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ARTICLE

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Video consultation and treatment in the community smoking cessation therapy success rates in patients with mental illness: a randomized controlled trial

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ABSTRACT

Purpose: Smoking is the single factor with the highest impact on reducing life expectancy of patients with mental illness. Patients experience difficulty in participating in smoking cessation programs but are concerned about the impact of tobacco on their health and finances. Smoking cessation advice via videoconferencing might be an alternative to an ordinary in-person consultation.

Material and Method: Randomized controlled trial with follow-up at 6 months. We included patients with diagnoses of schizophrenia and affective disorder from psychiatric outpatient clinics. Intervention 1 involved daily video consultations; intervention 2 was treatment as usual.

Results: Seventy patients were included. For both/all groups/interventions, rates of smoking cessation were 45% and predictors for a 50% reduction in smoking were antipsychotic medication load [odds ratio (OR) 0.54; $p=0.045$] and number of nicotine patches (OR 1.02; $p=0.06$). Predictors for a reduction in the number of cigarettes to < 10 were antipsychotic medication load (OR 0.52; $p=0.04$), number of nicotine patches (OR 1.01; $p=0.02$) and number of cigarettes at baseline [OR 0.95 ($p=0.09$); adjusted OR 0.94 ($p=0.02$)]. Patients prevented weight gain during the cessation period.

Conclusion: The smoking cessation rate was high. One of the reasons for the high cessation rate was that the intervention was carried out by highly experienced and professionally qualified staff. In addition, we used free nicotine patches to increase the patients' motivation to quit smoking. It is very important that we introduce these results into our clinical work with the patients.

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KEYWORDS

Smoking cessation; severe mental illness; randomized controlled trial; video conferencing; physical health

Purpose



In the last few decades, there has been a focus on physical health in patients with severe mental illness (SMI). An important cause of excess mortality and physical illness in people with SMI is cardiovascular disease (CVD) [1–3], resulting in a much shorter life expectancy than the general population [4]. The elevated risk rates of CVD can be explained by several factors, including an unhealthy lifestyle, smoking, poor diet and sedentary behavior [5, 6]. Many of these risk factors are modifiable when aiming to reduce the risk of CVD [7].


Smoking is probably the factor with the biggest impact on the reduced life expectancy of patients with SMI [8]. This is due to both the damaging health effects of smoking and to the elevated rates of smoking in patients with SMI [9]. In Denmark, it has been found that 38.8% of patients with a persistent mental health problem are smokers and that the rate of smoking in the general population is 19.8% [10]. An international survey

found even higher rates of smoking (55%) in patients with schizophrenia [8] and bipolar disorders (54%) [11].

A Spanish survey found that among almost 2000 patients treated for schizophrenia in outpatient clinics the rate of smoking was as high as 55.5% vs. 31.5% in the general Spanish population [8]. Finally, in a systematic review from USA it was concluded that the rate of smoking in patients with mental illness is double that of the general population [12]. Furthermore, smoking is associated with increased risk of developing depression [13] and patients with schizophrenia have shown considerably lower quality of life scores vs. healthy controls [14], underlining the potentially harmful consequences of smoking on mental health and supporting efforts to prevent and stop smoking.

Cigarette smoking can affect the pharmacokinetic and pharmacodynamic properties of psychotropic drugs and cigarette smoking may increase drug clearance, necessitating higher doses of medication [15,16]. Studies have shown that

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nicotine replacement therapy (NRT) and bupropion, given separately or in combination, was effective and well tolerated in patients on psychotropic treatment [17–21].

Patients with mental illness live with psychiatric symptoms and may experience problems participating in ordinary smoking cessation programs offered in the community. This might be true especially for patients with schizophrenia who may have trouble changing their unhealthy lifestyle because of factors related to their illness, cognitive disturbances, negative and positive symptoms, and the side effects of psychotropic medication. Patients with a diagnosis of bipolar disorders or depression may also face obstacles in following a smoking cessation program successfully due to symptoms related to their psychiatric illness. Nevertheless, many smokers living with mental illness are concerned about the impact of tobacco use on their health and finances, and are motivated to quit; hence, treatment programs should be available to smokers with mental illness [22].

An unknown but probably considerable number of patients with SMI are unable to access smoking cessation therapies due to their location, financial limitations or transportation issues. Videoconferencing addressing smoking cessation might be a useful alternative to face-to-face consultation at a clinic, because the patients can access the treatment at home while still interacting with a consultant [23]. The effectiveness of a videoconferencing smoking cessation intervention was investigated in Canada for smokers in rural areas and the study found no difference in abstinence rates between the in-person and videoconferencing (telehealth) interventions (28% vs. 26%) [23]. A study in the USA that compared videoconferencing and telephone-based smoking cessation interventions for smokers in primary care clinics found that abstinence rates were similar between the two approaches (10% vs. 12%) [24].

Psychiatric treatment *via* videoconferencing has shown equivalent efficacy to face-to-face psychiatric treatment and telepsychiatry can be an effective means of delivering mental health services to psychiatric outpatients [25,26]. Nevertheless, there is limited research on the effectiveness of videoconferencing in smoking cessation in patients with SMI. Therefore, we aimed to compare the rates of smoking cessation in patients allocated to one of two interventions (1): daily video consultants and (2) treatment as usual (TAU). Furthermore, we investigated possible predictors for a reduction in the smoking rate to >50% and for a reduction in cigarettes smoked daily to <10.

Material and methods

This study was a two-armed randomized controlled trial (RCT) with a 6-month follow-up.

We included patients with the diagnoses of schizophrenia and affective disorder from our psychiatric outpatient clinics. A diagnosis of schizophrenia, bipolar disorder or depression were based on the patients' clinical diagnoses at our psychiatric department. Participants were recruited from the Region of Southern Denmark.

It was only possible to include 57 patients from the original outpatient clinic; hence, we decided to include patients

from three other outpatients clinics connected to the same psychiatric hospital. These patients (non-randomized group) were offered the video intervention because it was not appropriate to randomize them to TAU; because the patients were connected to another municipality that followed different treatment regimens than the main clinic in the RCT.

We offered NRT to help with smoking cessation as it is known to be effective in achieving smoking cessation and maintaining smoking cessation [27]. Nicotine substitutes are available as patches, chewing gums, mouth sprays, nasal sprays and tablets. Only a small number of people cannot tolerate nicotine replacement drugs following their recommended use. The most frequent side effects seen with overdose are dizziness, palpitations, irritation, nausea and insomnia. NRT is recommended for at least 8–12 weeks and up to a maximum of 12 months. The plan for withdrawal and discontinuation of nicotine substitutes was a part of the two interventions included in the trial.

It is common to offer medication to help with smoking cessation (bupropion or varenicline) if the patient cannot stop smoking with nicotine replacement drugs and professional guidance. We recommended this to the patients in the trial, considering their overall psychiatric treatment, and was prescribed by patients' psychiatrists at the outpatient clinic or the patients' general practitioners and evaluated on an ongoing basis in collaboration with the nurses participating in the project. Owing to Danish rules medicine subsidies, the patients themselves had to cover the cost of bupropion and varenicline, which was often >€100 monthly.

The program was designed to provide flexible support tailored to the needs of the individual patients and conducted by health professionals experienced and knowledgeable in treating people with mental health problems.

Sample size calculations

For the primary outcome – abstinence from smoking at the 6-month follow-up – we calculated the smallest sample size to give statistically valid results. The smallest number in both interventions under the condition that the video intervention would be 2.5 times more effective than TAU (e.g. 25% in the video intervention group vs. 10% in the TAU group). The smallest number required was found to be 53 patients in each arm. Sample size calculation for the secondary outcome – change in mean number of cigarettes smoked daily per patient at the 6-month follow-up – a conservative estimate was calculated based on a previous study where patients smoked 35 cigarettes per day with a standard deviation of 10 [28]. Given two intervention groups of 50 patients in each, this allowed us to detect a reduction of five cigarettes daily (Cohen's $D=0.5$) with 80% power.

Randomization

Patients were allocated to one of two intervention arms using a uniform 1:1 allocation ratio and a computer-generated simple randomization procedure. The study leader (P.H.) was given randomly generated treatment allocations within sealed

opaque envelopes. Once a patient had consented to enter the trial, the envelope was opened and the patient offered the allocated treatment regimen.

Owing to the nature of the intervention the staff responsible for the smoking cessation therapy in both interventions were not blinded.

Measures

The primary outcome was abstinence from smoking at the 6-month follow-up. The secondary outcome was the change in the mean number of cigarettes smoked daily per patient at the 6-month follow-up.

Other outcome data included the number of videoconference sessions and number of attendances at the weekly community sessions. Data on age, sex, body mass index (BMI), diagnosis(es) and use of antipsychotic drugs (in daily defined doses; DDD) were extracted from the electronic patient records.

We used the Fagerstrom test for measuring nicotine dependence at baseline [28,29].

The patients were required to self-report at each follow-up visit whether they had been abstinent or were still smoking. Follow-up data were not blinded for the health professionals performing the interventions.

Inclusion

First contact with the patient was made at the outpatient clinic, where all patients were asked about their smoking status as part of the regular treatment.

Patients were between 20 and 70 years and smoking at least five cigarettes daily for the past 6 months or longer. Furthermore, patients were required to be willing to try to quit smoking within the 8 weeks following baseline assessment.

Patients on psychotropic drugs known to interfere with smoking were also included.

Exclusion

Any patients with an elevated and ongoing risk of suicide at baseline were excluded.

Intervention

This was a two-armed RCT with additional patients participating in the first arm (video consultation).

Video consultations

The video consultations were ad hoc appointments between the patients and a research nurse. The patients were able to video call the nurse for advice and support during the intense and difficult time from the decision to quit smoking and the following months. The program was designed to one daily video contact or contact according to the patients' need for guidance and help. The intervention was organized so

that it was up to the individual patient to decide how many smoking cessation consultations they wanted. During the video appointment, patients could ask for advice regarding smoking cessation and decide on, in collaboration with the nurse, relevant topics to discuss and that would help keep the patients abstinent from smoking. The nurse used relevant behavioral and motivational techniques for smoking cessation aimed at patients with mental illness and advised individuals accordingly [30–35]. NRT was recommended and delivered free of charge [36]. Pharmacotherapy (bupropion and varenicline) for smoking cessation was used if it was found to be advisable, taking into consideration patients' overall psychiatric treatment [17,21,37–41].

The video consultants followed well defined practice and patients were informed about practical matters and safety with using video (www.videokonsultationer.dk).

TAU

TAU consisted of one weekly face-to-face meeting between the patients and the health practitioner (psychomotor therapist) responsible for smoking cessation. The meeting took place in a community office at a fixed time once weekly. The intervention was organized so that it was up to the individual patient to decide how many smoking cessation consultations they wanted. The therapist used relevant knowledge and motivational techniques for smoking cessation in patients with mental illness, considering each patient individually [30–35]. NRT was used free of charge. Furthermore, pharmacotherapy (bupropion) for smoking cessation was used if it was found to be useful and advisable bearing in mind the patients' overall psychiatric treatment [17,21, 37–41].

Statistical analyses

Characteristics are reported as mean (SD) for continuous variables (age at baseline, Fagerstrom test for nicotine dependence at baseline, medication load at baseline (DDD), BMI at baseline, number of cigarettes smoked at baseline and end of the study, and how many stopped smoking) or as n (%) for categorical variables (sex and smoking cessation) for all participants together as well as stratified on treatment group (randomized to video, randomized to TAU, non-randomized to video). The characteristics were compared between groups using chi-squared tests for categorical variables and Wilcoxon rank sum tests for continuous variables. A dropout analysis was conducted, comparing key baseline characteristics between participants, who completed the treatment, and participants who dropped out.

Linear regression was used to compare outcomes (BMI, number of cigarettes and DDD) between study start and end (6 months later) for all outpatients using cluster robust SEs. Two binary outcomes (>50% daily reduction and reduction to <10 cigarettes smoked daily) were considered. Predictors for each of the binary outcomes were analyzed using multivariable logistic regression, adjusting for sex, age, number of contacts and use of nicotine patches. All statistical analyses were performed with STATA version 16 (StataCorp, College Station, TX, USA), and the significance threshold was set at a p-value of 0.05.

Ethical considerations

The Ethical Committee in the Region of Southern Denmark approved the trial (nr Acadre 19/30232).

Data protection

The project followed the duty of notification and the Region of Southern Denmark notified according to normal practice. All data were stored in Share Point and the Data Protection Authority's rules for anonymity were followed (Project nr 19/29165).

Results

Seventy patients were included in the study; 10 dropped out, leaving 60 patients for follow-up. A drop out analysis showed no significant differences between the patients who dropped out and those remaining in the study (see Table S1). Twenty-eight patients were not smoking at the 6-month follow-up.

See Figure 1 for the study flowchart.

Any patient with an elevated risk of suicide at baseline and throughout the study period were excluded. The suicide risk was assessed by the staff at the outpatients clinic as part of normal practice. No patients were excluded for that reason.

On average, the patients were heavy smokers at index, and they were almost all nicotine dependent [mean Fagerstrom test 6.4 (SD 1.7)] meaning that, on average, the patients were highly to very highly dependent on nicotine. Bupropion were used by only two patients.

The participating patients were overweight, with an average BMI at index of 30.0 kg/m²; at follow-up the average BMI was unchanged ($p=0.93$). See Table 1.

Analysis of the randomization process showed no statistical differences between the video group, TAU group or the non-randomized group when measured according to sex, age, BMI, cigarette use, medication load and nicotine dependency. See Table 2.

Rates of smoking cessation at the 6-month follow-up were between 45% and 50% in the three groups, and there were no statistical differences between the groups concerning cessation rate and average number of cigarettes smoked daily at follow-up.

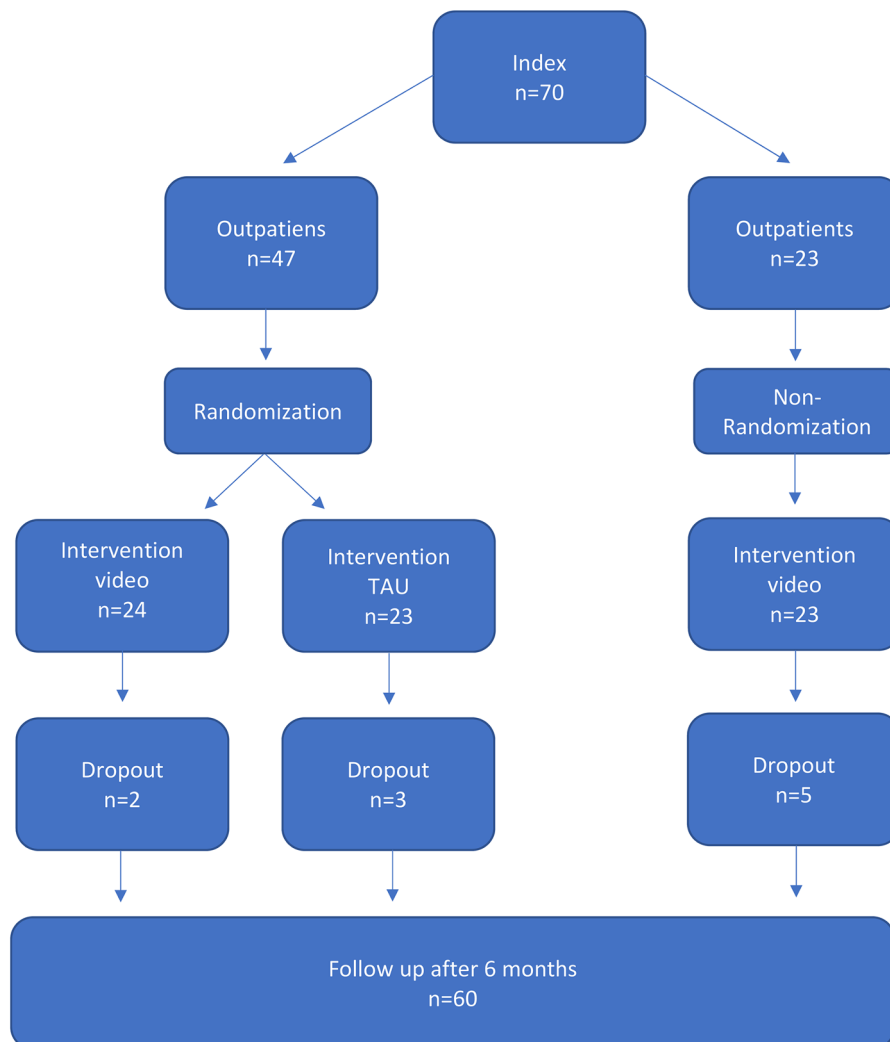


Figure 1. The study flowchart.

As we could not demonstrate a statistical difference between the three groups, we combined data from all groups in the following analyses to gain more strength in our statistical tests.

We analyzed possible predictors for $a > 50\%$ reduction in smoking (see Table 3), and antipsychotic medication load measured with DDD [odds ratio (OR) 0.54; $p=0.045$], number of nicotine patches used (OR 1.02; $p=0.06$) were found to be of importance. When investigating for predictors of a reduction to < 10 cigarettes smoked daily per patient (see Table 4), we found that antipsychotic medication load (DDD) (OR 0.52; $p=0.04$), number of nicotine patches (OR 1.01; $p=0.02$) and

number of cigarettes smoked at baseline [OR 0.95 ($p=0.09$); adjusted OR 0.94 ($p=0.02$)] to be of significance.

Discussion

We recruited 57 patients from an outpatient clinic to our RCT and also included 13 patients from three other outpatient clinics connected to our psychiatric hospital. The 'additional' patients were offered the video intervention. The statistical analysis were adapted and changed to these changes from the original study design. The rate of smoking cessation was 45% overall; contrary to our expectations, we did not discover any difference in smoking cessation rates across the two different interventions.

After 6 months, the smoking cessation rate was 45%, which is high compared with other studies of people with SMI. Our high cessation rate might be because we had skilled health professionals, with extensive experience in psychiatric nursing and motivational techniques, carry out the intervention; furthermore, they had the latest knowledge gained from smoking cessation training. Additionally, we did not use a fixed number of sessions. In collaboration with the health professional, the patients decided how many sessions were needed to maximize their cessation rate in the best possible way. This may explain the relatively high smoking cessation rate found in our study.

Lower smoking cessation rates than found in our study were observed in an Australian program involving people with mental illness. The smoking cessation rate was 22.5% and the program involved 8–15 sessions over an 8–10-week period [22]. Three programs were located within hospitals and 145 were run in 15 community-based mental health services across the Adelaide metropolitan area. The size of the group usually ranged from 8 to 15 people. The programs were facilitated by a peer worker and a mental health worker [22].

Quit rates among the general population were examined in a study by Carlson et al. in an evidence-based group

Table 1. Baseline characteristics of randomized and non-randomized outpatients ($n=70$).

Sex, % (n)	
Female	42.86 (30)
Male	57.14 (40)
Age (years), mean (SD)	40.59 (11.81)
Outpatient clinic, % (n)	
1	67.14 (47)
2	15.71 (11)
3+4	17.15 (12)
Fagerstrom test for nicotine dependence, mean (SD)	6.39 (1.72)
Fagerstrom test for nicotine dependence > 2 , % (n)	98.57 (69)
Medication load start, mean (SD)	
Antipsychotic medication ^a	1.08 (0.93)
Antidepressive medication ^{ab}	0.70 (0.99)
BMI (kg/m ²), mean (SD) ^b	29.70 (7.56)
BMI groups, % (n) ^b	
Underweight (<18.4)	0
Normal weight (18.5–24.9)	35.29 (24)
Overweight+Obesity class I (25.0–34.9)	44.12 (30)
Obesity class II+Obesity class III (>35)	20.59 (14)
Cigarettes smoked daily, mean (SD)	25.31 (13.19)
Cigarettes smoked daily groups, % (n)	
<10	5.71 (4)
11–20	52.86 (37)
20–30	27.14 (19)
<30	14.29 (10)

^aDaily defined doses.

^bmissing values (n): antidepressive medication (2), BMI (2).

Table 2. Baseline characteristics stratified on the three groups of patients (randomized to videoconference, randomized to treatment as usual, non-randomized to videoconference), $n=70$.

	Randomized to videoconferencing ($n=24$)	Randomized to treatment as usual ($n=23$)	Non-randomized to videoconferencing ($n=23$)	p -value
Sex, % (n)				
Female ($n = 19$)	41.67 (10)	39.13 (9)	47.83 (11)	–
Male ($n = 28$)	58.33 (14)	60.87 (14)	52.17 (12)	0.83
Age (years), mean (SD)	41.88 (12.37)	40.83 (10.97)	39 (12.34)	0.65
Fagerstrom test for nicotine dependence mean (SD)	6.63 (2.04)	6.26 (1.29)	6.26 (1.79)	0.52
Number of sessions ^a , mean (SD)	15.13 (17.73)	10.90 (9.16)	19.87 (23.20)	0.47
Nicotine patches ^a , mean (SD)	32.38 (60.03)	48.67 (79.73)	55.74 (73.08)	0.40
Medication load start, mean (SD) ^b				
Antipsychotic medication	0.93 (0.84)	1.06 (0.87)	1.27 (1.08)	0.57
Antidepressive medication ^a	0.75 (0.94)	0.62 (0.94)	0.73 (1.12)	0.86
BMI start (kg/m ²), mean (SD) ^a	30.02 (9.08)	28.93 (5.25)	30.16 (8.12)	0.94
Cigarettes smoked daily, mean (SD)				
At baseline	29.04 (15.13)	21.09 (7.74)	25.65 (14.57)	0.06
At study end ^a	9.73 (11.51)	10.35 (12.52)	7.33 (10.40)	0.75
Stopped smoking ^a , % (n)	45.45 (10)	45.00 (9)	50.00 (9)	0.94

^amissing values (n): number of sessions (2), nicotine patches (2), antidepressive medication (2), BMI (2), cigarettes smoked daily at study end (10), stopped smoking (10).

^bDaily defined doses.

Table 3. Predictors for $\alpha > 50\%$ reduction in cigarette use ($n=60$).

	Halved use		Associations	
	No	Yes	OR (p-value), crude	OR (p-value), adjusted ^a
Total, % (n)	30.00 (18)	70.00 (42)	–	–
Sex, % (n)				
Female	29.63 (8)	70.37 (19)	–	–
Male	30.30 (10)	69.70 (23)	0.97 (0.96)	0.85 (0.78)
Age (years), mean (SD)	40.78 (10.90)	41.40 (12.54)	1.00 (0.85)	1.00 (0.97)
Fagerstrom test for nicotine dependence, mean (SD)	6.17 (1.62)	6.33 (1.78)	1.06 (0.73)	1.01 (0.96)
Number of sessions, mean (SD)	10.94 (19.74)	19.00 (17.94)	1.04 (0.15)	1.02 (0.51)
Nicotine patches used, mean (SD)	14.78 (18.42)	60.86 (80.53)	1.02 (0.06)	1.02 (0.10)
Medication load at baseline, mean (SD) ^b				
Antipsychotic medication	1.50 (0.93)	0.96 (0.89)	0.54 (0.045)	0.47 (0.04)
Antidepressive medication	0.62 (0.84)	0.71 (0.99)	1.11 (0.60)	1.05 (0.90)
BMI (kg/m ²), mean (SD)	29.91 (5.06)	29.91 (8.92)	1.00 (1.00)	1.00 (1.00)
Cigarettes smoked daily at baseline, mean (SD)	24.06 (9.14)	25.21 (13.90)	1.01 (0.74)	1.00 (0.99)

^aAdjusted for sex, age, number of sessions and number of nicotine patches used.

^bDaily defined doses.

Table 4. Predictors of a reduction in the number of cigarettes smoked daily to < 10 per patient ($n=58$).

	< 10 cigarettes smoked daily		Associations	
	No	Yes	OR, crude (p-value)	OR (p-value), adjusted ^a
Total, % (n)	46.55 (27)	53.45 (31) ^b	–	–
Sex, % (n)				
Female	52.00 (13)	48.00 (12)	–	–
Male	42.42 (14)	57.58 (19)	1.47 (0.47)	1.52 (0.48)
Age (years), mean (SD)	40.93 (11.32)	42.10 (12.73)	1.01 (0.71)	1.00 (0.97)
Fagerstrom test for nicotine dependence, mean (SD)	6.52 (1.40)	6.39 (1.54)	0.94 (0.73)	0.95 (0.78)
Number of sessions, mean (SD)	11.59 (16.63)	21.45 (19.88)	1.04 (0.08)	1.03 (0.28)
Nicotine patches used, mean (SD)	22.81 (35.88)	71.16 (86.91)	1.01 (0.02)	1.01 (0.09)
Medication load at baseline, mean (SD)				
Antipsychotic medication	1.43 (0.97)	0.89 (0.84)	0.52 (0.04)	0.51 (0.05)
Antidepressive medication	0.56 (0.83)	0.79 (1.05)	1.30 (0.36)	1.52 (0.26)
BMI (kg/m ²), mean (SD)	30.20 (6.51)	29.11 (8.88)	0.98 (0.60)	0.98 (0.60)
Cigarettes smoked daily at baseline, mean (SD)	28.70 (11.81)	22.71 (12.26)	0.95 (0.09)	0.94 (0.02)

^aAdjusted for sex, age, number of sessions and number of nicotine patches used.

^bTwo participants were already smoking < 10 cigarettes daily and were excluded.

smoking cessation program where they used telehealth videoconferencing for rural/remote smokers. Their program consisted of eight 90-minute sessions over a 15-week period, and had cessation rates of 39.2% for Calgary and 37.2% for rural sites [23].

Against our expectations the quit rate was similar in the two interventions. We had expected that the intervention with video was better hence there were possibilities for the patients to receive guidance and support on a daily basis. Furthermore, video techniques are not subject to transportation issues –patients can access the treatment at home while still having face-to-face interaction. We cannot explain the same success rate found in both our interventions, despite offering the same free NRT and help from health professionals with similar qualifications.

Weight gain among participants is normal in smoking cessation programs. In a meta-analysis, smoking cessation was associated with a mean increase of 4–5 kg in body weight after 12 months of abstinence, and most weight gain occurs within 3 months of quitting. Variation in weight change was significant, with 16% of quitters losing weight and 13% gaining >10 kg [42]. In our study, the patients were, on average, able to prevent weight gain and this is remarkable as

quitting smoking usually results in weight gain. The health professional in this study focused on patients' body weights and provided advice accordingly. Furthermore, all patients had their weight measured at baseline, which may have heightened awareness of the risk of weight gain during the smoking cessation period.

Smoking is associated with several health risks, and it can be assumed that the patients in this study achieved better health during the intervention by quitting smoking. Smoking cessation is known to improve health as reported in a meta-analysis where smoking cessation was found to reduce the risk of CVD and all-cause mortality, despite weight gain and an increased risk of type 2 diabetes [43].

Almost all our patients ($n=68/70$) were nicotine dependent according to the Fagerstrom test before they began our program. Nicotine patches were an important part of the intervention; our patients used, on average, 32 patches in the randomized to videoconferencing group and 49 patches in the randomized to TAU group and finally 56 patches in the non-randomized group to videoconferencing group, respectively. We had good experiences with the nicotine patches, and used different nicotine doses in the later stages of cessation. We are convinced of the effectiveness of nicotine

patches, which is in agreement with robust evidence of their use as nicotine replacements [27,36].

We analyzed for possible predictors for more than 50% reduction in cigarette use and for reduction in the numbers of cigarettes smoked daily to less than 10 per patients and found that lower doses of antipsychotic medication lead to a higher tendency to reduce smoking. Patients with less severe symptoms take lower doses of antipsychotic medication than patients with more severe ones. Furthermore, the number of nicotine patches used was found to increase the reduction in cigarette use. A higher number of nicotine patches used indicated that a patient was actively trying to quit smoking.

Limitations

Our study had an inclusion criterion that patients should be willing to quit smoking within the 8 weeks following the baseline assessment. Therefore, we may have included patients with a greater willingness and personal resources to quit smoking than the general population of patients with SMI who smoke. The study's results may therefore be influenced by selection bias, which may mean that we have higher smoking cessation rates in the study than you would experience in similar groups of patients without selection.

It was not possible for us to follow precisely the CONSORT guidelines for conducting a RCT [44], and we decided to modify a number of the recommendations. Firstly, we combined data from the two randomized group with the data from the third non randomized group to gain more strength in our statistical tests. Secondly, we did not blind the data as recommended, owing to the nature of the intervention where the nurse and psychomotor therapist responsible for the smoking cessation therapy in both interventions were not blinded.

Additionally, patients were asked to self-report whether they had been abstinent or were smoking at each follow-up. It is our experience that patients are aware of how many cigarettes they smoke and therefore we assumed that the data on number of cigarettes smoked were precise. Health professionals performing the interventions were not blinded to the data as data collection was done by staff already familiar with the participants; this was designed to make the patients feel comfortable and safe, maximizing the validity of the self-reported number of cigarettes smoked or abstinence.

The study was conducted during the COVID-19 pandemic, which may have influenced the results. Owing to clinics being closed to patients for two periods of a total of 6 months, the TAU intervention carried out as one weekly telephone conversation instead of face-to-face attendance. This may have resulted in the two interventions being more similar than first planned, as videoconference and telephone calls are similar in many respects.

Strengths

We included patients with SMI and patients treated with high doses of psychotropic drugs known to interfere with

smoking, yet we experienced a high smoking cessation rate. In our view, our results can be explained by the qualifications of the health professionals who performed the interventions. Furthermore, as recommended in the literature, we offered patients free-of-charge NRT [36], increasing patients' motivation to quit smoking. It is known that many patients are driven by economic reasons [22], and smoking is expensive, especially for people on low incomes, which was applicable to most of our patients. In an Australian study of people with mental illness, 56% of patients wanted to quit smoking for financial reasons [22].

Conclusion

The overall rate of smoking cessation in our study was 45%. This high cessation rate might be due to the fact that we had very skilled health professionals conduct the intervention. Additionally, we did not have a fixed number of sessions with patients. Contrary to our expectations, the quit rate was similar in both interventions. We had expected that the video intervention would be better as there was the possibility for patients to receive guidance and support on a daily basis. We had no reason to expect the same success rate in both interventions, despite the fact that we offered the same free NRT and help from health professionals with similar qualifications.

Predictors for $a > 50\%$ rate of reduction in smoking were antipsychotic medication load and number of nicotine patches used. Predictors for a reduction to < 10 cigarettes smoked daily per patient were antipsychotic medication load, number of nicotine patches used and lower number of cigarettes smoked daily at baseline. Finally, patients were able to prevent weight gain during the smoking cessation period.

It is very important that we introduce these results into our clinical work with the patients.

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Disclosure statement

All authors declare that they have no conflict of interest.

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Data availability statement

The data associated with the paper are kept secure in OPEN a statistical department under University of Southern Denmark. The data is available,

and can be accessed only by the first and last author of the paper due to ethical and security concerns.

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