

A combined cessation intervention with brief advice, nicotine replacement therapy sampling and active referral (BANSAR) for smoking fathers: a multicenter, single-blinded, pragmatic randomised controlled trial

Principal applicant

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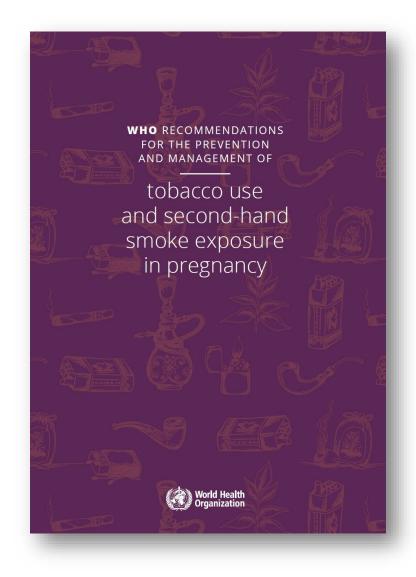
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Introduction

- Pregnant non-smokers exposed to secondhand smoke had higher risk of adverse perinatal outcomes, including stillbirth, congenital anomaly and developmental delay
- Pregnancy is a teachable moment to engage expectant fathers in smoking cessation, but evidence from randomised controlled trials were limited
- The World Health Organization¹ strongly recommend and calls for more research on how to help expectant fathers quit smoking to protect their partners from secondhand smoke exposure





¹ World Health Organization. (2013). WHO recommendations for the prevention and management of tobacco use and second-hand smoke exposure in pregnancy. World Health Organization. <u>https://apps.who.int/iris/handle/10665/94555</u>

Hong Kong



- In Hong Kong, 3 out of 10 partners of mothers with a new born were smokers²
- Most expectant fathers accompany their partners for prenatal visit at least once, but those who smoke rarely receive any cessation support from the clinicians
- Study objective:
 - To test the effectiveness of a brief intervention combining 3 simple strategies
 (Brief Advice, Nicotine replacement therapy (NRT) Sampling and Active
 Referral) in promoting smoking cessation in expectant fathers who smoke

Methods

- **Design:** Pragmatic, multicentre randomised controlled trial
- Settings: Prenatal clinics in 7 public hospitals in Hong Kong
 - Kwong Wah Hospital
 - Queen Elizabeth Hospital
 - Queen Mary Hospital
 - United Christian Hospital
 - Tuen Mun Hospital
 - Pamela Youde Nethersole Eastern Hospita
 - Princess Margaret Hospital

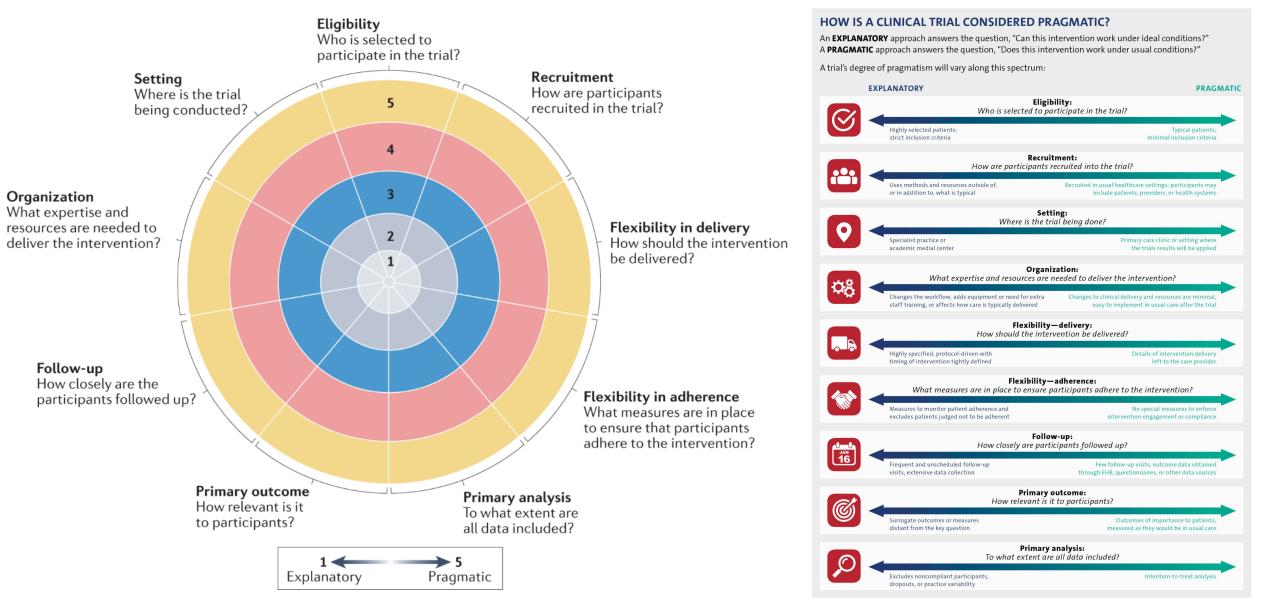
Luk TT, Hsieh CJ, Leung WC, Leung KY, Cheung KW, Kwa C, Siong KH, Tang KK, Lee KW, Li WHC, Lam TH, Wang MP. Brief cessation advice, nicotine replacement therapy sampling and active referral (BANSAR) for smoking expectant fathers: study protocol for a multicentre, pragmatic randomised controlled trial. Contemp Clin Trials. 2020; 93: 106006.





Pragmatic trial design









- Male daily cigarette smokers whose partners were pregnant and non-smokers
- Both expectant fathers and mothers were Hong Kong residents aged 18+ years and living together in the past 7 days, and able to communicate in Cantonese or Mandarin
- Participants were randomised 1:1 to the intervention group or control group

Intervention group



- Three components of the intervention
 - 1. Brief advice to quit smoking (AWARD model)
 - <u>Ask about the smoking status</u>
 - Warn about the health risk of perinatal tobacco smoking exposure
 - Advice to quit as soon as possible
 - Refer: active referral to SC services (point 3 below)
 - <u>D</u>o-it-again: telephone boosters x 2 within the first month
 - 2. Nicotine replacement therapy (NRT) sampling
 - 3. Active referral to SC service

Intervention leaflet



Health warning leaflet with information on local cessation services

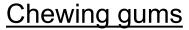


1-week free NRT sample



- 1-week free NRT sample with an instruction card
 - Dosage based on cigarettes per day









如何使用戒煙香回膠。尼古丁補充癔法

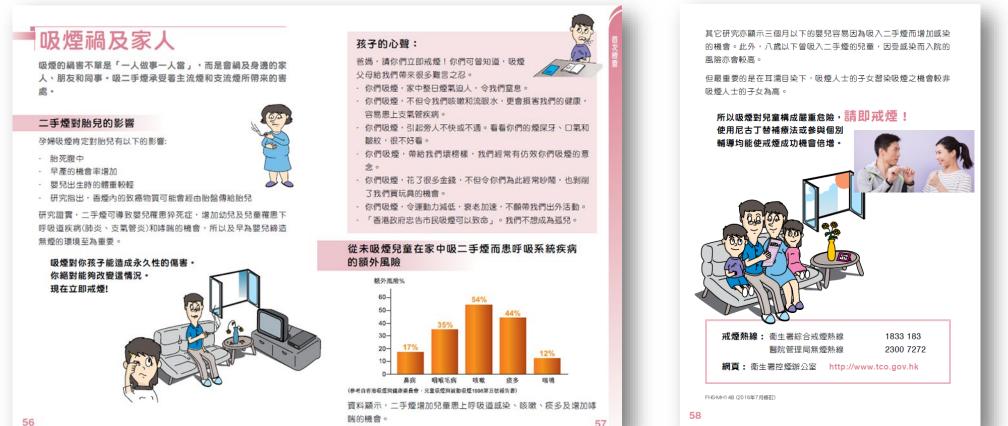
戒煙貼片需要時使用/約每小時使用一粒 每日最多使用粒
使用戒煙香口膠期間必須停止吸煙 [,] 以免導致過量尼古丁吸收及加劇身體對尼古丁的需求。
<mark>· 建議用法:</mark> ····································
1.慢慢咀嚼10-15次。
2.將香口膠置於面頰與牙肉之間1-2分鐘讓尼古丁吸收。
3.重複以上的步驟直至香口膠全無味道為止或咀嚼30分鐘。
4.咀嚼香口膠時或使用前15分鐘,應避免飲食,
尤其避免酸性飲品,如汽水、咖啡、果汁。
一般注意事項: 如何使用戒度者口题
- 可能有喉嚨痛、打嗝。
- 不適合有牙散疾患、口腔炎、喉炎、容易胃痛及配戴可拆除假牙的人士。 (如本)
對尼古丁替代療法有任何疑問或諮詢,請聯絡:
戒煙輔導護士 電話:5368 5893 🕑 🍋 📰 School of NURSING Control Notice Tell Windows The School of NURSING Tell Windows Tell Windows Tell Windows Tell Windows Context Tell Windows Conte

Control group



Control group only receive advice to guit smoking and a standard leaflet by the

Department of Health on the hazards of perinatal tobacco smoke exposure



Outcomes

- Primary outcome:
 - Biochemical validated tobacco abstinence at 6 months postrandomisation
 - Verified by an exhaled carbon monoxide test <4 ppm
- Secondary outcomes:
 - Self-reported 24-week continuous abstinence at 6 months
 - Self-reported 7-day point-prevalent abstinence
 - Quit attempt, use of NRT, use of cessation service





Sample size calculation



• Intervention effect was based on previous RCT on active referral for

smoking cessation³

- 6-month biochemical validated abstinence in the control group: 5%
- Effect size = 1.85
- Allocation ratio 1:1, 80% Power, 2-sided 5% level of significance
- Total participants needed: 1148 (574 per group)

³ Wang MP, Suen YN, Li WH, Lam CO, Wu SY, Kwong AC, Lai VW, Chan SS, Lam TH. Intervention With Brief Cessation Advice Plus Active Referral for Proactively Recruited Community Smokers: A Pragmatic Cluster Randomized Clinical Trial. JAMA Intern Med. 2017;177(12):1790-1797. doi:10.1001/jamainternmed.2017.5793.

Statistical analyses



- Main analyses:
 - Intention-to-treat
 - Participants with missing outcome were assumed to be continuing smokers
- Sensitivity analyses
 - Multivariable analyses to adjust for baseline prognostic factors
 - Multiple imputation
 - Complete case analyses

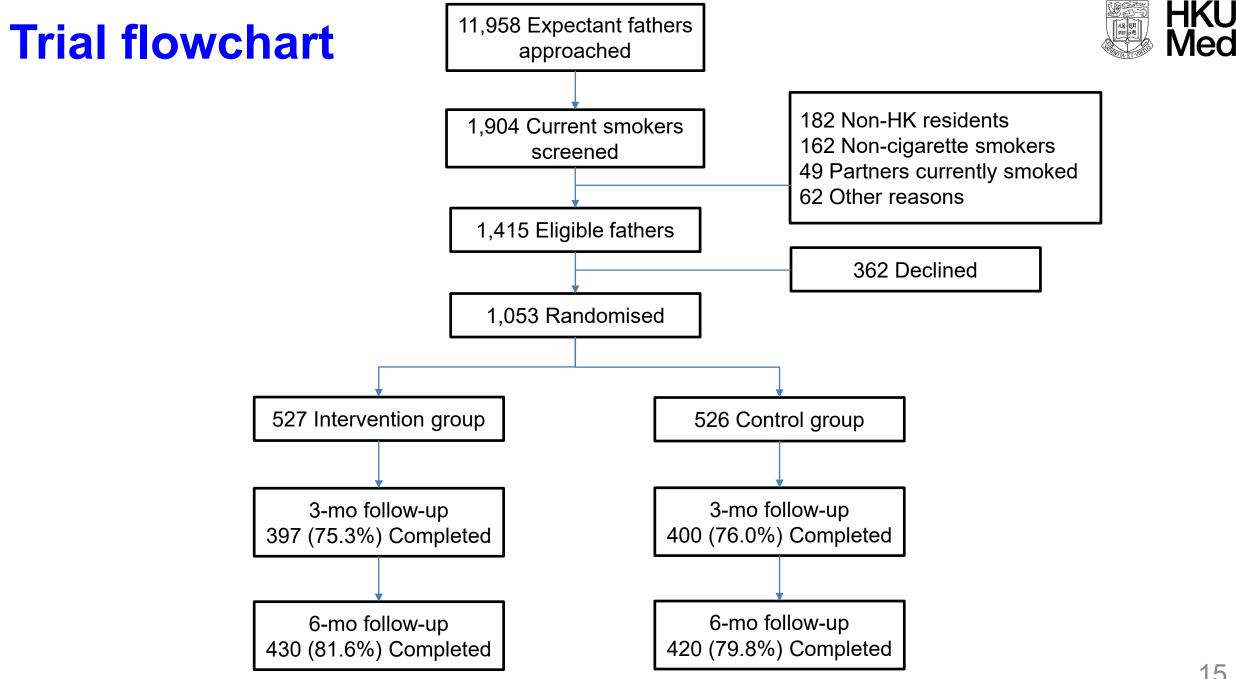




- Recruitment period: Oct 2018 to Feb 2020
- Recruitment suspended in Feb 2020 because of COVID-19
 - Participants enrolled = 1053 (91.7% of the target sample size)
- An independent data monitoring committee concluded that the trial can be

terminated early for efficacy in Sept 2020

– HMRF approved the trial termination in Oct 2020



Baseline characteristics



	Intervention group	Control group
Characteristic	(n = 527)	(n = 526)
Age group, y		
18-25	59 (11.3)	42 (8.1)
26-35	272 (51.8)	280 (53.7)
36-45	168 (32.0)	183 (35.1)
46-55	25 (4.8)	16 (3.0)
56-65	1 (0.2)	0
Educational level		
≤Junior secondary	155 (30.3)	156 (30.5)
Senior secondary	243 (47.5)	224 (43.8)
Tertiary	114 (22.3)	132 (25.8)
Daily cigarette consumption		
Median (IQR), No.	10 (5-15)	10 (5-15)
1-10	365 (69.3)	362 (68.8)
11-20	153 (29.0)	158 (30.0)
≥21	9 (1.7)	6 (1.1)
Time to first cigarette of the day, min		
<5	141 (26.8)	122 (23.2)
5-30	72 (13.7)	88 (16.7)
31-60	77 (14.6)	76 (14.4)
>60	237(45.0)	240 (45.6)

Heaviness of smoking index ^b		
Median (IQR)	1 (0-3)	1 (0-3)
Light: 0-2	355 (67.4)	370 (70.3)
Moderate: 3-4	165 (31.3)	150 (28.5)
Heavy: 5-6	7 (1.3)	6 (1.1)
Exhaled carbon monoxide level, median (IQR), ppm	14 (8-23)	14 (8-22)
Previous quit attempt		
Never	206 (39.1)	198 (37.7)
>12 mo	260 (49.3)	283 (53.9)
Within 12 mo	61 (11.6)	44 (8.4)
Readiness to quit		
Undecided	403 (76.5)	397 (75.5)
Within 60 d	21 (4.0)	19 (3.6)
Within 30 d	47 (8.9)	50 (9.5)
Within 7 d	56 (10.6)	60 (11.4)
Perception of quitting, median (IQR) ^c		
Importance	9 (7-10)	8 (7-10)
Difficulty	8 (5-10)	8 (5-10)
Confidence	5 (5-8)	5 (5-8)
Use of heated tobacco products		
Never	300 (57.0)	291 (55.4)
Just tried	187 (35.6)	192 (36.6)
Current: past 30 d	39 (7.4)	42 (8.0)

First	108 (21.1)	105 (20.5)
Second	290 (56.8)	288 (56.3)
Third	113 (22.1)	119 (23.2)
Smoking status of the expectant mother		
Never	272 (52.1)	308 (59.5)
Just tried	73 (14.0)	62 (12.0)
Quit		
Before pregnancy	48 (9.2)	45 (8.7)
After pregnancy	129 (24.7)	103 (19.9)
Living with another smoker		
No	411 (79.5)	406 (78.7)
Yes	106 (20.5)	110 (21.3)

Abbreviations: IQR, interquartile range; ppm, parts per million.

^a Sample sizes varied because of missing data on some variables.

^b Scores ranged from 0 to 6, with higher scores indicating greater cigarette dependence.

^c Scores ranged from 0 to 10, with higher scores indicating greater importance, difficulty, or confidence.

Higher rates of quitting in intervention group

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	No. (%)			
Outcome	Intervention group (n = 527)	Control group (n = 526)	OR (95% CI)	P value
Primary outcome				
Biochemically validated abstinence at 6 mo after intervention initiation	36 (6.8)	19 (3.6)	1.96 (1.11-3.46)	.02
Secondary outcomes				
Self-reported 24-wk continuous abstinence at 6 mo after intervention initiation	38 (7.2)	21 (4.0)	1.87 (1.08-3.23)	.03
Self-reported 7-d PPA				
3 mo After intervention initiation	91 (17.3)	65 (12.4)	1.48 (1.05-2.09)	.03
6 mo After intervention initiation	139 (26.4)	90 (17.1)	1.74 (1.29-2.34)	<.001
24-h Quit attempt				
3 mo After intervention initiation	213 (40.4)	171 (32.5)	1.41 (1.08-1.80)	.008
6 mo, Cumulative	314 (59.6)	259 (49.2)	1.52 (1.19-1.94)	<.001
Use of NRT				
3 mo After intervention initiation	150 (28.5)	9 (1.7)	22.6 (11.4-45.0)	<.001
6 mo, Cumulative	184 (34.9)	10 (1.9)	27.7 (14.4-53.1)	<.001
Use of smoking cessation service				
3 mo After intervention initiation	15 (2.8)	7 (1.3)	2.17 (0.88-5.37)	.09
6 mo, Cumulative	25 (4.7)	15 (2.9)	1.70 (0.88-3.26)	.11

Abbreviations: NRT, nicotine replacement therapy; OR, odds ratio; PPA, point prevalence abstinence.

Planned sensitivity and subgroup analyses



- Results from GEE model, multivariable models, multiply-imputed data analyses and complete case analyses were consistent with that of main analyses
- Results were similar across participants of different characteristics
 - Cigarette dependence
 - Readiness to quit
 - Previous quit attempt
 - Stage of pregnancy
 - Presence of other smokers at home
 - Ever smoking status of the pregnant women

Better outcomes in continuing smokers of intervention group

	No./total No. (%)		
Outcome	Intervention group	Control group	P value ^b
Smoking reduction			
3 mo Follow-up	95/436 (21.8)	83/461 (18.0)	.16
6 mo Follow-up	97/388 (25.0)	103/436 (23.6)	.65
Change in heaviness of smoking index, mean (SD) ^c			
3 mo Follow-up	-0.38 (1.2)	-0.28 (1.1)	.26
6 mo Follow-up	-0.37 (1.0)	-0.15 (1.1)	.003
Change in readiness to quit, mean (SD) ^d			
3 mo Follow-up	-0.11 (1.0)	-0.09 (0.9)	.82
6 mo Follow-up	-0.06 (1.1)	-0.12 (1.0)	.46

^a The denominators in both intervention and control groups included only participants who continued to smoke during follow-up periods and hence were not representative of all randomized participants.

^b *P* value of χ^2 test or 2-sample *t* test.

^c Mean change from baseline to follow-up periods. Scores ranged from 0 to 6, with higher scores indicating greater cigarette dependence.

^d Mean change from baseline to follow-up periods. Scores ranged from 0 to 3, with higher scores indicating greater readiness to quit.

Higher satisfaction levels on the intervention



Rating	Intervention group	Control group	P value ^a
Perceived appropriateness of brief advice ^b			
No. of participants	356	345	
Mean (SD) score	4.2 (0.8)	4.1 (0.9)	.11
Median (IQR) score	4 (4-5)	4 (4-5)	.22
Perceived helpfulness of brief advice ^b			
No. of participants	355	350	
Mean (SD) score	3.4 (1.0)	3.4 (1.0)	.97
Median (IQR) score	4 (3-4)	4 (3-4)	.74
Perceived helpfulness of leaflet ^b			
Read the leaflet, No./total No. (%)	241/356 (67.7)	238/343 (69.4)	.63
Mean (SD) score	2.6 (1.1)	2.7 (1.1)	.72
Median (IQR) score	3 (2-4)	3 (2-4)	.74
Intervention satisfaction ^c			
No. of participants	346	311	
Mean (SD) score	6.3 (2.2)	5.7 (2.6)	.004
Median (IQR) score	7 (5-8)	6 (5-7)	.01

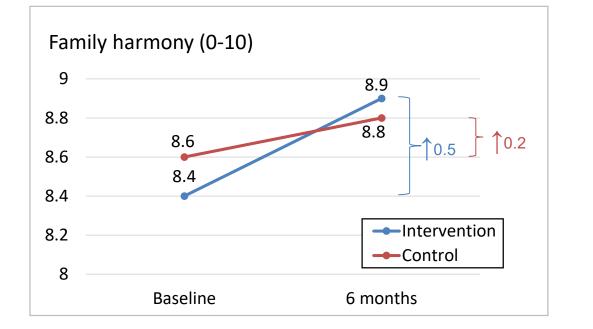
Abbreviation: IQR, interquartile range.

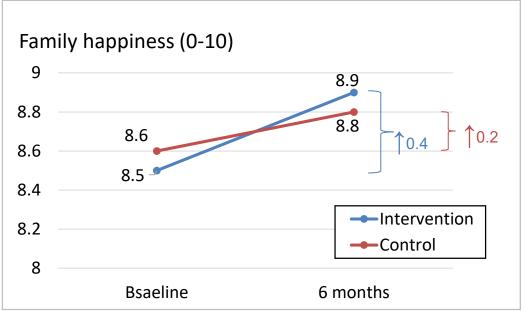
^a *P* value of 2-sample *t* test or Wilcoxon rank-sum test.

^c Scores ranged from 0 to 10, with higher scores indicating greater satisfaction.

^b Scores ranged from 1 (not appropriate/helpful at all) to 5 (very appropriate/helpful).

Improved perceived family relationship





	Mean (SE)				
	Intervention (N=527)	Control (N=526)	Unstandardized, B (95% CI)ª	P value	
Perceived family	/ harmony ^b			•	
Baseline	8.43 (0.07)	8.57 (0.07)			
6 months	8.95 (0.06)	8.80 (0.07)	0.28 (0.063 to 0.50)	.01	
Perceived family	/ happiness ^b				
Baseline	8.53 (0.06)	8.64 (0.06)			
6 months	8.87 (0.06)	8.80 (0.06)	0.17 (-0.041 to 0.38)	.12	

^a Coefficient for the time × group interaction, which denotes the difference in change in perceived family harmony/ happiness from baseline to 6 months (intervention vs control)

^b Scores ranged from 0 to 10, with higher scores indicating better perceived family harmony/ happiness



Discussion

- Providing brief advice, 1-week NRT sampling and active referral can nearly double the quit rate when compared with brief advice alone in expectant fathers who smoke
- The real-world intervention effect is likely larger since expectant fathers typically do not receive any cessation support in usual practice in HK, but the control group at least receive brief advice
- The increase in family harmony refuted previous concern that communicating the risk of perinatal tobacco smoke exposure could fuel conflicts between the expectant father and mother

Implications



- Failure to engage expectant father in smoking cessation is a missed opportunity to promote smoking cessation and reduce secondhand smoke exposure
- A unique opportunity to help expectant fathers quit smoking when they are still relatively young and healthy, a period in which they are less likely to consult a doctor and to benefit from opportunistic cessation intervention in primary care
 - Smoking cessation by the age of 40 years could avert the risk of smoking-related death by nearly 90%, compared with continued smoking⁴
- Providing brief cessation intervention to expectant fathers should be a part of routine practice in prenatal care

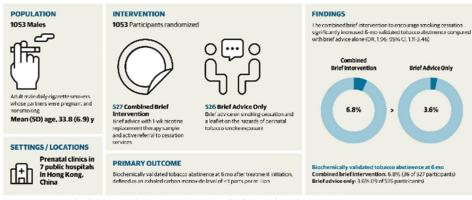
Full trial results

Citation:

Luk TT, Lam TH, Leung WC, Leung KY, Cheung KW, Kwa C, Siong KH, Tang KK, Lee KW, Hsieh CJ, Wu YS, Li WH, Wang MP. Brief Advice, Nicotine Replacement Therapy Sampling, and Active Referral for Expectant Fathers Who Smoke Cigarettes: A Randomized Clinical Trial. JAMA Internal Medicine 2021;181(8):1081-1089. doi: 10.1001/jamainternmed.2021.2757

JAMA Internal Medicine

RCT: Brief Advice, Nicotine Replacement Therapy Sampling, and Active Referral for Expectant Fathers Who Smoke Cigarettes



Luk TT, Lam TP. Leang WC, et al. Brief advice, nicotine replacement therapy sampling, and active referral for expectant fathers who smoke cigarettes: a randomized clinical trial. JAKA letere JASI. Published online June 14, 2021. doi:10.1001/jamainternmed.2021.252 Research

JAMA Internal Medicine | Original Investigation

Brief Advice, Nicotine Replacement Therapy Sampling, and Active Referral for Expectant Fathers Who Smoke Cigarettes A Randomized Clinical Trial

Tzu Tsun Luk, PhD; Tai Hing Lam, MD(HK); Wing Cheong Leung, MD(HK); Kwok-Yin Leung, MD(HK); Ka Wang Cheung, MBBS; Carina Kwa, MBChB; Kar-Hung Siong, MBBS; Kwok-Keung Tang, MBChB; Kai-Wan Lee, MBBS; Chi Ju Hsieh, MSc; Yongda Socrates Wu, PhD; William Ho-Cheung Li, PhD; Man Ping Wang, PhD

IMPORTANCE Pregnancy presents an opportunity to engage expectant fathers in smoking cessation, but evidence from randomized clinical trials is scarce.

OBJECTIVE To evaluate the effectiveness of a proactive, combined intervention for smoking cessation in expectant fathers.

DESIGN, SETTING, AND PARTICIPANTS This pragmatic randomized clinical trial in prenatal clinics in 7 public hospitals in Hong Kong proactively recruited and enrolled 1053 participants from October 10, 2018, to February 8, 2020. Included male adults were 18 years or older, smoked cigarettes daily in the past 3 months, had partners who were pregnant and nonsmoking in the past 30 days, and had a landline or mobile telephone number for follow-up. These participants were randomized to either the intervention group or the control group. The primary analyses used an intention-to-treat approach.

INTERVENTIONS The intervention group received brief cessation advice, a 1-week free sample of nicotine replacement therapy (NRT), and active referral to a community-based smoking cessation service. The control group received only brief cessation advice with a leaflet on the hazards of perinatal exposure to tobacco smoke and the toll-free quitine telephone number.

MAIN OUTCOMES AND MEASURES The primary outcome was biochemically validated tobacco abstinence at 6 months after intervention initiation defined by an exhaled carbon monoxide level of 3 parts per million or lower. The secondary outcomes included self-reported 24-week continuous abstinence at 6 months after intervention initiation as well as 7-day point prevalence abstinence, use of any NRT, and use of a smoking cessation service at 3 and 6 months after intervention initiation.

RESULTS All 1053 randomized participants were male adults with a mean (SD) age of 33.8 (6.9) years. The retention rate at 6-month follow-up was 80.7%. The primary outcome of biochemically validated tobacco abstinence at 6 months after intervention initiation was significantly higher in the intervention group than in the control group (6.8% [36 of 527 participants] vs 3.6% [19 of 526]; odds ratio [OR], 1.96; 95% CI, 1.11-3.46; *P* = .02). The main secondary outcomes of self-reported 24-week continuous abstinence at 6 months (OR, 1.87; 95% CI, 1.08-3.23; *P* = .03) and 7-day point prevalence abstinence at 3 months (OR, 1.48; 95% CI, 1.02-3.24; *P* < .001) were also significantly higher in the intervention group. The intervention group had a significantly higher increase in perceived family harmony (score range, 0-10, with a higher score indicating a higher level of harmony) from baseline to 6 months (B = 0.28; 95% CI, 0.063-0.50; *P* = .01).

CONCLUSIONS AND RELEVANCE This trial found that combining brief advice with a 1-week sample of NRT and referral to smoking cessation programs nearly doubled the odds that expectant fathers who smoked would achieve validated abstinence compared with providing brief advice alone. The intervention was also effective in promoting family harmony.

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TRIAL REGISTRATION Clinical Trials.gov Identifier: NCT03671707

JAMA Intern Med. 2021;181(8):1081-1089. doi:10.1001/jamainternmed.2021.2757 Published online June 14, 2021.

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Visual Abstract

Supplemental content

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<mark>NEJM</mark> Journal Watch

SUMMARY AND COMMENT | GENERAL MEDICINEPSYCHIATRY

INFORMING PRACTICE

July 13, 2021

Simple and Effective Multimodal Smoking-Cessation Intervention for Expectant Fathers

Paul S. Mueller, MD, MPH, FACP, reviewing Luk TT et al. JAMA Intern Med 2021 Jun 14

Brief cessation advice plus free nicotine-replacement products helped some men quit smoking.

News From the JAMA Network

August 3, 2021

Simple Intervention Motivates Expectant Fathers to Quit Smoking

Anita Slomski

JAMA. 2021;326(5):378. doi:10.1001/jama.2021.12117



Evidence-Based Cancer Control Programs (EBCCP)

Home Search for Programs∨ Program Areas∨ Case Studies Program Submission Process∨ Help & Resources∨ About∨

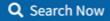
Search All EBCCP

Second Se

- · A new program has been posted: Enhance*Fitness
- A new case study has been added: The Witness Project in Rochester

Transforming Research into Community and Clinical Practice

The **EBCCP** (formerly RTIPs) website is a searchable database of evidence-based cancer control programs and is designed to provide program planners and public health practitioners easy and immediate access to program materials.



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Informed Decision Making	Obesity	Physical Activity	Prostate Cancer Screening	Public Health Genomics	Sun Safety
		Survivorship / Supportive Care	Tobacco Control		

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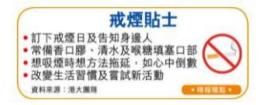
HKU Med HKUMed finds simple intervention effective in helping fathers-to-be quit smoking



領導和統籌是次研究的港大醫學院護理學院副教授王文炳博士(左)及助理教授(研究)陸子璡博士(左)



▲港大團隊建議將措施引入產檢,並籲醫護主動識別準爸爸煙民。左為陸子璡,右為王文炳。(冼偉倫攝)





▲ 港大醫學院一項研究發現, 在產檢時為吸煙的準爸爸提供簡單的戒煙介入, 可增戒煙成功率近9成。(冼偉倫攝)

孕婦吸入二手煙或會增加胎兒胎死腹中、孩子發展遲緩等健康風險。港大醫學院一項研究發現,在產檢時為吸煙的 準爸爸提供簡單介入,包括戒煙建議、轉介戒煙服務等,可以將戒煙成功率增加近9成;另可增加家庭的和諧度及 家庭快樂指數。團隊期望將有關方法納入為產前護理的恆常程序,以幫助準爸爸戒煙。





介入小組會為準爸爸提供簡短戒煙建議、一周分量的尼古丁替代療法樣本,亦會轉介他們 至本地戒煙服務。



港大醫學院研究發現,為吸煙準爸爸提供戒煙介入(如戒煙建議及輔助藥物),成功戒煙 率能增9成。

港大團隊研究 盼納恒常程序

該學院助理教授(研究)陸子雖指,新生兒的出 現是一個黃金機會讓準爸爸戒煙,亦是對小朋友最 好的第一份禮物。他又引述研究指,若 40 歲或以前 戒煙,將來患上與煙草有關的疾病風險可減近 9 成。 團隊期望可將簡單戒煙介入納入產前護理的恒 常程序,並期望尋找更多研究資金,為成功戒煙者 在小朋友出世後 3 年後作隨訪。 61



近9成。 (洗偉倫攝) 單的戒煙介入,可增戒煙成功率 在產檢時為吸煙的準爸爸提供師

HA PRCC in Advanced Gynaecological Nursing









Lifestyle issues: Reducing smoking and secondhand

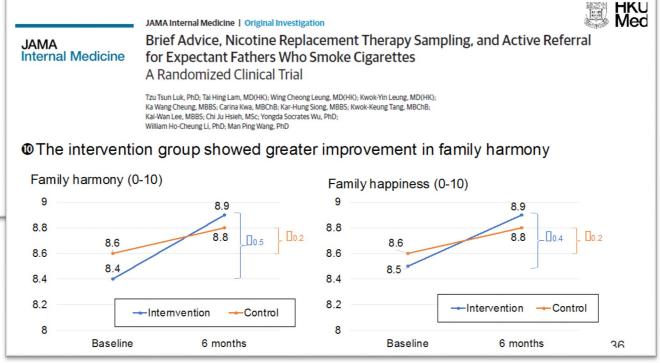
smoke exposure in women

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PRCC in Advanced Gynaecological Nursing 15 June 2022



Community-based smoking cessation program (CSCP)

- Goals
 - To investigate new models of smoking cessation (SC) intervention
 - To improve the effectiveness and coverage of SC services
- Key parts
 - Proactive approach smokers for delivering opportunistic interventions
 - Develop brief effective SC advices
 - Integrate effective components of SC services
 - Information communication technologies (ICTs) for personalized behavioral support





THANK YOU !



Acknowledgement

Health and Medical Research Fund

Pregnant women and smoking partners

Clinical collaborators

- Dr Leung Wing-cheong
- Dr Leung Kwok-yin
- Dr Cheung Ka Wang
- Dr Kwa Carina
- Dr Siong Kar-hung
- Dr Tang Kwok-keung
- Dr Lee Kai-Wan

HKU Smoking Cessation Research Team

HKU LKS Faculty of Medicine Outstanding Research Output 2022

