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CLINICAL HEALTH PROMOTION

Research & Best Practice for patients, staff and community

In this issue

Research and Best Practice

News from the HPH Network

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WHO-CC, Clinical Health Promotion Centre
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Denmark

The Official Journal of the International Network of Health Promoting Hospitals and Health Services

CLINICAL HEALTH PROMOTION

Aim

The overall aim of the journal is to support the work towards better health gain by an integration of Health Promotion into the organisational structure and culture of the hospitals and health services. This is done by significant improvement of a worldwide publication of clinical health promotion based on best evidence-based practice for patient, staff and community.

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Editorial

Where can I get the best help to quit smoking?

Hanne Tønnesen

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This is an important question to many smokers. However, as practitioner of evidence-based medicine, you might be able to inform about interventions with high efficacy based on literature reviews, but only after you have defined the kind of smoker who asks, have identified what smoking cessation intervention to look for compared to which control description, and have chosen the outcome parameter (1). However, you would seldom be able to inform about, how these programmes work in real life.

Despite being a relatively simple question, it is often found difficult to answer. One reason is that today, systematic reports on follow-up results from smoking cessation services (SCS) are often inadequate, lacking or sometimes even kept in secret for the users. In addition, there is not an established tradition for documentation of SCS outcomes in daily life - neither in hospitals nor in other settings.

Many countries offer support via quitlines or websites that disseminate good advices on how to give up smoking (2). The advices can be tailored to the individual smoker and may even inform about SCS in the neighbourhood, but they seldom offer the adequate information about the question in focus.

Some SCS offer evidence-based cessation programmes, based on systematic reviews of randomised trials (3). However, only few nations follow-up or publish on the results of the SCS in order to secure the quality as well as benchmark and base the health planning on local and systematically collected outcomes.

Few examples of nationwide databases, that collect and publish the quit-rates from real life settings, exist around the world - one of them being The Danish Smoking Cessation Database (SCDB). This database is supported by the Danish Ministry of Health, and all Danish SCS offering face-to-face programmes can use it free of charge (4).

The Danish SCDB is used for documentation, quality assurance and benchmarking on five indicators, namely Compliance, Smoke-free at end of programme, Follow-up rate, 6 months Quit-rate (continuously), and Satisfaction. The national standards are high; 80% for the first three indicators, 50% for the fourth, and 90% for the fifth indicator. The results are updated annually at the public website and available for the smokers looking for help to quit (5). This year one Danish SCS meets four of the five standards, and 35 SCS meet three or less standards.

It is necessary to establish more SCDBs around the world. This way, smokers could easily find the answer to the important question “Where can I get the best help to give up smoking?”

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Nicotine lozenges to promote brief preoperative abstinence from smoking: pilot study

David O. Warner & Sandeep Kadimpati

Abstract

Background Even brief preoperative abstinence from smoking can favorably affect intra-operative physiologic parameters such as carboxyhemoglobin concentrations, but many patients continue to smoke the morning of surgery.

Objective The goal of this pilot study was to determine the feasibility and potential effect size of nicotine lozenges as an adjunct to maintain brief preoperative abstinence, defined as not smoking the day of surgery.

Methods Forty six cigarette smokers scheduled for elective surgery were randomized in a double-blinded fashion to receive active or placebo nicotine lozenges, beginning the night prior to surgery, combined with brief advice to both groups to maintain abstinence on the morning of surgery. The primary outcome was the exhaled carbon monoxide (CO) level in the preoperative holding area.

Results Preoperative CO levels tended to be less in the active group (8.3 ± 7.5 and 12.7 ± 10.9 ppm in active and placebo groups, respectively, p = 0.12, Cohen's d = 0.47). Of the 46 subjects, 26 (57 %) tried at least one lozenge, with proportions similar in both groups. When those who tried at least one lozenge were analyzed, preoperative CO levels were significantly lower in those who received active lozenges (3.8 ± 3.0 and 12.7 ± 11.5 ppm in active and placebo groups, respectively, p = 0.009).

Conclusion This study suggests the feasibility of nicotine lozenges as an aid to maintain brief preoperative abstinence and provided preliminary evidence of efficacy. Methods to increase lozenge utilization, and a larger efficacy trial, are indicated.

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Introduction

Cigarette smoking is a risk factor for several perioperative complications (1). Abstinence from smoking can reduce risk for some of these complications by allowing the effects of smoke constituents such as carbon monoxide to dissipate preoperatively (2-4). The minimum duration of abstinence needed for benefit is unknown (5;6), and may vary according to complication, but there are biologically-plausible reasons to believe that for some complications, even brief preoperative abstinence may be beneficial (7). However, despite efforts to encourage prolonged preoperative abstinence, current evidence suggests that in the absence of interventions the majority of smokers continue cigarette consumption until immediately before entering the surgical facility (8). Surgical providers insist upon fasting from food beginning the night before surgery to promote patient safety; a similar requirement to "fast" from cigarettes has been advocated (9). We have recently shown that physician advice to maintain brief preoperative abstinence is efficacious, but many smokers still are successful in doing so (10).

Nicotine replacement therapy (NRT) is a useful adjunct to help patients maintain prolonged abstinence; whether it might also be efficacious in helping smokers maintain brief preoperative abstinence is not known. The goal of this pilot study was to determine the feasibility and potential effect size of nicotine lozenges as an adjunct to maintain brief preoperative abstinence, defined as not smoking the day of surgery. The primary outcome of this randomized, double-blinded study in patients scheduled for elective surgical procedures was the exhaled CO concentration measured immediately prior to surgery, with a secondary outcome being the self-reported duration of smoking abstinence before admission to the surgical facility.

Methods

This study was approved by the Mayo Clinic Institutional Review Board.

Subjects were recruited from patients evaluated at the Mayo Clinic Rochester PreOperative Evaluation Center in preparation for elective surgery. Approximately 20% of adult patients undergoing a wide variety of surgical procedures at Mayo Clinic Rochester are seen in the POE (other surgical patients are evaluated preoperatively using other mechanisms). Eligibility criteria included age ≥ 18 years and current smoking before the scheduling of surgery, defined as > 100 cigarettes lifetime consumption and self-report of smoking either every day or some days. Exclusion criteria included current receipt of pharmacotherapy and/or behavioral therapy for smoking cessation, or medical conditions such as pregnancy or unstable angina that would be relative contraindications to nicotine replacement therapy. Recruitment was performed on a convenience basis, and written informed consent was obtained.

After enrollment, subjects were randomized to receive either active or placebo nicotine lozenges. The time to first cigarette (< or ≥ 30 min) and the classification of surgical procedure (inpatient vs. outpatient) were designated as stratification factors (8), with the goal of randomizing equal numbers of subjects to each of the two interventions for each strata. Randomization was performed within these 4 strata. A randomization schedule for each strata was generated by our Biostatistics Core using blocks of size 4 to ensure that after every fourth subject enrolled in a given strata an equal number of subjects were assigned to each intervention group within that strata. Using these randomization schedules, study personnel that did not have any subject contact prepared study medication packets which were labelled according to strata specific subject ID numbers and contained the appropriate study medication for the treatment assignment for the given subject. At the time of enrollment, a subject was assigned the next sequential subject ID number for the appropriate strata and the appropriate study medication was dispensed.

All subjects regardless of group assignment received a brief (~ 2 min) behavioral intervention advising abstinence from smoking after 7 PM the night before surgery, including the potential benefits of abstinence, and asking them to consider using a lozenge at times when they would usually smoke, including the morning of surgery. After this intervention, the subjects received the study medication dosed according to time to first morning cigarette. If the subject normally smoked the first cigarette within 30 min of awakening, a 4 mg lozenge (or appropriately labeled placebo) was dispensed. If the subject normally smoked the first cigarette more than 30 min of awakening, a 2 mg lozenge (or appropriately labeled placebo) was dispensed. Each subject received 16 lozenges, sufficient to cover at least the period of time from 7 PM the night before surgery to the time of admission to the surgical facility (which could be up to 1-2 PM the following day).

Assessments were performed at the following times: 1) at the time of study enrollment (in the preoperative clinic); 2) on the morning of surgery, and 3) one week postoperatively. At the initial assessment, demographic information and co-morbidity were recorded, and a baseline smoking history was obtained (including the Fagerström Test for Nicotine Dependence (11) and the Minnesota Nicotine Withdrawal Questionnaire (12)).
On the morning of surgery, self-reported smoking behavior since the last assessment was determined, with recent smoking assessed using expired carbon monoxide measurements. At one week after surgery, smoking behavior was assessed (via telephone).

Data analysis

The primary outcome for evaluating the effect of the study medication was the expired CO concentration measured in the preoperative holding area. Secondary outcomes included self-reported abstinence the morning of surgery and time to last cigarette. Comparisons were made using a two-sample t-test for continuous variable and Fisher's Exact test for categorical variables. Two-sided p-values ≤ 0.05 were considered statistically significant.

Results

Forty-six subjects were randomized with 24 receiving placebo lozenges and 22 receiving active lozenges. All randomized subjects received the assigned intervention and underwent surgery. There were no significant differences between groups in baseline characteristics, with the exception that those in the placebo group had made a significantly greater number of quit attempts (Table 1). At baseline assessment, the majority of subjects in both groups expressed an intent to maintain preoperative abstinence.

Preoperative CO levels tended to be lover in the active group (8.3 ± 7.5 and 12.7 ± 10.9 ppm in active and placebo groups, respectively, p = 0.12). CO values were consistent with self-reported abstinence the morning of surgery (73% and 54% in active and placebo groups, respectively, p = 0.23). The accuracy of self-report was further suggested by plotting CO levels in self-reported abstainers and smokers (Figure 1), with a threshold of 10 ppm suggesting abstinence. The time to last cigarette tended to be shorter in the active group (Table 2).

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Of the 46 subjects, 26 (56.5 %) tried at least one lozenge, with proportions similar in both groups (Table 2). Of these, 2 subjects in each group objected to the initial taste of the lozenge and did not finish their first one. The proportion of subjects who used any lozenges and felt that they were helpful was similar in both groups, and the proportion of subjects who correctly identified their group assignment was not significantly different. When CO values were plotted according to whether any lozenges were used (Figure 2), lower preoperative CO levels clustered among those who used lozenges. When those who tried at least one lozenge were analyzed, preoperative CO levels were significantly lower in those who received active lozenges (Table 2). Among those who did not use at least one lozenge, there was no significant difference in CO levels (14.5 ± 13.4 and 9.0 ± 8.4 ppm in active and placebo groups, respectively, p=0.87).

Self-reported abstinence at postoperative day 8 was similar between groups.

Table 1 Baseline characteristics

	Placebo (n=24)	Active (n=22)	p
Age (M ± SD)	49.8 ± 12.8	54.7 ± 14.0	0.21*
Sex (Male, %)	12 (50%)	10 (45%)	0.78**
Inpatient surgery (Y, %)	13 (55%)	12 (54%)	0.85**
Number of cigarettes per day (M ± SD)	17.9 ± 7.2	16.8 ± 6.7	0.61*
Previous quit attempts (M ± SD)	1.7 ± 0.7	1.0 ± 1.0	0.01*
FTND (M ± SD)	6.1 ± 1.4	6.7 ± 1.2	0.11*
Nicotine Withdrawal Score (M ± SD)	1.5 ± 1.0	1.5 ± 0.9	0.83*
Intent to abstain prior to surgery (Y, %)	19 (79%)	18 (82%)	1.0**

* Unpaired t test; **Fisher's exact test

Figure 1 Carbon monoxide (CO) levels in the preoperative holding area according to self-reported abstinence the morning of surgery.

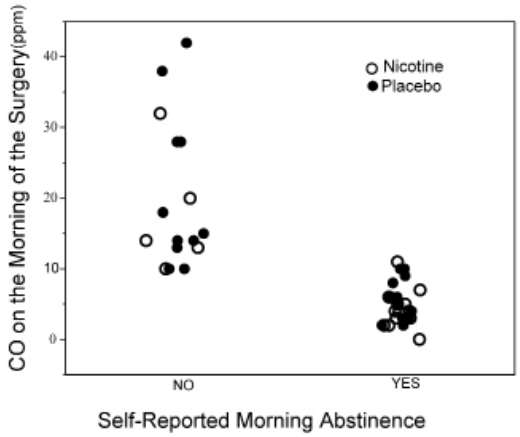

Figure 2 Carbon monoxide (CO) levels in the preoperative holding area according to whether subjects reported using any lozenges.

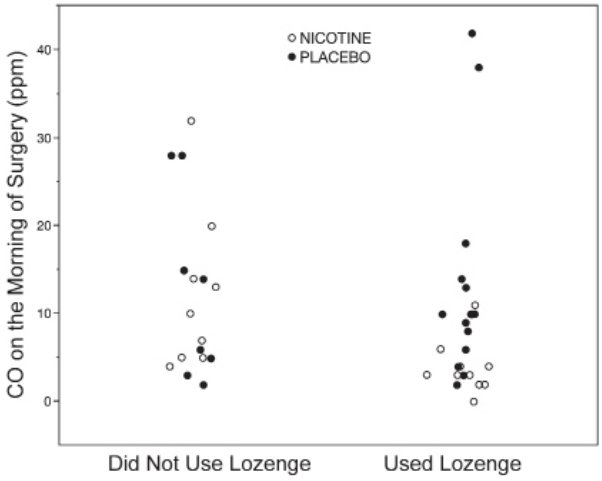

Table 2 Outcomes

	Placebo (n=24)	Active (n=22)	p
Preoperative CO (ppm, M ± SD)	12.7 ± 10.9	8.3 ± 7.5	0.12*
Self-reported morning abstinence (Y, %)	13 (54%)	16 (73%)	0.23**
Time to last cigarette (h, M ± SD)	16.7 ± 11.3	21.8 ± 19.5	0.29*
Preoperative Nicotine Withdrawal Score (M ± SD)	1.4 ± 0.9	1.3 ± 1.0	0.93*
Tried at least one lozenge (Y, %)†	16 (67%)	10 (45%)	0.23**
If yes:			
- Do you think the lozenge contained nicotine? (Y, %)	9 (53%)	9 (75%)	0.27**
- Were lozenges helpful? (Y, %)	7 (44%)	5 (50%)	1.0**
- Preoperative CO levels (M ± SD)	12.7 ± 11.5	3.8 ± 3.0	0.009*
Self-reported abstinence postoperative day 8 (Y, %)	11 (46%)	11 (50%)	1.0**

* Unpaired t test; **Fisher's exact test; † of these, 2 subjects in each group objected to the initial taste of the lozenge and did not finish their first lozenge.

Discussion

The main findings of this pilot study are that the use of nicotine lozenges to aid preoperative abstinence is feasible and that there is preliminary evidence of efficacy for this indication.

Prolonged abstinence from smoking decreases the rate of perioperative complications (3), and tobacco interventions should be provided to presurgical patients as early as possible (2;13). However, these interventions are not always successful, nor are they feasible in many surgical settings. There are physiological reasons why even brief preoperative abstinence may have benefits (7). For example, increased CO levels are correlated with ischemia in anesthetized patients as CO decreases the oxygen-carrying capacity of the blood (14). Also, impaired tissue

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oxygenation due to increased carboxyhemoglobin levels may also impair wound healing (15). Because the half-life of carbon monoxide in the body is relatively short (~ 4 h), even short-term abstinence from smoking will significantly decrease carboxyhemoglobin levels and thus may be beneficial for surgical patients. Similarly, the short half-life of nicotine (~ 1 h) means that relatively brief abstinence will significantly reduce nicotine levels. In a prior study, we provided indirect evidence that brief advice to abstain from smoking on the morning of elective surgery is efficacious, but still not all patients maintained abstinence. NRT has proven efficacy to increase the success rate of quit attempts, but has not been used previously to promote brief smoking abstinence. NRT is associated with side effects and requires instructions for use, so it was not certain that such "acute" use in patients not previously exposed to this form of NRT would prove feasible. We chose nicotine lozenges based one relative ease of use compared with nicotine gum and relatively rapid onset of action and limited duration of effect compared with nicotine patches (16).

On an intention to treat basis, this pilot study found preliminary evidence of efficacy for the effect size of group assignment on preoperative CO levels, indicating a medium effect size. A somewhat smaller effect size was found for the secondary endpoint of self-reported time to first cigarette. These results were consistent with self-reported morning smoking status, which was highly accurate according to CO verification. For those subjects who tried lozenges, about half (in both groups) thought the lozenges were helpful, although patients were often unable to correctly identify lozenge content, perhaps suggesting some degree of placebo effect. Nonetheless, when analysis was restricted to those who actually used the lozenges, there was a significant treatment effect, even with relatively small numbers in each group. These findings suggest that there is preliminary evidence of efficacy.

These results also show that there are issues that would need to be addressed in a larger study or in implementation into clinical practice. Almost half of patients were not willing to try a lozenge to maintain abstinence, even in this study situation. Unused medications cannot be efficacious, and strategies should be explored to increase the lozenge utilization rate. Also, 15% of those who tried lozenges complained of a bitter taste and did not finish even a single lozenge (including two who received placebo lozenges), so that methods to increase the acceptability of NRT in this setting should also be investigated. This could include better instructions regarding this potential effect, or the use of nicotine gum or other delivery methods.

Conclusion

In conclusion, although this is a pilot study and was not powered to detect significant differences, this study suggests the feasibility of nicotine lozenges as an aid to maintain brief preoperative abstinence and provided preliminary evidence of efficacy. Given the potential benefits of preoperative abstinence, these results provide the rationale for a larger efficacy study.

Contribution details

Conception and design: DOW
Acquisition of data: DOW
Analysis and interpretation of data: DOW, SK
Drafting the article: DOW, SK
Revising the article critically for important intellectual content: DOW, SK
Final approval of the version to be published: DOW, SK

Competing Interests: None declared.

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Research and Best Practice

Reduced wound healing capacity in alcohol abusers – reversibility after withdrawal

Hanne Tønnesen[1], Susanne Pedersen[2], Michael Lavrsen[2], Jon Ivar Tuxøe[2], Christian Frøkjær Thomsen[3]

Abstract

Background Alcohol abusers have increased risk of wound complications following surgical procedures, however the development of complications is reduced after preoperative withdrawal from alcohol. Therefore the aim of the study was to evaluate wound healing at alcohol abuse and after withdrawal.

Methods In total 16 alcohol abusers were included and tested. Nine abusers were able to abstain from alcohol and were retested after 8 weeks of abstinence. No patients had clinical or biochemical signs of hepatic or renal disease.

Collagen and total protein accumulation in wound granulation tissue were evaluated from the deposited amount of hydroxyproline and proline in two subcutaneously implanted polytetrafluoroetylene tubes.

Results The amount of proline and total protein increased significantly after 8 weeks of abstinence, median 81.3 nmol/mm (inter-quartile range: 77.1-92.9) versus 69.3 nmol/mm (68.5-76.3), $p < 0.05$, and 632 nmol/mm (505-1,127) versus 571 nmol/mm (544-831), $p < 0.05$, respectively. There was no significant change of hydroxyproline.

Conclusion This study showed a change in the protein level of the wound healing process among alcohol abusers, which seemed reversible after withdrawal.

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Introduction

Alcohol abusers have three to four times increased postoperative morbidity after surgical procedures (1-3). Especially wound complications are often seen (1-2). However, the knowledge of impact of alcohol on wound healing is sparse.

Wound healing is a dynamic process characterised by clot inflammation, local inflammatory response and deposition of mature collagen and non-collagenous proteins by fibroblasts. The amino acid proline is found in all proteins deposited in the granulation matrix of a wound. Hydroxylation at proline in the procollagen molecules precedes the formation at triple helical mature collagen molecule, which is especially rich in hydroproline (4). The healing process is influenced by many factors, including alcohol (5).

A standard wound healing model consists of subcutaneously inserted tubes of expanded polytetrafluoroetylene (ePTFE) with a 90-120 micro-millimetre pore size, which allows ingrowths of inflammatory cells and fibroblasts. After removal, the subcutaneous accumulation of hydroxyproline, proline and total protein is measurable (6). In this model, the accumulated collagen in the ePTFE tube has been found to correlate with the tensile strength at experimental wounds (7).

The aim of the study was to evaluate wound healing at alcohol abuse and after withdrawal.

Material

After informed consent, sixteen alcoholic outpatients (12 men and 4 women) were included for evaluation of wound healing capacity, when they entered the Alcohol Unit for treatment of alcohol abuse. The patients had been drinking 240 g (median) ethanol daily (range 72-1,020) for at least three months before inclusion. They were all in relatively good physical condition; however, two patients suffered from chronic bronchitis in mild to moderate degree, and one from non-insulin dependent diabetes mellitus. None of the abusers had clinical or biochemical signs of hepatitis or hepatic cirrhosis.

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Seven men and two women were re-examined for wound healing capacity after eight weeks of total abstinence; the treatment comprehended supervised disulfiram 800 mg twice weekly, chlordiazepoxide 50-100 mg daily according to withdrawal symptoms, and behaviouristic support). The other patients had relapsed before eight weeks and were therefore not included in the re-evaluation. The characteristics are given in Table I.

Table I Characteristics of all alcohol abusers and of the alcohol abusers who remained abstinent for eight weeks (median and range)

	Alcohol abusers n=16	Abstinent patients n=9
Women/men	4 / 12	2 / 7
Age (yrs)	45 (36-51)	45 (40-48)
Smoking (cigarettes per day)	22 (0-40)	20 (0-40)
Body mass index (kg/m^2)	23 (19-29)	23 (20-28)
PN (%)[1]	29 (20-45)	34 (10-45)
Haemoglobin (mmol/litre)	8.9 (7.2-11.8)	8.9 (7.6-11.4)
Albumin (mol/litre)	624 (527-711)	613 (550-874)
Bilirubin (U/l)	12 (7-19)	10 (7-13)
Creatinine (micromole/litre)	75 (62-90)	71 (59-1 09)
CRP (nmol/litre)[2]	<95 (<95 - 474)	< 95

[1] Prognostic nutrition index (8), [2] Lower detection limit is 95 nmol/litre

Methods

A paired design was used. Two ePTFE tubes (International Polymeer Engineering inc., Tempe, Arizona, USA), 6 cm length, 12 mm inner diameter, 2.4 mm outer diameter, 90—120 micrometers pore size were inserted subcutaneously in the upper arm under local anaesthesia as described previously (6). The tubes were removed ten days after implantation.

High-Performance Liquid Chromatography (HPLC-assay): 3 cm of the middle part of the ePTFE was delipized in acetone and diethyl ether and dried. The length of each section was measured before hydrolysis for 24 hours in concentrated hydrochloric acid and liquefied phenol at 114°C. The samples were prepared for chromatographic analysis after re-dissolving the dried hydrolysates. The samples were evaporated to dryness and re-dried with triethylamine for removal of traces from hydrochloric acid and reacted with phenylisothiocyanate.

The resulting phenylthiocarbamyl derivatives from the amino acids were re-dissolved in sample diluents and analysed in a system using a Hypersil 6DB C18 column analyser (Shandon, Runcorn, Chesire, UK) with increasing concentrations from acetonitrile in an acetate buffer pH 5.70. The UV-absorbency of the eluate from the column was monitored at a wavelength of 254 nm using instruments from Waters (Milford, MA, USA). Calibration curves for the individual amino acids were constructed from equal analysis of standard samples from the "Amino Acid Standard H" (Pierce, Rockford IL USA) and L-4-hydroxyproline (Merck, Darmstadt, Germany).

Based on all the amino acids measured in the assays, the amounts of hydroxyproline, proline and total protein, were calculated from the chromatograms by averaging the results from two injections of the same hydrolysate, and the contents were expressed as the amount per mm at dry delipidised ePTFE tubes.

Prior to wounding procedure venous blood was sampled for routine analysis of haemoglobin (1-12, Bayer, New York, USA), electrolytes and liver enzymes (SMAG, Bayer, New York, USA). The local Scientific Ethical Committee (No KA 93062) approved the study. The Wilcoxon test was used for statistical analyses of paired samples, and the Mann-Whitney test for unpaired results. A level of 5% was chosen for statistical significance.

Results

The characteristics of the nine abstinent patients, who were reinvestigated after alcohol withdrawal, did not differ significantly from the seven, who were only investigated once.

The proline, hydroxyproline and total protein measurements are given in Table 2 and Figure 1.

There were no complications in relation to the implanted material.

Table 2 The proline, hydroxyproline and total protein content in experimental wounds (Median and range)

	Alcohol abusers all patients.	**Alcohol abusers** with follow-up.	**Alcohol abusers** with follow-up.
	n=16	Before abstinence from drinking. n=9	After 8 weeks withdraw from drinking alcohol. n=9
Proline (nmol/l)	72.0 (62.7-95.5)	69.3 (62.8-85.5)	81.3 (76.9-98.0)
Hydroxyproline (nmol/l)	1.1 (0.3-4.4)	1.1 (0.3-3.0)	1.1 (0.4-7.8)
Total Protein (nmol/l)	651 (425-1,080)	571 (425-971)	632 (526-1,186)

Median and range

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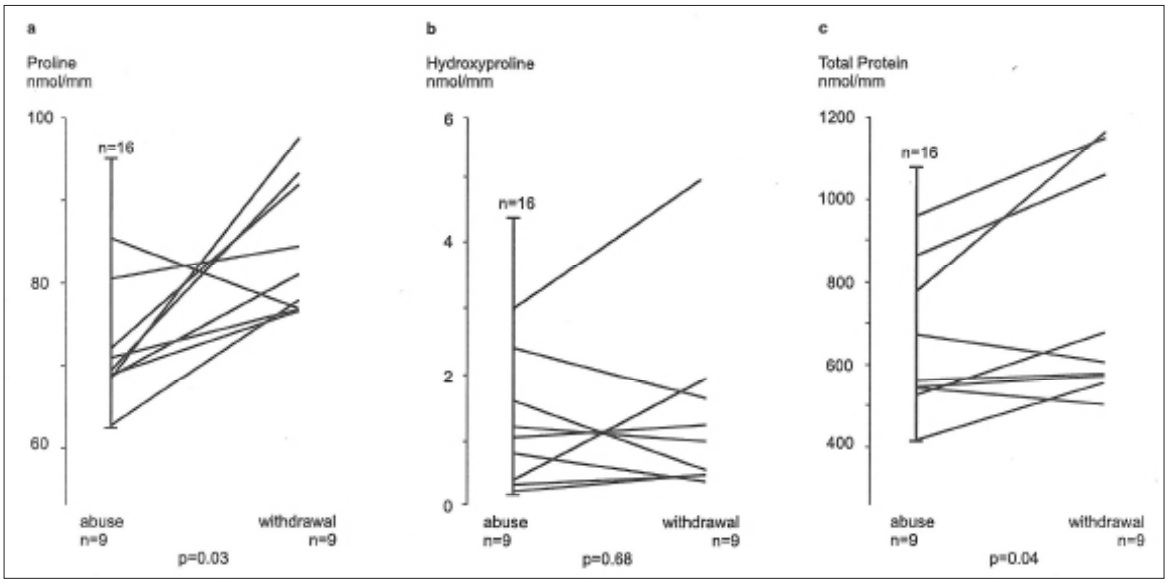
Figure 1



1a: Accumulated proline in the nine alcohol abusers before and after eight weeks at abstinence. * $p < 0.05$.

1b: Accumulated hydroxyproline in the nine alcohol abusers before and after eight weeks of abstinence.

1c: Accumulated total protein in the nine alcohol abusers before and after eight weeks at abstinence. * $p < 0.05$.

Discussion

We found the slowed healing process in alcohol abusers to be associated with decreased amount of proline as well as total protein. The process normalises after abstinence from alcohol.

The mechanism of reduced synthesis and/or secretion of proline and total protein in the wounds of alcohol abusers are unknown. Ethanol has a direct toxic effect on the ultra structure and function of mitochondria as well as endoplasmatic reticulum (9). Disperse reduction of protein synthesis and cell atrophy follows (7;10), as it is often reflected in alcohol-induced skeletal and cardiac myopathy (11-12).

Alcohol-induced suppression of the immune capacity may also be of importance. Mobilisation, adhesion and signal transduction across the cell membrane of the inflammatory cells relevant for wound healing are reduced (12), and probably followed by a delay of the inflammatory phase in the healing process.

The reversibility of proline deposition in wounds after abstinence from alcohol may be parallel to the myopathy and immune-suppression, which normalise after three and two months of abstinence, respectively (12;14-15).

There are other potential factors to delay the healing process in the alcohol abusers of the actual study: malnutrition, dehydration and illness (16-19). Alcoholism may be associated with malnutrition, and though the patients in the present study were not malnourished, reduced concentration of minerals, vitamins and oxygen-derived free radicals cannot be excluded, and they may all be of importance for a normal healing process. Ethanol blocks the anti-diuretic hormone leading to dehydration in alcohol abusers, which was however not found in the abusers of the actual study, who all had normal biochemical values. Likewise there was no difference between the groups concerning illness evaluated by history and C reactive protein.

Smoking has been reported to depress accumulation of collagen, but not proline or total protein, in the ePTFE wound healing model by inducing hypoxia, which leads to reduction of the oxygen-demanding conversion from proline to hydroproline (20). The accumulation of collagen did not change during abstinence in our alcohol groups, nor did the smoking habits in the test period.

The constant production of collagen in this study is in agreement with in vitro experiments demonstrating that addition of clinical concentrations of alcohol to fibroblast cultures fails to inhibit the basal collagen synthesis (21). In contrast, the response to transforming growth factor beta (TGF-beta) was significantly reduced (21), corresponding to the direct binding of ethanol on membrane proteins followed by disturbance of signalling be-

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tween the cells (22). The influence of combined abstinence from both alcohol and tobacco may be a relevant subject of a future study.

The alcohol abusers stopped drinking when they underwent the first wounding procedure, and may therefore have developed symptoms of withdrawal, characterised by an overactive endocrine stress response, including hypercortisolaemia (23). Other authors have reported reduced collagen deposition secondary to treatment with corticosteroid (24), but similar to a transient endocrine over-activity during withdrawal, a single dose of intravenous prednisolon was not associated with changes in collagen accumulation in wound (25).

Low collagen concentration also follows increased regeneration, which is further characterised by simultaneously increased non-collagen protein (26). We did not find that combination, thus excluding an increased regeneration as an explanation of our results.

Major surgery reduces the collagen and thereby the strength of the surgical wound (27). Our results add to the pathogenesis of the severely increased wound complications after surgery in alcohol abusers (1-3). Furthermore, the results suggest that two months of preoperative soberness may reduce the wound complications postoperatively, which could be relevant in the risk reduction for elective surgery.

Limitations

The small number of included persons is a limitation to this study. The data should be confirmed with larger samples.

Conclusion

In conclusion, the wound healing capacity is slowed in alcohol abusers; however, the healing reverses to normal after eight weeks of abstinence.

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The influence of Antonovsky's sense of coherence on admission and psychosocial functioning

A clinical controlled trial of schizophrenic outpatients in psychoeducative multi-family intervention

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Abstract

Objective Psychosocial interventions can reduce admission rates and enhance the psychosocial functioning of patients suffering from schizophrenia. This study investigates the influence of Antonovsky's sense of coherence on psychosocial functioning and admission rate among participants of psychoeducative multi-family groups (PG) compared to a control group (CG).

Method 46 schizophrenic outpatients participated in a prospective study. They got treatment as usual in the psychiatric ambulance. Additionally they could choose participation with their relatives in the PG or join the CG. Patients were assessed with the Sense of Coherence scale (SOC-29) and the Global Assessment of Functioning scale (GAF). Admission rates (AR) were conducted from the hospitals basic documentation.

Results Before intervention PG and CG had a comparable AR, but the PG had significant lower GAF scores. After intervention the PG had a significant lower AR and higher GAF scores than the CG. In a comparison of subgroups (high vs. low SOC scores) PG participants with low SOC scores could reduce significantly their AR and enhance their GAF scores. Notably, all patients with high SOC scores had the lowest AR within all three measurement points.

Conclusion PG participants, especially those with low SOC scores, had a considerable profit in regards to AR and GAF compared to the CG. After intervention they showed the same AR and GAF scores as patients with high SOC scores. Implications for clinical practice and economic decisions are a pre-selection of patients with low SOC levels for targeted interventions and more therapeutic efforts to enhance the SOC.

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Introduction

Psychosocial interventions, and especially family interventions, are highly recommended by clinical guidelines for schizophrenia (1-2). Certain references state that treatment approaches which include psychosocial interventions are more effective for patients suffering from schizophrenia than approaches without such interventions (3). Many studies have shown that psychosocial interventions could reduce the relapse rates of patients suffering from schizophrenia significantly at an average of 20% (4; 8). But till now, it remains an open question, which group of patients benefits most from these interventions.

Psychoeducation as a special kind of psychosocial intervention is one of the standard treatments for schizophrenia beside an adequate antipsychotic medication (1; 2; 5). Psychoeducational interventions can reduce the relapse and readmission rates and enhance psychosocial functioning (6-7). This approach seems to be most effective when relatives are included into the treatment. In that case readmission rates can be reduced by 20% (4;8). With regard to special outcomes, multi-family interventions seem to be superior to single family interventions. McFarlane et al (9) found a relapse rate of 16% in the multi-family group and 27% in the single family treatment two years after intervention. In particular multi-family interventions can help to prevent isolation and offer an expanded social network for the participating families (10; 11). Although interventions lasting longer than 3 months are superior to shorter interventions, the results of the Munich PIP-Study showed that short interventions with eight sessions for

schizophrenic patients and their relatives had a positive long-term effect concerning readmission rate and hospital days compared to a control group. In a 7-year follow up, the rate of rehospitalisation per patient in the intervention group was 1.5 (n = 24) and 2.9 (n = 24) in the control group (12).

Schizophrenia is a severe illness that tends to chronicise. With an increasing length of the disease schizophrenic patients can loose their former social network. Therefore, family members are more and more involved in the assistance of the patients. They play an important role in providing help and support in social as well as in clinical domains of need (13). In contrast to every day clinical practice, family members are only infrequently involved in the treatment (14). On account of this, psychoeducative family intervention (15) is an option to close the gap between the wide deficiency of family related treatment offers and the need of imparting knowledge about the disease and providing effective support to the affected families. This intervention was conceptualized as a health promoting approach and adapted to the special needs of patients suffering from schizophrenia and their parents, siblings or partners.

A previous but not controlled study could demonstrate an enhancement of knowledge about the disease and the family climate as well as a reduction of the relapse rates and specific psychopathological symptoms within the participating patients of multi-family interventions (15). A further longitudinal study explored the influence of Antonovsky's sense of coherence (SOC) on schizophrenic patients' perceived quality of life (QOL) among participants of multi family groups. The SOC describes a person's belief that every day stressors are more or less comprehensible, manageable and meaningful. A strong SOC can activate personal or social resistance resources and lead to a healthier life (16). Group participants with a high SOC level could enhance their QOL scores, in contrast to a control group, to nearly the same level as the norm population. But especially participants with a low SOC level had the greatest over all progress from this intervention due to their QOL scores within a one-year period (17-18).

To our knowledge no other study had investigated the influence of the level of SOC as an independent variable on specific interventions for schizophrenic patients. But many studies had confirmed the influence and predictive value of the SOC on health related outcomes (19, 20). A recent study showed that the SOC was a strong predictor for a one-year prognosis of delusions when expressed emotion or depression was high in the acute state of schizophrenia (21). In a Swedish study, the SOC of schizophrenic patients was positively related to general health, subjective quality of life, global psychosocial functioning and global well-being (22). The outcomes of a non-clinical couple therapy study showed that a relatively short treatment was able to improve the SOC and reduce psychiatric symptoms (23). In a polish study, 101 patients with neurotic disorders took part in 10 sessions of a psychotherapeutic program. A significant enhancement of the SOC was found in patients with low SOC levels, while patients with high SOC levels had no observable changes. These effects remained stable over a six month period (24).

This study contributed to the evaluation of a three year pilot project for the implementation of an integrated health care unit for patients suffering from schizophrenia. The aim of this project was to improve the standard care for schizophrenic out-patients by providing a complete health promoting treatment option for schizophrenic patients and their family members or partners. Health promoting interventions are most effective when they are based on voluntary participation. In general, voluntary participants should have more intrinsic motivation to change their health related attitudes and behaviour than participants of prescribed treatment offers.

Therefore, one question of this study was how patients who voluntarily decide to participate in this kind of intervention might be characterized. Additionally, the study explored prospectively whether the level of SOC had an influence on the admission- and readmission rate (AR) and the psychosocial functioning (GAF) within participants of psychoeducative multi-family groups (PG) compared to a control group (CG). AR and GAF are widely used as indicators for the course of disease of schizophrenic patients (3-4; 7-8). It was hypothesised that patients with a high SOC level in general have a lower AR and a higher level of GAF scores than patients with low SOC levels. Therefore patients with a low SOC level should have the greatest benefits from participation in a PG due to their AR and GAF.

Methods

According to Bäuml et al (2007) who claimed that further research should continue to integrate family interventions into routine clinical settings (25), the study was first conceptualized as a waiting control group design in every day clinical practice. Due to organisational problems this design had to be rejected and changed to a prospectively designed field study. To be included in the study, patients needed (A) to have a diagnosis of schizophrenia according to ICD-10 (26), (B) to have had an acute schizophrenic episode within the last 3 months

with hospital admission and at present being in remission and (C) to have close connections to their family or a partner. Excluded were patients with an acute substance abuse and/or extreme cognitive disabilities. The ethical approval for this study was obtained from the Ethic Commission, Department of Psychology, Technische Universität Darmstadt (Germany).

The participating patients were recruited twice a year in a four week period in the acute wards of the Vitos Philippshospital Riedstadt (Germany) before discharge. After discharge all patients got treatment as usual including antipsychotic medication in the hospitals' psychiatric ambulance. To prove the indication for the multi-family intervention, patients could choose voluntarily if they wanted to participate with a family member or a partner in the PG (n = 25) or wanted to join the CG (n = 21). From February 2008 to June 2010, six PGs were conducted altogether. The PG size varied from 9 to 11 participants, each group consisting of 3 to 5 patients and 5 to 7 relatives. Each PG had ten training and two booster sessions. The groups were led by a psychiatrist and a psychologist and met once a week for two hours. The target of the PG was, on the one side, to improve the knowledge and manageability of the disease and, on the other side, to enhance the communication between the patients and their family members. First, participants got information about the disease, treatment options and strategies of crisis prevention and second, techniques from behavioural therapy (active listening, making legitimate demands, problem-solving and coping with stress) were trained by role-playing. After 6 and 9 months, the transfers of the learned techniques in every day life were discussed in booster-sessions.

All patients were assessed with the German version of the SOC scale and the German version of the Global Assessment of Functioning scale (GAF scale) at baseline, after three, nine and twelve months (27-28). The SOC scale is a self-rated instrument with 29 items rated on a seven-point Likert scale. Three sub scores cover the dimensions comprehensibility, manageability and meaningfulness; they were added to a total SOC score. The GAF scale is subjectively rated by clinicians and determines a patient's current functional status on a numeric scale from 1 to 100. It covers clinical, social and occupational factors.

The socio-demographic data and the AR before intervention were collected by structured interviews at T1. The AR was calculated as the quotient of number of hospitalizations and years of sickness. The AR was calculated again within the study period after one and after two years.

At T1, within the whole sample (PG plus CG), subgroups of patients with high and low SOC levels were built by median-splitting. Accordingly, four subgroups of patients (PG with high SOC level, PG with low SOC level, CG with high SOC level and CG with low SOC level) were created and used as independent variables. SPSS 15 was used for statistical analysis. All investigated variables were tested for Gaussian distribution by a Kolmogorov-Smirnov-test. Subject to normal distribution parametric or non-parametric tests were used. The baseline characteristics of the subgroups were compared by using Mann-Whitney U-tests or independent sample t-tests. To prove differences between the subgroups in regard to the dependent variables (AR and GAF), independent sample t-tests were used on all measurement points. Differences within the subgroups were proven by Wilcoxon-tests and dependent sample t-tests. By an analysis of variance, the effects of the PG compared to the CG were proven on the two SOC levels due to AR and GAF. The main effects were adjusted by Bonferroni-tests.

Results

From initially forty-six patients five patients dropped out in the PG between T1 and T2 due to different reasons (e. g. difficulties within the approach of the group sessions, personal reasons etc.) during the study period. So the long-term results are almost based on the data of 20 patients in the PG and 21 patients in the CG.

Comparison of PG and CG at Baseline

At T1 no significant differences between PG and CG occurred with regard to the socio- demographic data (see Table 1). Notably, most of the patients (80% in the PG and 66.7% in the CG) lived together with their families. All other patients had close connections to their family members or partners. By means, PG participants were younger (M = 34.2; SD = 11.27) than CG participants (M = 40.2, SD = 11.85); thus PG participants had been diseased since M = 6.3 years (SD = 7.58) and CG participants since M = 10.3 years (SD = 9.39). PG participants had clearly lower SOC scores than CG participants (M = 119.72; SD = 20.596 vs. M = 131.14; SD = 35.953; T = 1.348; p = .184).

No significant differences were found between PG and CG (M = .97; SD = .69 vs. M = .80; SD = .82; T = -.761; p = .451) due to AR (see Tab. 3). But PG participants had significant lower GAF scores than CG participants (M = 47.96; SD = 9.66 vs. M = 56.76; SD = 14.61; T = 2.445; p = .019).

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Table 1 Socio demographic data of the sample

Variables	PG (*n* = 25)		CG (*n* = 21)		p
Age					0.084
in years M (SD)	34.2	(11.27)	40.2	(11.85)	
Sex					0.808
Male	14	(56.0%)	11	(52.4%)	
Female	11	(44.0%)	10	(47.6%)	
Marital status					0.285
Unmarried	17	(68.0%)	16	(76.2%)	
Married	8	(32.0%)	5	(23.8%)	
Level of education					0.271
Primary school	8	(32.0 %)	8	(38.1 %)	
Secondary school	7	(28.0 %)	9	(42.9 %)	
High School	10	(40.0 %)	4	(19.0 %)	
Occupation					0.302
Employed	11	(44.0%)	8	(38.1%)	
Day care center	4	(16.0 %)	2	(9.5 %)	
Housewife/-man	6	(24.0 %)	9	(42.9 %)	
Student	4	(16.0 %)	2	(9.5 %)	
Living conditions					0.285
Single	5	(20.0 %)	7	(33.3 %)	
Together with family	20	(80.0 %)	14	(66.7 %)	
Diagnosis					0.452
Schizophrenic Psychosis (F 20)	17	(68.0 %)	12	(57.1 %)	
Schizoaffective Psychosis (F 25)	8	(32.0 %)	9	(42.9 %)	
Course of disease					0.128
in years M (SD)	6.3	(7.58)	10.3	(9.39)	

Abbr.: PG = Psychoeducational multi family group; CG = Control group; M = Mean; SD = Standard deviation
Statistics: Mann-Whitney U-test, independent samples t-test

Comparison of patients with high and low SOC levels at baseline

With regard to socio-demographic data, no significant differences were found between patients with high and low SOC levels, but by means, patients with high SOC levels were employed more frequently (56.5 % vs. 26.1 %) than patients with low SOC levels.

Significant differences between these two subgroups were found due to the AR and GAF scores. Patients with high SOC levels had a significant lower AR than patients with low SOC levels (M = .63; SD = .435 vs. M = 1.15; SD = .91; T = 2,501; p = .016) and also significant higher GAF scores (M = 57.78; SD = 12.93 vs. M = 46.17; SD = 9.92; T = -3.417; p = .001).

Comparison of PG and CG due to AR and GAF after intervention

The PG showed a significant decrease in AR (Table 2) and a significant enhancement of GAF scores (see Table 3) after intervention, while the CG had neither a significant enhancement nor a significant decrease of AR and GAF scores on all measurement points. In the PG the AR was reduced to 42% after one year and to 57% after two years. Additionally, the GAF scores were enhanced to 33% after one year in the PG.

The influence of SOC levels and intervention on AR

An analysis of variance with repeated measurement showed a marginal significant effect of test intervals (F2.36 = 3.024; p = .061; CHI-2 = .144; N = 41) and a marginal significant main effect of SOC levels (F1 = 3.541; p = .068; CHI-2 = .087; N = 41) on the AR. But no significant main effect of intervention on the AR was observed (p = .221). The pair wise comparison of test intervals showed no significant difference between T1 and T2, but marginal significant differences between T1 and T3 (p = .051) and significant differences between T2 and

Table 2 Changes in AR of PG and CG between T1 and T4; T4 and T5

	PG				CG			
	M	SD	Z	p	M	SD	Z	p
T1	0.97	(0.69)			0.80	(0.82)		
			1.835	0.067			-0.131	0.896
T4	0.55	(0.82)			0.90	(1.41)		
			2.637	0.008			-0.174	0.862
T5	0.40	(0.52)			0.76	(1.06)		

Abbr.: AR = Admission rate; T1 = Baseline; T4 = after one year; T5 = after two years; PG = Psychoeducational multi family group; CG = Control group; M = Mean; SD = Standard deviation
Statistics: Wilcoxon-test

Table 3 Changes in GAF of PG and CG between T1 and T2, T2 and T3, T3 and T4

	PG				CG			
	M	SD	T	p	M	SD	T	p
T1	47.96	(9.65)			56.76	(14.60)		
			-3.593	0.002			-0.434	0.669
T2	56.45	(10.55)			57.33	(14.51)		
			-5.597	0.000			-1.435	0.167
T3	61.25	(10.00)			58.90	(14.20)		
			-5.867	0.000			-0.943	0.357
T4	63.80	(11.70)			58.57	(14.94)		

Abbr.: GAF = Global functioning; T1 = Baseline; T2 = after 3 months; T3 = after 9 months; T4 = after 12 months; PG = Psychoeducational multi family group; CG = Control group; M = Mean; SD = Standard deviation
Statistics: dependent samples t-test

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T3 (p = .037). Additionally, the pair wise comparison between the AR of patients with high and low SOC levels showed a significant difference (p = .034).

A comparison by means (see Table 4) showed that patients with a high SOC level in the PG, as well as in the CG, had no significant difference due to AR after one and two years compared to baseline. In contrast, patients with a low SOC level in the PG could reduce their AR significantly after one year (minus 61%) and also after two years (minus 77%) compared to baseline, while patients with a low SOC level in the CG had a higher AR after one year (plus 10%) and a slightly reduced AR (minus 4%) after two years.

The influence of SOC levels and intervention on GAF

An analysis of variance with repeated measurement showed a significant effect of test intervals (F3.36 = 10.403; p = .000; CHI-2 = .464; N = 41) and a significant main effect of intervention (F3.36 = 4.328; p = .011; CHI-2 = .265; N = 41) on GAF. The level of SOC showed no significant effect due to GAF (F3.36 = .715; p = .549; CHI-2 = .056; N = 41). The pair wise comparison of test intervals showed significant differences between T1 and T2 (p = .015), T1 and T3 (p = .000) and T1 and T4 (p = .000).

Table 4 Comparison by means between subgroups at T1, T4 and T5

	PG SOC low		PG SOC high		CG SOC low		CG SOC high	
	M	SD	M	SD	M	SD	M	SD
T1	01.15	(0.81)	00.57	(0.33)	01.29	(1.15)	00.50	(0.30)
T4	00.54	(0.87)	00.57	(0.78)	01.50	(2.07)	00.54	(0.66)
T5	00.38	(0.58)	00.43	(0.44)	01.06	(1.34)	00.57	(0.86)

Abbr.: AR = Admission rate; T1 = Baseline; T4 = after one year; T5 = after two years; PG = Psychoeducational multi family group; CG = Control group; M = Mean; SD = Standard deviation

Table 5 GAF comparison by means between subgroups at T1, T2, T3 and T4

	PG SOC low		PG SOC high		CG SOC low		CG SOC high	
	M	SD	M	SD	M	SD	M	SD
T1	47.62	(10.82)	52.00	(7.61)	46.50	(8.12)	65.41	(14.27)
T2	56.07	(11.06)	57.14	(10.35)	47.50	(10.33)	65.75	(13.59)
T3	61.31	(10.18)	61.14	(10.46)	50.62	(10.33)	66.41	(14.15)
T4	63.08	(12.28)	65.14	(11.33)	52.12	(12.88)	64.83	(15.16)

Abbr.: GAF = Global functioning; T1 = Baseline; T2 = after 3 months; T3 = after 9 months; T4 = after 12 months; PG = Psychoeducational multi family group; CG = Control group; M = Mean; SD = Standard deviation

Again, a comparison by means (see Table 5) showed that at T1, PG participants with high SOC levels had significant lower GAF scores than CG participants. But after one year, PG participants with high SOC levels could enhance their GAF scores from M = 52 at T1 to M = 65 at T4 (plus 25%), while CG participants with a high SOC level had no significant difference due to GAF scores between T1 and T4 (M = 65 vs. M = 64). PG participants with low SOC levels could enhance their GAF scores from M = 47 at T1 to M = 63 at T4 (34%), while CG participants with low SOC levels had a slight enhancement of GAF scores from M = 46 at T1 to M = 52 at T4 (plus 13%).

Discussion

The given results have some methodological limitations. All patients who joined the study lived with their families or had close connections to them, so the results might only be representative for this certain subgroup of patients suffering from schizophrenia. Indeed, the effects of the multi-family intervention with regard to changes in attitude, way of communication and family climate were investigated by open questions, but the results of this enquiry were not available for this article yet. Additionally, the comparability of PG and CG was limited by the fact that PG participants had significant lower GAF scores before intervention than CG participants. This difference might be due to the possibility that patients could choose to participate either in the PG or in the CG. It seemed that patients with a lower level of psychosocial functioning were more motivated to participate in a PG because they might have hoped to enhance their state of health or their course of disease through such an intervention. The comparability of the results from the PG and the CG indeed has a confinement, but the study describes conditions of a real setting in a clinical practice (high ecological validity).

According to former studies (8, 9, 10), the results showed that the patients had a clear profit from multi-family intervention. Obviously, this profit was influenced by the patients' level of SOC. Already before intervention, patients with a high SOC level had a lower AR and higher GAF scores than patients with a low SOC level. These findings support the general hypothesis that SOC is a good predictor for different clinical outcomes (18, 20). Furthermore, in this study we considered that the SOC might had worked as a moderator variable within the patients in the PG as well as in the CG. Patients with a high SOC level seemed to dispose of better personal resistance resources and therefore had a comparable lesser profit from the intervention than patients with a low SOC level.

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After intervention, a significant influence of SOC was found in the PG due to AR and also to GAF. Patients with a high SOC level had nearly the same comparably low readmission rates at a two year follow up compared to their AR at baseline. These findings were independent from whether patients participated in the PG or in the CG. But especially patients with a low SOC level had the greatest and most significant profit from their participation in a PG. They could reduce their AR about 61%, respectively, 77% to the same level as patients with a high SOC level. This profit was considerably higher than the profits in comparable studies which did not consider moderating variables in their samples (8, 10). In contrast, no significant changes in the AR within patients with a low SOC level in the CG were observable in the same period; overall, this subgroup had the highest admission and readmission rates within the sample.

The influence of SOC on GAF was similar but inverse to the AR. Patients with a high SOC level in the CG started with a comparable high GAF score. Within a one year period, they constantly showed the highest GAF scores compared to all other patients in the sample, while patients with a low SOC level in the CG constantly showed the lowest GAF scores. The greatest progress of GAF scores (plus 34%) was found within the PG participants with low SOC scores. This subgroup started on the same comparably low GAF level as the patients with low GAF scores in the CG. But they could enhance their GAF scores to nearly the same level as CG participants with a high SOC level within a one year period. This enhancement might be considerably supported through their participation in a PG.

Finally, the results led to the assumption that, beside the SOC as a coping style, also the multi-family intervention had an influence on the explored outcomes. However, the SOC seems to have a stronger influence on the AR than the multi-family intervention. Although the observed effect sizes are quite small, the effect sizes of SOC were stronger than the effect sizes of the intervention (CHI-2 = .093 vs. CHI-2 = .039). Whereas PG participants with high SOC scores could profit from their way of coping and might have activated their previous resistance resources, PG participants with a low SOC level had obvious benefits from the intervention.

Vice versa, the multi-family intervention seems to have a greater influence on the GAF than the SOC. Here, the effects are similarly low, but the intervention tended to show a stronger effect on GAF than the SOC. As well, PG participants with high and low SOC scores could enhance their GAF scores significantly, against which no significant changes due to GAF scores were observable within CG participants with high and low SOC levels.

Of course this study had the confinement that the given results were based on a small sample size. Further research on related constructs should be performed in clearly bigger samples. But overall, patients with low SOC scores seemed to have the greatest benefit from the PG concerning both observed variables. Therefore, the potential implication for clinical practice concerns pre-selection of patients with a low SOC level for psychosocial interventions and especially for multi-family interventions.

Contribution Details

All authors read and met the ICMJE criteria for authorship and agree with the results and conclusions. WG designed the study. OC and WG analysed the data. WG and HB collected data. WG and OC wrote the first draft of the paper. HB contributed to the writing of the paper. WG and OC contributed to the interpretation of the data. WG, HB and OC contributed to the discussions of the design and interpretation of the study.

Competing interests: None declared.

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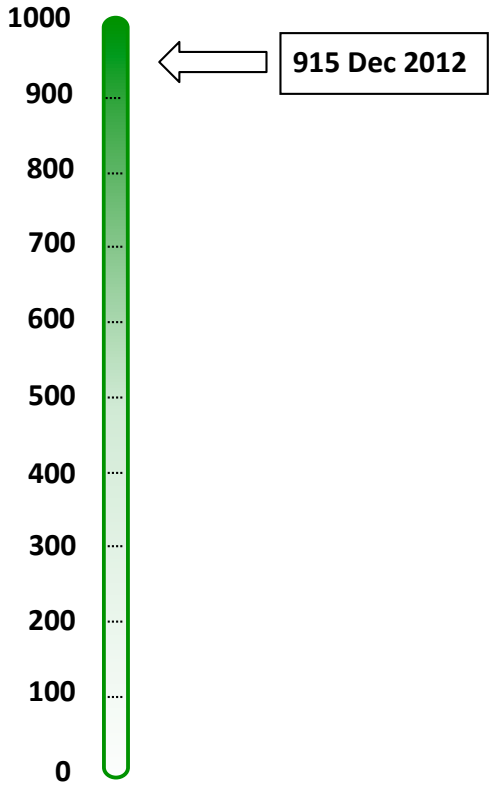

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Taipei Bus Drivers' Attitude and Intention to Control Hypertension

Mei-Ju Chen[1], Chu-Shin Zheng[2], Huey-Mei Jeng[2]

Abstract

Background This study aims to examine the prevalence rate of hypertension and the perception of hypertension, health belief and other factors among hypertensive and none-hypertensive bus drivers.

Methods The Health Belief Model (HBM) was used as a tool for examination of bus drivers in Taipei. The key variables of HBM are perceived susceptibility to contracting a health condition, perceived severity, perceived benefits, perceived barriers and cues to action. Face-to-face interviews using standardized questionnaire based on the HBM were administered. A total of 1,091 employees from a bus company in Taipei, who were professional drivers and without psychiatric conditions, participated in the cross-sectional study in July and August, 2011.

Results Twenty percent of male bus drivers suffered from hypertension. Regarding knowledge of hypertension, the group with hypertension scored higher than the non-hypertensive group ($p<0.001$), although scores remained quite low. The key variables of the HBM after controlling for the confounders, regularly BP checking helped identify early hypertension (perceived benefits), perceived likelihood of developing hypertension (perceived susceptibility) and information received from health care providers (cues to action), non-hypertensive respondents perceived significantly lower likelihood than their hypertensive counterparts, with OR = 0.037 ($p < 0.05$), 0.081 ($p < 0.001$) and 0.396 ($p < 0.01$), respectively.

Conclusions This investigation found that bus drivers had inadequate knowledge and attitude about hypertension. Data showed relatively low perceived severity of disease. Although perceived benefits were higher than perceived barriers, cues to action remained insufficient. Their behavioral intention also needed to be enhanced.

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Introduction

Bus drivers, when compared to employees of other occupational groups, have higher rates of mortality and morbidity from hypertension, gastrointestinal illnesses and musculoskeletal problems (1). Wellbeing of bus drivers is associated with safety of travelers and other road users, and therefore researchers have been concerned about the physical and mental health of bus drivers (2-4). Some studies on health of professional drivers in Taiwan identified cardiovascular disease (such as hypertension, coronary artery disease, myocardial infarction), cerebral vascular disease (stroke), gastrointestinal illnesses (such as peptic ulcer and digestive problems, musculoskeletal disorders (including back and neck pain), cancer, etc. to be common diseases and ailments among bus drivers (5;6).

Researchers have defined lifestyle as behaviors or habits that affect individual health (7). Among bus drivers, the percentages of substance use were: smoking 65%, chewing betel nuts 21%, drinking tea 79%, drinking coffee 71%, and consuming energy enhancing drinks 40%. Only 26% of bus drivers regularly exercise (8). Bus drivers tend to exercise less and work under stress due to the nature of their work. Any health impairment not only affects the driver's wellbeing but may cause undesired consequences for passengers and traffic safety (9).

Based on expectancy theory, the Health Belief Model (HBM) (Figure 1) postulates that health-seeking behavior is influenced by a person's perception and motivation (10). It addresses the relationship between a person's beliefs and behaviors. Self-efficacy is a powerful construct in the model and can be used to predict and explain a person's health behaviors. Recent studies using self-efficacy to understand health-related behaviors such as smoking, weight control, birth control, alcohol abuse and cardiovascular disease prevention proved that self-efficacy was significantly associated with behavior change and maintenance (11-15).

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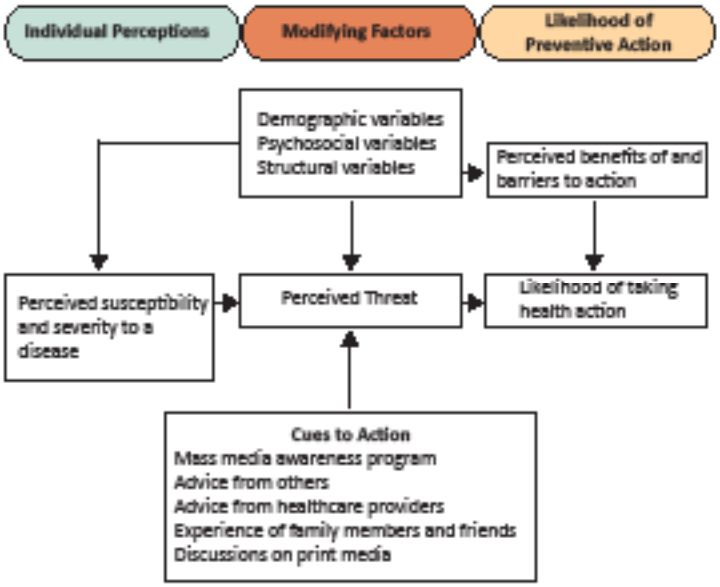
Figure 1 Health Belief Model (10)



In Taiwan, research applying the HBM to explore factors associated with cardiovascular diseases and hypertension found that 38% of the variance of modifying behaviors was explained by self-efficacy, actual risk factors, work status and health beliefs. Self-efficacy was the strongest predictor (16). In other cases, research that adopted HBM examined a community sample of Korean Americans and concluded that knowledge of hypertension, self-efficacy and self-care behaviors were positively associated with hypertension self-care. Self-efficacy emerged as the most significant contributor (17).

In terms of cues for action, previous research indicated that lecture-based health education and telephone counseling were effective to improve knowledge, self-efficacy and health-related quality of life among patients with chronic diseases, but ineffective in modifying smoking and exercise behavior (18). Media awareness programs targeting hypertensive patients showed significantly reduced blood pressure (BP) compared to control (19). Other important factors that influence health behaviors also include work site policies and environment (20).

This study aims to examine the prevalence rate of hypertension and the perception of hypertension, health belief and other factors among hypertensive and none-hypertensive bus drivers.

Methods and Materials

Subjects

1,091 out of the total of 1,100 employees from a bus company in Taipei participated in the cross-sectional study. All were professional drivers and without psychiatric conditions. Subjects were recruited through signing a consent form during the company's annual health examination in July and August 2011.

Methods

Face-to-face interviews using a standardized questionnaire were administered collecting data on perceptions regarding hypertension prevention, susceptibility, severity, benefits and barriers, cues to action, taking health action, etc.

A five-member expert panel was convened to ensure validity of the first draft questionnaire. The total CVI (content validity index) was 0.88, indicating high content validity. Modification was made accordingly. Thereafter, the questionnaire was pilot tested in a group of 31 taxi drivers and further revised before being administered by trained staff. This study was approved by the ethics committee of Taipei City Hospital (TCHIRB-1000508-E).

Measurements

The questionnaires came in three parts:

- Part I obtained demographic data including sex, age, educational level, length of service, presence of hypertension, presence of chronic disease, self-perceived health, self-reported economic status, exercise habits, frequency of measuring BP, etc.
- Part II contained 8 items regarding knowledge of hypertension control, where correct responses scores 1 point and incorrect or 'don't know' responses scored 0 point.
- Part III: Key variables of the HBM include perceived susceptibility of a health condition, perceived severity of a health condition, perceived benefits and barriers, cues to action and taking health actions. Reliability of perceived susceptibility, perceived severity, perceived benefits and barriers, cues to action and taking health action was 0.916, 0.849, 0.790, 0.703 and 0.851 measured by Cronbach's α, indicating good reliability.

Statistical Analysis

SPSS 17.0 was used for descriptive and inferential analyses including chi-square tests and logistic regression. We used those with hypertension as reference group and adjusted for demographic variables and knowledge of hypertension.

Results

A total of 1,091 interviews were conducted. Some surveys were excluded because of incomplete data, leaving 963 valid copies for analysis. It represented a response rate of 88%.

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Demographic profile of the sample is shown in table 1. The majority of the respondents were men (n=936), accounting for 97%. Among male respondents, 20% or 187 of them had hypertension. Age distribution of hypertension was 18% in the 30-40 age group, 41% in the 40-50 age group, and 42% in the group over age 50. Most (70%) were high school graduates.

80% of hypertensive drivers also suffered from other chronic diseases ($p < 0.001$). However, no significant difference was observed regarding smoking, betel nut chewing, alcohol use and exercise between hypertensive and non-hypertensive respondents.

As BP checking was required before each duty regardless of having hypertension or not, no statistical difference was observed between two groups. 72% of drivers had their BP regularly checked, but 28% below 3 times per week.

Table 1 indicated better hypertension knowledge in the hypertension group (28%) than its counterpart (15%), but overall scores remained low ($p < 0.001$).

Table 2 (appendix) and Table 3 show that the perceived susceptibility part, where 71% of non-hypertensive respondents did not think they were likely to develop hypertension; 54% hypertensive and 30% non-hypertensive respondents perceived a likeliness of developing cerebral vascular disease due to poor BP control ($p<0.001$). Non-hypertensive respondents perceived significantly lower likelihood than their hypertensive counterparts, with OR = 0.081 ($p < 0.001$).

Table 1 Bivariate analysis of the dimensions in Health Brief Model

	No Hypertension		Hypertension		Total		*p*-value
	n	%	*n*	%	*n*	%	
Sex					963	100%	N.S.
Male	749	97%	187	98%	936	97%	
Female	22	3%	5	3%	27	3%	
Age					963	100%	< 0.000
<30	34	4%	0	0%	34	4%	
30-40	251	33%	34	18%	285	30%	
40-50	294	38%	78	41%	372	39%	
50-60	176	23%	76	40%	252	26%	
>60	16	2%	4	2%	20	2%	
Education					956	100%	N.S.
Junior school or less	210	27%	56	29%	266	28%	
High school	531	70%	136	71%	667	70%	
College	23	3%	0	0%	23	2%	
Missing value					7		
Driving Seniority					963	100%	< 0.000
<5 yrs	289	37%	41	21%	330	34%	
5-10 yrs	253	33%	70	36%	323	34%	
10-20 yrs	101	13%	31	16%	132	14%	
20-30 yrs	101	13%	40	21%	141	15%	
>30 yrs	27	4%	10	5%	37	4%	
Other Chronic disease					963	100%	< 0.000
No	712	92%	38	20%	750	78%	
Yes	59	8%	154	80%	213	22%	
Smoking					956	100%	N.S.
Quit	104	14%	38	20%	142	15%	
Everyday	333	44%	79	41%	412	43%	
Occasionally	79	10%	13	7%	92	10%	
Never	249	33%	61	32%	310	32%	
Missing values	6		1		7		

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Chewing Betnuts					947	100%	N.S.
Quit	141	19%	32	17%	173	18%	
Everyday	18	2%	6	3%	24	3%	
Occasionally	88	12%	29	15%	117	12%	
Never	510	67%	123	65%	633	67%	
Missing values	14		2		16		
Drinking					959	100%	N.S.
Quit	40	5%	8	4%	48	5%	
Everyday	17	2%	3	2%	20	2%	
Occasionally	362	48%	111	58%	473	50%	
Never	340	45%	68	36%	408	43%	
Missing values	12		2		14		
Exercise					943	100%	N.S.
No	232	31%	66	35%	298	32%	
1 time/week	268	36%	65	35%	333	35%	
2-3 times/week	159	21%	33	18%	192	20%	
4-5 times/week	63	8%	13	7%	76	8%	
6-7 times/week	33	4%	11	6%	44	5%	
Missing values	16		4		20		
BP Measurement Habit					940	100%	N.S.
No	33	4%	4	2%	37	4%	
1 time/week	133	18%	24	13%	157	17%	
2-3 times/week	51	7%	19	10%	70	8%	
4-5 times/week	77	10%	27	15%	104	11%	
6-7 times/week	451	61%	111	60%	562	60%	
Missing values	16						
Perceived Economic status						100%	N.S.
Very good		2%	1	1%	19	2%	
Good		11%	17	9%	98	10%	
Common		70%	144	75%	683	71%	
Bad		13%	26	14%	126	13%	
Worst		4%	3	2%	31	3%	
Missing values			1		6		
Perceived Health status						100%	0.000
Very good		5%	4	2%	40	4%	
Good		29%	35	18%	254	27%	
Common		61%	131	69%	589	62%	
Bad		5%	18	9%	54	6%	
Worst		1%	2	1%	10	1%	
Missing values			2		16		
Knowledge about Hypertension*						100%	0.000
Score < 8		85%	138	72%	795	83%	
Score> = 8		15%	54	28%	168	17%	

The sum of items does not equal the total number of items because of missing values. When test assumptions were violated, Fisher's exact test was used. Also, the Bonferroni correction was used in this study.

* The respondents were asked 8 questions about hypertension: (1) What are threshold values for hypertension? (2) Hypertensive disorders can be effectively controlled. (3) Hypertension patients should follow physician's medication advice. (4) Irregular lifestyle or fatigue can cause elevated BP. (5) You can talk while taking your BP. (6) The arm should be at the level of the heart when taking BP. (7) You should avoid caffeine-containing drinks 30 minutes before taking BP. (8) Eating more pickles can prevent elevated BP.

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Table 3 Logistic regression of the dimensions in Health Brief Model

	O.R.	*P*
Perceived Benefits		
Checking BP regularly helps identify early stages of hypertension.	.037	0.017
Perceived Barriers		
You do not know the causes of hypertension.	.799	N.S.
You do not know how to take BP.	.508	N.S.
No BP measuring instrument is available in the place you live.	1.505	N.S.
Perceived Severity		
You agree that your company places emphasis on employee's health.	.650	N.S.
You will be mentally disturbed if you develop high BP	2.105	N.S.
Your physical condition will be seriously affected if you develop high BP	.712	N.S.
Your social life will be seriously affected if you develop high BP	1.572	N.S.
Your family's livelihood will be seriously affected if you develop high BP	1.378	N.S.
Your career prospects will be seriously affected if you develop high BP	1.651	N.S.
Perceived Susceptibility		
How likely do you feel you may develop hypertension?	.081	0.000
How likely do you feel you may develop cerebral vascular disease due to poor BP control?	.780	N.S.
How likely do you feel you may develop cardiovascular disease due to poor BP control?A3	2.379	N.S.
How likely do you feel you may develop kidney disease due to poor BP control?	.578	N.S.
How likely do you feel you may develop eye complications due to poor BP control?	1.424	N.S.
Cues to Action		
You have read electronically transmitted messages about hypertension control from TV, radio, internet or outdoor LCD monitor.	1.479	N.S.
You have read messages about hypertension control from print media such as magazines, newspapers, booklets, posters or pamphlets.	.738	N.S.
You have received information about hypertension control from friends and family members.	.919	N.S.
Your have received information about hypertension control from healthcare providers	.396	0.002
-2 Log likelihood	**473.037**	

Reference group: hypertension subgroup
Control variables: age, driving seniority, others chronic disease history, knowledge, perceived health status.

As for the perceived benefits and barriers, only regular BP measuring was significantly different between two groups ($p < 0.05$). Nonetheless, 97% of respondents agreed that regular BP checking helped identify early hypertension. Non-hypertensive respondents perceived significantly lower likelihood than their hypertensive counterparts, with OR = 0.037 ($p < 0.05$).

Regarding cues to action (Table 4), information acquired from health care providers (75%). Distribution among the hypertensive respondents in the above mentioned items was significantly higher than the non-hypertensive group ($p < 0.001$). Non-hypertensive respondents perceived significantly lower likelihood than their hypertensive counterparts, with OR = 0.396 ($p < 0.01$).

Other variables of the HBM, after controlling for the confounders, did not reach the significantly different level in our study.

Discussion

Creating Health Promoting Workplace

The main finding from this project investigating knowledge, attitude and intention about hypertension among bus drivers was that about 1/5 suffered from hypertension. The prevalence doubled for drivers older than 45 years of age, and the large majority of hypertensive drivers had supplemental co-morbidity. Although the scores on knowledge remained quite low, the hypertension group scored significantly higher than the none-hypertensive group.

Although the prevalence rate seems to have declined when compared with data in 2001 (21), it was still higher than other populations receiving health examinations. Prevalence of everyday smoking (43%), chewing betel nut (3%), drinking alcohol (2%) and no regular exercise (32%) became lower than in 2008 (2).

In Sweden, a 15-year follow-up study observed a 50% increase in mortality from myocardial infarction among male drivers compared to other groups of employment. Moreover, bus drivers are also at high risk of ischemic heart disease (IHD), as seen in a 10-year panel study in Denmark of bus drivers working in a high traffic intensity area (22).

Another study using medical records of annual physical examinations in Taipei Municipality indicated significant higher prevalence of IHD among bus drivers (9). Similarly, hypertension rate for bus drivers in Taipei Municipality was significantly greater than the reference group after adjusting for age. In our study, 80% of hypertensive drivers also suffered from other chronic diseases.

In our study, almost everyone agreed that regular BP

Table 4 Bivariate analysis of the action cues in the Health Brief Model

	No Hypertension		Hypertension		Total		*P-value*
	n	%	n	%	n	%	
Have participated in any lecture-based hypertension control health education					957		N.S.
No	654	85%	155	81%	809	85%	
Yes	112	15%	36	19%	148	15%	
Missing data					6		
Have read electronically transmitted messages about hypertension control from TV, radio, internet or outdoor LCD monitor.					958		0.003
No	398	52%	76	40%	474	49%	
Yes	369	48%	115	60%	484	51%	
Missing data					5		
Have read messages about hypertension control from print media such as magazines, newspapers, booklets, posters or pamphlets.					957		0.000
No	384	50%	57	30%	441	46%	
Yes	383	50%	133	70%	516	54%	
Missing data					6		
Have received information about hypertension control from friends and family members.					956		0.000
No	377	49%	52	28%	429	45%	
Yes	390	51%	137	72%	527	55%	
Missing data					7		
Have received information about hypertension control from health-care providers.					957		0.000
No	429	56%	48	25%	477	50%	
Yes	339	44%	141	75%	480	50%	
Missing data					6		

The sum of items does not equal the total number of items because of missing values. When test assumptions were violated, Fisher's exact test was used. And the Bonferroni correction was used in this study.

checking helped identify early hypertension, but about one third of all respondents did not know the causes of hypertension one fifth to one quarter did not know how to take a BP, did not have a BP measuring instrument around or even considered BP measuring troublesome. Results from local and international research suggest a necessity to improve hypertension knowledge, control and occupational health awareness.

In general, the bus drivers demonstrated insufficient knowledge and attitude about hypertension, despite a higher likelihood in the hypertension group of receiving health education from health providers due to their physical condition.

Moreover, there remained room for improved behavioral action. Road passenger transport industry should be responsible for not only quality transport but safety for both passengers and other road users, and the key to ensure safety is driver's physical and mental health. Work conditions play a critical role in driver's overall performance. The job requires long periods of sitting in the same position as well as over time and shift work. Therefore, it is necessary for professional drivers to have adequate knowledge and attitude about hypertension.

It is believed that personal trait and experience, perception of a particular behavior and consequence of the behavior are three important factors that contribute to health promoting behavior change (23). To achieve this, interventions that ensure tangible benefits and produce cost-effective results in a short time might be a good strategy. Health promoting workplace should be a good approach to start with.

At present, tobacco control was the main agenda for the Bureau of Health Promotion in the workplace setting. We suggest that knowledge and health behaviors

regarding chronic diseases and creating a friendly environment to exercise should be integrated in the workplace health promoting programs, particularly in the passenger transport industry.

In reality, managers' intention about worksite health promotion seem to be influenced by their beliefs, moral responsibility and social expectation, in addition to cost (24). Social expectations and public incentives played a significant role to motivate business owners to implement worksite health promotion programs (25).

Accessibility of Diversified Health Education

Our findings indicate that in three items, i.e. regularly BP checking helped identify early hypertension, perceived likelihood of developing hypertension and information received from health care providers, non-hypertensive respondents perceived significantly lower likelihood than their hypertensive counterparts.

Findings from this study point out that bus drivers with hypertension do not perceive their disease to be of high severity. But although they perceived higher benefits than barriers, cues to action were still lacking, leaving room for improved likelihood of behavior change.

A minor part participated in health education lectures but more reported other channels of receiving information such as electronic media, print media , friends and family, and health care providers, with higher prevalence in the hypertensive group. It suggests that traditional approaches like lectures was not effective for professional drivers and therefore do not achieve expected results. Nevertheless, non-hypertensive bus drivers reported a lower likelihood to receive health information from health care providers than hypertensive drivers did.

Multiple channels of information transmission and localized health promotion strategy should be highlighted in today's work site health promotion programs. As Maibach and colleagues pointed out (26), health communication is a key component of disease prevention and health promotion. Providing persuasive health information is part of the socialization process in which every individual is empowered to view health as his own business.

In Taiwan, health issues such as wide application of biotechnology, universal health insurance, spread of epidemics, litigation against physicians and fitness awareness have become an increasingly vital part in life. Health has also gained prominence in the political agenda. In recent years, people's increased attention to environmental factors and preventive medicine prompted them to seek health-related information.

Studies in other countries have shown that media campaigns are effective to facilitate behavioral change, which in turn reduce risks, mortality and morbidity. Health communication through media has evolved from using single channel to multiple mass media such as TV, radio, newspaper, magazine and internet. Traditional consumer-oriented strategy has also applied the concept of integrated marketing communication, encompassing elements like social marketing, public relations, advertisement, health education, personal influence, media strategy and entertainment.

Health campaign for bus drivers should be tailored and different from other segments of the population in order to meet their need. For example, chronic diseases prevalence in this group should be identified and addressed in work site health screening programs and policies. Campaign scheduling should also take into account work pattern of bus drivers. Health communication should be made easily accessible, easy to understand, up-to-date and digitalized whenever needed.

The limitation of this study is the lack of self-efficacy and health-related quality of life domains. And the managers' intention would be a critical variance in the workplace; it is needed for further evaluation.

Conclusions

This investigation found that bus drivers had inadequate knowledge and attitude about hypertension, and that their behavioral intention also need to be enhanced. Data showed relatively low perceived severity of disease. Although perceived benefits were higher than perceived barriers, cues to action remained insufficient. Thus, likelihood of preventive action need a boost.

Safety of passengers and other road users are major concern of the mass transportation industry. Work site health promotion will be effective strategies to ensure safety. Intentions of corporate managers and executives to implement work site health promotion programs are influenced by cost-containment, personal belief, moral responsibility and social norms. It is a common challenge for employees, employers, unions and health professionals to tackle in order to come up with a model that caters to workers of different characteristics.

In this study we found that the two groups showed no significant difference in terms of health lecture, one of the cues to action. Only 15.5% attended such lectures,

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but about 70% of them received information from other means such as electronic media, print media, friends and family and health providers. It could be concluded that since lecture-based health promotion was proven ineffective, efforts should be made towards diversified health communication and context-specific health promotion. It is important to further explore the potential of media, today's main source of health information for most people, in order to improve individual and public health.

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Competing Interests: None declared.

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Appendix: Table 2 Bivariate analysis of the dimensions in Health Brief Model

	No Hyper-tension		Hyperten-sion		Total		*P*-value
	n	%	*n*	%	*n*	%	
Perceived Benefits							
Checking BP regularly keeps you informed of current health condition.					955		N.S.
Disagree	45	6%	9	5%	54	6%	
Agree	721	94%	180	95%	901	94%	
Missing data					8		
Checking BP regularly helps identify early stages of hypertension.					958		<0.038
Disagree	25	3%	1	1%	26	3%	
Agree	743	97%	189	99%	932	97%	
Missing data					5		
Good BP control helps reduce medical expenditure.					957		N.S.
Disagree	39	5%	8	4%	47	5%	
Agree	727	95%	183	96%	910	95%	
Missing data					6		
Good BP control helps improve work efficiency.					958		N.S.
Disagree	51	7%	9	5%	60	6%	
Agree	717	93%	182	95%	899	94%	
Missing data					5		
Perceived Barriers							
You do not know the causes of hypertension.					953		0.000
Disagree	347	45%	120	63%	467	49%	
Agree	416	55%	70	37%	486	51%	
Missing data					10		
You do not know how to take BP.					947		<0.001
Disagree	516	68%	154	81%	670	71%	
Agree	242	32%	37	19%	279	29%	
Missing data					16		
No BP measuring instrument is available in the place you live.					948		<0.041
Disagree	525	69%	145	77%	670	71%	
Agree	234	31%	44	23%	278	29%	
Missing data					15		
You think BP control is a lot of trouble.					951		N.S.
Disagree	522	69%	134	71%	656	69%	
Agree	240	32%	55	29%	295	31%	
Missing data					12		
Company policies and environment							
You agree that your company places emphasis on employee's health.					953		<0.045
Disagree	116	15%	18	10%	134	14%	
Agree	648	85%	171	90%	819	86%	
Missing data					10		
You agree that health benefits provided by your company meet your need					956		N.S.
Disagree	145	19%	28	15%	173	18%	
Agree	622	81%	161	85%	783	82%	
Missing data					7		

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You agree that your company provides diversified health care					954		N.S.
Disagree	159	21%	36	19%	195	20%	
Agree	605	79%	154	81%	759	80%	
Missing data					9		
Perceived Severity							
You will be mentally disturbed if you develop high BP					959		0.000
Disagree	102	13%	57	30%	159	17%	
Agree	666	87%	134	70%	800	83%	
Missing data					4		
Your physical condition will be seriously affected if you develop high BP					959		0.000
Disagree	166	22%	77	40%	243	25%	
Agree	602	78%	114	60%	716	75%	
Missing data					4		
Your social life will be seriously affected if you develop high BP					958		0.000
Disagree	297	39%	112	59%	409	43%	
Agree	470	61%	79	41%	549	57%	
Missing data					5		
Your family's livelihood will be seriously affected if you develop high BP					959		0.000
Disagree	204	27%	91	48%	295	31%	
Agree	564	73%	100	52%	664	69%	
Missing data					4		
Your career prospects will be seriously affected if you develop high BP					958		0.000
Disagree	165	22%	81	42%	246	26%	
Agree	602	78%	110	58%	712	74%	
Missing data					5		
Perceived Susceptibility							
How likely do you feel you may develop hypertension?					960		0.000
Disagree	542	71%	31	16%	573	60%	
Agree	226	29%	161	84%	387	40%	
Missing data					3		
How likely do you feel you may develop cerebral vascular disease due to poor BP control?					960		0.000
Disagree	538	70%	88	46%	626	65%	
Agree	230	30%	104	54%	334	35%	
Missing data					5		
How likely do you feel you may develop cardiovascular disease due to poor BP control?					956		0.000
Disagree	513	67%	80	42%	593	62%	
Agree	251	33%	112	58%	363	38%	
Missing data					5		
How likely do you feel you may develop kidney disease due to poor BP control?					958		0.000
Disagree	534	70%	96	50%	630	66%	
Agree	232	30%	96	50%	328	34%	
Missing data					5		
How likely do you feel you may develop eye complications due to poor BP control?					958		0.000
Disagree	507	66%	98	51%	605	63%	
Agree	259	34%	94	49%	353	37%	
Missing data					5		

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Taking Action Intension							
In the next month you will check BP every day before driving.					960		N.S.
Disagree	186	24%	44	23%	230	24%	
Agree	582	76%	148	77%	730	76%	
Missing data					3		
At home, you will remember to check BP without others reminding.					960		N.S.
Disagree	215	28%	49	26%	264	28%	
Agree	553	72%	143	74%	696	73%	
Missing data					3		
At home, you will remember to check BP even without presence of other physical abnormalities.					958		N.S.
Disagree	111	14%	21	11%	132	14%	
Agree	655	86%	170	89%	825	86%	
Missing data					5		
You will choose low-salt diet to prevent BP from elevating.					956		N.S.
Disagree	250	33%	56	29%	306	32%	
Agree	517	67%	134	71%	651	68%	
Missing data					7		
You will exercise 5 times a week for at least 30 minutes to prevent BP from elevating.					958		N.S.
Disagree	414	54%	106	56%	520	54%	
Agree	353	46%	85	45%	438	46%	
Missing data					5		
You will actively participate in company's health programs.					956		N.S.
Disagree	264	35%	67	35%	331	35%	
Agree	501	65%	124	65%	625	65%	
Missing data					7		
You will relay hypertension control messages to people in need.					960		N.S.
Disagree	248	32%	55	29%	303	32%	
Agree	520	68%	137	71%	657	68%	
Missing data					3		

The sum of items does not equal the total number of items because of missing values. When test assumptions were violated, Fisher's exact test was used. And the Bonferroni correction was used in this study.

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Impact of compliance on quit rates in a smoking cessation intervention: population study in Denmark

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Abstract

Objectives Primary objective was to evaluate whether patients completing at least 75% of the smoking cessation program had a higher quit rate after 6 months than patients participating in less than 75% of the program. Secondary objective was to evaluate whether there might be a more appropriate compliance level than 75% .

Methods The study included all patients (17,439) who participated in the National Gold Standard Smoking Cessation Program in Denmark (GSP) with planned follow-up for smoking cessation at 6 months. Patients were randomly divided into two groups (datasets) in order to investigate and re-validate the objectives on two separated groups of smokers. Sensitivity analyses were undertaken for non-responders.

Results Patients who completed at least 75% of the program sessions had higher quit rates in comparison to patients who completed less than 75% of the program (OR = 0.27; 95% CI 0.24 - 0.31 and 0.31; 0.27 - 0.35) for the first and second dataset, respectively. However patients who completed the whole program had higher quit rates compared to patients completing only 75% (0.49; 0.43 - 0.56, and 0.54; 0.47 - 0.62, respectively). The sensitivity analysis showed that baseline characteristics were similar between patients with missing and available follow-up data.

Conclusion Compliance to 75% of the national smoking cessation program (GSP) is shown to be effective; however, 100% compliance leads to even higher quit rates.

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Introduction

According to the Danish Cancer Society, around 20% of Danes aged 15 years and older were daily smokers in 2010 (1). Moreover, it is estimated that over 800,000 Danes are daily smokers, and around 14,000 Danes die annually due to smoking, while 4,500 die of cancer, where smoking is one of the main contributing risk factors. Consequently, Danish public health and tobacco control strategies include nationwide smoking cessation interventions. A national smoking cessation database (SCDB) was established to monitor and improve the clinical quality of smoking cessation programs (2). The leading and dominant intervention on smoking cessation in Denmark is a comprehensive evidence based intervention called the Gold Standard Program (GSP) (3). This program combines pharmacotherapy and psychological interventions in an intensive 6 week manual-based program; such an approach has been shown to be more effective than less intense interventions (4;5). For instance, such intensive programs on smoking cessation are the ones considered most relevant for hospitalised patients (6).

The program is delivered as a group or individual intervention by trained counsellors to patients who are referred by their doctors, other health professionals, or enter on their own initiative. The program is delivered at diverse settings including hospitals, municipality clinics, general practices, pharmacies, and companies. It consists of five manual-based face-to-face sessions along with supportive medications over six weeks.

As a general principle, a patient is often considered as having completed a treatment program, if patient compliance/adherence to the program is at least 75%. This compliance level has been used for our smoking cessation program GSP, and for evaluating the program effectiveness at the national level in a previous study (7). However, the appropriateness of this compliance level has never been evaluat-

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ed before. Therefore, the main aim of this study is to evaluate the evidence for this compliance level. Counselling compliance is one of the specified predictors for smoking cessation in the literature (8). In a meta-analysis of 45 studies, smoking cessation rates increased with the increase in the number of counselling sessions attended (8). The literature therefore indicates an established relationship between intensity in terms of program duration and/or number of sessions and effectiveness of the smoking cessation interventions (8-11). Nevertheless, there is little evidence on typical number and duration of smoking cessation interventions (10;12).

Objectives

- The primary objective was to investigate whether smokers completing at least 75% of the smoking cessation intervention had higher quit rates after 6 months than smokers participating in less than 75% of the program.

- The secondary objective was to investigate whether there might be a more appropriate compliance level than the 75% compliance level.

Methods

The Gold Standard Program

This is a standardised program in terms of setting a standard orientation and training program for all smoking cessation counsellors who are responsible for delivering the Standard Smoking Cessation Program, standardised delivery of the program aided with a manual and standardised data collection procedure (3).

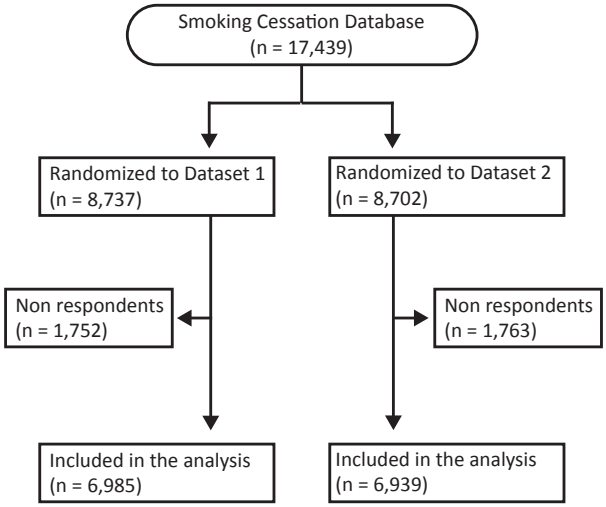
Patients

In total, 299 smoking cessation units provided patient data to the Smoking Cessation Database (SCDB) in Denmark. While 23,775 daily smokers who had enrolled in the GSP from 2006-2009, 6,336 (26%) were not included in this study, because some smoking cessation clinics had a priori decided not to follow-up on any of their patients. After 6 months, the included patients were contacted by phone and asked about their quitting status; at least four attempts including one in the evening were initiated to contact the patient. Only if all of the attempts failed was the patients' quitting outcome considered as missing (approximately 15 % of patients) (Figure 1).

Main independent variable

The main exposure is the different compliance levels expressed as the number of sessions attended; data on attendance was entered into the SCDB for almost all patients since 2006.

Figure 1 Trial Profile



Quitting outcome measure

Patients were grouped according to the availability of 6-month follow up data on quitting outcomes into two "follow-up outcome" groups:

a) Patients with existing data on quitting outcomes at 6-months of follow up (base case scenario).
b) Patients with missing quitting outcome data due to failed follow-up attempts (non-responders). This group has been used in sensitivity analyses as worst and best case scenarios.

Design

We undertook a national population study using prospectively recorded data on patients and GSP characteristics. Patients' data was stratified by gender, age, and calendar year, and then randomly split into two datasets by a colleague not otherwise involved in the project. It is worth mentioning that population studies often generate many significant results, which requires further evaluation in new studies for confirmation. To overcome this methodological problem, we decided a priori to generate two datasets (dataset 1 and dataset 2) through random splitting of the original data in the SCDB; the second dataset was concealed from the researchers until the analysis of the first dataset had been finalised (Figure 1).

Statistical methods

The following analyses were performed and finalised for the first dataset "dataset 1", then repeated for the second dataset "dataset 2". Initially, logistic regression (LR) models were constructed, and two analyses compared the quit rates between different levels of compliance. The first analysis tested the primary objective and compared patients who completed less than 75% of the

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program (i.e. one, or two, or three sessions) and who attended at least 75% of the program (four or five sessions); using patients who attended less than 75% of sessions as the reference group. The second analysis tested the secondary objective and compared the quit rates for patients who attended one, two, three, four, or five sessions; using the last group as the reference group. The set of predictors used in the LR models along with level of compliance were; smoking cessation unit setting, calendar year, intervention type, setting, if relapse prevention strategy offered for the patient, if nicotine replacement therapy offered to the patient, age, gender, overall Fagerström score, smoking years, living with smoker, living with adult, living with child, previous attempts to stop smoking, employment status, level of education, and housing type. It is worth mentioning that predictors have been chosen after screening of relevant literature (7;12-14).

Two sensitivity analyses (worst- and best-case scenarios) were performed on both datasets by including the data on non-respondents. The worst-case scenario considered non-responding patients as smokers, while the best-case scenario considered them as quitters. Statistical analysis was undertaken using SPSS 19.

Ethical considerations

Written informed consent in the national language was obtained from all patients who participated in the smoking cessation interventions. SCDB is registered at the Scientific Ethical Committee (Prot.-Nr. H-C-FSP-2010-049). All data were analysed anonymously. The whole procedure on obtaining, storing, and utilising patients' information by the National Clinical Smoking Cessation Database Secretariat was approved by the Danish Data Protection Agency (J.-Nr. 2010-41-5463).

Results

Statistics on comparability of groups

Comparison of the different patient groups in terms of follow-up (base case and non-respondents) showed that the groups were similar for patient and program related characteristics, and for the two datasets (Table 1).

Quitting outcomes data

Table 2 shows quit rates at 6-months follow up in relation to different levels of compliance for the base case, and non-respondents (worst and best cases).

Main Results

Table 3 shows the main results along with results of the sensitivity analyses. Table 4 shows predictors of the relationship between compliance and quit rates on the two study objectives and for the two datasets.

Primary objective

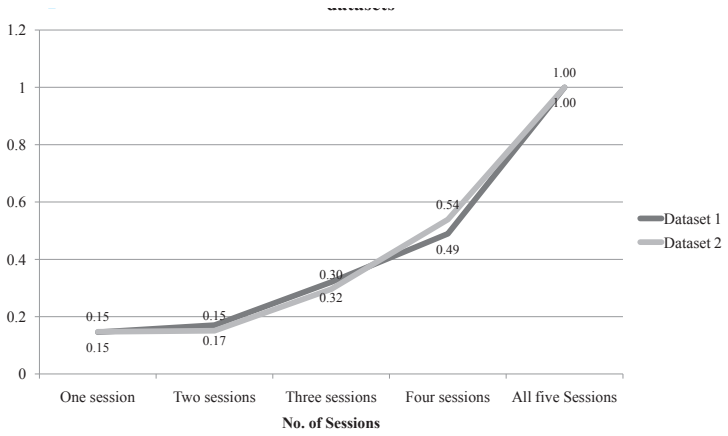
Considering the base case scenario in both datasets 1 and 2, patients who completed at least 75% of the pre-planned sessions (attended four or five sessions) had almost triple the quit rates in comparison to patients who attended less than 75% of pre-planned sessions (OR = 0.31; 95% CI 0.27 - 0.35, and 0.27 ; 0.24 - 0.31, for the first and second datasets) (See Table 3).

Secondary objective

Considering the base case scenario in both datasets 1 and 2, patients who attended one, two, three, or four sessions had a lower probability of quitting compared to patients who completed the whole program. For instance, patients who completed only 75% of the program (four sessions) had a lower probability of quitting (almost half) compared to patients who completed 100% of the program by attending all the five sessions (0.49; 0.43 - 0.56, and 0.54; 0.47 - 0.62, for the first and second datasets) (Table 3).

These results indicated an association between higher compliance levels and higher quit rates (Figure 2).

Figure 2 Adjusted ORs estimates on the secondary objective for both datasets*



*Reference group: patients who completed the whole programme (OR= 1)

Sensitivity analyses

Primary objective: In both datasets 1 and 2, the best and worst-case scenarios showed similar results to the base case scenario. Results showed that attending less than 75% of the pre-planned sessions was associated with a lower probability of quitting compared with attending at least 75% (at least four) sessions (Table 3).

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Table 1 Population cohort main characteristics in the two datasets, given in numbers (%) or median (range)

Dataset	Dataset 1 (N = 8,737)		Dataset 2 (N = 8,702)	
Patient group	**Base Case**	**Non-respondents**	**Base Case**	**Non-respondents**
Count	6985	1752	6939	1763
Percent of the total count %	58.6	14.7	58.5	14.8
Characteristics				
Unit Type %				
Pharmacy	24.9	23.2	24.7	25.4
Hospital Clinic incl. Midwives	10.8	10.4	10.9	9.8
Municipality and other practices	59.3	63.7	59.0	61.5
County coordinator	5.0	2.7	5.4	3.3
Year %				
2006	23.9	20.0	23.7	21.2
2007	28.1	28.5	27.8	27.0
2008	24.1	26.7	24.6	26.3
2009	24.0	24.8	23.9	25.6
Intervention type %				
Individual	8.0	8.2	8.1	9.9
Group and other interventions	92.0	91.8	91.9	90.1
Relapse Prevention %				
No	51.1	57.7	51.3	60.1
Yes	48.9	42.3	48.7	39.9
Nicotine Replacement %				
No	51.3	46.5	51.8	49.1
Yes	48.7	53.5	48.2	50.9
Age %				
Less than 35	14.2	21.4	13.6	22.1
From 35 to 54	43.7	44.2	45.1	44.8
More than 55	37.8	29.9	36.6	29.8
Missing Data	4.3	4.6	4.6	3.3
Gender %				
Women	61.7	60.9	62.3	61.7
Men	38.3	39.1	37.7	38.3
Fagerström Score %				
From 0 to 4	38.4	38.0	37.6	35.0
From 5 to 10	61.6	62.0	62.4	65.0
Living with smoker %				
No	64.8	67.6	64.7	64.8
Yes	34.5	31.5	34.6	34.7
Missing	.7	.9	.7	.5
Living with adult %				
No	43.2	48.0	44.4	47.2
Yes	55.7	50.8	54.6	51.8
Missing Data	1.1	1.2	1.0	1.0

Table 1 continues on the following page.

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Living with child %				
No	66.5	69.1	66.9	66.8
Yes	32.3	29.6	32.1	32.3
Missing Data	1.2	1.4		1.0
Previous quitting attempts %				
Non	38.9	40.5	39.2	39.1
1-3 times	49.4	48.1	49.9	49.1
more than 3 times	9.9	9.0	9.2	9.0
Missing Data	1.8	2.3	1.6	2.8
Employment status %				
with job	63.2	63.0	63.1	60.6
without job	34.6	34.0	34.4	36.6
Missing Data	2.2	3.1	2.5	2.8
Education %				
lower education = less than 11 years	59.8	58.4	60.2	63.0
higher and other education	37.2	38.0	36.7	33.5
Missing Data	3.0	3.6	3.1	3.6
Housing Type %				
Residential property+ other housing	51.9	42.5	52.2	39.0
Co-operative dwelling	9.0	11.4	8.9	10.4
Rented accommodation	37.3	44.5	37.3	48.4
Missing Data	1.7	1.6	1.6	2.2
Smoking (years)	32 (0-74)	29 (0-66)	32 (0-99)	30 (0-67)
Compliance/attendance (meetings)	4 (1-5)	3 (1-5)	4 (1-5)	3 (1-5)

Table 2 Quit rates in the two datasets

	Dataset 1			Dataset 2		
Total count	**Base Case**	**Worst Case**	**Best Case**	**Base Case**	**Worst Case**	**Best Case**
	n = 6,985	n = 8,737	n = 8,737	n = 6,939	n = 8,702	n = 8,702
Quitters	2266	2266	4018	2218	2218	3981
Percentage %	32.4	25.9	46.0	32.0	25.5	45.7
Compliance /Attendance						
1 Session	0.8	0.6	4.1	0.8	0.6	4.1
2 sessions	1.5	1.2	4.3	1.4	1.1	4.4
3 sessions	3.7	2.9	6.7	3.4	2.7	6.4
4 sessions	7.9	6.3	10.8	8.2	6.5	10.9
5 sessions	18.5	14.8	20.1	18.2	14.5	19.9
Less than 75%	6.0	4.8	15.1	5.6	4.5	14.9
At least 75%	26.5	21.2	30.9	26.3	21.0	30.9

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Table 3 Main results along with the two sensitivity analyses; evaluating whether smokers completing at least 75% of the smoking cessation intervention had higher quit rates after 6 months than smokers participating in less than 75% of the program; and investigating whether there might be a more appropriate compliance level than the 75% compliance level (Please, observe that all results were significant). The value 1 was the reference.

	Dataset 1			Dataset 2		
Scenario	**Base Case**	**Worst Case**	**Best Case**	**Base Case**	**Worst Case**	**Best Case**
	OR (95% CI)	**OR (95% CI)**	**OR (95% CI)**	**OR (95% CI)**	**OR (95% CI)**	**OR (95% CI)**
> 75% Attendance	1	1	1	1	1	1
< 75% Attendance	0.31 (0.27-0.35)	0.29 (0.25-0.33)	0.64 (0.58-0.71)	0.27 (0.24-0.31)	0.27 (0.24-0.31)	0.57 (0.52-0.63)
All 5 sessions	1	1	1	1	1	1
4 sessions	0.49 (0.43-0.56)	0.49 (0.43-0.56)	0.61 (0.54-0.69)	0.54 (0.47-0.62)	0.54 (0.48-0.62)	0.66 (0.58-0.74)
3 sessions	0.32 (0.27-0.38)	0.32 (0.27-0.37)	0.52 (0.45-0.59)	0.30 (0.25-0.35)	0.31 (0.26-0.37)	0.46 (0.40-0.53)
2 sessions	0.17 (0.14-0.22)	0.17 (0.13-0.21)	0.43 (0.37-0.50)	0.15 (0.12-0.19)	0.15 (0.12-0.19)	0.42 (0.36-0.49)
1 session	0.15 (0.11-0.20)	0.11 (0.08-0.16)	0.69 (0.58-0.83)	0.15 (0.11-0.20)	0.12 (0.09-0.17)	0.64 (0.54-0.76)

Table 4 Predictors on the association between attendance and quitting rates for smokers completing at least 75% of the smoking cessation intervention and for smokers attending all sessions. The value 1 was the reference.

	Attendance and quitting rates for smokers completing at least 75% of the smoking cessation intervention				Smokers attending all sessions			
	Dataset 1		Dataset 2		Dataset 1		Dataset 2	
	Sign	OR 95% CI	Sign	OR 95% CI	OR 95% CI	Sign	OR 95% CI	
Unit Type								
County coordinator	-	1	-	1		1		1
Pharmacy	0.090	1.27 (0.93-1.73)	0.034	1.39 (1.03-1.89)	0.104	1.26 (0.92-1.72)	0.049	1.36 (1.00-1.85)
Hospital Clinic incl. Midwives	0.079	1.31 (0.94-1.84)	0.009	1.57 (1.12-2.20)	0.087	1.35 (0.96-1.90)	0.006	1.61 (1.14-2.26)
Municipality and other practices	0.120	1.23 (0.91-1.67)	0.006	1.52 (1.13-2.05)	0.110	1.25 (0.92-1.69)	0.012	1.47 (1.09-1.99)
Year								
2009	-	1	-	1	-	1	-	1
2006	0.016	0.80 (0.67-0.96)	0.635	1.01 (0.84-1.22)	0.017	0.80 (0.66-0.96)	0.685	1.00 (0.83-1.20)
2007	0.070	0.87 (0.74-1.01)	0.097	0.89 (0.76-1.04)	0.085	0.87 (0.74-1.02)	0.092	0.87 (0.74-1.02)
2008	0.000	0.71 (0.61-0.84)	0.063	0.86 (0.73-)1.01	0.000	0.72 (0.61-0.85)	0.059	0.85 (0.72-1.01)
Intervention type								
Group and others	-	1	-	1	-	1	-	1
Individual	0.017	1.29 (1.05-1.60)	0.094	1.18 (0.95-1.46)	0.0875	1.18 (0.95-1.47)	0.285	1.10 (0.88-1.36)
Relapse Prevention								
Yes		1		1	-	1	-	1
No	0.070	0.90 (0.79-1.01)	0.072	0.89 (0.79-1.01)	0.089	0.91 (0.81-1.03)	0.0909	0.91 (0.81-1.03)
Nicotine Replacement								
Yes	-	1	-	1	-	1	-	1
No	0.321	0.95 (0.84-1.09)	0.658	1.00 (0.88-1.15)	0.282	0.95 (0.83-1.08)	0.6139	1.01 (0.88-1.15)
Age								
> 55 years	-	1	-	1	-	1	-	1
35 - 54	0.025	0.82 (0.69-0.98)	0.069	0.86 (0.72-1.03)	0.011	0.71 (0.55-0.92)	0.064	0.77 (0.59-1.02)
< 35	0.004	0.68 (0.53-0.88)	0.036	0.75 (0.57-0.98)	0.045	0.84 (0.70-1.00)	0.143	0.89 (0.75-1.06)

Table 4 continues on the following page.

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Gender								
Men	-	1	-	1	-	1	-	1
Women	0.000	0.76 (0.68-0.86)	0.000	0.81 (0.72-0.91)	0.000	0.78 (0.69-0.88)	0.000	0.81 (0.71-0.91)
Fagerström Score								
High (5-10 points)	-	1	-	1	-	1	-	1
Low (0-4 points)	0.000	1.38 (1.23-1.55)	0.000	1.49 (1.32-1.67)	0.000	1.38 (1.23-1.55)	0.000	1.49 (1.32-1.68)
Smoking Years	0.000	0.99 (0.98-0.99)	0.003	0.99 (0.98-1.00)	0.000	0.99 (0.98-0.99)	0.002	0.99 (0.98-1.00)
Living with smoker								
Yes	-	1	-	1	-	1	-	1
No	0.006	1.19 (1.05-1.36)	0.123	1.09 (0.96-1.24)	0.010	1.18 (1.04-1.35)	0.101	1.10 (0.97-1.25)
Living with adult								
Yes	-	1	-	1	-	1	-	1
No	0.052	0.88 (0.78-1.00)	0.043	0.88 (0.77-1.00)	0.094	0.90 (0.79-1.02)	0.041	0.87 (0.77-0.99)
Living with child								
Yes		1		1	-	1	-	1
No	0.430	1.04 (0.90-1.19)	0.312	0.95 (0.82-1.09)	0.547	1.02 (0.88-1.18)	0.272	0.94 (0.81-1.08)
Previous attempts to stop smoking								
More than 3 times	-	1	-	1	-	1	-	1
Non	0,140	0.88 (0.72-1.07)	0.693	1.00 (0.82-1.23)	0.138	0.88 (0.72-1.07)	0.659	0.99 (0.81-1.22)
1-3 times	0.031	0.81 (0.67-0.98)	0.383	0.94 (0.77-1.15)	0.029	0.81 (0.67-0.98)	0.351	0.93 (0.77-1.14)
Employment status								
Non-Employed	-	1	-	1	-	1	-	1
Employed	0.039	1.16 (1.01-1.34)	0.331	1.05 (0.91-1.22)	0.050	1.15 (1.00-1.33)	0.264	1.07 (0.92-1.24)
Education								
Higher	-	1	-	1	-	1	-	1
Lower (< 11 years)	0.059	0.89 (0.79-1.00)	0.000	0.81 (0.72-0.91)	0.047	0.89 (0.79-1.00)	0.000	0.80 (0.71-0.90)
Housing Type								
Rented accommodation	-	1	-	1	-	1	-	1
Residential property and others	0.000	1.28 (1.12-1.45)	0.000	1.36 (1.19-1.55)	0.000	1.28 (1.13-1.46)	0.000	1.34 (1.18-1.53)
Co-operative dwelling	0.249	1.10 (0.89-1.36)	0.584	1.02 (0.82-1.28)	0.268	1.10 (0.89-1.36)	0.511	1.04 (0.83-1.30)

Secondary objective: In both datasets 1 and 2, the worst-case scenario had similar results to the base-case scenario results. The best-case was quite different on the first session. Nevertheless, the results from the best-case scenario were reflecting the same findings as the base-case and worst-case scenarios; attending less than five sessions (from one to four sessions) was associated with a lower probability of quitting compared with attending all the pre-planned five sessions (Table 3).

Discussion

We found that the results supported the principle of defining completion of the smoking cessation intervention as completion of at least 75% of sessions, while completing the whole intervention (all sessions) was associated with even better outcomes. The obtained results were robust to sensitivity analyses. The total quit rate was 32% (base-case scenario), originating from 26% of those with at least 75% compliance and 6% from those attending less than 75% of the meetings.

Considering our base-case scenario for both datasets, the observed quit rates were relatively comparable to results reported in similar studies conducted in Canada and the USA (32% quit rate for 8 sessions program, and 21% for 4-8 sessions' programs, respectively) (15-17). The 'dose-response relation' shown in figure 2 between higher completion of the programme and better quit-rate could be a direct consequence of that those, who spent more time on smoking cessation intervention received a higher dosage of effective intervention and thereby got a better outcome. Another part of the explanation on the 'dose-response relation' could be that

participants, who continued to smoke or relapsed after a short quitting would to a higher degree stay away from the following sessions, while only the quitters would take part of the programme. This study can not give the answer, and further studies on attitudes and experiences would be required.

We did not validate quit rates using the carbon monoxide "CO" test. However, in two studies from the UK and USA, the difference between self-reported and "CO" validated quit rates were minor (16;18-19). Moreover, evaluating UK NHS short and long term smoking quit rates showed that there was only a very minor increase in non-quit rates when including participants whose self-reported quitting was disproved by CO test (0.5% and 0.2% for short and long term quit rates, consecutively). (16;19) In a systematic review on the effectiveness of the UK NHS smoking cessation services reported cessation rates of around 60% for self-reporters and 53% for "CO" validated rates over four weeks (short term outcome), and around 17% for self-reporters and 15% for "CO" validated rates over one year (long term outcome)(20). It is worth noting that the study on long term (one year outcome) effectiveness of NHS smoking services included only self-reported quitters who quit in the short term (four weeks) (20), while our study included all patients' outcomes at six months, irrespective of short term outcomes. Indeed, the total quit rate (32%) in our study was high compared to previous literature (10), even when compared with the above studies from the UK where the long term follow up only included short term quitters (20).

In a US study on short-and long-term smoking cessation for different levels of intensity of behavioural treatment, biochemically confirmed quit rates at 26 weeks follow-up were higher for the high intensity program compared with less intense interventions (21). In a large systematic review concerning setting guidelines on "Treating Tobacco Use and Dependence in the USA", it was concluded from included meta-analyses that provision of at least four sessions enhances quit rates compared with provision of fewer sessions (10). Another study from the USA found that comprehensive prolonged smoking treatment programs that combine medications and psychological approaches are able to produce higher quit rates than those reported in the literature (4). Indeed, the significant increase in quit rates associated with different degrees of program completeness in our study could partly be explained by the structure of the GSP itself. It is manual-based and includes most of the prognostic factors that influence the success of quitting attempts, such as qualified counselling, nicotine replacement therapy, and relaps prevention strategies. Hence, the longer a participant remains in the GSP, the more prognostic factors are addressed. Another possible explanation for the association is that some of the patients who did not quit may have stopped participating in the GSP before those who managed to quit. On the other hand, some of the early quitters may not feel they need to complete the treatment program. A further strength of the study is that all relevant aspects of the GSP were standardised across all smoking cessation treatment centres.

It is worth considering that this study is a large nationwide population study and thereby results can be generalised to the country as a whole. However, our results should be interpreted with caution when generalising the results to other countries with different smokers, settings, and intervention programs. It is also worth noting that this is not a randomised controlled trial. Other strengths are that the study includes both genders, all age groups, wide geographic coverage, smokers from different socio-economic groups, cover long-term follow-up period (6 months), and data was prospectively collected.

Regarding the study design, predictive models were developed on data simulated from the population included in the database. The utilisation of a validation cohort "dataset 2" was helpful to avoid relying on what could be optimistic or underestimated OR estimates from "dataset 1" on the association between compliance levels and quit rates. Yet, statistical modelling used for data analysis represents a simplified illustration of reality; consequently, many unforeseen variables that represent predictors and confounders related to the quit rates, could exist and not be included in the model (22). Thus, there is still a possibility that this study finding could be either overestimating or underestimating the real results. Nevertheless, the LR models have been validated (goodness of fit) by using the second dataset "dataset 2" which showed similar results to the first dataset "dataset 1"(22).

Concerning the clinical population cohort, this study used only data from a four-year period, as data on compliance/attendance was not routinely collected prior to this. Missing data on quitting outcomes was considered in the data analysis strategy according to the reason for the missing data. Another group of patients without planned follow-up due to lack of resources by the smoking cessation unit was not evaluated. The fact that some patients were not routinely followed up represents a potential weakness in the study. However, the results on the two tested objectives from the two sensitivity analyses showed similar findings to the base case sce-

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nario. Moreover, patient data on different predictors for quitting has been collected and recorded for almost all included patients, which represents strength. In future studies, the generalisability of study findings may be enhanced by research cooperation with similar programs that have similar interventions and databases in other countries.

Implications

From a clinical perspective, it is important to reinforce the advice to adhere to at least 75% of the pre-planned sessions. However, to maximize the benefit from attending this program, patients should be encouraged to attend the whole program. Crucially, in terms of achieving the highest quit rates, there is a need for changes in tobacco control strategies implied by healthcare personnel and policy makers, where more attention should be given to maintain patients in smoking treatment programs instead of only recruiting them into such programs. Smoking cessation units that have chosen not to follow up on their patients should be supported in increasing their follow-up to improve the quality of further studies. The high participation rate in data collection by smoking cessation counsellors from a wide range of diverse units in Denmark enhances the generalisability of the results, and the ownership of this research study, which may encourage uptake of the results into practice.

From a research point of view further qualitative and quantitative research is needed to investigate predictors on different compliance levels and what triggers higher and lower compliance by patients who are participating in the GSP. Additionally, missing data on quit rates could be addressed through a separate study, specifically analysing missing quitting outcomes (23). It is also important to evaluate different contextual factors and social phenomena involved with the GSP. Integrating such quantitative and qualitative research findings could contribute to the amount of available evidence on compliance as a key predictor of smoking cessation. In addition, such research may be used to identify possible mechanisms to establish a long-term relationship with patients to reinforce important messages concerning smoking cessation and sustained quitting (24).

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Competing Interests

None declared.

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News from the International HPH Network

HPH Awards – now open for your nominations!

2012 was the first time International HPH Awards were given out. This took place at an official ceremony at the annual HPH conference in Taipei. The possibility to nominate candidates for the 2013 HPH Awards has now opened.

About the HPH AWARDS

The purpose of the HPH awards is to promote HPH visibility, enhance publication numbers, recognise fulfilment of strategic goals and recognise extraordinary fulfilment of WHO standards.

Winners are selected each year at the International HPH Conference. Along with the award the winners receive a free Conference pass and a special HPH certificate honouring the great achievement.

The HPH Award Entry Form can be found online at www.hphnet.org in the toolbox

Contact:
The International HPH Secretariat
jeff.svane@bbh.regionh.dk

The International HPH Secretariat welcomes nominations for HPH Awards.

So if someone you know has done exceptionally well in terms of HPH in 2012 – it is now the time to let us know about it by making your nomination.

Like last year, the three categories for nominations are:

1.
Outstanding Fulfilment of WHO HPH Standards

(for a Hospital / Health Service)

2.
Outstanding Fulfilment of HPH Strategy

(for a National/Regional Network)

3.
Outstanding Scientific Publication

(for an individual author or group of authors)

All the HPH awards are yearly, and this is the second time the awards are given out. The winners will be formally awarded at the 21st International HPH Conference in Gothenburg, Sweden. They will be informed of their award in advance, and each of the winners will receive one (1) free Conference pass besides a special HPH certificate honouring the achievement.

Nominations for the Strategy Award and the Standard Award will be examined and judged by a selected committee of HPH Governance Board members, and the award for Scientific Publication by the Editorial Office of the Clinical Health Promotion Journal.

The nomination deadline has been extended to February 1, 2013
For full information about the HPH Awards Framework, please download and read the HPH Awards Framework document from hphnet.org toolbox.

To make your nomination, the Toolbox contains an awards entry form to fill out.

News from the International HPH Network

The HPH National/Regional Network and Task Force Progress Reporting is now open online

It is now time for the bi-annual reporting of HPH progress. The reporting is mandatory for all National/Regional Networks and Task Forces and takes place through the online HPH Toolbox. The reporting deadline is ultimo January 2013 and the system is now open for submissions at hphnet.org

About REPORTING

Instructions and tips which can be helpful to read before submitting:

- Go to hphnet.org -> Tools -> Progress Report
- Print out appendix
- Open survey.
- Fill out survey form in one go (it will not automatically remember information before you hit submit)
- While filling out online survey form, note in your printed appendix where you wish to provide further information
- Fill out appendix document on your screen, save the file - and email it to secretariat

Links and information is supplied on the site. If you have questions regarding the Progress Report contact the HPH Secretariat.

Contact:
The International HPH Secretariat
jeff.svane@bbh.regionh.dk

As decided by the General Assembly of the International HPH Network, all National/Regional Networks and Task Forces must deliver a Progress Report every second year.

In 2010, when the reporting was carried out for the very first time, good comments and input were received on the format and usability of the report from many Networks and Task Forces. So with this key input in hand, this year's format has been improved in many ways.

The Progress Report this year is an online form with tick-box answers plus an appendix for detailed information. There are separate forms for N/R Networks and for Task Forces, and you can easily find them by visiting hphnet.org -> Toolbox -> Progress Reports.

Access to the Progress Reports opened in October 2012 and the deadline for completing your submission is ultimo January 2013. The Secretariat will then prepare the information for the General Assembly in Gothenburg (May 2013).

The Assembly is presented with a collated report, covering key details on strategic developments and progress from all Networks and Task Forces. This report will be used to monitor overall progress and identify core challenges and successes.

The collated report will be made publicly available at hphnet.org. Likewise, all the individual reports received will be made public in unedited form, and can be found on the hphnet.org subsite of the submitting Network or Task Force. To access the information from the previous reporting please visit hphnet.org.

The International HPH Secretariat looks forward to receiving your Progress Report.

HPH in Progress...

News from the International HPH Network

WHO HPH Autumn School in Indonesia attracts more than 100 attendees

Over the course of 3 days, the WHO-HPH Autumn School attracted approximately 100 hospitals managers and clinicians from all over the country.

About the NATIONAL HPH NETWORK OF INDONESIA

The first Indonesian member hospital, R. Syamsudin, SH Regional Hospital signed the Letter of Intent in August 2011.

The Indonesian Network was established and approved by Governance Board in June, 2012. The Network now consists of 11 member hospitals and health services.

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The WHO-HPH School was held in the city of Bandung in West Java, Indonesia from Octber 30 to November 1, 2012. The topic of the school was management and sustainability of Health Promotion in hospitals and health services, and it was arranged jointly by the National HPH Network of Indonesia and the WHO Collaborating Centre in Copenhagen. As with most HPH activities in the region, the School also had very strong support from WHO SEARO. High-profile representatives from SEARO even took part in the school as speakers. Additionally the Indonesian Ministry of Health played a key supportive role, also contributing with speakers and presentation of relevant insight.

As the main purpose, the WHO-HPH School sought to help the relatively young Indonesian HPH Network further along. The school also sought to add insights on issues such as the international work of HPH, the national Indonesian work of HPH, the WHO Standards and Indicators for HP in Hospitals, HP integration into the Clinical Pathway, Development of HP Policy, HP integration into DRG, Evidence-based HP and more. The agenda also featured presentations and discussions of HP research, such as the international WHO HPH recognition Project in which Indonesia may take part, and additional possibilities for research undertakings of the Indonesian HPH Network.

Also, a main aim of the school was to allow hospitals to share experiences and discuss challenges at hand. For this purpose the agenda also featured a series of workshops, poster sessions and presentations from many hospitals of their HPH work in various areas.

The WHO-HPH School in Bandung was very successful and proved a good opportunity for the National HPH Network of Indonesia to generate further attention to the ongoing efforts on all fronts. On site, several Indonesian hospitals signed up for the International HPH Network, among these member number 900: Dr. Maewardi Regional Hospital.

News from the International HPH Network

Update on the WHO HPH Recognition Project

Being part of core documents such as the work plan for the WHO HPH Memorandum of Understanding and the Global HPH Strategy 2011 – 2013, The WHO HPH Recognition Project is one the current key undertakings.

About the WHO HPH RECOGNITION PROJECT

The project has received widespread attention from many parts of the world.

By now the total number of participating departments have reached 36 out of the needed 88. So all further interested parties are encouraged to make contact.

THE PROJECT GROUP

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The WHO HPH Recognition Project is a multicentre RCT, aiming for 88 included hospital departments from all over the world, to have adequate sample size. All clinical hospital departments are eligible for participation (except palliative and paediatric). So far 36 of these have been recruited – and more are in the immediate pipeline.

The participation so far is from Taiwan (21), the Czech Republic (8), Thailand (4), Slovenia (2), Canada (1). The departments that have already declared intention to take part are from many of the other HPH network – such as Indonesia, Finland, Norway, to mention a few.

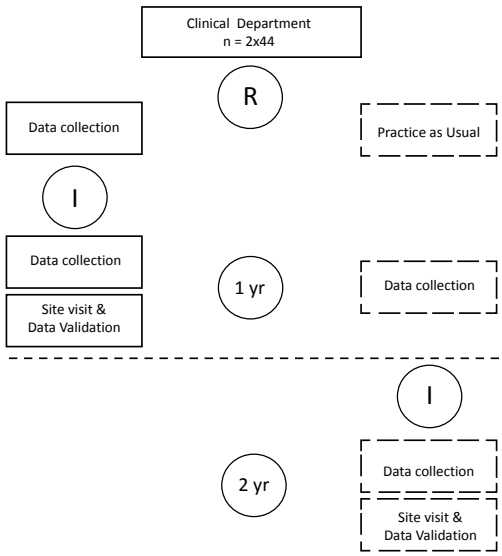
The project is approved by the Danish Data Protection Agency (international studies) and IRB commitee of Bispebjerg University Hospital. It is also registered at ClinicalTrials.org.

The project aims to evaluate whether a WHO-HPH recognition / certification process generates:
- More health service deliveries
- Better health gain for patients and staff

The main hypotheses of the study are, that hospital departments undergoing to the recognition process will after one year:
- Deliver more health promotion services
- Improve health gain for patients and staff (Compared to the departments allocated to the study's control group, who continue their routine clinical practice).

The study is designed as an RCT, in order to obtain the highest possible level of evidence. The study allocates the hospital departments randomly to one of two groups, where they either:
- Undergo the Recognition Process immediately = Intervention group
- Continue their usual routine = Control group

The trial profile



As the project aims for a total of 88 departments from all over the world, to have adequate sample size, we still have 52 departments to go before the target is reached. So we cordially invite all interested HPH Networks and hospitals to please make contact to hear more or to sign up for participation!

CLINICAL HEALTH PROMOTION

Acknowledgements

During 2012 we have been so fortunate to have all submitted papers peer reviewed by our honoured panel of international scholars.

For their excellent service during the year, we would like to thank all peer reviewers:

Carlo Favaretti	Tim Neumann
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Jin-Ding Lin	

If you would like to join our peer review panel, please contact the Editorial Office.

E-mail: editorialoffice@clinhp.org

HPH Meetings and Events

WHO HPH Course for Hospital Managers
May 15 – 17, 2013. WHO-CC and WHO Europe, Copenhagen and Malmö.

WHO HPH Summer School 2013
May 20 – 21, 2013. The Swedish Exhibition Centre, Gothenburg.

WHO HPH National/Regional Coordinators' Summer School
May 21, 2013. The Swedish Exhibition Centre, Gothenburg.

HPH General Assembly
May 22, 2013. The Swedish Exhibition Centre, Gothenburg
(National/Regional HPH Coordinators and observers from upcoming Networks upon invitation)

21st International HPH Conference
May 22 – 24, 2013. The Swedish Exhibition Centre, Gothenburg.

Deadline for abstracts to 21st International HPH Conference
January 5, 2013.

HPH Newcomers' Workshop
May 25, 2013. The Swedish Exhibition Centre, Gothenburg

HPH Symposium at 8th Global Conference on Health Promotion
June 10 – 14, 2013. Finlandia Hall, Helsinki.

HPH Symposium at 38th World Hospital Congress (IHF2013)
June 17, 2013. Oslo.

Master of Clinical Health Promotion
Start of 1st semester, September 2013.

For further information and registration – please visit www.hphnet.org