of patient characteristics on physician's smoking cessation strategies. Preventive Medicine. 36(4):464-70, 2003 Apr.

Frikart M. 2003
Five-day plan for smoking cessation using group behaviour therapy. Swiss Medical Weekly. 133(3-4):39-43, 2003 Jan 25.

Moolchan ET. 2003
Characteristics of African American teenage smokers who request cessation treatment: implications for addressing health disparities. Archives of Pediatrics & Adolescent Medicine. 157(6):533-8, 2003 Jun.

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A smoking cessation intervention for parents of children who are hospitalized for respiratory illness: the stop tobacco outreach program. Pediatrics. 111(1):140-5, 2003 Jan.

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Preventive care in the emergency department: diagnosis and management of smoking and smoking-related illness in the emergency department: a systematic review. Academic Emergency Medicine. 9(7):720-9, 2002 Jul.

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National evaluation of the new Smoking cessation services: Targeting disadvantaged Smokers (NESTS) (NRR)

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Public knowledge and attitudes regarding smoking and smoking cessation treatments.[comment]. New Zealand Medical Journal. 115(1153):219-22, 2002 May 10.

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Effectiveness of a clinic-based strategy for implementing the AHRQ Smoking Cessation Guideline in primary care. Preventive Medicine. 35(3):293-301, 2002 Sep.

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Using a telephone survey to acquire genetic and behavioral data related to cigarette smoking in "made-anonymous" and "registry" samples. American Journal of Epidemiology. 156(1):68-77, 2002 Jul 1.

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The prevalence and predictos of smoking cessation following treatment of head and neck cancer. (NRR)

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Appendix 1

Inclusion and Exclusion Criteria

Selection Items	Inclusion Criteria	Exclusion Criteria
Population	1. Smokers. 2. Smoking at least a puff of a cigarette per day (cpd). 3. Motivated to quit smoking.	1. Patients at the terminal stage. 2. Pregnant or lactating women. 3. Not motivated to quit smoking.
Intervention	1. Participants in one arm received nicotine replacement therapy, and in another arm received nicotine replacement therapy plus telephone counseling. 2. Follow-up to at least 6 months.	1. A study which lacked of either arm of NRT or NRT+counseling. 2. NRT medicine was purchased by participants, not provided by the researchers. 3. Telephone counselling was initiated only reactively. 4. Not follow up to 6 months.
Comparison	1. At lease an arm of nicotine replacement therapy without telephone counselling. 2. Follow-up evaluation.	No treatment arm which could reveal additional effect of telephone counselling.
Outcome	1. Point prevalence of abstinence. 2. Continuous abstinence.	1. No clear definition of outcome. 2. Six-month Point prevalence was not reported. 3. Outcomes were not focused on the additional effect of telephone counselling (e.g. effects evaluated focused on the use of NRT or self-help materials).
Study design	Randomized controlled trial.	1. Studies were not RCTs. 2. Studies were not explicit about study design.
Setting	Clinical or community-based.	Study setting not explicitly described.

Appendix 2

Search strategy used in searching the Medline

1	randomized controlled trial.pt.
2	controlled clinical trial.pt.
3	randomized controlled trials/
4	exp clinical trials/
5	exp research design/
6	random allocation/
7	(double or triple).tw.
8	(mask$ or blind$).tw.
9	placebos/ or placebo.tw.
10	or/1-9
11	*smoking/
12	nicotine replacement
13	smoking cessation/
14	nicotine patch$.
15	nicotine gum$
16	nicotine nasal spray$
17	nicotine tablet$
18	or/11-16
19	telephone/
20	*telephone/
21	telephone.ti.
22	or/18-20
23	10 and 18 and 22

Appendix 3

Data Extraction Form (1)

Reviewer: Chien-Yuan, Wu **Date:** 10/07/03 **Study ID: 1**

Authors	Simon JA. Carmody TP. Hudes ES. Snyder E. Murray J.
Article Title	Intensive smoking cessation counseling versus minimal counseling among hospitalized smokers treated with transdermal nicotine replacement: a randomized trial.
Journal	American Journal of Medicine
Year of publication	114(7):555-62, 2003 May.
Publication type	Randomized Controlled Trial
Country/origin	U.S.
Data source	Published / Unpublished / Pharmaceutical / Other

Is this the main report for this study? Yes / No

(A) Study design

Randomization

1. Study described as randomized?	Yes / No
2. Information provided on how randomization sequence was generated?	Yes / No (computerized algorithm was used)
3. Was it appropriate?	Adequate (third party, opaque sealed envelope) Not clear Inadequate (date of birth, date of admission, hospital numbers or alternation) Not assigned
Any blinding?	Yes / No
Were withdrawals and dropouts being described?	Yes / No
Type of trial	Parallel / crossover
Setting	Clinical / Community / Others

(B) Participants

Inclusion criteria

Age Not specified.

Cigarette per day (cpd) >=20 during the pre-hospitalization week

Others Current smokers admitted for at least 2 days.

Exclusion criteria

1. Patients who were hospitalized for a psychiatric or terminal illness
2. Patients who had a contradiction to nicotine replacement
3. Patients at the contemplation or action stage of quitting.

Recruitment procedures

Eligible patient who had been hospitalised at the San Francisco Veterans Affairs Medical Center for at least 2 days.

Baseline addiction assessed? Yes / No / Unsure
Was the study adequately powered? Yes / No / Not clear
Was incentive offered to enhance participation? Yes / No

(c) Intervention

NRT With Telephone counseling

NRT (free)

Type (gum / patch / nasal spray / tablet)

Duration 2 months after discharge

Does Bases on the number of cigarettes smoked before hospitalization (exact does not described)

(Supplement: self-help literature was distributed)

Telephone Counselling

Counsellor Trained Nurses or public health educators

Experience of counselor Not specified.

Frequency Five proactive telephone counseling.

Timing Two counseling were occurred t the 1st, 3rd weeks after discharge, and the following 3 calls were occurred in the next three months.

Content Base on social learning theory and the stages of change model, to continue the skills training initiated during the initial counseling cession. Participants who had relapsed were encouraged to set new quit days.

Others Counseling given by the same counselor.

Follow-up

Duration 12 months (52 weeks)

Frequency Two telephone follow-up.

Interval The 6th month and 12th months after discharge.

(D) Control Intervention

NRT Without Telephone counselling

NRT (free)

In the identical as given in the experimental group.

Follow-up

Duration and frequency were identical to the experimental group.

(E) Outcome

1. Population characteristics

	Experimental group	Control group
Number of people randomized	107	116
Mean Age (SD)	55 (11)	54 (11)
Ethnicity (% white)	69	69
Gender (% female)	2	3

2. Baseline health information

	Experimental group	Control group
Mean no. Cigarette per day (SD)	25 (12)	24 (14)
Mean no. of years smoking (SD)	Not available	Not available
Mean FTQ score (SD)	4 (2)	4 (2)

3. Withdrawals and dropouts

	Experimental group	Control group
% withdrawals	Not available	Not available
Reason of withdrawal	Not available	Not available
% losses to follow up	3/102	4/107

Were these groups comparable at baseline? Yes / No / Unsure

4. Abstinence

	Experimental group % (n/N) (95% C.I.)	Control group % (n/N) (95% C.I.)
Point prevalence		
3 months	Not available	Not available
6 months* (or 26 weeks)	35% (36/103) (% - %)	21% (23/109) (% - %)
12 months (or 52 weeks)	16% (16/102) (% - %)	9% (10/107) (% - %)
18 months	Not available	Not available
Continuous abstinence		
3 months	Not available	Not available
6 months (or 26 weeks)	Not available	Not available
12 months (or 52 weeks)	Not available	Not available
18 months	Not available	Not available

*Self-reported not validated.
RR of quitting at 6-month = 1.7 (1.1-2.7)
RR of quitting at 12-month = 1.6 (0.76-3.3)

5. Counselling

	Experimental group	Control group
Average calls received by each subject	Not available	-
Length of Time for each counselling (min)	30	-

Other sources of telephone contact? Yes/ **Not clear / No**

Was outcome definition clear? Yes / Not clear / No

Was abstinence confirmed by a biomedical method? Yes / Not clear / No

(In this study, salivary cotinine level $\geq$15 ng/mL was used as an indicator of current tobacco use)

Assessment of compliance undertaken? Yes / Not clear / No

"Intention-to-treat" analysis undertaken? Yes / Not clear / No

(F) Conclusion

Characteristics of participants

In this study, readiness to quit of participants was assessed, participants recruited were already at the contemplation or action stage of quitting, which could be different from the general population. Alcohol and drug abuse were common in this study population.

At 12-months, confirmed rates were not significantly different (29% vs. 20% p=0.07) based on intention-to-treat analysis, but was significantly different using self-reported data.

Data Extraction Form (2)

Reviewer: Chien-Yuan, Wu **Date:** 20/06/03 **Study ID: 2**

Authors	Solomon LJ. Scharoun GM. Flynn BS. Secker-Walker RH. Sepinwall D.
Article Title	Free nicotine patches plus proactive telephone peer support to help low-income women stop smoking.
Journal	Preventive Medicine
Year of publication	31(1):68-74, 2000 Jul.
Publication type	Randomized Controlled Trial
Country/origin	U.S.
Data source	Published / Unpublished / Pharmaceutical / Other

Is this the main report for this study? Yes / No

(A) Study design

Randomization

1. Study described as randomized?	Yes / No
2. Information provided on how randomization sequence was generated?	Yes / No
3. Was it appropriate?	Adequate (third party, opaque sealed envelope) Not clear Inadequate (date of birth, date of admission, hospital numbers or alternation) Not assigned
Blinding	Yes / No
Were withdrawals and dropouts being described?	Yes / No
Type of trial	Parallel / crossover
Setting	Clinical / Community / Others

(B) Participants

Inclusion criteria

Age between 18 and 50 years of age

Cigarette per day (cpd) >=5

Others Subjects were Medicaid income eligible; had adequate command of English, had high intention of quitting smoking in the next two weeks; had a home telephone; live in Chittenden County, Vermont; had no plans to move in the next 6 months; were not currently using nicotine replacement; had no contraindications for the use of nicotine patches (no history of heart disease, pregnant or intending to become pregnant in the next three month, breast-feeding).

Exclusion criteria

1. Not between 18 and 50 years of age
2. Income too high
3. Cigarette per day (cpd) <5
4. Live outside of Chittenden County, Vermont
5. Had no home telephone
6. Plan to move in the next 6 months
7. Current breast-feeding
8. History of heart disease
9. Unable to be reached for baseline assessment

Recruitment procedures

Women respond to flyers posted in health care facilities, human service agencies, and public bulletin boards, and called to a local office telephone number to be screened.

Baseline addiction assessed? Yes / No / Unsure
Was the study adequately powered? Yes / No / Unsure
Was incentive offered to enhance participation? Yes / No / Unsure

(c) Intervention

NRT With Telephone counseling

NRT (free)

Type (gum / patch / nasal spray / tablet)

Duration 8 or 10 weeks

Does Women who reported smoking >10 cpd
21 mg for 1^{st}-6^{th} weeks
14 mg for 7^{th}-8^{th} weeks
7 mg for 9^{th}-10^{th} weeks

Women who reported smoking 5-10 cpd
14 mg for 1^{st}-6^{th} weeks
7 mg for 7^{th}-8^{th} weeks

(Supplement: not mentioned)

Telephone Counselling

Counsellor Ex-smokers who had received 7 hours of training for the support role.

Experience of counsellors Not mentioned.

Frequency Three scheduled counseling plus subsequent calls on a weekly to bi-weekly basis in 3 months time; subject can end the calls at any time.

Timing
1st call took place before the quit day
2nd call occurred on or shortly after the quit day
3rd call was four days later
Subsequent calls were initiated by counselors, on a weekly to biweekly basis for up to 3 months.

Content To provide encouragement, guidance, much reinforcement for quitting smoking , and helped the woman cope with high risk for smoking situation using semi-structured protocols.

Others
Each subject was assigned to one counselor.
Brief quality control check for counseling was conducted by a research assistant.

Follow-up

Duration 6 months

Frequency three times telephone assessment.
Interval The 10-day, 3-months, 6-months after the TQD.

(D) Control Intervention

NRT Without Telephone counselling

NRT (free)

Type, duration, does and supplement were identical to the experimental group.

Follow-up

Duration and frequency were identical to the experimental group.

(E) Outcome

1. Population characteristics

	Experimental group	Control group
Number of people randomized	106	108
Mean Age (SD)	32.9 (8.0)	33.2 (9.1)
Ethnicity (% Caucasian)	90	91
Gender (% female)	100	0

2. Baseline health information

	Experimental group	Control group
Mean no. Cigarette per day (SD)	23.0 (12.0)	24.3 (11.5)
Mean no. of years smoking (SD)	Not available	Not available
Mean FTQ score (SD)	5.7 (2.3)	5. 6 (2.3)

Were these groups comparable at baseline? Yes / No / Unsure

3. Withdrawals and dropouts

	Experimental group	Control group
% withdrawals	Not available	Not available
Reason of withdrawal	Not available	Not available
% losses to follow up	Not available	Not available
% respond rate at 3-month	95% (101/106)	85% (87/92)

4. Abstinence

	Experimental group % (n) (95% C.I.)	Control group % (n) (95% C.I.)
Point prevalence		
3 months	42% (44/106) (% - %)	28% (30/108) (% - %)
6 months (or 26 weeks)	23% (24/106) (% - %)	19% (20/108) (% - %)
12 months (or 52 weeks)	Not available	Not available
18 months	Not available	Not available

	Experimental group	Control group
3 months	Not available	Not available
6 months (or 26 weeks)	Not available	Not available
12 months (or 52 weeks)	Not available	Not available
18 months	Not available	Not available

OR of being 3-month abstinent=2.0 (1.09-3.68)

5. counselling

	Experimental group	Control group
Average calls received by each subject	7	-
Length of Time for each counselling (min)	9	-

Other sources of telephone contact? Yes/ **Not clear / No**

Was outcome definition clear?	Yes / Not clear / No
Was abstinence confirmed by a biomedical method? (In this study, CO reading of <= 8 ppm was considered inactive of non-smoking.)	Yes / Not clear / No
Assessment of compliance using NRT undertaken?	Yes / Not clear / No
"Intention-to-treat" analysis undertaken?	Yes / Not clear / No

(F) Conclusion

Characteristics of participants
Women having lower intention to quit on a 3-points scale were excluded or eliminated form the study (but the authors did no mention in detail.).
For low income-women, most calls occurred in the quitting process, low intensity in the following month

Outcomes
Conclusion was made on self-reported data, where there is a significant difference at 3-month (42% vs. 28% p=0.03), but turned out to be not significant at 6-month (23% vs. 19% p>0.05). only parts of breath samples were obtained from participants reporting abstinent, which was considered by the authors as "tended to corroborate subject reports".

Data Extraction Form (3)

Reviewer: Chien-Yuan, Wu **Date:** 19/06/03 **Study ID: 3**

Authors	Reid RD. Pipe A. Dafoe WA
Article Title	Is telephone counselling a useful addition to physician advice and nicotine replacement therapy in helping patients to stop smoking? A randomized controlled trial.
Journal	CMAJ Canadian Medical Association Journal
Year of publication	160(11):1577-81, 1999 Jun 1.
Publication type	Randomized Controlled Trial
Country/origin	Canada
Data source	Published / Unpublished / Pharmaceutical / Other

Is this the main report for this study? Yes / No

(A) Study design

Randomization

1. Study described as randomized?	Yes / No
2. Information provided on how randomization sequence was generated?	Yes / No (Random number table and maximization randomization and was handled by a study coordinator.)
3. Was it appropriate?	Adequate (third party, opaque sealed envelope) Unclear Inadequate (date of birth, date of admission, hospital numbers or alternation) Not assigned
Any blinding?	Yes / No
Were withdrawals and dropouts being described?	Yes / No
Type of trial	Parallel / crossover
Setting	Clinic / Community / Others

(B) Participants

Inclusion criteria

Age >=18 years

Cigarette per day (cpd) >=15 during the past year

Others Subjects were interested in quitting smoking within 30 days.

Exclusion criteria

1. People who had recent or severe heart disease, variant angina or active and untreated arrhythmias
2. Women who were pregnant or lactating
3. People who had alcohol dependence or a history of drug abuse
4. People with a coexisting psychiatric illness
5. People with biochemical evidence of kidney or liver dysfunction.

Recruitment procedures

Volunteers smokers recruited through radio advertisements.

Baseline addiction assessed? Yes / No / Unsure
Was the study adequately powered? Yes / No / Unsure
Was incentive offered to enhance participation? Yes / No

(c) Intervention

NRT With Telephone counseling

NRT (free)

Type (gum / patch / nasal spray / tablet)

Duration 12 weeks

Does 15-mg for 1st-8th weeks
10-mg for 9th -10th weeks
5-mg for 11th-12th weeks

(Supplement: a self-help booklet and three physician advises in accordance with the programme "Guide Your Patients to a Smoke-Free Future")

Telephone Counselling

Counsellor Trained nurse-counsellors

Experience of counselor Not mentioned

Content Scripted interventions by Orleans and colleagues.

Frequency Three telephone counseling.

Interval At the 2nd, 6th and 13th weeks after the target quit day (TQD).

Others Not specified.

Follow-up Duration 52 weeks

Frequency Four times postal questionnaires.
Interval The 4th,12th,26th and 52nd weeks after the TQD.

(C) Control Intervention

NRT Without Telephone counselling **NRT (free)**

Type, duration, does and supplement were identical to the experimental group.

Follow-up Duration and frequency were identical to the experimental group.

(E) Outcome

1. Population characteristics

	Experimental group	Control group
Number of people randomized	197	199
Number completed trial	Not available	Not available
Mean Age (SD)	38.4 (8.2)	37.5 (7.9)
Ethnicity	Not available	Not available
Gender (% female)	47.2	47.7

2. Baseline health information

	Experimental group	Control group
Mean no. Cigarette per day (SD)	24.2 (8.5)	22.8 (6.9)
Mean no. of years smoking (SD)	21.9 (8.2)	21.3 (8.1)
Mean FTQ score (SD)	7.2 (1.9)	7.1 (1.7)

3. Withdrawals and dropouts

	Experimental group	Control group
% withdrawals	15.2	14.6
Reason of withdrawal	Changed address Could not be contacted	Changed address Could not be contacted
% losses to follow up	Not available	Not available

Were these groups comparable at baseline? Yes / No / Unsure

4. Abstinence

	Experimental group % (n/N) (95% C.I.)	Control group % (n/N) (95% C.I.)
Point prevalence		
3 months	Not available	Not available
6 months (or 26 weeks)	26.9% (/) (% - %)	30.2% (/) (% - %)
12 months (or 52 weeks)	23.4% (/) (17.5% - 29.3%)	24.1% (/) (18.2% - 30.0%)
18 months	Not available	Not available
Continuous abstinence		
3 months	Not available	Not available
6 months (or 26 weeks)	Not available	Not available
12 months (or 52 weeks)	Not available	Not available
18 months	Not available	Not available

5. Counseling

	Experimental group	Control group
Average calls received by each subject	Not available	-
Length of Time for each counselling (min)	Not available	-

Other sources of telephone contact? Yes/ **Unclear / No**

Was outcome definition clear?	Yes / Unclear / No
Was abstinence confirmed by a biomedical method?	Yes / Unclear / No
(CO concentration <= 9 ppm was used to validated abstinence)	
Assessment of compliance undertaken?	Yes / Unclear / No
"Intention-to-treat" analysis undertaken?	Yes / Unclear / No

(F) Conclusion

Characteristics of participants

Participant selection was strict about health condition. Participants with abnormal liver and kidney function tests were excluded, and alcohol dependence or history of drug abuse as well. According to the authors, these participants were more likely to be motivated to quit, but not being assessed or not.

Outcome

The conclusion was based on self-reported abstinence (but authors claimed that measurement of CO verified self-reported abstinence reach 98%). No significant difference was found at any stage of follow-up.

Data Extraction Form (4)

Reviewer: Chien-Yuan, Wu **Date:** 20/06/03 **Study ID: 4**

Authors	Lando HA. Rolnick S. Klevan D. Roski J. Cherney L. Lauger G.
Article Title	Telephone support as an adjunct to transdermal nicotine in smoking cessation.
Journal	American Journal of Public Health.
Year of publication	87(10):1670-4, 1997 Oct.
Publication type	Randomized Controlled Trial
Country/origin	U.S.
Data source	Published / Unpublished / Pharmaceutical / Other

Is this the main report for this study? Yes / No

(A) Study design

Randomization

1. Study described as randomized?	Yes / No
2. Information provided on how randomization sequence was generated?	Yes / No (A random block design was used in which each sequential set of orientation sessions included all study condition)
3. Was it appropriate?	Adequate (third party, opaque sealed envelope) Unclear Inadequate (date of birth, date of admission, hospital numbers or alternation) Not assigned
Any blinding?	Yes / No
Were withdrawals and dropouts being described?	Yes / No
Type of trial	Parallel / crossover
Setting	Clinical / Community / Others

(B) Participants

Inclusion criteria

Age between 18 and 65 years of age

Cigarette per day (cpd) >=20 during the past two year

Others Subjects were interested in quitting smoking within 30 days; female subjects using an acceptable method of birth control if sexually active.

Exclusion criteria

1. people who self-reported positive history of heart disease, symptomatic peripheral vascular disease, or diabetes
2. People who self-reported history of skin irritation or known allergy to adhesives that would preclude use of a transdermal system
3. Current or recent treatment for psychiatric illness or chemical dependency (less than 6 months since completion of treatment)
4. Current excessive use of alcohol (consuming seven drinks more than three times per week)
5. People who self-reported regular use of psychotropic medications, systemic steroids, or antihistamines
6. Pregnancy, lactation, or intention to become pregnant during the study
7. Current use of any alternative forms of nicotine replacement therapy.

Recruitment procedures

Eligible patient in a home maintenance organization (HMO) were interviewed by study staffs.

Baseline addiction assessed? Yes / No / Unsure
Was the study adequately powered? Yes / No / Unsure
Was incentive offered to enhance participation? Yes / No

(c) Intervention

NRT With Telephone counseling

NRT (free)

Type (gum / patch / nasal spray / tablet)

Duration 8 weeks

Does 22-mg for 1st-2nd weeks
22-mg for 3rd-6th weeks
11-mg for 7th-8th weeks (optional)

(Supplement: orientation cessation, reactive telephone support, self-help materials "Lederle Support Services")

Telephone Counselling

Counsellor Experienced smoking cessation counselors.

Experience of counsellors Not mentioned.

Frequency Four proactive telephone counseling.

Timing At the 1st, 4th, 7th to 9th, 12th weeks after the target

quit day (TQD).

Content To ascertain the compliance of patches, reaction to the problems with the patches, aided the relevant coping strategies, reinforce success abstinence.

Others Not specified.

Follow-up

Duration 12 months (52 weeks)

Frequency Six times postal questionnaires.

Interval The 2nd, 5th, 8th, 12th weeks, 6th month and 12th months after the TQD.

(C) Control Intervention

NRT Without Telephone counselling

NRT (free)

Type, duration, does and supplement were identical to the experimental group.

Follow-up

Duration and frequency were identical to the experimental group.

(E) Outcome

1. Population characteristics

	Experimental group	Control group
Number of people randomized	162	173
Number completed trial	Not available	Not available
Mean Age (SD)	41.6 ( )	42.9 ( )
Ethnicity	Not available	Not available
Gender (% female)	60.5	61.3

2. Baseline health information

	Experimental group	Control group
Mean no. Cigarette per day (SD)	27.4 ( )	28.5 ( )
Mean no. of years smoking (SD)	23.2 ( )	23.7 ( )
Mean FTQ score (SD)	5.0 ( )	5.1 ( )

3. Withdrawals and dropouts

	Experimental group	Control group
% withdrawals	Not available	Not available
Reason of withdrawal	Not available	Not available
% losses to follow up	Not available	Not available

Were these groups comparable at baseline? Yes / No / Unsure

4. Abstinence

	Experimental group % (n/N) (95% C.I.)	Control group % (n/N) (95% C.I.)
Point prevalence		
3 months	Not available	Not available
6 months (or 26 weeks)	25% (/) (% - %)	19% (/) (% - %)
12 months (or 52 weeks)	21% (/) (17.5% - 29.3%)	20% (/) (18.2% - 30.0%)
18 months	Not available	Not available
Continuous abstinence		
3 months	Not available	Not available
6months (or 26 weeks)	17% (/) (% - %)	15% (/) (% - %)
12months (or 52 weeks)	13% (/) (% - %)	13% (/) (% - %)
18 months	Not available	Not available

5. Counselling

	Experimental group	Control group
Average calls received by each subject	3.8	-
Length of Time for each counselling (min)	10-15	-

Other sources of telephone contact? Yes/ Unclear / No
(toll-free line from pharmaceutical company)

Was outcome definition clear?	Yes / Unclear / No
Was abstinence confirmed by a biomedical method?	Yes / Unclear / No
(In this study, it was verified by CO concentration)	
Assessment of compliance undertaken?	Yes / Unclear / No
"Intention-to-treat" analysis undertaken?	Yes / Unclear / No

(F) Conclusion

Characteristics of participants

The requirements for participation in the current study were stringent (readiness was to be at least 7 on a 0 -10 scale).

Also, this study has limited the telephone contact to discriminate assessment calls and interventional calls.

Outcome

The outcome differences between the treatment group and control group at any point were not significant, but they were indecisive about the conclusion that telephone counseling is not effective.

Data Extraction Form (5)

Reviewer: Chien-Yuan, Wu **Date:** 17/07/03 **Study ID:** 5

Authors	Ockene JK. Kristeller J. Goldberg R. Amick TL. Pekow PS. Hosmer D. Quirk M. Kalan K.
Article Title	Increasing the efficacy of physician-delivered smoking interventions: a randomized clinical trial
Journal	Journal of General Internal Medicine.
Year of publication	6(1):1-8, 1991 Jan-Feb
Publication type	Randomized Controlled Trial
Country/origin	U.S.
Data source	Published / Unpublished / Pharmaceutical / Other

(A) study design

Randomization

1. Study described as randomized?	Yes / No
2. Information provided on how randomization sequence was generated?	Yes / No
3. Was it appropriate?	Adequate (third party, opaque sealed envelope) Unclear Inadequate (date of birth, date of admission, hospital numbers or alternation) Not assigned
Any blinding?	Yes / No
Were withdrawals and dropouts being described?	Yes / No
Type of trial	Parallel / crossover
Setting	Clinical / Community / Others

(B) Participants

Inclusion criteria

Age Between 18-75 years of age.

Cigarette per day (cpd) At least a puff of a cigarette during the previous week.

Others Not specified.

Exclusion criteria

1. People who did not have a telephone.
2. People who were planning to move out of the area within the next year.
3. People who were already using nicotine-containing gum (NCG), or were participating in a smoking cessation program.
4. People were medically ineligible for use of NCG.

Recruitment procedures

Patients were recruited from two internal medicine and three family practice clinics affiliated with the university of Massachusetts Medical School's (UMMS), but details of recruitment were not revealed.

Baseline addiction assessed? Yes / No / Unsure
Was the study adequately powered? Yes / No / Unclear

(c) Intervention

NRT With Telephone counseling

NRT (free)

Type (gum / patch / nasal spray / tablet)

Duration Not Available.

Does Not Available.

(Supplement: A 5-10 minutes face-to-face physician counselling with open-ended patients-centered questions and self-management recommendations.)

Telephone Counselling

Counsellor Master's degree-level psychologists or health educators.

Experience of counselor Not mentioned.

Frequency Three calls.

Timing At approximately one, two, three months after initial contact.

Content Open-ended questions similar to those used by physician, provided behavioral recommendations and negotiated a cessation or maintenance plan.

Others One counselor made all calls to a given call subject.

Follow-up

Duration Two years.

Frequency Approximately four times.

Interval At six-month intervals for two years after study entry.

(D) Control Intervention

NRT Without Telephone counselling

NRT (free)

In the identical as given in the experimental group.

Follow-up

Duration and frequency were identical to the experimental group.

Was NRT identical in both arms? Yes / No
Was follow up period identical in both arms? Yes / No

(E) Outcome

1. Population characteristics

	Experimental group	Control group
Number of people randomized	263	117
Mean Age (SD)	Not available	Not available
Ethnicity (% white)	Not available	Not available
Gender (% female)	Not available	Not available

NB Average age of the two groups was 35.2.
Percentage of female of the two groups was 56.8%

2. Baseline health information

	Experimental group	Control group
Mean no. Cigarette per day (SD)	Not available	Not available
Mean no. of years smoking (SD)	Not available	Not available
Mean FTQ score (SD)	Not available	Not available

NB Mean number of cigarette per day of the two groups was 23.3.
Mean **FTQ score** of the two groups was 5.1.

3. Withdrawals and dropouts

	Experimental group	Control group
% withdrawals	Not available	Not available
Reason of withdrawal	Not available	Not available
% losses to follow up	Not available	Not available

Were these groups comparable at baseline? Yes / No / Unsure

4. Abstinence

	Experimental group % (n) (95% C.I.)	Control group % (n) (95% C.I.)
Point prevalence		
3 months	Not available	Not available
6 months (or 26 weeks)	18.3% (/263) (% - %)	15.4% (/117) (% - %)
12 months (or 52 weeks)	Not available	Not available
18 months	Not available	Not available

Continuous abstinence		
3 months	Not available	Not available
6 months (or 26 weeks)	Not available	Not available
12 months (or 52 weeks)	Not available	Not available
18 months (or 52 weeks)	Not available	Not available

5. Counseling

	Experimental group	Control group
Average calls received by each subject	Not available	-
Length of Time for each counselling (min)	20	-

Other sources of telephone contact? Yes/ Unclear / No

Was outcome definition clear? Yes / Unclear / No

Was abstinence confirmed by a biomedical method? Yes / Unclear / No

Assessment of compliance undertaken? Yes / Unclear / No

"Intention-to-treat" analysis undertaken? Yes / Unclear / No

(F) Conclusion

Characteristic of participants

This study included a very broad spectrum of smokers seen in a primary care setting; eligible smokers were encourage to take part in "regardless of their desire to stop smoking". This program involve a large amount of work of physicians providing patient-centered counseling, and may be considered as the focus of the study.

Intervention

Each telephone counseling was followed by one supportive letter, so it should be kept in mind when there were significant effects in the intervention arm over the control arm.

Outcomes

The authors did not conduct an independent statistical analysis of the sole effect of telephone counseling, comparing the two arms in the "counseling plus NCG" group, but based on the data (15.4% vs. 18.3%), they claimed that the provision of follow-up counseling by ancillary staff did not independently contribute to cessation.

Appendix 4

Quality Assessment Checklist

Items	Quality				
	Simon	Solomon	Reid	Lando	Ockene
Randomization					
Was the study described as randomized?	Yes	Yes	Yes	Yes	Yes
Did the authors describe how the randomisation sequence was generated?	Yes	No	Yes	Yes	No
Was this generation of allocation sequences adequate?	Yes	Unclear	Yes	Yes	Unclear
Was there an adequate concealment of allocation sequences?	Unclear	Unclear	Unclear	Unclear	No
Were these groups comparable in terms of prognostic factors at baseline?	Yes	Yes	Yes	Yes	Unclear
Inclusion and exclusion criteria					
Were the inclusion criteria specified?	Yes	Yes	Yes	Yes	Yes
Were the exclusion criteria specified?	Yes	Yes	Yes	Yes	Yes
Study Power					
Was the study power adequate?	Unclear	Unclear	Yes	Yes	Unclear
Intervention and control					
Was the intervention protocol being clearly described?	Yes※	Yes	Yes	Yes	Yes※
Was the comparison protocol being clearly described?	Yes※	Yes	Yes	Yes	Yes※
Was there equal provision of care apart from treatment under evaluation	Yes	Yes	Yes	Yes	Yes
Outcome assessment					
Were there clear outcome definitions?	Yes	Yes	Yes	Yes	Yes
Was the outcome assessors blinded?	Unclear	Unclear	Unclear	No	Unclear
Was self-reported outcome validated by biological method?	Yes	Yes	Yes	Yes	No
Were the point estimates and measure of variability presented for the primary outcome measure	Yes	Yes	Yes	No	No
Were withdrawals and dropouts being described?	Yes	No	Yes	No	No
Did the analysis include an intention-to-treat analysis?	Yes	Yes*	Yes	Yes	Yes

* Not consistent throughout the study

※ The does of nicotine patch/gum was not specified.