RESEARCH COMMUNICATION

Primary Tobacco Prevention in China - A Systematic Review

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Abstract

Objectives: This systematic review of randomized controlled trials aims to identify and describe primary tobacco prevention programs conducted in China and to evaluate their quality and effectiveness. Methods: Published studies in English or Chinese were searched in MEDLINE, EMBASE, GLOBAL HEALTH, PsycINFO, Wanfang and CNKI. Eligible studies were randomized controlled trials tailored for a Chinese population. Primary preventive non-pharmacological interventions for smoking cessation or reduction were evaluated. Trials were included if they applied at least one predefined outcome suited for measuring the reduction of smoking rates or the reduction of smoking related morbidity. Two reviewers independently assessed studies for inclusion. The risk of bias in individual studies was evaluated by determining the adequacy of methodological quality criteria. Results: A total of 21 eligible studies investigating 53,520 patients (range 88 – 30,544) an age between 9.6 and 65 years were identified. All interventions were based on some kind of health education programs. In most cases standard health advice was given and booklets were distributed. The overall methodological quality of the studies was low. Seven studies (33%) showed a statistical significant effect of the described intervention in all predefined outcomes. Conclusion: The documentation of smoking prevention interventions in China is not sufficient to develop effective and reliable action programs. A lack of quality in the design can be discerned rather than a lack in starting interventions. We therefore recommend future interventions to be planned, implemented and conducted in compliance with high quality standards for example Guideline for Good Clinical Practice. Furthermore for preparing reports of RCT findings we recommend the Consolidated Standards of Reporting Trials.

Keywords: Systematic review - tobacco prevention - China - RCT

Asian Pacific J Cancer Prev, **12**, 2973-2980

Introduction

Tobacco use is one of the major threats to public health in China. It can be assumed that cigarette smoking is responsible for 7.9 percent of the total premature mortality in China (He et al., 2005). According to WHO, current tobacco smoking prevalence is at 57.4% among Chinese men and 2.6% among women (World Health Organization, 2011). Thus, with 31.4% overall prevalence of current tobacco smoking, China is among the countries with the highest tobacco consumption in the world. Beyond prevalence rates for adults, tobacco use among young people is becoming a severe problem in China. The average age of onset of smoking is decreasing and the Global Youth Tobacco Survey revealed that 9% to 17% of 13-15 year-old students in China smoke (Global Youth Tobacco Survey Collaborative Group, 2002; Johnson et al., 2006). Smoking prevalence among Chinese youths differs widely between 8% past-month smoking among academic high school students and 26% among vocational high school students (Johnson et al., 2006).

It is known that tobacco use is one of the greatest risk factors for non-communicable diseases especially cardiovascular disease, lung cancer, and other kinds of lung diseases such as COPD (Barnes et al., 2000; Benowitz et al., 2003). The high smoking prevalence in China is reflected in a high incidence rate in lung cancer (GLOBOCAN IARC, 2008). Incidence of lung cancer among men living in China amounts to 45.9 per 100,000 persons and 21.3 per 100,000 among women. The estimated lung cancer mortality is 39.6 per 100,000 men and 18.3 per 100,000 women (GLOBOCAN IARC, 2008). However, the incidence of tobacco use among Chinese women is increasing. Morbidity and mortality due to tobacco consumption will play a major role in the female part of the population in the future (Ho et al., 2010).

Tobacco consumption is a modifiable behavioral risk factor, which should be targeted by primary prevention strategies (Asaria et al., 2007). Nevertheless, the current state of art in tobacco prevention in China falls short of the WHO Framework Convention on Tobacco Control which was signed by China in 2003 (Zhang et al., 2011b). Given the high prevalence rate of tobacco consumption in China and the increasing incidence of lung cancer, further implementation of public health strategies is an important requirement to reduce morbidity and premature mortality in China (Yoo et al., 2010). However, according to limited resources, prevention strategies need to be

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tailored and based on the principles of evidence based health promotion.

This systematic review of randomized controlled trials aims to identify and describe primary tobacco prevention programs conducted in the Chinese population. Additionally, we evaluate the quality and effectiveness of the reported preventive interventions to gain best level evidence on whether or not the interventions showed reliable and generalizable results.

Materials and Methods

Search strategy and study selection

We searched for randomized controlled trials of tobacco prevention programs conducted in China in MEDLINE, EMBASE, GLOBAL HEALTH, PsycINFO, and the Chinese medical databases Wanfang (http://so.med.wanfangdata.com.cn/) and CNKI (www.cnki.net). The search was limited to years of publication starting in 2000. There was no limitation in terms of publication status or language. The search includes findings up to March 2011. We used combinations of the following search terms: 'prevention', 'health promotion', 'community health services', 'health education', 'smoking', 'smoking cessation', 'tobacco', and 'China'. We also searched reference lists of included meta-analyses and websites.

Study selection and eligibility criteria

Titles and abstracts of identified studies were screened independently by two authors (MSG and AMP) to determine whether they meet the inclusion criteria. Disagreements were resolved by a third reviewer (AG). Chinese databases were screened by one person (MZ). Obscurities regarding the publications found in Chinese databases were resolved by discussion groups. Studies that seemed to meet the inclusion criteria were included in the full text screening. Studies were eligible for inclusion in the systematic review if they: 1) dealt with non-pharmacological primary preventive interventions for smoking cessation or reduction in the Chinese population; 2) chose randomised controlled trials as required study design; and 3) at least compared one predefined outcome suited for measuring the reduction of smoking rates or the reduction of smoking related morbidity.

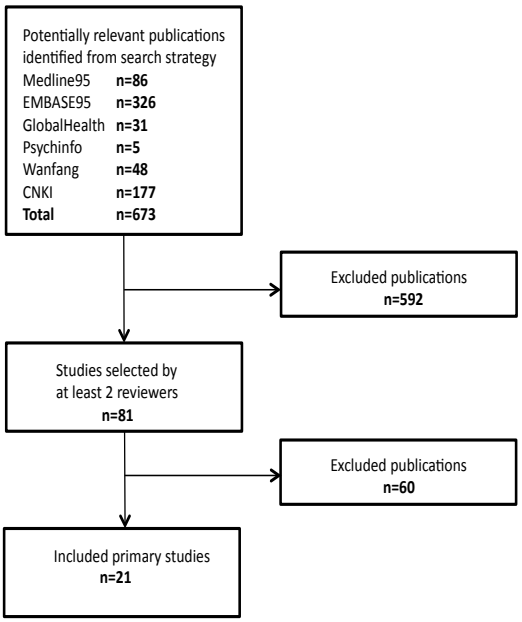

Figure 1. Potentially Relevant Publications Identified from Search Strategy

Data extraction and quality assessment

One reviewer (MSG) extracted data from the selected studies. Another reviewer (AMP) controlled the data extraction. Data extraction for studies only available in Chinese language was conducted by one reviewer (MZ) and data extraction was discussed in group sessions afterwards. Reviewers resolved disagreements about data extraction by consensus with a third reviewer (AG).

Details of the studies were extracted using standardized tables. Information was extracted from each included study on 1) interventions and settings, 2) age and gender of the study participants, 3) outcome measures, 4) length of follow-up and follow-up effect sizes, 5) duration of the intervention, 6) sample size, and 7) risk of bias.

The risk of bias in the selected studies was assessed by determining the adequacy of the following quality criteria developed by Institute for Quality and Efficiency in Health Care (IQWiG), Germany (Institute for Quality and Efficiency in Health Care, 2011): adequate sequence generation, allocation concealment, blinding of data collectors, analysis method (intention-to-treat versus per protocol analysis), freedom of selective reporting, description of drop-outs, predefinition of outcomes. The item validation of measurement instruments (questionnaires etc.) was added by us. IQWiG methodological quality criteria furthermore evaluated blinding of the participants allocation status to participants and all other involved professionals. Since blinding of allocation status is generally not feasible in prevention and health promotion interventions, we did not use this criterion for quality assessment in this study. The blinding of data collectors and evaluators, however, is feasible and eligible in evidence based public health as it is in evidence based medicine. But even blinding of allocation status is generally difficult to carry out in public health the studies still have a risk of bias in this item.

Data Analysis

According to their performance in each quality criteria, studies show 'low risk of bias' or 'high risk of bias'. A high risk of bias indicates that the main conclusion of the study may be flawed due to low quality standards. Due to large heterogeneity of interventions, settings and outcome measures, meta-analysis was neither feasible nor appropriate. For comparison, we present characteristics and effects from the different studies by tables.

Results

Study selection

The initial database search retrieved 673 publications. After title and abstract screening, 592 publications were excluded due to eligibility criteria violations. The process of identifying relevant publications is shown in Figure 1. Eighty-one publications were included in the full text

Table 1. Quality Assessment

Study	Random -ization[1]	Allocation[2]	Blinding[3]	Analysis[4]	Drop-outs described[5]	Selective reporting[6]	Outcome definition[7]	Validation[8]	Risk of bias
Abdullah et al., 2005	No	Yes	No	ITT	No	Unclear	Yes	Yes	Low
Chan et al., 2008	No	Yes	No	ITT	(no dropout)	Unclear	Yes	Unclear	High
Chou et al., 2006	Yes	No	No	PP	Yes	Unclear	Yes	Unclear	High
Cui et al., 2006	No	No	Unclear	PP	No	Unclear	Yes	Unclear	High
Guo et al., 2009	Yes	Yes	Unclear	PP	No	Unclear	Yes	Unclear	High
Jiang et al., 2003	No	No	Unclear	PP	No	Unclear	Yes	Unclear	High
Ji et al., 2001	No	No	Unclear	PP	No	Unclear	Yes	Unclear	High
Lin et al., 2010	No	Yes	Unclear	PP	No	Unclear	Yes	Unclear	High
Lin et al., 2008	No	No	Unclear	PP	No	Unclear	Yes	Unclear	High
Liu et al., 2011	No	No	Unclear	PP	No	Unclear	Yes	No	High
Liu et al., 2004	No	No	Unclear	PP	No	Unclear	Yes	Unclear	High
Loke et al., 2005	No	Yes	No	ITT	No	Unclear	Yes	Unclear	Low
Mei et al., 2008	No	No	Unclear	PP	No	Unclear	Yes	Unclear	High
Wang et al., 2008b	No	No	Unclear	PP	No	Unclear	Yes	Unclear	High
Wang 2008b	Yes	No	Unclear	PP	No	Unclear	Yes	Unclear	High
Wen et al., 2010	Yes	Yes	Yes	PP	No	Unclear	Yes	Yes	Low
Wen et al., 2007	No	No	Unclear	PP	No	Unclear	Yes	Unclear	High
Xie et al., 2005	No	No	Unclear	PP	No	Unclear	Yes	Unclear	High
Zheng et al., 2005	No	No	Unclear	PP	No	Unclear	Yes	Unclear	High
Zheng et al., 2006	No	No	Unclear	PP	No	Unclear	Yes	Yes	High
Zheng et al., 2007	Yes	Yes	No	ITT	Yes	Unclear	Yes	Unclear	Low

[1]Adequate sequence generation?; [2]Allocation concealment (random allocation of participants) described; [3]Blinding in data collectors described; [4]Analysis (intention to treat or per protocol); [5]Drop-outs described; [6]Free from selective reporting; [7]Outcomes are predefined; [8]Validation of measurement tools (questionnaires etc.); *PP, Per Protocol; ITT, Intention-To-Treat

screening. Twenty-two publications identified by database search met all inclusion criteria. The study of Yan Li-yan (2007) was not included in this systematic review because it did not report baseline data and data after intervention in detail. Therefore our analysis is based on 21 RCTs. The hand search did not result in additional inclusions.

Methodological quality of the included studies

The overall methodological quality of the studies varied broadly (see Table 1). Four studies showed a low risk of bias (Abdullah et al., 2005; Loke et al., 2005; Zheng et al., 2007; Wen et al., 2010). The remaining 17 studies showed major deficiencies. Several potential sources of bias could be identified: Validation of outcome measure instruments are missing in 18 studies. ITT-analysis was not applied in 17 studies. Description of randomization was not explained in 16 studies and allocation concealment was lacking in 14 studies. A description of drop-outs was reported in 2 of 21 studies.

Characteristics of the studies

Table 2 shows the main characteristics of the 21 studies considered. The studies included a total of 53,520 patients (range 88 – 30,544) with an age between 9.6 and 65 years. Follow-ups were conducted and described in six studies with a range from 4 to 24 months (average 10.6 months).

Varying outcome parameters were considered in the studies: smoking cessation, temporary abstinence rate, smoking prevalence rate, status of ever smoking, average change of daily consumption, knowledge, and attitude. All studies, except for two (Mei et al., 2008; Liu et al., 2004), analyzed two or more outcomes (average 2.7). Only one study (Wang et al., 2008b) used a clinical outcome, the incidence of postoperative vascular crisis.

Interventions

All interventions were based on some kind of health education programs. In most cases standard health advice was given and booklets were distributed. Comprehensive smoking interventions including materials, sessions conducted by education professionals and training courses were described in 11 studies. Twelve interventions used health promotion as an active method in the programs (Ji et al., 2001; Abdullah et al., 2005; Chou et al., 2006; Zheng et al., 2005; 2006; 2007; Wen et al., 2007; 2010; Lin et al., 2008; 2010; Mei et al., 2008; Liu et al., 2011a). All studies were based on behaviour oriented prevention and two studies additionally used structural prevention techniques (Xie et al., 2005; Guo et al., 2009).

In six studies children and adolescents were in the focus of the intervention (Liu et al., 2004; Zheng et al., 2005; 2006; Chou et al., 2006; Wen et al., 2007; 2010) and four studies focused on parents (Liu et al., 2004; Abdullah et al., 2005; Loke et al., 2005; Chan et al., 2008). Two of the studies with focus on parents used the non-smoking part of the parents to help the spouses to quit smoking (Loke et al., 2005; Chan et al., 2008).

Another four interventions were addressed to medical staff in health facilities (Cui et al., 2006; Mei et al., 2008; Wang, 2008a; Guo et al., 2009). Five interventions did not explicitly define a target group; they chose urban or local communities as settings (Jiang et al., 2003; Xie et al., 2005; Zheng et al., 2007; Lin et al., 2008; 2010;). One of the interventions was conducted at university (Ji et al., 2001), one in a restaurant (Liu et al., 2011a) and one for hand-surgical patients (Wang et al., 2008b).

Effects of interventions

Seven studies showed a statistical significant effect

Table 2. Study Characteristics

Author & Year	Intervention	Age	Outcome	Statistical significance	Statistical significance after follow-up	M	n (subjects/ control)
Abdullah et al., 2005	Help non-motivated smoking parents of young children in Hong Kong to cease smoking by: 1) 20-30 min of telephone counselling delivered by trained nurses; 2) 4 day training course on smoking cessation: included combination of lecture, problem based learning, practice and clinical attachment; 3) Hotline number was provided.	n/a	1) 7 day point prevalence smoking cessation rate 2) 24 h point prevalence quit rate at 6 months without validation, continuous quit rate at 6 months without validation and validated 7 day point prevalence quit rate.	1) p<0.001 2) Significantly positive for each measure (p value missing)	-[1]	6	485/467
Chan et al., 2008	Health education program delivered by non-smoking mothers to help fathers of sick children quit smoking in general pediatric wards of 4 hospitals in Hong Kong. 1) Information material; 2) 5-min. standardized health advice on SHS; 3) Health education booklet to protect children; 4) Telephone-interview; 5) Self-help booklet.	n/a	1) Smoking cessation of fathers 2) Cessation attempt in the past 3 months 3) ≥ 50% reduction in the number of cigarettes consumed	1) p=0.03 2) p=0.01 3) p<0.001	1) p=0.21 (12 months) 2) p=0.87 (12 months) 3) p=0.14 (12 months)	3	752/731
Chou et al., 2006	Establish social norms among male adolescents regarding smoking based on a smoking prevention curriculum in middle schools in urban district of Wuhan. 13 consecutive 45min-classroom lessons with one lesson each week.	7th grade 12.5 years	1) Status of ever smoking 2) Status of recent smoking at follow-up	1) no (p value missing) (f) 2) no (p value missing) (f) 1) p=0.01 (m) 2) no (p value missing) (m)	-[1]	12	599/607 (f) 598/650 (m)
Cui et al., 2006	Smoking prevention and control among medical workers in community health service centre.	40.6 (m) 40 (f)	1) Knowledge 2) Persuading patients to quit smoking 3) Smoking rate	1) p< 0.01 2) p>0.05	-[1]	12	158/143 (f) n/a (m)
Guo et al., 2009	Increase ability to control smoking of the medical staff in hospitals in Fangshan district by concluding contracts with the hospital and health education sessions.	n/a	1) Knowledge 2) Smoking rate	1) p< 0.01 2) p>0.05	-[1]	8	330/320 (f)
Jiang et al., 2003	Antismoking intervention including flyers and booklets, major mass media, school-based health education conducted in Beijing, Shanghai and Changsha. Community health education.	53.6 (m) 52.9 (f)	1) Smoking rate 2) Passive smoking 3) Cessation rate	1) p>0.05(m); p>0.05 (f) 2) p>0.05(m); p>0.05 (f) 3) p>0.05(m); p>0.05 (f)	-[1]	36	1396/ 1439 (f) 1204/ 1270 (m)
Ji et al., 2001	Heath education program in young people at the university.	n/a	1) Knowledge 2) Attitude 3) Smoking rate 4) Empowerment	1) p<0.01 2) p>0.05 3) p>0.05 4) p<0.05	-[1]	3	412/363
Lin et al., 2010	Psychological intervention on smoking cessation in communities. Health belief model based on psychological intervention and team training program	45 (m) 45 (f)	1) Cessation rate 2) Smoking-related knowledge	1) p<0.01 2) p<0.01	-[1]	6	3/4(f) 80/69 (m)

Lin et al., 2008	Health behaviour-based psychological intervention on tobacco control in communities based on team training program	44.7 (m) 45 (f)	1) Cessation rate 2) Average reduction in the number of cigarettes 3) Empowerment	1) p< 0.01 2) p< 0.01 3) p< 0.01	-[1]	6	100/100 n/a (m)
Liu et al., 2011	Increase knowledge on the status of tobacco control on food services in Qingdao as well as influencing the attitude and knowledge of stuff and provide basis for further intervention for tobacco control in public and workplace by health promotion.	n/a	1)Signs for smoking control 2)Smoking rate in restaurant 3)Smoking rate in service personnel	1) p<0.05 2) no (p value missing) 3) p<0.05	-[1]	n/a	134/ 142 (f) 106/ 140(m)
Liu et al., 2004	School-based health education in students to decrease adolescent smoking rate and to motivate parents to stop smoking (reduction of passive smoking).	n/a	1) Smoking rate (pupils/ parents)	1) n/a	-[1]	12	n/a
Loke et al., 2005	Standardized advice from obstetricians in Guangzhou to non-smoking pregnant women with the aim to help their husbands to give up smoking. Educational booklet on passive smoking, which described simple strategies for helping their husbands to stop smoking and health reminders during subsequent prenatal visits. Advice session took about 2–3 min, and each reminder took about 1,5 to 2 min.	21-43 years	1) Attempts to give up in the past 7 days 2) Change in the number of cigarettes smoked per day in the last month of the pregnancy 3) Giving up smoking completely in the past 7 days 4) Giving up totally for 1 month or longer	1) p=0.02 2) p<0.0001 3) p=0.04 4) p=0.26	2) p>0.05 (3-5 months)	9	380/378
Mei et al., 2008	Smoking behaviour intervention approaches among community hospital staff members including training sessions of smoking control skills and health promotion	> 20 (m) > 20 (f)	1) Smoking rate	1) p<0.05	-[1]	12	85/81 (f) 64/42 (m)
Wang et al., 2008b	Smoking-control intervention on hand-surgical patients' tobacco control compliance. Health education in the hospital.	15-65 (m) 14-65 (f)	1) Smoking rate 2) Incidence of postoperative vascular crises	1) p<0.01 2) p<0.05	-[1]	Hospital stay	3/2 (f) 42/41 (m)
Wang 2008a	Health education programs on smoking behaviour and smoking control in health personnel in hospitals.	34.6 (m) 35.3 (f)	1) Knowledge 2) Attitude 3) Behaviour (seven aspects)	1) p<0.001 2) 6 aspects (2 NS 3) One p=0.001 Six: no	-[1]	6	387/374 (f) 109/127 (m)
Wen et al., 2010	Different interventions to increase students' smoking-related knowledge in two cohorts in 18 junior high schools in Huangpu district. Intervention included: Self-education materials, health curriculum, peer education, promotion, international anti-smoking events, environmental interventions (e.g. no-smoking school policy)	7th and 8 grade	1) Knowledge 2) Attitude	Cohort I 1) p<0.001 2) p=0.878 Cohort II 1) p<0.001 2) p=0.132	Cohort I 1) p=0.034 2) p=0.113 Cohort II 1); 2) p>0.05 all (24 months)	11	541/318 (Cohort I) 626/357 (Cohort II)

Wen et al., 2007	Enhancing smoking prevention and control in adolescence by health promotion school model.	13.5 (m) 13.4 (f)	1) Experimental smoking rate 2) Weekly smoking rate 3) Current smoking rate 4) Cessation rate	1) p<0.05 2) p<0.001 3) n/a 4) n/a	-[1]	12	1339/ 1004 (f) n/a (m)
Xie et al., 2005	Comprehensive intervention in community on smoking, chronic bronchitis, and asthma in rural areas of Beijing including education of former-smokers and improvement of living environment.	36.4 (m) 37.7 (f)	1) Smoking rate 2) Current smoking rate	1) p<0.001 (m) 2) p<0.001 (m) 1) p=0.367 (f) 2) p=0.223 (f)	-[1]	108	8264/ 7974 (f) 6981/ 7325 (m)
Zheng et al., 2005	School-based smoking prevention and control intervention program among elementary school students by comprehensive smoking interventions.	9.6 (m) 9.7 (f)	1) Smoking initiation rate 2) Passive smoking rate	1) p>0.05 2) p<0.01	p>0.05 (6 months)	12	245/ 321 (f)
Zheng et al., 2006	School-based smoking control program in middle school students.	Grade 1and Grade 2 students	1) Smoking initiation rate 2) Smoking rate 3) Passive smoking rate 4) Heavy passive smoking rate	1) p>0.05 2) p>0.05 3) p<0.05 4) p<0.05	1) p<0.05 2) p>0.05 3) p>0.05 4) p<0.05 all (6 months)	-	-
Zheng et al., 2007	Group smoking cessation intervention based on a social cognitive theory in the urban community of Changqiao, Shanghai. 8 subgroups with 13 to 15 members; 5 two-hour sessions, delivered by 3 health education professionals.	56.4 (m) 53.3 (f)	1) 7 day smoking cessation rate 2) Continuous abstinence rate of 6 month (%) 3) Average change of daily consumption	1) [24.2-46.8], 95% CI 2) [16.6-35.2], 95% CI 3) p<0.01	p>0.05 (12 months)	6	116/96

NS, not significant; 1= A follow-up was not conducted; CI= confidence interval; f= female; m=male; n/a= not available

of the described intervention in all predefined outcomes (Abdullah et al., 2005; Zheng et al., 2007; Chan et al., 2008; Lin et al., 2008; 2010; Mei et al., 2008; Wang et al., 2008b). Of these seven interventions, five used health promotion techniques. Settings were diverse between the seven studies that reported statistical significant effects in all predefined outcomes of the intervention.

One study (Jiang et al., 2003) could not find a statistical reduction of smoking in the intervention group in any predefined outcome. In all other studies, at least one outcome was statistically significant. In all of the six studies which included knowledge as a predefined outcome, significant increases in the smoking related knowledge could be observed in the intervention group. Of eight interventions that aimed at smoking cessation, six could (Abdullah et al., 2005; Loke et al., 2005; Zheng et al., 2007; Chan et al., 2008; Lin et al., 2008; 2010) find a significant difference between the intervention and the control group while two could not (Wen et al., 2007; Jiang et al., 2003). However, cessation rates in three of the successful interventions were measured by seven day abstinence, which might not be enough to give reliable information on actual cessation rates.

Follow-ups were conducted in six studies (Zheng et al., 2007; Chan et al., 2008; Wen et al., 2010; Loke et al., 2005; Zheng et al., 2005; 2006). After 6 months, one study (Zheng et al., 2006) found significantly reduced rates in smoking initiation and heavy passive smoking. However, baseline characteristics of intervention and control group were significantly different, such that no distinct effect of the program could be verified.

Discussion

The reviewed randomized controlled trials on tobacco prevention in China differ widely in their outcome parameters, in their effectiveness and in their methodological quality. Regarding the effectiveness, interventions applying health promotion techniques were more often successful than interventions that were only based on health education. The outcome parameters with the highest rate of significant improvements in the

intervention group were smoking related knowledge and smoking cessation rate. Yet, the reliability of these results is questionable. Knowledge is a relatively objective 'soft' outcome parameter. Recent studies provide evidence for a correlation of tobacco related knowledge and negative attitudes (Lim et al., 2009). However, in the present review only one out of six interventions which showed significant increase in tobacco related knowledge also gave evidence for a change in smoking related attitudes. Thus, an actual improvement in smoking habits and in smoking related diseases cannot be deduced from an increase in knowledge in this systematic review.

Smoking cessation is considered to be a more comprehensive 'hard' outcome parameter than smoking related knowledge. A consequent smoking cessation leads to a substantial decline in smoking related diseases, which for example could be proven for lung cancer risk in an Asian population by Wong (2010). 75% of the reviewed interventions which aimed at smoking cessation provided evidence for a significant higher rate of smoking cessation in the intervention group. As a matter of fact, the informative value of this outcome is limited, since cessation rates in half of the successful interventions were measured by seven day abstinence. To assume a decline in smoking related diseases due to smoking cessation, a much broader period of time must be observed.

Against this background, it is inevitable for future research to observe long term effects of smoking prevention interventions in China. Only six out of 21 studies included in this systematic review conducted follow-up analysis. The average follow-up period was ten months with a minimum of three and a maximum of 24 months. Effects after follow-up were only reported in three of the six studies. Evidence for a significant effect after six months follow-up could be provided in Zhen (2006) on smoking initiation rate and heavy passive smoking rate in middle school students. Given that the smoking rate in young people is increasing while the age of onset of tobacco smoking is decreasing at the same time, this trial's result is positive. But again, results must be judged with caution due to flaws in the methodological quality of the study.

Overall, the quality of the reviewed studies suffered from serious methodological shortcomings including nonequivalent control groups, no blinding of the data collectors, no explanation of sample size calculation, per protocol instead of intention-to-treat analysis, no sufficient explanation of drop outs and missing validation of outcome measurement tools. Methodological bias is more prevalent in Chinese publications compared to publications in English language. Except for one (Wang, 2008a), none of the Chinese studies sufficiently described the randomization process and only two (Guo et al., 2009; Lin et al., 2010) described a random allocation of participants. Although all studies refer to themselves as randomized controlled trials, the missing description of the randomization processes and the random allocation of participants show that the indicated level of evidence actually was not accomplished in the studies.

Regarding to methodological quality, our findings are confirmed by Zhang et al. (2011a), who analyzed the quality of trials conducted in China and in India in comparison to trials reported in European or North American journals. They showed that the Western trial reports had considerably fewer methodological flaws. According to this, studies published in Chinese language journals were more likely to report statistically significant results.

The aim of this study is to give best level evidence on the effectiveness of primary Chinese tobacco prevention interventions. We therefore concentrated on randomized controlled trials which are graded as best level evidence in evidence based medicine (Sackett et al., 2000). Additionally, we conducted a comprehensive methodological quality assessment to evaluate the reliability of the intervention results.

We account for some limitations in this study which may have biased the results. Chinese databases were searched by only one person. Thus, eligible studies might have been missed. The extraction of data in studies written in Chinese language also was accomplished by only one Chinese native speaker. The eligibility of all Chinese studies included in the review and the correctness, completeness and suitability of the data extraction was discussed in group sessions.

Against the epidemiological background of tobacco consumption in China, two groups should be in the focus of interventions in smoking prevention. Firstly, the decrease in the age of onset makes children and adolescents the foremost target group of interventions. Six studies included in this review analysed interventions conducted in schools and five studies at least partly found improvements in smoking related outcomes in the intervention group. Secondly, the need for action seems to be much higher in Chinese men than in Chinese women. Although the tobacco smoking prevalence in women is increasing, the smoking rate in men is still about tenfold higher. Future preventive interventions should amongst others be aimed at reducing tobacco consumption rates in men to the level in women.

The documentation of smoking prevention interventions in China is not sufficient to develop effective and reliable action programs. A lack of quality in the design can be discerned rather than a lack in starting interventions (Liu et al., 2011b). We therefore recommend future interventions to be planned, implemented and conducted in compliance with high quality standards for example the Guideline for Good Clinical Practice (GCP) provided by International Conference on Harmonization (ICH) (ICH 2002). Furthermore for preparing reports of RCT findings we recommend the Consolidated Standards of Reporting Trials (CONSORT) (Schulz et al., 2010)

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