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Implications of Switching from Conventional to Electronic Cigarettes on Quality of Life and Smoking Behaviour: Results from the EQualLife Trial

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Keywords
E-cigarette · Abstinence · Harm reduction · Quality of life · Smoking cessation · Switching from conventional cigarette

Abstract
Introduction: Electronic cigarettes and "vaping" have become popular since their appearance in Europe and the USA in approximately 2006. They are often perceived as having fewer health risks than conventional cigarettes, which makes them of interest as a support tool in smoking cessation. However, its efficacy regarding cessation or reduction of smoking under real-life conditions remains controversial. Our objective was to clarify this question in an observational study of smoking habits after initiating vaping without targeted intervention, as compared to a validated cessation programme. ***Methods:*** From October 2015 to April 2018, 80 subjects (60 in the e-cigarette group and 20 in the supervised smoking cessation group) were included in two trial visits, one at the start of the trial and the second after 3 months, plus 4 questionnaire surveys: at the start of the trial and after a 1, 2, and 3 month period. The questionnaire included a nicotine use inventory, a modified Fagerström test for nicotine dependence, and the WHO-QOL-BREF survey. ***Results:*** E-cigarettes were effective, leading to a significant ($p < 0.03$) reduction ($p < 0.03$) in tobacco consumption and nicotine dependence, with an abstinence rate of 43% after 3 months. Compared to participants in the smoking cessation programme, their use was not associated with an improvement in quality of life during the quitting attempt, and there were no significant differences in clinical symptoms between groups. The reduction in nicotine dependence was more pronounced ($p < 0.012$) for the smoking cessation programme, with higher abstinence rates ($p = 0.011$ after 12 weeks) and lower ($p < 0.003$) remaining tobacco consumption compared to electronic cigarettes. ***Discussion/Conclusions:*** The use of electronic cigarettes reduced nicotine dependence and tobacco consumption, but a supervised smoking cessation programme was superior in terms of achieved cessation in both regards. Electronic cigarettes did not improve the quality of life. Since e-cigarettes could be associated with long-term health risks,

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their usefulness in smoking cessation remains questionable, and a professionally guided and validated smoking cessation programme still appears to be superior and preferable, in terms of achieved cessation. Although this trial is limited regarding the number of participants and follow-up time, it highlights the need for additional, large clinical trials evaluating the efficacy of e-cigarettes for smoking cessation in comparison to a professionally guided smoking cessation programme.

Introduction

Currently, approximately 1.1 billion people around the world are consuming tobacco products, leading to more than 7 million deaths annually [1]. Therefore, tobacco consumption constitutes one of the most relevant and avoidable risk factors for good health. Although the prevalence of tobacco smokers decreased, according to WHO data, from 2000 to 2015 in all age groups, and the decrease is expected to continue [1], electronic cigarettes are steadily becoming more popular. They are well established on the global market and are now available in 4 different generations [2]. The assessment of possible harm and possible benefit is made more difficult by the immense variety of products and the interference with conventional tobacco consumption. Many customers perceive them as "healthier" and "less harmful" than conventional cigarettes [3].

Studies showed lower levels of tobacco-related emissions with e-cigarettes compared to tobacco cigarette use [4], and in tests with smoking machines, e-cigarettes showed lower concentrations of harmful substances [5]. The public health system of Great Britain has even actively recommended electronic cigarettes for smoking cessation [6, 7], pursuing a "harm-reduction strategy" [8], although their efficacy as a tool for smoking cessation remains controversial [9] after a multitude of studies and should only be used when other guideline-based methods have failed [10]. An increase in e-cigarette use in the population may lead to a lower prevalence of smoking and also to a lower burden of disease in the long term, especially if use can be solely limited to smoking cessation support [11].

In a randomised controlled trial [12], 886 participants who attempted to quit smoking used a nicotine replacement product of their choice (a combination of more than one product was encouraged) or a refillable electronic cigarette. The 1-year abstinence rate was 18.0% in the electronic cigarettes group, versus 9.9% in the nicotine replacement group. Contrary to these results, a large-scale pragmatic trial enrolling approximately 6,000 participants did not observe a perceptible benefit of e-cigarettes towards smoking cessation [13], and a large meta-analysis claimed an overall negative effect of e-cigarette use on the success rate of cessation [14]. The disparity in outcomes could be linked to the fact that the amount of nicotine released maximally varies markedly between nicotine replacement products [9, 15, 16]. In addition, selection effects are likely to play a role in the controlled trials; thus, well-designed, real-life, observational studies with no intervention and minimal selection might provide useful additional information. Another potentially important factor is the impact of e-cigarettes on psychological factors, particularly quality of life during attempts to quit smoking, which has not yet been investigated. This is of probable relevance, as quality of life has a major influence on the success of smoking cessation and the persistence of tobacco abstinence [17–19]. Based on these considerations, the aim of the study was to investigate the effectiveness of electronic cigarettes in reducing smoking in a prospective cohort study. The recruitment took place in a real-life setting where participants were free to choose the type of electronic cigarettes and liquids. All participants expressed a desire to quit smoking if possible. The main objective was to assess the impact of electronic cigarettes on quality of life and clinical symptomatic endpoints. The control group did not use e-cigarettes but participated in a group cognitive-behavioural smoking cessation programme and had the option to use one or more conventional nicotine replacement products of their choice. The special feature of the study was that the subjects were recruited in a real-life setting and intensively observed afterwards. Lung function and airway responsiveness to inhaled mannitol were also measured, but these data points have already been published and do not interfere with the data presented here [20].

Materials and Methods

Study Design

This study had a prospective, open-label, non-randomised design and was conducted at a single study site: Department for Psychiatry and Institute and Outpatient Clinic for Occupational, Social and Environmental Medicine at the Ludwig Maximilian University of Munich, Germany. In the e-cigarette group, the enrolled participants were planning to completely switch from conventional tobacco cigarettes to e-cigarettes. The participants were free to choose any model, liquid type, and strength of their liking. The e-cigarette, as well as the liquids, had to be purchased by

the participants themselves, as the researchers only observed their attempts.

The control group participated in the "Rauchfrei" smoking cessation programme at Department for Psychiatry at the Ludwig Maximilian University of Munich, Germany. The "Rauchfrei Programme (IFT)" is a cognitive behavioural group programme for smoking cessation developed in 2009 and has been implemented in numerous health centres in Germany, where it is one of the most widely distributed programmes of its kind. It is standardised and has been evaluated [21, 22] contains elements of multicomponent treatment and modern psychotherapy, such as dialectical behaviour therapy and acceptance/commitment therapy, as well as psycho-education [23]. Participants in the control group were not required to use electronic cigarettes, but the use of one or several nicotine replacement products of choice was encouraged. Nicotine replacement products had also to be purchased by participants themselves.

Both trial groups received an equal financial allowance of 50 euros for complete participation, with attendance of all follow-up appointments as a precondition. The recruitment of the e-cigarette group took place in selected e-cigarette stores in the city of Munich, where potential participants were contacted by members of the study coordination team. Additionally, flyers were used for recruitment purposes. To qualify for inclusion, participants had to be a minimum of 18 years of age and legally competent to give consent. They had to consume cigarettes for a minimum of 5 years, with a daily consumption of 10 cigarettes. For inclusion in the e-cigarette group, the intention to completely switch to e-cigarettes was required at the time of recruitment, while for the control group, participation in the "Rauchfrei" smoking cessation programme was required. The test persons of the control group were recruited via regular smoking cessation course of the tobacco ambulance of Department for Psychiatry at the Ludwig Maximilian University of Munich, Germany by informing the participants of the option to participate in the control group. Exclusion criteria for both groups were ongoing pregnancy, breast feeding, relevant allergies, acute psychiatric disorders, ongoing drug, alcohol, or illegal substance abuse, a malignant disease within the last 5 years, severe cardiovascular comorbidities (such as severe coronary artery disease, myocardial infarction, cardiac pacemaker), severe pulmonary comorbidities with respiratory insufficiency (i.e., COPD GOLD IV), and severe active infectious diseases. A smoking cessation attempt, which was defined as any self-reported smoking cessation, irrespective of the duration of abstinence within the previous 3 months, was a reason for non-inclusion.

The study was carried out according to the Declaration of Helsinki and approved by the Ethics Committee of the Medical Center (LMU Munich, project number 374–15). Written informed consent was obtained from all study participants for participation in the study.

Assessments

Recruitment was carried out between October 2015 and April 2018. Follow-up ended in July 2018. During the trial, two in-person trial visits were held, in which the study coordinators examined the participants. Before the start of e-cigarette consumption or the smoking cessation programme, the first study visit was made. The second visit was scheduled after 3 months. During the study, a total of 4 questionnaire surveys were carried out: at the first visit, and after 1 month, 2 months and 3 months, respectively. All surveys could be answered online, by postal delivery, or by telephone, according to the attendee's choice. The questionnaires included a nicotine use inventory (NUI) to assess smoking habits and a modified version of the Fagerström test for nicotine dependence. This test is among the instruments most commonly used to quantify tobacco dependence [24]; its items can be found in the publication by Fagerström [25]. For the present study, the test was modified by excluding the question "How many cigarettes do you smoke on average per day?" since it is not relevant to e-cigarette consumers. In accordance to the conventional Fagerström test, nicotine dependence was assessed by summing up the scores of the remaining five questions of the Fagerström test. Therefore, the maximally achievable points regarding nicotine addiction ranged from 0 to 7, instead of 0 to 10 in the conventional Fagerström test. This modified version has been previously described [26]. Abstinence rates were assessed 1 month, 2 months, and 3 months after trial initiation, respectively. Abstinence was thereby self-reported by the participant in a questionnaire and was defined as complete abstinence from conventional cigarettes within the last 7 days and within the last 30 days, respectively. The use of electronic cigarettes within the intervention group (e-cigarette group) was not interpreted as breach of abstinence, irrespective of the amount of nicotine present in the e-cigarettes. Quality of life was assessed using the WHO-QOL-BREF questionnaire, which consists of the following 4 domains: physical health, psychological health, social relationships, and environmental quality of life [27]. At the first visit the participants were additionally asked for sociodemographic data of the participants. During follow-up, a multitude of clinical symptoms, as well as changes in the sense of smell and taste, were evaluated using a specific questionnaire. Clinical symptoms and changes in sensory perception were evaluated at every trial contact. Each clinical symptom was ranked, ranging from 1 = no symptoms to 5 = strong symptoms.

Data Analysis

The present analysis focuses on the data on the course of quality of life and symptoms during the study period. Data on lung function that were obtained at baseline and 3 months, but not in intermediate evaluations, have been previously published [20]. Results are given as numbers or percentages or as mean values and standard deviations (SD). For statistical comparisons, we used analysis of variance (ANOVA) with repeated measures design or *t* tests for continuous variables and contingency tables and χ^2 statistics or the Mann-Whitney U test for categorical variables. A p value of <0.05 was considered significant. Statistical analysis was performed with the SPSS software package (IBM® SPSS Statistics, version 25.0, Armonk, NY, USA).

Results

Baseline Characteristics

During the recruitment period, 80 participants were found to fit the recruitment criteria and included, 60 of them in the e-cigarette group and 20 in the control

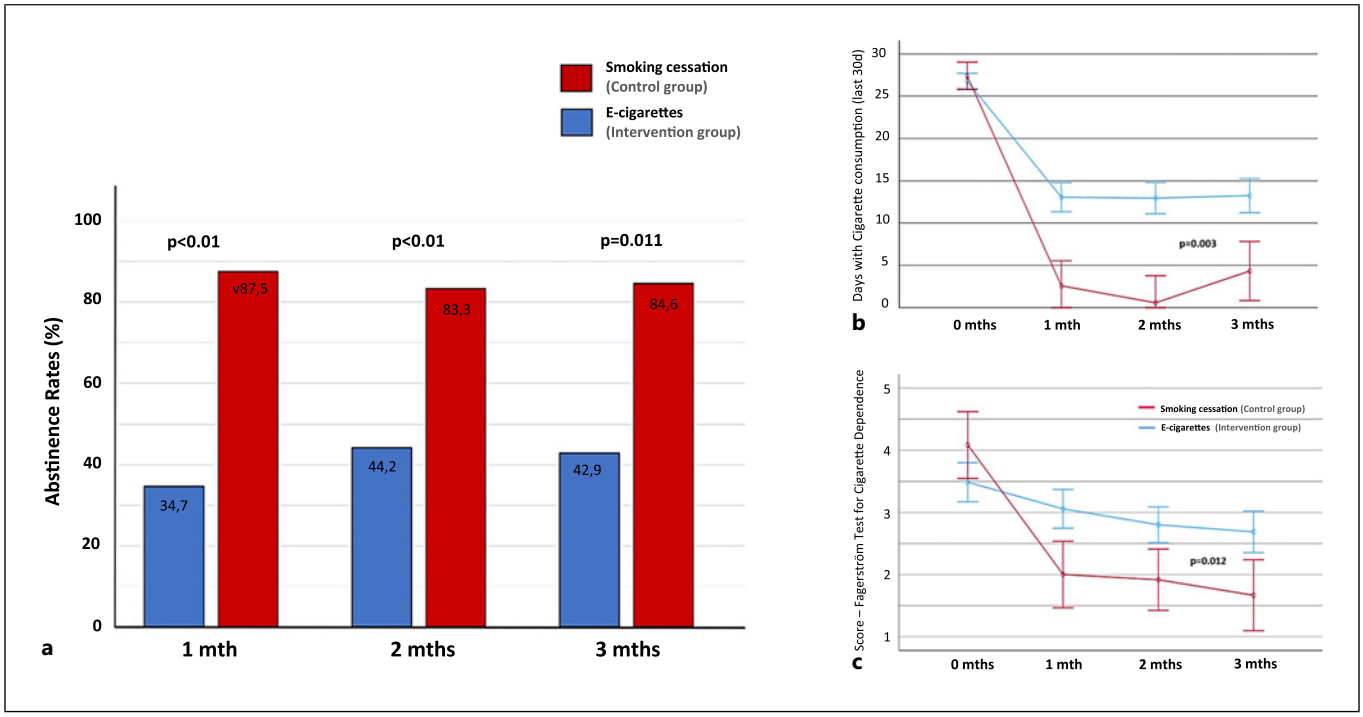

Fig. 1. a Abstinence rate was evaluated at indicated time points after target quit date and was defined as self-reported complete abstention from conventional cigarettes, over the last 7 days before the respective assessment. **b** Days on which conventional cigarettes were consumed were assessed starting from the target quit date. **c** Cigarette dependence was evaluated by the Fagerström test. Test scores are depicted for the time after quit date. Mean values and standard deviations of mean are given.

group. There were no statistically significant differences between the baseline characteristics of the two groups. The mean age (SD) was 43.7 (±12.7) years in the e-cigarette group and 48.4 (±11.9) years in the control group (p = 0.16). Upon enrolment, the participants of the e-cigarette group were smoking for a time of 20.9 (±12.2) years and, in the control group, for 27 (±10.3) years (p = 0.06). Daily consumption of cigarettes upon inclusion was 19.7 (±10.7) cigarettes/day and 17.5 (±7.0) cigarettes/day in the e-cigarette and control group, respectively (p = 0.25). Nicotine dependence upon inclusion showed moderate dependence for both groups, with a test score of 3.5 (±1.9) points on the e-cigarette and 4.1 (±1.5) points in the control group (p = 0.17).

Follow-Up Characteristics

There were no significant differences in adherence to the trial between the two groups. The median number (quartiles) of follow-up appointments attended was 4 (3–4) in the e-cigarette group and 4 (3–4) in the control group (p = 0.92), with 61.7% of the participants in the e-cigarette group and 55% in the control group attending all 3 follow-up appointments.

In the e-cigarette group, adherence to these products was high, with 71.7% of participants reporting daily use 1 month after inclusion, while after 3 months there was a slight, non-significant decrease (p = 0.31) to 64.1%. The mean liquid consumption per month also decreased slightly among e-cigarette users, from 3.6 (±3.1) mL after 1 month to 3.3 (±2.7) mL after 3 months, again not significantly different (p = 0.87). Due to the large number of superordinate model types (N = 17) with various subtypes of models used and thus many subgroups with very limited statistical significance, a separate analysis of the e-cigarette models used was not performed.

Cigarette Consumption during Follow-Up

During 3 months of follow-up, tobacco consumption decreased in the e-cigarette group. The number of days on which conventional cigarettes were consumed in the last month (30 days) before each evaluation decreased significantly (p < 0.001) from initially 26.8 (±5.4) to 13.3 (±13.0) days (Fig. 1b).

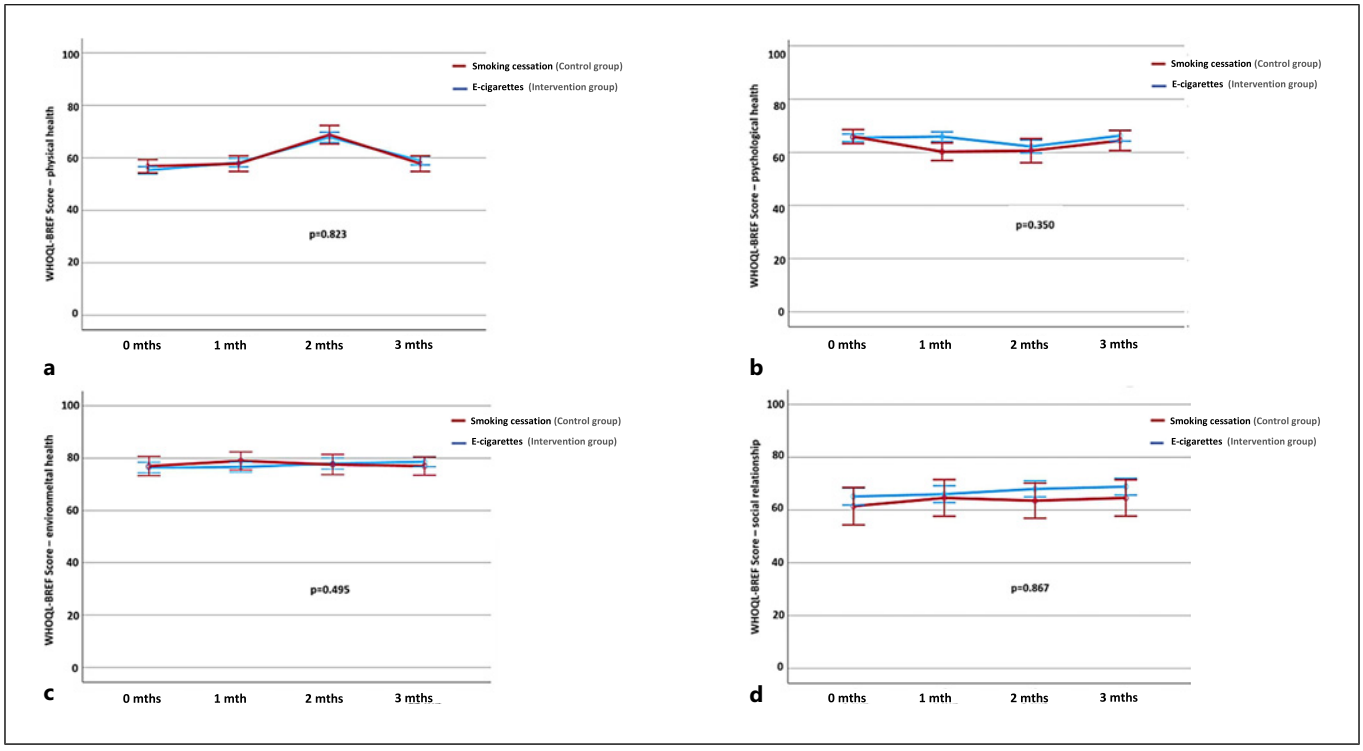

Fig. 2. Quality of life was assessed using the WHO-QL-BREF Score at each trial contact. The four domains are reported separately for the physical health domain (**a**), the psychological health domain (**b**), the environmental health domain (**c**), and the social relationship domain of the WHO-QL-BREF Score (**d**). Mean values and standard errors of mean are given.

In the e-cigarette group, the 7-day abstinence rate at the end of the study (after 3 months) was 42.9% of the participants (n = 18). In the control group, the 7-day abstinence rate was 84.6% of the participants (n = 11). It decreased from 87.5% to 84.6% after 3 months (p < 0.001).

The abstinence of the control group was significantly higher (p = 0.01) compared to the e-cigarette group at all follow-up time points. 30-day abstinence rates at all follow-up visits were also measured. Complete abstinence from conventional cigarettes in the last 30 days after 3 months was significantly higher in the control group (p = 0.017) than in the e-cigarette group, with values of 64.3% (n = 9) and 28.6% (n = 12), respectively. Complete abstinence over the entire period of the study was shown by 31.4% in the e-cigarette group and 83.3% in the control group (p = 0.002) (Fig. 1a).

The motivation to quit cigarette consumption was self-reported by the participants and was not significantly different between the two trial groups (p = 0.17). Among participants who did not achieve abstinence, both interventions decreased the amount of residual tobacco cigarette consumption (p < 0.001 each), but the decrease was significantly (p = 0.003) more pronounced in the control than in the e-cigarette group (Fig. 1b). Consequently, at 3 months, the number of days on which conventional cigarettes were consumed during the last 30 days was 4.3 (±9.0) days for the control group and 13.3 (±13.0) days for the electronic cigarettes group.

Nicotine Dependence

In the e-cigarette group, the modified Fagerström score decreased significantly from 3.5 (±1.9) upon inclusion to 2.7 (±1.9) after 3 months (p = 0.025), while in the control group it decreased (p = 0.012) from 4.1 (±1.7) to 1.7 (±2.1) (Fig. 1c). Again, this change was more pronounced (p = 0.012) in the control group (Fig. 1c).

Quality of Life and Symptoms

The assessment of quality of life with the WHO-QOL-BREF questionnaire was carried out with its four domains. In none of these domains, there were significant differences between the control and the e-cigarette group during the trial, despite a tendency towards improved

psychological and social health in the e-cigarette group, but without statistical significance (Fig. 2).

Clinical symptoms were assessed in the two groups 3 months after inclusion. The e-cigarette group showed significantly more irritation of the throat than the control group ($p = 0.04$), while participants in the control group reported a greater increase in appetite ($p = 0.003$). Regarding the other clinical symptoms, there were no significant differences between the two groups, nor were there significant differences in the sense of smell and taste.

Discussion

The rapidly growing global consumption of e-cigarettes [28] has led to an increased scientific interest in the topic in the last decade. Most of the current research focuses on its potential as a nicotine replacement tool for tobacco abstinence or on possible long-term detrimental health effects, as well as on epidemiological surveys regarding prevalence, awareness, and reasons for using e-cigarettes in the population [29].

The aim of the study was to compare e-cigarettes with already-known and established smoking cessation interventions. For this purpose, a design was chosen that is as close as possible to real-life conditions while being sufficiently monitored. Successful cessation of smoking leads to an improvement in quality of life [30]; conversely, quality of life improves the success rate and long-time abstinence [31], but surprisingly, the impact of e-cigarettes on quality of life has rarely been scarcely investigated [32]. Therefore, quality of life was included in assessments in order to provide additional psychological insights.

In the trial design, which did not include intervention or guidance, the use of e-cigarettes resulted in a reduction in tobacco consumption and a significant reduction in self-reported nicotine dependence. The Fagerström test that was used allows for a quantification of nicotine dependence. It is also predictive of the success of smoking cessation attempts, with a higher predictive power in men than in women [21]. After 3 months of self-determined behaviour, participants using e-cigarettes achieved a 7-day-point prevalence abstinence of more than 40%, suggesting that e-cigarettes may be a useful tool for smoking cessation. However, participants who participated in the professional smoking cessation programme achieved a much higher abstinence rate and a reduction in residual tobacco consumption.

These results differ from those of a large randomised trial [12], which reported a significantly better 1-year abstinence rate of 18.0% in participants using e-cigarettes to quit smoking, compared to 9.9% in the control group using established nicotine replacement products only. On the other hand, the absence of advantages of e-cigarettes over conventional approaches has been found in other randomised trials and in meta-analyses [13, 14, 33], thus the findings do not constitute a unique finding. Many authors attribute the divergence of the results primarily to differences in the models of electronic cigarettes and liquids used. Especially modern, refillable models are often more effective in nicotine delivery and offer a higher user comfort than older non-refillable cartridge products [12, 34]. In this trial, participants had the freedom to use whatever e-cigarette model and nicotine-containing liquids they preferred. This and the absence of any intervention could be factors contributing to the high adherence to e-cigarette consumption in the study and, at the same time, support the view that the study was close to real-life conditions.

Another reason for discrepancies between trials may be the differences in the control groups that were implemented. For example, offering participants a professional introduction to the handling of nicotine replacement products, as well as the possibility of using a combination of multiple nicotine replacement products, appears to increase the success of abstinence attempts [35]. In this context, this trial stands out since the control group attended a professional smoking cessation programme, receiving detailed information on the use of nicotine replacement therapy and being encouraged to use one or more products of their choosing. According to current guideline recommendations, this combination of behavioural therapy intervention and medication represents the most promising treatment for tobacco dependence [36]. In addition, it is certainly worth mentioning that the Smoke-Free Programme is one of the programmes with the best prospects of success in the field of tobacco cessation in German-speaking countries. There are various standardised and manualised versions that adapt to specific needs of those affected, such as the clinic version for patients in inpatient treatment or day courses for companies. In this case, the basic version of the Smoke-Free Programme was nine units, with two units per week each [23]. Among the multitude of all programmes, this certainly represents one of the most intensive versions. This intensive support could be the reason for the above-average success rates in tobacco reduction and abstinence, with a 7-day-point prevalence of abstinence of 84.6% after a period of 3 months.

Interestingly, the use of e-cigarettes did not lead to a significantly improved quality of life compared to the control group. To increase statistical power and determine the progression of time, quality of life was assessed three times during follow-up. The WHO-QOL-BREF questionnaire that we used is a well-established instrument, especially in the context of substance abuse [37], and has already been validated in smokers [38]. None of its four domains showed significant differences between the two groups. Of course, the possibility cannot be excluded that an increased quality of life at baseline, compared to other smokers, led to the decision to try a quitting attempt by e-cigarette or to participate in the cessation programme, with the result that no further improvements could be observed. Evaluation of clinical symptoms during the quitting attempt did not reveal substantial differences between the two groups. Although participants in the e-cigarette group reported more irritation of the throat at the end of the follow-up, an effect also observed in other trials [12], changes and differences were small. Therefore, it seems unlikely that these side effects significantly affected abstinence rates.

After 3 months, 64.1% of the participants reported daily use of e-cigarettes. This is in line with the findings that after 1 year, up to 80% of users, who were abstinent with regard to conventional cigarettes, were still regularly using e-cigarettes [12], upholding their nicotine dependence and exposing themselves to the potential long-term health effects of electronic cigarettes. Unfortunately, their positive potential in reducing tobacco consumption, as confirmed in this investigation, contrasts with the high rates of coconsumption of electronic and conventional cigarettes. The health consequences of this coconsumption are currently not well studied, underlining the need for large-scale studies addressing both the short-term potential of e-cigarettes as smoking cessation tool and their long-term health effects. This might be achieved in trials that mimic real-life conditions and include the full spectrum of users. This study shows that this is possible, as the initial concerns about the willingness of e-cigarette starters to participate in such a study turned out to be unfounded. The results also underline that the control group should be chosen carefully, offering the maximum support for smoking cessation that can be provided according to current knowledge.

The study has some limitations. The design could not fully exclude the possibility of a selection bias of recruitment into the two groups or regarding the comparability between these groups. Additionally, the group sizes, especially in the control group, were small. The total follow-up time was limited to 3 months, with follow-up data being collected every month. In addition, the trial included the determination of spirometric parameters and airway responsiveness, both at inclusion and at the end of follow-up [20].

Conclusion

In a study conducted with minimal intervention regarding the behaviour of participants, the use of e-cigarettes supported its significant role in reducing tobacco consumption and partially even stopping after 3 months. However, a comprehensive, approved, and established smoking cessation programme was much superior in this regard. This included a stronger reduction in nicotine dependence, which could have played a role in greater success. In order to better answer this question, it would be informative to carry out a case-control study in addition to the explorative approach, as was done here, as this could provide further valuable correlations. Regarding the implications of e-cigarette usage on quality of life, the study did not detect a significant alteration in quality of life during 3 months of smoking cessation, as none of the four domains of the WHO-QOL-BREF questionnaire, nor the evaluated clinical symptoms showed significant differences between the two groups. These findings point to potential drawbacks of the continued consumption of nicotine-containing products and the habit of smoking that compensate for potential benefits. The findings also emphasise the role of a proper control group in the study of the effectiveness of electronic cigarettes for smoking cessation.

Acknowledgments

We thank all the subjects of the study for their willingness to participate and cooperate.

Statement of Ethics

This study was carried out according to the principles outlined in the Helsinki Declaration (Br Med J 1964; ii: 177). The conduct of the trial was approved by the Ethics Commission of the Medical Faculty of LMU University, project number 374-15. Our study is registered under the clinical trial number NCT02635620. Written informed consent was obtained from all study participants for participation in the study. This study protocol was reviewed and

approved by the ethics commission of the medical faculty of LMU University, approval number 374-15. This clinical trial was registered before patient enrolment.

Conflict of Interest Statement

D.N. and T.R. are members of the Pfizer Advisory Board on smoking cessation issues.

Funding Sources

There were no funding sources for this study.

Author Contributions

A.R., L.C., R.A.J., D.N., and T.R. were responsible for the study concept and design. L.C., E.F., and K.K. were responsible for data collection. A.R., L.C., R.A.J., D.N., O.P., and T.R. were responsible for data analyses and interpretation. All authors read and approved the final manuscript.

Data Availability Statement

All data generated or analysed during this study are included in this article. Further enquiries can be directed to the corresponding author.

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