



Editorial

Will it be Easier to Diagnose Alcohol Dependency in the Future?

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A medical student once said that unhealthy alcohol consumption is defined by an alcohol intake higher than the doctor's consumption. And one way or the other, there seems to be an attitude of 'us and them', in that we only drink socially, while the others seem to be drinking a lot more. However, more specified definitions exist. Some are based on drinking a certain amount of alcohol exceeding (different) national limits, while others are more related to the mental and behavioral symptoms, such as dependence.

On one hand, a definition that clearly categorize the dependent and the non-dependent drinkers separately may seem attractive from a treatment and prognostic perspective (1;2). Then the patients with dependency can be offered specialized care in addiction centers, while the others can receive intervention in the generalized care. On the other hand, this simplification does not always portray reality, as unhealthy alcohol consumption reflects a continuum rather than clearly separated categories. As an example, about one third of emergency patients undergoing ankle fracture surgery who also had a high alcohol intake were simultaneously diagnosed with syndrome of dependence (3).

Are you familiar with the new dependence terminology and criteria of ICD-11?

In the latest version of the International Classification of Diseases (ICD-11) version from April 2019, a new classification related to alcohol and other psychoactive substances was released. An important aim was to make diagnosing easier in both primary and secondary healthcare. Consequently, the number of symptoms related to alcohol dependence were collapsed from 6 to now only 3 (Table 1).

The new criteria for the dependence diagnosis including having at least two symptoms daily or almost daily within the last month or to have at least two symptoms repeated several times during the last year. However, the numbers are not quite clear in the updated browser for clinical use; "the features of dependence are usually evident over a period of at least 12 months, but the diagnosis may be made if alcohol use is continuous (daily or almost daily) for at least 1 month".

Interestingly, this may lead to a higher prevalence of the dependence diagnosis compared to using the previous Diagnostic and Statistical Manual: Mental Disorders (DSM-4) and ICD-10 criteria, as well as by using the updated DSM-5 criteria for moderate or severe alcohol use disorder (AUD). The young adults with ICD-11 diagnosed dependence most often had symptoms of tolerance and of spending much time on drinking or recovering afterwards (5).

What about the terminology and criteria of DSM-5?

Already in 2013, the American Psychiatric Association (APA) released the updated DSM-5 with an integration of the two previous diagnoses (alcohol abuse and alcohol dependence) into a single alcohol use disorder (AUD) (6). It now includes 11 symptoms (Table 1) and the criteria for the AUD diagnosis are to have at least two of the symptoms during the past year. Based on the number of co-existing symptoms three groups have been proposed representing mild, moderate, and severe AUD.

All clinicians and many other health professionals will from time to time meet patients, who drink too much, and they may even have symptoms of dependence.

Clin Health Promot 2019; 9:3-4



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Table 1 Comparing the symptoms of alcohol abuse, alcohol dependence and alcohol use disorder (AUD) based on the updated and previous DSM and ICD versions.

| | DSM-5 | DSM-4 | ICD-11 | ICD-10 |
|--|-------|------------|--|----------------------------------|
| Role impairment | AUD | Abuse | – | – |
| Hazardous use | AUD | Abuse | – | – |
| Legal problems | – | Abuse | – | – |
| Interpersonal problems | AUD | Abuse | – | – |
| Tolerance | AUD | Dependence | Dependence: Physical symptoms of tolerance, withdrawal symptoms with or without craving | Dependence |
| Withdrawal | AUD | Dependence | | Dependence |
| Urge or craving | AUD | – | | Dependence |
| Loss of control | AUD | Dependence | Dependence: Impaired control | Dependence |
| Repeated attempts or strong desire to reduce or stop use | AUD | Dependence | | |
| Reduce activities to use alcohol | AUD | Dependence | Dependence: Priority of use | Combined into 1 item: Dependence |
| Much time spent using | AUD | Dependence | | |
| Use despite psychological or physical problems | AUD | Dependence | | |

Maybe such meetings take place more often than realized, because diagnosing alcohol dependency is often forgotten or directly neglected in healthcare. The neglect has serious consequences for the individual, the family, the workplace, the health care, and the society at large, as unhealthy alcohol consumption (with or without dependence) is an important risk factor adding significantly to the burden of diseases and early death (7).

Has it become easier to identify alcohol dependence in primary and secondary care?

Yes and no. Yes, because the revisions of the ICD and the DSM criteria have made them more understandable. No, because they are not in agreement and no longer based on a similar basic understanding of alcohol use disorder.

The ICD has kept alcohol dependence as a separate diagnosis and even reduced the number of criteria. Thus, it may be easier to get the diagnosis of dependence – at least among young persons. In contrast, the DSM reflects a larger bit of the continuum by considering symptoms of both abuse and dependence as parts of the broader understanding of the term alcohol use disorder. This may, however, be challenging for the alcohol intervention – at least until the term has become routine.

There is a call for new research considering cultural and social differences around the world. However, give it a try, and hopefully the patient, family, workplace, health care and society will gain from the improved ef-

forts aiming at opening the door to an increased focus on unhealthy alcohol intake. Both WHO and APA welcome feedback on the use of the updated diagnoses.

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A new initiative of this scientific journal is to report and comment upon news in clinical health promotion published in other journals.



Comments on New Research on Clinical Health Promotion

Prevalence of limited health literacy among patients with type 2 diabetes mellitus: A systematic review

Abdullah A, Liew SM, Salim H, et al. *PLoS ONE* 2019;14:e0216402. doi.10.1371/journal.pone.0216402

Study description

Diabetes type II increases all over the world, and living with diabetes requires a high degree of patient's empowerment and self-management that may be challenged by limited functional health literacy (F-HL). A new systematic review summarises the frequency of F-HL among patients with type II diabetes in different countries.

The study is based on 29 observational studies including 13,457 participants, mainly from the US, but also from Canada, Brazil, Switzerland, Netherlands, Marshall Island, South Korea and Taiwan. The quality of the studies ranges from moderate to good.

The results show a wide range in limited F-HL from 7.3% in Switzerland over 29% in the US to 82% in Taiwan. In addition, frequency also varied with the different tools used for measurement. Across the countries, the highest frequency of limited F-HL was seen in community populations and in population with shorter education.

Comments from Professor Jürgen Pelikan

There is a longer tradition in researching the relationship of diabetes self-management with health literacy, and there even has been developed a specific more comprehensive instrument for measuring diabetes health literacy. There also exists evidence that health literacy matters for self-management of diabetes. Surprising of the results of this review is that (functional) limited health literacy varies so much by country, but partly this seems to be a consequence of different instruments used for measuring (functional) health literacy in the included studies. Since there also has been demonstrated a social gradient for (functional) health literacy it is necessary to offer specific procedures for empowering diabetes patients for self-management that take into account limited health literacy of disadvantaged vulnerable patients. One way to achieve this would be to improve the organizational health literacy or health literacy sensitivity of health services and health professionals.

A Randomized Trial of E-Cigarettes versus Nicotine-Replacement Therapy

Hajek P, Phillips-Waller A, Przulj D, et al. *N Engl J Med* 2019;380:629-37. Doi: 10.1056/NEJMoa1808779

Study description

World-wide, smoking is still a major risk factor for increased morbidity and early mortality. There are two ways to reduce smoking; one aims not to start smoking at all and the other aims at successful quitting for those still smoking.

In a recent sizable randomised trial Hajek and colleagues compares e-cigarettes with nicotine replacement therapy (NRT) for smoking cessation. The study includes 886 participants, receiving either 3 months of NRT of their own preference or an e-cigarette starter pack with a refillable e-cigarette with nicotine e-liquid. All participants receive weekly behavioural support for at least 4 weeks.

The results show a significantly higher biochemically validated quit-rate after 1 year; 18% in the e-cigarette group compared to 10% in the NRT group. The frequency of side-effects is relatively high in both groups; significantly more in the e-cigarette group experiences mouth and throat irritation (65% versus 51%), while significantly more in the NRT group reports nausea, cough and phlegm. After one year, 80% of the quitters in the e-cigarette group still uses e-cigarettes compared to 9% using NRT in the NRT group.

Comments from Professor Charlotta Holm Pisinger

Professor and chair of the European Union Respiratory Society Charlotta Holm Pisinger (MD MPH PHD) from Copenhagen University comments that 'the results are in disagreement with two previous pragmatic randomized trials, which do not show significant effect on smoking cessation rates (1;2). Longitudinal real-life studies find that the use of e-cigarettes (EC) is associated with lower abstinence rates (3), and on population level the EC users (re)starting smoking after using ECs outnumber those who stop smoking after using ECs (4). The use of evidence-based pharmacotherapy and smoking cessation services has declined in Europe while use of ECs has increased (5), which is very worrying. Further, the authors haven't considered the growing body of evidence indicating negative health effects of long-term EC use (6;7); 80% of "smoke-free" participants assigned to ECs in the trial continued to use ECs – they still inhale toxicants and carcinogens. There is neither enough evidence supporting the safety of EC use nor their use as a smoking cessation tool.'



Comments on New Research on Clinical Health Promotion

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Adherence to Home Exercise Programmes and its Associated Factors among Patients Receiving Physiotherapy

Obinna C. Okezue, Geoffrey C. Nwafor, Obinna A. Ezeukwu, Jenevivi N. John, Chigozie I. Uchenwoke

Abstract

Objective: Home exercise programmes (HEPs) ensure the enhancement of therapeutic gains and enable patients assume responsibility for managing their conditions. This study investigated patients' adherence to HEPs, determined its association with their personal characteristics and identified factors influencing their engagement.

Methods: A cross-sectional design was used to recruit 139 consenting patients who completed self-report questionnaires. Data were analysed via descriptive and inferential statistics.

Results: Most participants, 105 (75.5%) were non-adherent to HEPs whilst 34 (24.5%) were adherent. HEP adherence had significant associations with age ($p < 0.001$), sex ($p = 0.001$) and educational status ($p = 0.048$). There were significant negative relationships ($p < 0.05$) between HEP adherence and these influential factors; fatigue, forgetfulness, pain, deeming exercises as injurious, exercises perceived as less beneficial and need for physical assistance. A significant positive relationship ($p = 0.038$) between HEP adherence and family/ friend support was also established.

Conclusion: Adherence to HEPs was revealed to be poor in this study. Older, female and less/uneducated patients displayed a high tendency of non-adherence. Several factors which exhibited patients' challenges were revealed to have substantial negative influences on their HEP adherence. Social support from patients' family/friends was linked to facilitating HEP adherence.

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Introduction

Physiotherapy offers patients a range of treatment options, which include exercise as a core component of rehabilitation. Evidence exist on the effectiveness of exercises used by physiotherapists in the management of various conditions (1-5). Such exercises need to be properly designed and executed to ensure their provision of health benefits (6). These gains significantly depend on sustained participation, hence a home exercise programme (HEP) is prescribed as a fundamental part of physiotherapy management (7).

Home exercise programmes aid patients to assume responsibility for managing their conditions as this ensures the maintenance of functional gains and continual progress (8). Executing prescribed exercises is considered vital to attaining positive

rehabilitation outcomes (9). However, there must be a change in lifestyle to include regular exercise in order to reap its benefits and ensure adherence (7).

The extent to which patients adhere to HEPs is considered to be partly responsible for the success of many physiotherapy programmes (10;11). Adherence to prescribed exercises has been associated with improved treatment outcomes of physical performance and functional ability (12). In contrast, patients who do not adhere to HEPs have exhibited reduced positive outcomes (13). Furthermore, non-adherence has been reported as a reason for physiotherapists to unnecessarily alter treatment programmes by believing that they are ineffective (13;14). Research reveals that patients' HEP adherence rates are not as high as many physiotherapists would have preferred



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(15;16), and studies show that less than 40% of patients fully adhere to HEPs (17-19). This denotes a general poor adherence to HEPs, which has been emphasised by other authors (11;20;21). Fortunately, efforts are being made to address this issue as current reviews offer evidence of associated factors (7;16) and strategies to improve HEP adherence (22).

The problem of non-adherence to HEPs extends to Nigeria, as researchers have highlighted its significant rates and contributory factors (23;24). However, there is a dearth of relevant literature in the country and this prompts the need for more data. Such information would enhance a deeper understanding of this predicament as it pertains to the local environment in order to improve adherence and ultimately, recovery. Therefore, this study sought to investigate patients' adherence to HEPs, determine its association with their personal characteristics and identify factors influencing their engagement.

Methods

Research design

A cross-sectional design was utilised for this study. Participants were recruited via purposive sampling in 3 prominent hospitals in Enugu, Nigeria. These comprise University of Nigeria Teaching Hospital, Enugu State University Teaching Hospital and Nigeria Army Reference Hospital. Patients, receiving outpatient physiotherapy services, were identified from the departmental register in each hospital and screened to determine their eligibility to participate. Ethical approval was obtained from the research/ethics committee of the selected hospitals as well as permission from the head of each physiotherapy department before the start of the study.

Participants

A total of 139 patients undergoing physiotherapy management, aged between 16 and 75 years participated in the study. Participants receiving a minimal of one week treatment including a HEP prescription were selected. Patients who had deficits in their memory, understanding and communication were excluded alongside those with diagnosed psychological problems. The patients were educated about the study objectives and procedure for data collection: highlighting voluntary and anonymous involvement. Informed consent was duly obtained from all participants.

Instrument

A three section, self-report questionnaire was developed for this study based on previous research on adherence

to HEPs (8;17;18;23-26). The first section collected the participants' personal characteristics: age, sex, marital and educational statuses. The second section assessed each patient's adherence to the HEP prescribed as part of physiotherapy treatment. Four questions based on each principle of exercise: frequency, intensity, time and type were utilised. Each question addressed the participant's performance of the exercise(s) that was prescribed and sought a single response on a four-point scale: 'Always', 'Often', 'Rarely' and 'Never' respectively. These responses were weighted in percentage; with 'Always' at 100%, 'Often' at 66%, 'Rarely' at 33% and 'Never' at 0%. The total score for the four responses was calculated for each participant and divided by 4 to get the average. Mean scores from 70 – 100% were regarded as adherence whilst those below this range indicated non-adherence. The last section addressed influential factors that determine their adherence to HEPs. To examine factors with a potential influence on adherence, an instrument used in Sluijs et al. (17) was adapted to the study. 12 questions indicating these factors were used and participants identified the relevance of each to their HEP engagement rated on a four-point scale, from strongly agree to strongly disagree. An internal consistency test for these 12 questions on all participants, yielded a high Cronbach's alpha value of 0.76; indicating an acceptable reliability of their assessment of relevant influential factors in this study.

Procedure

The developed questionnaire was vetted and corrected by six physiotherapists (engaged in both HEP prescription and exercise research) to improve the relevance of its content. A pilot study involving 8 eligible patients was conducted and in their feedback, they stated that using common words in clear and understandable sentences would improve the questionnaire. The 8 patients were interviewed within 3 days and their verbal responses supported their initial feedback, which confirmed its reliability. Subsequently, the above mentioned physiotherapists agreed that the improved questionnaire was in line with the study objectives. Duplicates were given to the participants who immediately completed and returned them to the researchers. Information were meticulously extracted and kept confidential.

Data analysis

The data obtained were analysed with the SPSS Software version 23 for Windows (IBM, Chicago, IL, USA). Adherence to HEPs and personal characteristics of the participants were presented descriptively in tabular form by using percentage frequencies. Association



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between personal characteristics and adherence to HEPs was examined using Chi-square test. Binary logistic regression (BLR) analysis was used to ascertain the relationship between adherence to HEPs and influential factors. This analysis was adjusted for the influential factors, as they were all entered together. The BLR model was appropriately evaluated for its effectiveness. The level of significance was set at $p < 0.05$ for all tests and BLR analysis.

Results

Participants' characteristics and their adherence to HEPs

139 patients who were receiving outpatient physiotherapy services in hospitals in Enugu metropolis participated in this study. Table 1 shows the demographic profile of the participants; 77 men (55.4%) and 62 women (44.6%); most within the age group 36–55 years (54%). 117 participants (84.2%) were married and 76 (54.7%) had up to a secondary school education. It further reveals 34 (24.5%) participants were adherent to HEPs.

Association between personal characteristics and adherence to HEPs

The association between the participants' characteristics and their adherence to HEPs is presented in Table 2. A significant association existed between decreased adherence and advancing age ($p < 0.001$). Adherence to HEPs was highest (61.5%) in those aged 16–35 years and lowest (10.5%) in those aged 56–75 years. A significant association was also observed between gender and adherence to HEPs ($p = 0.001$). Notably, 27 (35.1%)

Table 1. Demographic characteristics and adherence of participants

| Participants' characteristics and their adherence to HEPs | |
|---|------------------|
| Age (years) | |
| 16–35 | 26 (18.7) |
| 36–55 | 75 (54.0) |
| 56–75 | 38 (27.3) |
| Sex | |
| Female | 62 (44.6) |
| Male | 77 (55.4) |
| Marital status | |
| Single | 15 (10.8) |
| Married | 117 (84.2) |
| Widowed or Separated | 7 (05.0) |
| Educational status | |
| No formal education | 3 (02.1) |
| Primary | 8 (05.8) |
| Secondary | 76 (54.7) |
| Tertiary | 52 (37.4) |
| Adherence to HEPs | |
| Adherent | 34 (24.5) |
| Non adherent | 105 (75.5) |
| Total | 139 (100) |

Data are presented as n (%)

men were adherent while 7 (11.3%) women adhered to HEPs. In contrast, there was no significant association between the participants' marital status and adherence to HEPs ($p = 0.120$). A significant association was observed between adherence to HEPs and improved educational status ($p = 0.048$). For patients with no formal education or only primary education, no adherence (0%) were reported, while 25 (32.9%) of secondary school graduates were adherent.

Table 2. Association between personal characteristics and adherence to HEPs

| Personal characteristics | Adherent | Non adherent | χ^2 | p-value |
|---------------------------|-----------|--------------|----------|---------|
| Age (years) | | | | |
| 16–35 | 16 (61.5) | 10 (38.5) | 24.701 | 0.000* |
| 36–55 | 14 (18.7) | 61 (81.3) | | |
| 56–75 | 4 (10.5) | 34 (89.5) | | |
| Sex | | | | |
| Female | 7 (11.3) | 55 (88.7) | 10.506 | 0.001* |
| Male | 27 (35.1) | 50 (64.9) | | |
| Marital status | | | | |
| Single | 6 (40.0) | 9 (60.0) | 4.245 | 0.120 |
| Married | 28 (23.9) | 89 (76.1) | | |
| Widowed or Separated | 0 (00.0) | 7 (100.0) | | |
| Educational status | | | | |
| No formal education | 0 (00.0) | 3 (100.0) | 7.928 | 0.048* |
| Primary | 0 (00.0) | 8 (100.0) | | |
| Secondary | 25 (32.9) | 51 (67.1) | | |
| Tertiary | 9 (17.3) | 43 (82.7) | | |

Data are presented as n (%)

* Indicates statistical significance ($p < 0.05$)



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Evaluation of the BLR model

Table 3 shows that the model correctly classified most of the cases, which demonstrates its high prediction accuracy (sensitivity=70.6%, specificity=99%, positive prediction=96.0% and negative prediction=91.2%). This model also provided a good fit to the data, as it showed statistical significance ($p < 0.001$). The complementary Hosmer & Lemeshow test was insignificant ($p = 0.339$).

Table 3. Evaluation of the Binary Logistic Regression Model

| Adherence status classification ^a | | | |
|--|-----------------|--------------|-----------|
| Observed cases | Predicted cases | | Correct % |
| | Adherent | Non adherent | |
| Adherent | 24 | 10 | 70.6 |
| Non adherent | 1 | 104 | 99.0 |
| Positive prediction value | | 96.0 | |
| Negative prediction value | | 91.2 | |
| Test for significance | | | |
| Omnibus (Model) | 62.873 | 0.000* | |
| Hosmer & Lemeshow | 9.036 | 0.339 | |

^a The cut value is 0.5

* Indicates statistical significance ($p < 0.05$)

Relationship between influential factors and adherence to HEPs

Presented in Table 4, BLR analysis showed that there were significant negative relationships ($p < 0.05$) between adherence to HEPs and the influential factors; 'fatigue', 'forgetfulness', 'exercise is painful', 'exercise can cause injury', 'exercise is not very beneficial' and 'need for

physical assistance'. It also showed that there was a significant positive relationship ($p = 0.038$) between adherence to HEPs and the influential factor; 'family/friend support'. Notably, patients were 4.75 times more likely to adhere to HEPs when they receive this support to perform home exercises. Conversely, there were no significant relationships ($p > 0.05$) between adherence to HEPs and other influential factors like 'limited time', 'exercise is hard', 'exercise is boring', 'exercise does not fit daily routine' and 'need for physiotherapist's presence'.

Discussion

Adherence to HEPs

Approximately a quarter of the patients in our study were adherent to HEPs (34/139), which corresponds to a study by Adeniyi and Zandam where 25.9% of physiotherapy patients adhered to HEPs (24). This original study supports our finding by revealing that poor adherence to HEPs prevails in our communities. However, another study reported a higher adherence rate of 55.8% amongst similar patients (23). This difference might be due to a variation in study methods; as patients had to rate their level of adherence each week. This process might have influenced some patients' engagement, for it has been mentioned that certain procedures can boost adherence as they remind patients to perform their HEPs (27).

An adherence rate of 24.5% in this study contradicts the results of previous studies which showed different adherence rates. Sluijs et al. noted that 35% of physiotherapy patients fully adhered to HEPs (17) whilst Chan and Can reported this fully adherent rate in

Table 4. Relationship between influential factors and adherence to HEPs

| Factor | B | Wald | p | Exp (B) ^a |
|--------------------------------------|--------|--------|--------|----------------------|
| Fatigue | -5.156 | 9.946 | 0.002* | 0.006 |
| Limited time | -2.062 | 3.249 | 0.071 | 0.127 |
| Forgetfulness | -3.735 | 13.304 | 0.000* | 0.024 |
| Family/friend support | 1.558 | 4.005 | 0.038* | 4.751 |
| Exercise is hard | -0.366 | 0.299 | 0.584 | 0.694 |
| Exercise is boring | -0.494 | 0.974 | 0.324 | 0.610 |
| Exercise is painful | -2.853 | 15.038 | 0.000* | 0.058 |
| Exercise can cause injury | -3.292 | 4.988 | 0.026* | 0.037 |
| Exercise is not very beneficial | -1.614 | 4.685 | 0.030* | 0.199 |
| Exercise does not fit daily routine | -1.084 | 0.829 | 0.362 | 0.338 |
| Need for physical assistance | -3.009 | 15.204 | 0.000* | 0.049 |
| Need for physiotherapist's presence. | -0.492 | 1.193 | 0.275 | 0.611 |

^a Represents the adjusted odds ratio

* Indicates statistical significance ($p < 0.05$)



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similar patients to be 39% (18). These rates would rise above 70% in both studies, when the patients' good/ rather regular performances of HEPs are included. However, the increase in adherence to HEP for their participants remains unsatisfactory, as this denotes partial adherence, which reflects an aspect of non-adherence. Overall, our finding reveals significant poor adherence to HEPs amongst physiotherapy patients, which has also been identified by other authors (11;19-21).

Association with age

The results of this study revealed a decline in the adherence of older adults, as they were nearly six times less likely to adhere to HEPs when compared to the youngest population. This concurs with the finding of Pickering et al. who reported that adherence reduced with increasing age amongst patients. The rate of performance of prescribed home exercises by the above patients decreased by 10% per 10-year increase in age (28). Though Pickering et al. did not entail teenagers or younger adults, this similar finding suggests that routine physical activity/exercise progressively reduces with age (29). Findorff et al. also showed that HEP adherence reduces overtime when growing old. It should be noted that the study participants were sedentary and the use of telephone counseling as well as goal-oriented nurse visits could not optimally boost adherence (30). Contrastingly, some authors have found no association between age and HEP adherence (31;32), while other researchers have reported that age is a consistent predictor of decreased physical activity (33;34). Older patients might not necessarily deviate from executing HEPs; however, our study indicate that non-adherence needs to be actively addressed with regards to age.

Association with gender

Our findings demonstrate that men were three times more likely to adhere to HEPs than women. This conforms with other studies showing that men display higher levels of physical activity than women (33;34). Several studies though, have found no significant link between sex and HEP adherence (10;23;24;35). In support of our findings, another HEP study found that men performed 15% more repetitions than women; although this difference was not reported as statistically significant (28). Mannion et al. (36) have also reported that women were significantly less adherent than men in completing their home exercises and further revealed that female gender predicts non-adherence. Though no direct explanation can be made, higher adherence shown by men in this present study may be attributed

to the peculiarity of our social environment. Culturally, men in Nigeria are expected to be more physically active and hence, might enjoy more support from our local communities. Such backing might boost their HEP execution whilst Nigerian women would not typically receive this extra incentive. This postulation has to be verified by appropriate and prospective research.

Association with educational status

In this study, we observed that all 11 patients with little or no formal education were non-adherent, whilst HEP adherence was displayed only in groups with better educational backgrounds. As this finding relates to a rather small population in groups with little or no formal education, it is difficult to make a conclusion on this basis. A systematic review seemed to support this finding as it provided evidence that people with better education were more likely to adhere to exercise programmes (7), though it solely involved the elderly and did not exclusively address HEPs. Conversely, other studies did not report a significant association between adherence to HEPs and educational status (18;23;24;31).

Better adherence linked to an improved educational status might be attributed to the patients' health literacy levels. Other researchers have shown that improved educational status leads to better health literacy (37-39), which enables individuals to acquire, process and comprehend basic health information or services needed to make appropriate health decisions. Some authors have bemoaned the poor health literacy status prevalent in the present study environment (40;41). Hence, patients who had little or no formal education in our study might have been unable to make positive health decisions that would improve their adherence to HEPs. This stance calls for a better and suitable exploration.

Relationship with influential factors

Pain, forgetfulness, perceiving exercise as less beneficial and fatigue had significant negative relationships with patients' adherence to HEPs in this study. This is confirmed by other authors who have reported a similar negative influence of pain on HEP adherence (8;23). They evaluated stroke patients and found fatigue as a possible cause (23). Other authors did not find a significant influence of pain on adherence to HEPs (17,35). A systematic review supports the results of the present study on pain as a barrier to physiotherapy treatment adherence (42). Forgetfulness has also been found to negatively influence HEP adherence in other studies (17,23), where authors state that even though



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forgetfulness is an unintentional process, it may have been influenced by the patients perception of barriers or inadequate importance attached to the HEP. This negative influence of attributing little importance to HEPs was highlighted by our study finding of the tendency of being non-adherent, if home exercises were perceived as not being beneficial. Some researchers have shown that patients were less adherent to HEP, if they thought it would not help considerably (17), while others reported increased adherence among patients who understood the importance of home exercises (18). Fatigue was similarly shown to have a significant adverse relationship with HEP adherence (23). Contrastingly, another study did not show a significant relationship between HEP adherence and fatigue (18). As patients would engage in other daily activities, forgetfulness and fatigue might inadvertently lead to non-adherence if these factors are not properly addressed.

Our study also demonstrated that patients tend not to adhere to HEPs if exercises were perceived as injurious or if they had a need for physical assistance. Fear of injury has been reported as a perceived barrier to physical activity in a general adult population (43), which seems to support our finding. Some authors have also stated that patients reported the fear of falling and their concern about getting hurt while exercising, as reasons for non-adherence to HEPs (8). Ogwumike et al. support our finding of a significant negative relationship between HEP adherence and patients' need for physical assistance (23). However, another study did not find this relationship with adherence (17). The need for physical assistance was suggested to emanate from challenges to function posed by diseases (23). Our finding could also mean that patients doubt their own ability to successfully perform HEPs without manual assistance from others; indicating a low self-efficacy. Hence, it would be interesting to investigate for links between this particular need and self-efficacy, which has been strongly reported to predict adherence to home-based physiotherapy (44).

Lastly, our study revealed a remarkable positive relationship between adherence to HEPs and support from one's family or friends. Several authors have supported this finding with reports of high levels of social support facilitating adherence to physiotherapy treatment (11;42;44;45). This denotes the encouraging effect of social support from loved ones. Based on this finding, it could be postulated that a wider support network in the local community might further motivate patients to adhere to their HEPs.

Clinical implications

This study's findings emphasize the importance of careful patient screening in routine clinical assessments, so as to identify relevant data, which could determine adherence. Specific attention should be given to older, female and less/uneducated patients; as non-adherence might be likely in these populations. Constant re-evaluation of patient's HEP performance is key to facilitating adherence, not depending on the exercise's efficacy or tailored programme design; as negative influences can be detected, addressed and curbed. Education given to patients by physiotherapists may not be sufficient to address this issue, hence this study's authors suggest the implementation of specific strategies targeted at improving adherence as they may help patients overcome any challenge(s). Seeking the active involvement of a patient's family and friends towards ensuring strict HEP execution could boost their provision of social support, potentially inhibiting non-adherence.

Limitations

The use of a self-report questionnaire is in line with recommendations in literature, however it's predisposition to response bias provides a probability of influencing this study's outcomes. Causal inferences cannot be made due to this study's design. Furthermore, it was not possible to carry out a longitudinal study which would account for long term adherence to HEPs.

Conclusion

Adherence to home exercise programmes was low in this study as most patients did not stick to their prescribed regimens. Older, female and less/uneducated patients displayed a high tendency of non-adherence and should be given specific attention. Several factors which exhibited patients' challenges were revealed to have substantial negative influences on their adherence to HEPs; emphasizing the need for effective detection and curtailment. Social support from loved ones was linked to facilitating adherence to HEPs, hence it should be encouraged to extend to a larger network in the community.

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Appendix 1. Developed questions used to assess the participants' adherence status

| Principle | Question |
|-----------|---|
| Frequency | Did you perform the Exercise(s) as many times per day/week as was prescribed? |
| Intensity | Did you perform the Exercise(s) with the amount of effort that was prescribed? |
| Time | Did you perform the Exercise(s) for the length of time that was prescribed? |
| Type | Did you perform the kind of Exercise(s) that was prescribed? |

Appendix 2. Developed questions used to assess possible factors influencing HEP adherence

| Factor | Statement seeking a response from participants |
|--------------------------------------|--|
| Fatigue | I get too tired to perform the Exercise(s) that was prescribed. |
| Limited time | I have little time to perform the Exercise(s) that was prescribed. |
| Forgetfulness | I do not remember to perform the Exercise(s) that was prescribed. |
| Family/friend support | I get encouraged by my family or friends to perform the Exercise(s) that was prescribed. |
| Exercise is hard | It is difficult to perform the Exercise(s) that was prescribed. |
| Exercise is boring | It is not interesting to perform the Exercise(s) that was prescribed. |
| Exercise is painful | It is painful to perform the Exercise(s) that was prescribed. |
| Exercise can cause injury | It can harm the body to perform the Exercise(s) that was prescribed. |
| Exercise is not very beneficial | It is not very useful to perform the Exercise(s) that was prescribed. |
| Exercise does not fit daily routine | It does not match my daily plan to perform the Exercise(s) that was prescribed. |
| Need for physical assistance | I need a helping hand in order to perform the Exercise(s) that was prescribed. |
| Need for physiotherapist's presence. | I need the physiotherapist there in order to perform the Exercise(s) that was prescribed. |



Come & Quit: A new flexible, Intensive Smoking Cessation Intervention Programme

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Abstract

Aim Smoking cessation is a major challenge for many smokers, and it is necessary to develop and evaluate new programmes. The aim was to compare the effectiveness of 'Come & Quit', a flexible, intensive smoking cessation intervention (SCI) with the Danish gold standard programme (GSP). Second, we aimed to identify whether gender was important among disadvantaged and heavy smokers.

Methods This was a prospective cohort study based on the Danish National Smoking Cessation Database. From 2011-2016, we included 24,930 smokers from smoking cessation units throughout Denmark; 5,750 received 'Come & Quit', and 19,180 received the GSP.

Results A total of 16,348 respondents were included in the outcome analyses on continuous abstinence after six months. Thirty-five percent remained successful quitters. Under the Russell criterion, the crude quit rate was 23.0%. The most important predictor was compliance. Overall, men had 3.0-3.1% higher quit rates than women for both programmes. The fully adjusted model confirmed the significantly higher success among men (OR=1.15, 95% CI: 1.07-1.23). Two multivariable logistic regression analyses for men and women showed no statistically significant differences between 'Come & Quit' and the GSP for men (OR=1.06, 0.92-1.23) or women (OR=0.94, 0.82-1.08). Across gender, compliance with the programmes was the most important predictor of successful quitting. Minor predictors were calendar year, lack of social disadvantage and heavy smoking.

Conclusion The effectiveness of the intensive interventions compared in this study was similar across genders. However, overall, men had a significantly higher quit rate than women.

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Clin Health Promot 2019; 9:15-23

Introduction

Smoking is a major risk factor for the global disease burden. Approximately 80% of all smoking takes place in low- and middle-income countries, but smoking is still the leading risk factor in high-income countries. Worldwide, smoking killed 7.10 million persons in 2017 and was responsible for 182 million disability-adjusted life years (DALYs), understood as the number of years of healthy life lost (1).

Smoking cessation is on the agenda worldwide, and many actions are taken to reduce the smoking rate at national and local levels, aiming at preventing new smokers from starting and supporting smokers to quit – as recommended by the Framework Convention of Tobacco Control from the World Health Orga-

nization (2). Nevertheless, successfully quitting is still a major challenge for many smokers. Therefore, it is necessary to develop and evaluate new programmes to ensure success in quitting. Today, intensive smoking cessation intervention (SCI) programmes are recommended for vulnerable groups and hospital patients or is simply the standard programme for the general public (3).

Intensive SCI is defined by having at least four structured face-to-face meetings lasting more than 10 minutes per session and including elements of patient education (4). It is recommended but not mandatory to include pharmaceutical support (4). Many programmes contain a patient education part, relapse prevention and follow-up, which is also the case for the national gold standard programme (GSP)



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in Denmark (5-8) (table 1). We have previously shown that women and smokers with high or medium-high levels of were overrepresented in the Danish SCI (9).

Some groups of smokers may not have the opportunity to take part in a programme with a fixed time schedule such as the GSP but could benefit from a more flexible intervention allowing participation when it fits into the smokers' life conditions in combination with adjusted content and increased support between meetings. The intention was also to attract groups of smokers other than those using the GSP to participate in SCI, especially men and smokers with little or no education. Thus, a more flexible but still intensive SCI called 'Come & Quit' was developed (10) (table 1).

The aim of this study was to compare the effectiveness of the new flexible 'Come & Quit' programme and the GSP in Denmark, measured as successful quitting after 6 months. Second, we wanted to investigate whether gender influenced the outcome among disadvantaged or heavy smokers among the users of the two programmes.

Methods

Participants

A total of 24,930 smokers participated in this study: 5,750 received 'Come & Quit', and 19,180 received the GSP. They originated from 136 SCI units throughout Denmark offering intensive face-to-face SCI in the period from January 2011 to December 2016, with a 6-month follow up through May 2017.

The inclusion criterion was being a smoker with completed or attempted follow-up after 6 months in the study period (n=33,487). The exclusion criteria were being smokers who did not want to be followed up (n=763), those below 15 years of age (n=39) and those not receiving the GSP or Come & Quit (n=7,755).

Data collection

The SCI units reported their activities in the national Danish Smoking Cessation Database. The database was established in 2001 with the purpose of monitoring, evaluating and improving the quality of face-to-face SCI in Denmark. To date, more than 130,000 smokers undertaking an SCI have been registered in the database after providing informed consent. The Smoking Cessation Database has been described in detail elsewhere (8).

The data reported in the SCDB used in this study included an individual smoking history and socio-demographic profile of each smoker as well as a description of the programme delivered and the smoking status at the 6-month follow-up (see table 2) (8).

Education was categorized into three levels: no education or short courses, less than three years of education, and three or more years of education. Compliance was measured as meeting attendance, and a smoker was defined as being compliant with the programme when participating in at least 75% of the planned sessions in the GSP (11) and at least four sessions in the 'Come & Quit' programme (8). Disadvantaged smokers were defined as having no education or short courses only and/or as having no employment (12). Heavy smokers were defined by at least one of the following characteristics: ≥ 20 pack years, ≥ 20 gram of tobacco per day and/or ≥ 7 points for the Fagerström score of nicotine dependency (13).

Interventions

The Gold Standard Program (GSP) (5-8) has been recommended as the standard intervention in Denmark since 1995 (14), and it includes 5 sessions over six weeks. A few participants attended extra meetings. The programme was manual based and was based on motivational counselling, individualised pharmaceutical support and structured patient education to increa-

Table 1. Characteristics of the two intensive programmes for smoking cessation intervention

| | 'Come & Quit' | Gold Standard Programme |
|------------------------------------|----------------------|--|
| Meetings (number) | Up to 8 ^A | 5 |
| Fixed order of meetings | No | Yes |
| Groups or individual sessions | Groups only | Groups or individuals |
| Duration per meeting (minutes) | 90 ^A | 120 for groups; 20 for individuals ^B |
| Pharmaceutical support recommended | Yes | Yes |
| Patient education in each session | Yes | Yes |

^A In addition to an individual introduction meeting of 60 min

^B Longer first meeting of 40 minutes for the individual sessions



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se the individual health literacy regarding smoking, cessation and strategies for handling situations with relapse risk. Homework between sessions supported smoking cessation. The large majority of the GSP took place in groups, but an individual GSP was also possible (details in table 1). The Smoking Cessation Database began registration for the GSP in 2001 when the database was established (8).

'Come & Quit' (8;10) was developed later, aiming to be a more flexible programme to attract more smokers with little or no education and more male smokers. All smokers began with an individual counselling session. Despite the intensive intervention structure and phar-

macological support, the programme was very flexible and took place in running groups where each smoker had the opportunity to jump in and out of eight different manual-based sessions on eight themes. This intervention aimed to increase the support between meetings by offering text messages, e-mails or phone calls. In addition, the quit date was made flexible to adapt to the individual needs of the participants, and the educational material that was developed contained only small amounts of text. Furthermore, each meeting was shortened (1.5 hours compared to 2 hours in the GSP). The Smoking Cessation Database began registration for 'Come & Quit' in 2011.

Table 2. Characteristics of the 24,930 included smokers categorized according to their SCI programme

| | GSP n (%) | Come & Quit n (%) | Total n (%) |
|-------------------------------|---------------|----------------------|----------------|
| Total ^a | 19,180 (100) | 5,750 (100) | 24,930 (100) |
| Year of onset of intervention | | | |
| 2011 | 3,241 (16.9) | 270 (4.7) | 3,511 (14.1) |
| 2012 | 2,925 (15.3) | 887 (15.4) | 3,812 (15.3) |
| 2013 | 2,192 (11.4) | 898 (15.6) | 3,090 (12.4) |
| 2014 | 2,230 (11.6) | 1,022 (17.8) | 3,252 (13.0) |
| 2015 | 4,269 (22.3) | 1,458 (25.4) | 5,727 (23.0) |
| 2016 | 4,323 (22.5) | 1,215 (21.1) | 5,538 (22.2) |
| Participants | | | |
| Sex | | | |
| Men | 8,232 (42.9) | 2,407 (41.9) | 10,639 (42.7) |
| Women | 10,948 (57.1) | 3,343 (58.1) | 14,291 (57.3) |
| Age (years) | | | |
| 15–24 years of age | 1,018 (5.4) | 275 (4.8) | 1,293 (5.2) |
| 25–34 years of age | 1,957 (10.2) | 462 (8.0) | 2,419 (9.7) |
| 35–44 years of age | 3,124 (16.3) | 812 (14.1) | 3,936 (15.8) |
| 45–54 years of age | 4,793 (25.0) | 1,490 (25.9) | 6,283 (25.2) |
| 55+ years of age | 8,287 (43.2) | 2,711 (47.2) | 10,998 (44.1) |
| Education | | | |
| No education | 5,730 (29.9) | 1,717 (29.9) | 7,447 (29.9) |
| Less education | 3,921 (20.4) | 1,228 (21.4) | 5,149 (20.7) |
| More education | 8,775 (45.7) | 2,676 (46.5) | 11,451 (45.9) |
| Employment | | | |
| No employment | 4,935 (25.7) | 1,838 (32.0) | 6,773 (27.2) |
| Employment | 8,551 (44.6) | 2,171 (37.8) | 10,722 (43.0) |
| Retired (due to age) | 4,049 (21.1) | 1,379 (24.0) | 5,428 (21.8) |
| Students | 1,075 (5.6) | 272 (4.7) | 1,347 (5.4) |
| Disadvantaged smokers | | | |
| Not disadvantaged | 9,480 (49.4) | 2,702 (47.0) | 12,182 (48.8) |
| Disadvantaged | 9,001 (46.9) | 2,935 (51.0) | 11,936 (47.9) |
| Smoking | | | |
| <20 pack years | 6,025 (31.4) | 1,644 (28.6) | 7,669 (30.8) |
| ≥20 pack years | 13,155 (68.6) | 4,106 (71.4) | 17,261 (69.3) |
| Fagerström 1–6 points | 13,556 (70.7) | 3,982 (69.3) | 17,538 (70.4) |
| Fagerström 7–10 points | 5,624 (29.3) | 1,768 (30.8) | 7,392 (29.7) |
| <20 grams of tobacco/day | 8,115 (42.3) | 2,419 (42.1) | 10,534 (42.3) |
| ≥20 grams of tobacco/day | 11,065 (57.7) | 3,331 (57.9) | 14,396 (57.8) |



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| | | | |
|-----------------------------------|---------------|--------------|---------------|
| Heavy smokers | | | |
| Not heavy smokers | 4,075 (21.3) | 1,070 (18.6) | 5,145 (20.6) |
| Heavy smokers | 15,072 (78.6) | 4,672 (81.3) | 19,744 (79.2) |
| Compliance | | | |
| Not compliant | 7,094 (37.0) | 1,943 (33.8) | 9,037 (36.3) |
| Compliant | 11,980 (62.5) | 3,716 (64.6) | 15,696 (63.0) |
| Living with smoker | | | |
| Not living with smoker | 13,221 (68.9) | 4,026 (70.0) | 17,247 (69.2) |
| Living with smoker | 5,749 (30.0) | 1,679 (29.2) | 7,428 (29.8) |
| Living alone or with others | | | |
| Living alone | 7,327 (38.2) | 2,357 (41.0) | 9,684 (38.8) |
| Living with children (+/- adults) | 5,001 (26.1) | 1,300 (22.6) | 6,301 (25.3) |
| Living with adults (no children) | 6,655 (34.7) | 2,047 (35.6) | 8,702 (34.9) |
| Housing situation | | | |
| Residential property | 7,464 (38.9) | 2,236 (38.9) | 9,700 (38.9) |
| Cooperative dwelling | 1,699 (8.9) | 335 (5.8) | 2,034 (8.2) |
| Rented accommodation | 9,251 (48.2) | 2,976 (51.8) | 12,227 (49.1) |
| Other housing | 337 (1.8) | 100 (1.7) | 437 (1.8) |
| Referral | | | |
| No referral | 6,077 (31.7) | 1,698 (29.5) | 7,775 (31.2) |
| Yes, from healthcare staff | 12,329 (64.3) | 3,891 (67.7) | 16,220 (65.1) |
| Earliest quit attempts | | | |
| None | 6,990 (36.4) | 2,139 (37.2) | 9,129 (36.6) |
| 1–3 attempts | 9,615 (50.1) | 2,938 (51.1) | 12,553 (50.4) |
| > 3 attempts | 2,141 (11.2) | 594 (10.3) | 2,735 (11.0) |
| Smoking cessation clinics | | | |
| Setting | | | |
| Municipal | 17,177 (89.6) | 5,619 (97.7) | 22,796 (91.4) |
| Other setting | 2,003 (10.4) | 131 (2.3) | 2,134 (8.6) |
| Geographic area | | | |
| Capital Region of Denmark | 7,074 (36.9) | 1,109 (19.3) | 8,183 (32.8) |
| Region Zealand | 2,749 (14.3) | 254 (4.4) | 3,003 (12.1) |
| Region of Southern Denmark | 4,195 (21.9) | 1,211 (21.1) | 5,406 (21.7) |
| Central Denmark Region | 4,159 (21.7) | 2,004 (34.9) | 6,163 (24.7) |
| North Denmark Region | 1,003 (5.2) | 1,172 (20.4) | 2,175 (8.7) |
| Smoking cessation intervention | | | |
| Programme format | | | |
| Individual | 5,591 (29.2) | 0 | 5,591 (22.4) |
| Group | 13,589 (70.9) | 5,670 (98.6) | 19,259 (77.3) |
| Target audience | | | |
| Patients and relations | 546 (2.9) | 85 (1.5) | 631 (2.5) |
| Employees (workplace courses) | 2,064 (10.8) | 338 (5.9) | 2,402 (9.6) |
| Ordinary citizens | 14,610 (76.2) | 4,634 (80.6) | 19,244 (77.2) |
| Mixed | 693 (3.6) | 257 (4.5) | 950 (3.8) |
| Pregnant women (and partners) | 148 (0.8) | 16 (0.3) | 164 (0.7) |
| Other | 1,119 (5.8) | 420 (7.3) | 1,539 (6.2) |
| Medication offered for free | | | |
| No free medication | 9,725 (50.7) | 3,311 (57.6) | 13,036 (52.3) |
| Free medication | 9,146 (47.7) | 2,365 (41.1) | 11,511 (46.2) |
| Unknown | 309 (1.6) | 74 (1.3) | 383 (1.5) |
| Counselling free of charge | | | |
| No | 30 (0.2) | 0 | 30 (0.1) |
| Yes | 18,894 (98.5) | 5,698 (99.1) | 24,592 (98.6) |
| Planned relapse prevention | | | |
| No | 11,696 (61.0) | 3,266 (56.8) | 14,962 (60.0) |
| Yes | 7,484 (39.0) | 2,484 (43.2) | 9,968 (40.0) |

^a The categories did not sum to the total number of participants (or 100%) for all variables. This is due to missing values, which are not shown in the table



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Statistics

The two programmes were compared by means of chi2 tests regarding participant characteristics. The quit rates were compared using a mixed-effect regression model by adjusting for selected predictors and hierarchical clustering. The final model was fitted based on initial logistic regressions adjusting for sex and age and based on established knowledge. These results were described as odds ratios (ORs) with 95% confidence intervals (CIs). The details of the analyses have been described previously (9). A result was considered statistically significant if the p-value was ≤ 0.05 .

Results

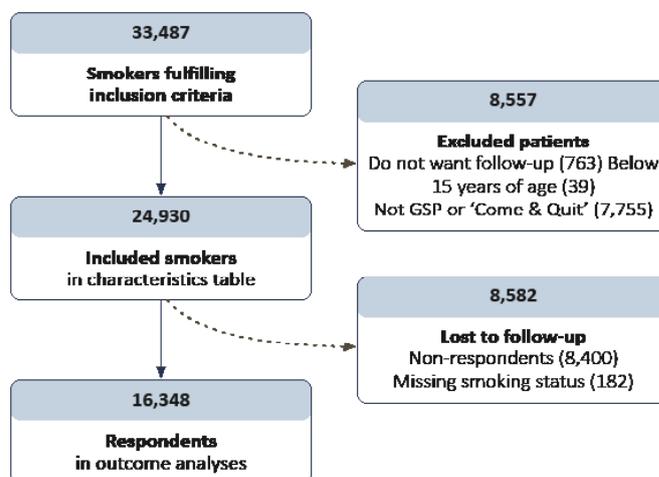
The characteristics of all 24,930 included smokers are presented in table 2. The large majority of smokers participated in the GSP (19,180; 76.9%), whereas 5,750 (23.1%) undertook the ‘Come & Quit’ programme.

Most of the participants in the GSP completed 4 and 5 meetings (corresponding to a meeting adherence above 75%) and experienced high quit-rates. The ‘Come & Quit’ was characterised by a more spread out meeting adherence. This group showed an increasing quit-rate closely related to number of meetings (figure 2 + 3).

The successful follow-up rate was 66% (trial profile in figure 1). The proportion of smokers not wanting the follow-up was slightly higher in the ‘Come & Quit’ programme than in the GSP (2.8% versus 2.4%, respectively, $p = 0.04$). There was no difference regarding the other exclusion criteria.

Most of the participants in the GSP completed 4 or 5 meetings (corresponding to a meeting adherence rate above 75%) and experienced high quit rates. ‘Come & Quit’ was characterised by a wider range of meeting

Figure 1. Trial profile



adherence. This group showed an increasing quit rate closely related to the number of meetings attended (figure 2 and 3).

Successful quitting rates are presented in table 3 as crude rates according to the programme, sex, level of education and calendar year at the onset of the intervention. Overall, 35.0% (5,752) of the 16,348 respondents included in the outcome analyses reported continuously being successful in smoking cessation after six months. When considering the 8,400 non-respondents as smokers, the crude quit rate was 23.0% (table 3). Men had a higher quit rate than women for both programmes: 3.0% and 3.1% higher in the base case for ‘Come & Quit’ and the GSP, respectively. The fully adjusted model confirmed a significantly higher quit rate among men (OR=1.15, 95% CI: 1.07-1.23; $p < 0.001$).

Furthermore, from the gender perspective for ‘Come & Quit’ and GSP, the two separate multivariable logistic regression analyses for men and women, respectively,

Figure 2. Participants in terms of the number of meetings in the GSP (5 planned meetings) and ‘Come & Quit’ (8 sessions allowing flexible order and number)

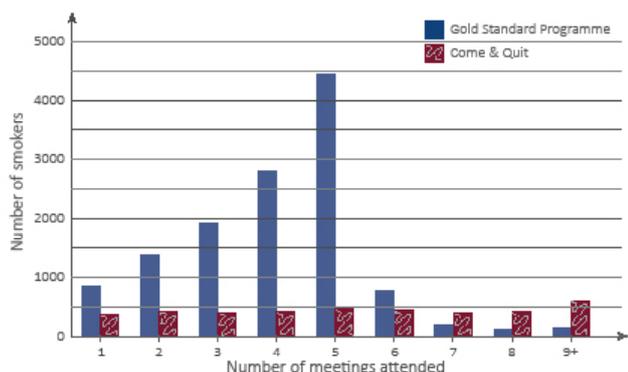
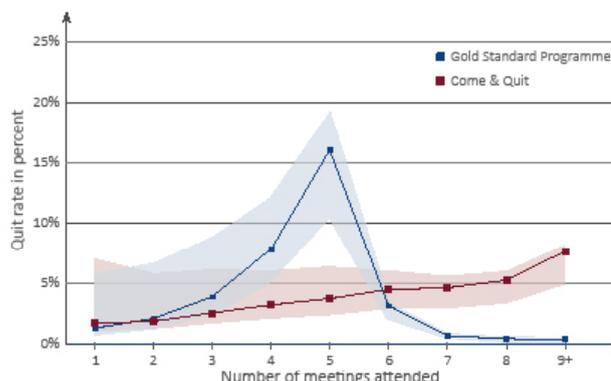


Figure 3. Successful quit rates after 6 months for each number of meetings





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Table 3. Proportion of continuously successful quitters. Crude quit rates according to smoking cessation intervention. The worst case assumed non-respondents to having relapsed

| | Base case (RECORD criteria (14)) | | Worst case (RUSSEL criteria (15)) | |
|-------------------------------|-------------------------------------|------|--------------------------------------|------|
| | All | | All | |
| | n | (%) | n | (%) |
| Come & Quit | 3,787 | 34.7 | 5,750 | 22.9 |
| Sex | | | | |
| Men | 1,620 | 36.4 | 2,407 | 24.5 |
| Women | 2,167 | 33.4 | 3,343 | 21.8 |
| Education | | | | |
| No education | 1,067 | 30.5 | 1,717 | 19.0 |
| Less education | 826 | 32.0 | 1,228 | 21.6 |
| More education | 1,810 | 38.3 | 2,676 | 26.0 |
| Year of onset of intervention | | | | |
| 2011 | 191 | 29.8 | 270 | 21.1 |
| 2012 | 597 | 31.7 | 887 | 21.3 |
| 2013 | 592 | 30.1 | 898 | 19.9 |
| 2014 | 661 | 33.3 | 1,022 | 21.5 |
| 2015 | 966 | 39.0 | 1,458 | 25.9 |
| 2016 | 780 | 37.4 | 1,215 | 24.3 |
| GSP (standard intervention) | 12,561 | 35.3 | 19,180 | 23.2 |
| Sex | | | | |
| Men | 5,548 | 37.1 | 8,232 | 25.0 |
| Women | 7,013 | 34.0 | 10,948 | 21.8 |
| Education | | | | |
| No education | 3,598 | 33.6 | 5,730 | 21.2 |
| Less education | 2,582 | 34.3 | 3,921 | 22.6 |
| More education | 5,908 | 36.9 | 8,775 | 24.8 |
| Year of onset of intervention | | | | |
| 2011 | 2,368 | 31.6 | 3,241 | 23.1 |
| 2012 | 1,976 | 34.5 | 2,925 | 23.3 |
| 2013 | 1,444 | 34.1 | 2,192 | 22.4 |
| 2014 | 1,461 | 35.0 | 2,230 | 23.0 |
| 2015 | 2,655 | 36.0 | 4,269 | 22.4 |
| 2016 | 2,657 | 39.5 | 4,323 | 24.3 |

showed no statistically significant differences between the programmes, either for men (OR=1.06, 0.92-1.23) or for women (OR=0.94, 0.82-1.08); see table 4. For both men and women, being compliant with the programme was the most important predictor of successful quitting. Other minor predictors across genders were calendar year, lack of social disadvantage or heavy smoking (table 4).

Analysis of non-responders

The analysis of non-respondents compared with respondents showed no differences regarding SCI programme, amount of tobacco per day or format (group or individual counselling). All other factors, including age, employment, social disadvantage, pack year and living condition, differed up to 5 percentage points, except for compliance with the programme, which differed by 14.5 percentage points.

Overall, the non-respondents tended to be individuals from a more disadvantaged group.

Discussion

This study showed that both 'Come & Quit' and GSP were followed by similarly high quit rates of 35% after 6 months among those followed up or 23% if the third group not responding to follow-up were considered to be still smoking. Overall, men had a significantly higher quit rate than women. The most important predictor was the compliance measure of attendance.

Overall, the intensive SCI is more effective than shorter interventions (4) and represents the standard for SCIs in Denmark (5-8). The proportion of successful quitting found in this study is similar to that in previous studies on the effect of a GSP (11-13;17;18) but high compared to that in other studies of intensive SCIs



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Table 4. Predictors included in the two separate multivariable logistic regression analyses. Statistical significance is marked with an asterisk

| | Multivariable analysis ^a OR (95% CI) | Multivariable analysis ^a OR (95% CI) | Interaction with sex p |
|---------------------------------------|--|--|---------------------------|
| | Men n=7,168 (6,841 in the analysis) | Women n=9,180 (8,716 in the analysis) | |
| Intervention programme | | | |
| Standard intervention (GSP) | 1 | 1 | |
| Come & Quit | 1.10 (0.94-1.23) | 0.94 (0.83-1.08) | 0.613 |
| Year of onset of intervention | | | |
| 2011 | 1 | 1 | |
| 2012 | 1.08 (0.89-1.31) | 1.10 (0.93-1.30) | 0.959 |
| 2013 | 1.10 (0.89-1.36) | 1.11 (0.93-1.33) | 0.805 |
| 2014 | 1.06 (0.86-1.31) | 1.18 (0.98-1.40) | 0.697 |
| 2015 | 1.10 (0.91-1.33) | 1.27 (1.07-1.50) * | 0.877 |
| 2016 | 1.31 (1.09-1.59) * | 1.27 (1.07-1.50) * | 0.186 |
| Participants | | | |
| Age (years) | | | |
| 15–24 years of age | 1 | 1 | |
| 25–34 years of age | 1.13 (0.80-1.59) | 1.44 (1.08-1.93) * | 0.346 |
| 35–44 years of age | 1.16 (0.84-1.61) | 1.26 (0.96-1.65) | 0.893 |
| 45–54 years of age | 1.24 (0.91-1.71) | 1.30 (1.00-1.69) | 0.909 |
| 55+ years of age | 1.15 (0.84-1.57) | 1.28 (0.99-1.66) | 0.886 |
| Disadvantaged smokers | | | |
| Not disadvantaged | 1 | 1 | |
| Disadvantaged | 0.74 (0.67-0.83) | 0.77 (0.70-0.84) | 0.790 |
| Heavy smokers | | | |
| Not heavy smokers | 1 | 1 | |
| Heavy smokers | 0.78 (0.67-0.91) * | 0.71 (0.63-0.80) * | 0.183 |
| Compliance | | | |
| Not compliant | 1 | 1 | |
| Compliant | 2.82 (2.49-3.19) * | 2.60 (2.33-2.89) * | 0.203 |
| Living with smoker | | | |
| Not living with smoker | 1 | 1 | |
| Living with smoker | 0.85 (0.76-0.96) * | 0.91 (0.82-1.00) | 0.475 |
| Smoking cessation clinics | | | |
| Setting | | | |
| Municipal | 1 | 1 | |
| Other setting | 1.04 (0.83-1.29) | 1.06 (0.86-1.29) | 0.969 |
| Geographic area | | | |
| Capital Region of Denmark | 1 | 1 | |
| Region Zealand | 1.19 (0.94-1.52) | 1.45 (1.16-1.83) * | 0.142 |
| Region of Southern Denmark | 1.05 (0.85-1.31) | 1.27 (1.03-1.58) * | 0.146 |
| Central Denmark Region | 0.88 (0.71-1.09) | 1.05 (0.85-1.30) | 0.202 |
| North Denmark Region | 1.16 (0.85-1.57) | 1.36 (0.99-1.87) | 0.477 |
| Smoking cessation intervention | | | |
| Programme format | | | |
| Individual | 1 | 1 | |
| Group | 0.74 (0.64-0.86) * | 0.92 (0.81-1.06) | 0.215 |
| Medication offered for free | | | |
| No free medication | 1 | 1 | |
| Free medication | 1.11 (0.97-1.25) | 1.02 (0.90-1.14) | 0.041 |
| Unknown | 1.22 (0.79-1.89) | 1.44 (1.00-2.08) * | 0.582 |
| Hierarchical cluster | | | |
| | Variance (95% CI) | Variance (95% CI) | |
| Smoking cessation clinic | | | |
| | Variance of random intercepts | 0.05 (0.02-0.11) | |



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(19-24). The difference may be due to differences in the programme details but also to the settings, the smokers included and the use of validation as described below. It is important to evaluate new intensive interventions such as 'Come & Quit', as they are generally recommended for vulnerable and disadvantaged groups (3).

'Come & Quit' has involved considerations related to health literacy. On a practical and individual-oriented level, 'Come & Quit' heeds the call of international policies, such as the World Health Organization's (WHO) 2016 Shanghai Declaration, concerning the improvement of health literacy (25) of people – namely, the knowledge and skills needed to make healthy choices in life (26). Health literacy is defined as the skills, knowledge and confidence that determine the motivation and ability of individuals to gain access to, understand and use information in ways that promote and maintain good health, such as by quitting smoking (25;27). On the level of individual/groups, such health promotion actions that include elements of education, counselling, support and empowerment in terms of health literacy can contribute considerably to population health as valuable complimentary strategies to the more structural health promotion actions and strategies such as governance-level initiatives. Interestingly, this was not reflected in the results, as both programmes attracted similar groups of smokers.

From the clinical perspective, health care professionals need to become familiar with the new 'Come & Quit' programme to be able to offer it to smokers. From the smokers' perspective, it is beneficial to have more intensive programmes with a similarly large effect to choose between, as preferences may differ from one smoker to another. At the healthcare and societal level, the results support the recommendation for using an intensive SCI. An existing challenge to be addressed in further research is that even though 'Come & Quit' was developed to attract smokers with little or no education and male smokers, no difference was observed regarding these characteristics.

Bias and limitations

The increasing use of 'Come & Quit' over the study period could introduce a bias from a learning curve, where people show increasingly better outcomes over time. The follow-up interviews were performed by the

Danish Quit-line but not validated otherwise by, e.g., CO or nicotine measurement. The lack of validation may have resulted in over-estimating the quit rate. Another bias originates from the one-third of individuals not responding to follow-up. They were considered to be still smoking, but the quit rate may differ between individuals in the two programmes and among the individual smokers. The non-respondent analysis is, however, a strength of this study. The study also has limitations, as the intervention tool was situated in a Danish context with a widespread cluster of SCI units all over the country, and the results may therefore not be transferable to other settings.

In conclusion, the two intensive interventions 'Come & Quit' and the Danish GSP were both effective with similar quit rates of 35%; however, in both programmes, men had a higher quit rate than women, though the difference was small. The most important predictor was the compliance measure of attendance.

Conclusion

Thank you to the Ministry of Health, the Danish National Board of Health, Bispebjerg & Frederiksberg Hospital for financing the Smoking Cessation Database and to the Danish Cancer Society for partly financing the present project. Additionally, thank you very much to all the smokers who have agreed to provide information about their smoking cessation programmes and outcomes in the Smoking Cessation Database, as well as to the staff at the smoking cessation units.

Acknowledgements

Thank you to the Ministry of Health, the Danish National Board of Health, the Bispebjerg & Frederiksberg Hospital, and the Danish Cancer Society for financing the smoking cessation database.

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All authors participated in the development of the research project. Mette Rasmussen performed the analyses. All authors took part in the interpretation. Hanne Tønnesen wrote the manuscript. All authors edited and approved the final version.



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