

Adherence to blended smoking cessation treatment

Master's Thesis



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Abstract

Even though the combination of face-to-face and online sessions seems a promising new approach in the field of smoking cessation interventions, important information regarding patients' adherence to such interventions, such as the extent to which the patients adhere, how valid is the measurement of adherence and which factors predict adherence, is lacking, while no clear guidelines on how to assess adherence are available. To address this knowledge gap, two separate measures for the evaluation of adherence to a blended smoking cessation treatment offered by Medisch Spectrum Twente and Tactus Addiction Treatment were created, one minutes-based and one features-based measure.

Several analyses were performed for the validation of the two measures. In sum, they both exhibited good construct validity (i.e. good convergent and divergent validity), good content validity (i.e. kappa test showed moderate agreement between the two measures) and quite good criterion validity (i.e. good concurrent validity, as the two measures were highly correlated with each other, but poor predictive validity, as adherence did not significantly predict smoking abstinence as expected). Notably, the features-based measure seemed to show better construct and predictive validity and better diagnostic accuracy than the minutes-based measure.

Compared to adherence rates reported in previous face-to-face smoking cessation interventions (i.e. 70% adherence on average), a rather low adherence rate of between 20% (using the features-based measure) and 47.1% (using the minutes-based measure) was found. Notably, most non-adherence occurred in the web-based components of this blended intervention. Some possible reasons for that might include characteristics of the technology means used (e.g. low compatibility), of the treatment itself (e.g. too intensive treatment), of the sample investigated (e.g. lower physical or/and mental health than the general population) or/and of the measures used to assess adherence (e.g. too strict measures). The only common predictors of non-adherence between the two measures were health complaints and health and smoking complaints. Taken together, non-adherence was predicted by a lower physical and mental health status (i.e. more health and smoking complaints, more symptoms of anxiety and stress, worse mental health and decreased quality of life), by some cognitive determinants of smoking cessation (i.e. more negative attitude towards smoking cessation and higher social modelling of smoking) and by some demographic variables (i.e. female gender, lower age and absence of a partner).

1. Introduction

1.1. The importance of assessing adherence to this blended treatment

In the present study, data collected in the 'Livesmokefree' study (trial number: NTR5113) were analysed. The latter is still in progress and one of its secondary goals is to identify mechanisms underlying smoking cessation. The present study contributes to this goal by assessing adherence to the blended smoking cessation treatment offered by the Outpatient Smoking Cessation Clinic of Medisch Spectrum Twente (MST) in cooperation with Tactus Addiction Treatment. The combination of face-to-face and online sessions is a new and innovative approach in the field of smoking cessation interventions which is hypothesized to incorporate the key advantages of both face-to-face and online treatments (e.g. therapist-patient alliance and tailoring, respectively) while being able to avoid their main pitfalls (e.g. therapist drift and low adherence, respectively) (Siemer, Pieterse, Brusse-Keizer, Postel, Ben Allouch, & Sanderman, 2016). In the following lines there are presented some of the main reasons why measuring adherence to such a treatment has scientific interest.

Recent studies claim that tobacco consumption is the leading cause for preventable deaths worldwide (Eriksen, Mackay, Schluger, Islami, & Drope, 2015; Samet, 2013). According to Eriksen and colleagues (2015), tobacco abuse is responsible for about six million deaths per year globally, with this number expected to reach ten million by 2025, as it is projected by another study (Hatsukami, Stead, & Gupta, 2008). Prolong abstinence from tobacco use is hard to be achieved, especially without guidance or support provided by professionals. Precisely, it is reported that only 3-5% of self-quitters manage to abstain from smoking for six months or more after a reported quit attempt (Hughes, Keely, & Naud, 2004). These findings pinpoint the importance of developing efficient interventions to help people quit smoking.

Most of the published studies focus their attention on evaluating the effectiveness of various smoking cessation interventions but, the majority of them, does not address other important issues which might lead to the improvement of the interventions and may further increase their effectiveness. Adherence is one of these key issues. Adherence is the extent to which a user or patient complies with health-related recommendations received from experts (López-Torrecillas, Rueda, López-Quirantes, Santiago, & Tapioles, 2014).

The importance of adherence to smoking cessation treatment is highlighted by the fact that adherence to the treatment as a whole (Alterman et al., 1999; Fish et al., 2009) or to specific features of the treatment, such as adherence to quit dates set during treatment sessions (Westman, Behm, Simel, & Rose, 1997), was found to predict smoking abstinence. Actually, as it is reported by Westman and colleagues (1997), patients who adhered to their quit dates had about ten times lower odds to relapse compared to patients who did not adhere. Furthermore, especially for interventions which are delivered partially or completely online, poor adherence is a major impediment for effectiveness (An et al., 2006; Donkin, Christensen, Naismith, Neal, Hickie, & Glozier, 2011; Kelders, Kok, Ossebaard, & Van Gemert-Pijnen, 2012).

Given that adherence has the potential to predict the effectiveness of the blended treatment (i.e. smoking abstinence) (Alterman et al., 1999; Fish et al., 2009; Westman et al., 1997), the assessment of adherence is an objective of major importance. Nevertheless, to our knowledge, this is the first study which aimed to assess adherence to a blended smoking cessation treatment combining face-to-face and web-based sessions.

Furthermore, considering that adherence was found to predict smoking abstinence in previous studies (Alterman et al., 1999; Fish et al., 2009; Westman et al., 1997), one interesting question (for both clinical and research purposes) would be which patients' characteristics predict adherence to the blended treatment. Due to the fact that there are no studies in which predictors of adherence to blended smoking cessation treatments were reported, the present study had a rather exploratory character regarding this analysis. Precisely, evidence-based predictors of smoking abstinence [i.e. depression, anxiety, stress, mental health, medication (general, physical, psychiatric, other), health complaints, health and smoking-related complaints, attitude, self-efficacy, social support, social modelling, motivation to quit and readiness to quit] (Siemer et al., 2016), evidence-based predictors of adherence to either face-to-face or online interventions (i.e. self-efficacy, motivation to quit, nicotine dependence, smoking related symptoms, active pharmacological treatment) (see paragraph 1.2 for references), as well as some demographic variables (i.e. age, gender, main daily activity, education, marital status and housing situation) and internet skills were selected opportunistically in order to identify predictors of

adherence, a research question which was added post-hoc in this study.

The identification of predictors could indicate for which patient profile the blended treatment provides the best fit. Ultimately, this could enable the healthcare providers to tailor their intervention to patients' needs, for instance, by offering different modes of delivery to patients with certain characteristics. Tailoring was found effective in improving adherence to various interventions in healthcare domain (e.g. Dowshen, Kuhns, Johnson, Holoyda, & Garofalo, 2012; Miller, Hui, Wen, Scarpato, Zhu, Buzaglo, & Hernandez, 2013).

1.2. Predictors of adherence in the literature

In the following lines, some of the main predictors of adherence to either face-to-face or web-based smoking cessation interventions are presented. The first category of predictors includes several cognitive factors. Literature has shown that perceptions and cognitions predict adherence to smoking cessation interventions. Two of those key cognitive constructs, according to “Social Cognitive Theory” (SCT), are outcome expectations and outcome expectancies (Bandura, 1986). SCT posits that individual's subjective judgment regarding the likely outcome of a particular behaviour (i.e. outcome expectation) and the positive or negative evaluation of the expected outcome of a behaviour (i.e. outcome expectancy) determine, among other factors, whether the person will perform this behaviour (Bartholomew, Parcel, Kok, & Gottlieb, 2016). Furthermore, “Expectancy Theory” claims that lifetime experiences shape individual's expectancies concerning the consequences of certain behaviours and those expectancies determine the motivation and the performance of these behaviours (Hendricks, Reich, & Westmaas, 2009).

In line with these theories, smokers with negative expectancies towards smoking reported greater motivation to quit compared to smokers with positive expectancies (Pulvers, Catley, Okuyemi, Scheibmeir, McCarter, Jeffries, & Ahluwalia, 2004). In addition, increased motivation to quit predicted adherence to smoking cessation face-to-face counselling in some recent studies (Asfar, Al Ali, Rastam, Maziak, & Ward, 2014; Heffner, Lewis, & Winhusen, 2013).

Another important determinant of adherence to smoking cessation interventions, deriving from SCT, is self-efficacy (Bandura, 1986), a construct which is also known as perceived behavioural control in “Theory of Planned Behaviour” (TPB) (Ajzen, 1991). As it is underlined by Omar (2015), in the context of smoking

cessation treatment, self-efficacy reflects the strength of one person's belief about his/her own ability to quit smoking. The importance of self-efficacy as a determinant of adherence to smoking cessation interventions is highlighted by the fact that smokers' self-efficacy towards quitting, at baseline, predicted adherence to face-to-face smoking cessation interventions (Asfar et al, 2014; Heffner et al, 2013).

A second class of predictors is patients' smoking-related behaviours. As reported by Hays, Leischow, Lawrence and Lee (2010), smoking abstinence early in the treatment (i.e. at the second week of the program) was significant predictor of adherence to their twelve-week smoking cessation intervention. To elaborate on this finding, early success in quitting seems to be important because continuing smoking found to predict drop-out which in turn predicted adherence to smoking cessation treatment in some other studies (Alterman, 1999; Busnello, Melchior, Faccin, Vettori, Petter, Moreira, & Fuchs, 2001). Finally, Borrelli, Papandonatos, Spring, Hitsman and Niaura (2004) found that active pharmacological treatment for smoking cessation significantly predicted adherence to their face-to-face smoking cessation intervention.

A third division of predictors includes nicotine dependence and smoking-related symptoms. Precisely, Taleb and colleagues (2015) found that lower number of cigarettes per day, as well as fewer withdrawal symptoms, at baseline, predicted adherence to face-to-face counselling sessions for smoking cessation.

The last category of predictors concerns some demographic characteristics. More specifically higher age (Hays et al., 2010; Taleb et al., 2015), male gender (Taleb et al., 2015) and being unemployed (Asfar et al, 2014) have been reported as predictors of adherence to face-to-face smoking cessation interventions.

Additionally, some studies on other health-related behaviours indicate that internet skills could predict adherence to online interventions. Precisely, in a study regarding adherence to an online physical exercise intervention, patients with good internet skills found to be more likely to show at least 75% adherence to the intervention than patients with poor internet skills (Mathew, Morrow, Frierson, & Bain, 2011). Finally, in a qualitative study investigating adherence to a self-management program for depression, the patients reported their own inadequate internet skills as one of the main barriers of adherence (Gerhards, Abma, Arntz, De Graaf, Evers, Huibers, & Widdershoven, 2011).

1.3. Adherence measurements in the literature

Despite the absence of clear guidelines on how to evaluate adherence to blended treatment, in the literature several different methods are proposed to measure adherence to smoking cessation treatment in either face-to-face or web-based interventions (e.g. Danaher, Boles, Akers, Gordon, J. S., & Severson, 2006; Graham, Jacobs, Cohn, Cha, Abroms, Papandonatos, & Whittaker, 2016; López-Torrecillas et al., 2014).

In face-to-face counselling for smoking cessation adherence is mostly evaluated by the attendance at the counselling sessions or/and the completion of homework assignments, such as keeping a smoking diary or keeping records of cravings or/and withdrawal symptoms (Balmford, Borland, Hammond, & Cummings, 2011; López-Torrecillas et al., 2014; Patterson, Jepson, Kaufmann, Rukstalis, Audrain-McGovern, Kucharski, & Lerman, 2003).

Concerning web-based smoking cessation treatment, adherence is mainly assessed through measurements of the frequency and intensity of the use of the intervention. Such measurements include total number of log-ins to the website, number of features used, number of pages viewed or videos watched and amount of time spent on site in total or daily (Cobb, Graham, Bock, Papandonatos, & Abrams, 2005; Danaher et al., 2006; Donkin et al., 2011; Graham et al., 2016).

1.4. Exploring adherence to this blended treatment

To our knowledge, this is the first study which aims to assess adherence to a blended smoking cessation treatment, combining face-to-face and web-based sessions. Considering the lack of previous records on the evaluation of adherence to blended smoking cessation treatment and due to the exploratory character of this study, it was determined to systematically collect and report as much accessible information concerning patients' adherence as possible. Precisely, adherence to the blended treatment was decided to be assessed in two ways. The first is the minutes-based measure, which includes an easy-to-measure and time saving way of assessing adherence using the already existing data regarding patients' time spent in treatment as they are reported by the counsellors (this has been done until now for administrative and funding purposes). The second is the features-based measure, which entails a more in-depth and thorough assessment of adherence based on the

performance of several activities or tasks by the participants which are indicative of their adherence.

Each measure serves different purposes. Adherence measured through the minutes-based measure enables the assessment of adherence to be performed in a fast and cost-efficient manner. Moreover, it might enable the identification of specific profiles of patients who tend to underuse (i.e. spend less time as intended on the treatment) or overuse (i.e. spend more time than intended) the blended treatment, without much time and effort requested to be invested on behalf of the researchers. This information could also facilitate the identification of the reasons for overuse or/and underuse. In addition, it could motivate the healthcare providers to take appropriate measures to limit these phenomena. A decrease in underuse might improve patients' adherence, acceptance and satisfaction and increase the effectiveness of the intervention. A decline in overuse may also improve patients' satisfaction, while, saving resources and limiting costs.

On the other hand, the features-based measure could answer different kind of research questions, such as how the patients make use of the intervention and which extent of use of the features is linked to higher or lower adherence. This information indicates the depth of patients' adherence to the intervention (i.e. the extent to which they follow the intervention protocol and make use of the features as intended). In addition, it may help the developers of the intervention to identify weaknesses of the intervention which could be addressed to increase adherence, for example, by re-designing some features. Another way to improve adherence could be to apply some persuasive elements-features in the treatment (e.g. praise, rewards, reminders, social facilitation, normative influence, third-party endorsements etc.) (Kelders et al., 2012; Oinas-Kukkonen & Harjumaa, 2009).

1.5. The importance of assessing validity

Overall, the existence of two separate measures to evaluate adherence serves an important methodological need, the assessment of validity of these two new methods of measuring adherence to this blended treatment. Validity represents the extent to which an instrument or procedure is, indeed, measuring the construct that it is supposed to measure (Wainer & Braun, 2013).

A major benefit of a valid test is that it is free from the "systematic error" which occurs when something aside from the variable being assessed, systematically

influences the assessment (Messick, 1989). More specifically, a valid instrument provides information about "test accuracy", which means the ability of the test to detect the condition requested, and "diagnostic accuracy" of the test, which refers to the precision of that detection (Messick, 1989; Saah & Hoover, 1997). Both of these test properties are important indicators of the validity of a test (Messick, 1989).

From a research perspective, a valid instrument is able to exclusively detect the requested substance or condition, rather than others, in a specific population, a test property which is called "analytical specificity". Moreover, a valid test should also detect accurately the condition even when the most subtle proportion of the substance is present, a property which is called "analytical sensitivity" (Saah & Hoover, 1997). High analytical specificity and sensitivity are of great importance for the validity of the test, since a test producing results in line with what the theory suggests is an indication that the test is valid. Furthermore, in presence of high analytical specificity and sensitivity, type I and type II errors are both minimised and, consequently, the methodological quality of the study is increased (Messick, 1989).

From a clinical point of view, the validity of a test is evaluated by its ability to correctly classify the patients having the condition (i.e. diagnostic sensitivity), as well as those who do not have the condition (i.e. diagnostic specificity) (Saah & Hoover, 1997). In clinical practice, a high diagnostic sensitivity is important in case of some disease, especially in cases where early detection increases significantly the possibility of an effective treatment (e.g. breast cancer) (Saah & Hoover, 1997). Nevertheless, in case of adherence, the correct detection of the patients not having the condition (i.e. non-adherent) might be more important. Given that non-adherence is a known impediment for the effectiveness of interventions delivered partially or exclusively online (An et al., 2006; Donkin et.al, 2011; Kelders et al., 2012), the correct identification of non-adherent patients could enable the taking of appropriate measures to decrease non-adherence and, hopefully, increase the effectiveness of the intervention, by targeting the group of non-adherent patients.

In the present study, several statistical analyses were performed in order to test the validity of each measure. The construct validity was tested by examining the association of adherence with several patients' baseline characteristics expected to be associated with adherence (i.e. convergent validity) and with some other patients' baseline characteristics assumed not to be associated with adherence (i.e. divergent

validity). The content validity was evaluated by examining the degree of agreement of both measures, in terms of their classification of adherent and non-adherent patients. Finally, criterion validity of the two measures was assessed by examining the correlation between them (i.e. concurrent validity) and by testing the ability of each measure to predict smoking abstinence (predictive validity).

1.6. Aims of the current study

The first aim of this study was to assess adherence to the blended treatment. To achieve this goal, two separate measures to evaluate adherence were developed. The minutes-based measure was an easy-to-measure and time-saving way of assessing adherence, while the features-based measure included a more in-depth and thorough assessment of adherence.

A secondary goal of the study was to validate both measures. To achieve that, the construct, content and criterion validity of both measures were examined.

The final goal of the study was to examine whether specific cognitive constructs (i.e. attitude, self-efficacy, social support, social modelling motivation to quit and readiness to quit), smoking-related factors (i.e. number of previous quit attempts, nicotine dependence and smoking complaints), health-related factors (i.e. depression, anxiety, stress, mental health, health complaints and medication), demographic characteristics (i.e. gender, age, marital status, education, housing situation and main daily activity) internet skills and quality of life predict adherence to the blended treatment.

2. Method

2.1. Participants

Data from 70 outpatients of the Smoking Cessation Clinic of the Department of Pulmonary Medicine of Medisch Spectrum Twente, Enschede, the Netherlands who participated in the 'LiveSmokefree study' were analysed. Inclusion criteria for the Livesmokefree study are: age of 18 or older, smoking of at least one cigarette per day, intention to quit smoking, internet access, use of email and ability to read and write in Dutch (Siemer et al., 2016). All patients provided their informed consent.

2.2. Intervention

As it is described by Siemer and colleagues (2016), the blended treatment consists of five face-to-face smoking cessation counselling sessions offered by the Outpatient Smoking Cessation Clinic of the Department of Pulmonary Medicine of Medisch Spectrum Twente and five web-based sessions available to the patients through the website www.rokendebaas.nl, developed by Tactus Addiction Treatment. Each session is focused on the performance of several tasks or activities by the participants. In total, eight face-to-face and ten web-based tasks of the participants were selected by the researchers as features of the blended treatment which indicate adherence. A complete overview of the features-indicators of adherence is presented in table 1, while more detailed information regarding the content of these features is provided by Siemer and associates (2016).

Table 1

An illustration of the features used in the blended treatment including the criteria of sufficient use set in each feature

| Feature | Mode of delivery | Sufficient level of use |
|---------------------------------|-----------------------|---|
| Smoking diary (days registered) | Web-based sessions | At least 3 days in which the patient reported an urge to smoke. |
| Smoking diary (moments reg.) | Web-based sessions | At least 3 moments in which the patient reported an urge to smoke. |
| Goal setting | Face-to-face sessions | An email containing a form to fill-in his/her goals was sent to the patient.* |
| Goal setting | Web-based sessions | The patient filled-in at least one character in this form. |
| Measures for self-control | Face-to-face sessions | An email containing information about 'measures for self-control' was sent to the patient.* |
| Measures for self-control | Web-based sessions | The patient replied to this email. |
| Measurement of CO | Face-to-face sessions | At least 2 CO measurements were reported by |

| | | |
|-------------------------|-----------------------|---|
| Dealing with withdrawal | Face-to-face sessions | the counsellor. An email containing information on how to deal with withdrawal was sent to the patient.* |
| Dealing with withdrawal | Web-based sessions | The patient reacted to this email. |
| Dealing with tempters | Web-based sessions | An email containing information on how to deal with tempters was sent to the patient. |
| Food for thought | Face-to-face sessions | An email containing some 'food for thought' was sent to the patient.* |
| Food for thought | Web-based sessions | The patient reacted to this email. |
| Think differently | Face-to-face sessions | An email encouraging the patient to think differently was sent to him/her.* |
| Think differently | Web-based sessions | The patient reacted to this email. |
| Do differently | Face-to-face sessions | An email encouraging the patient to do sth differently was sent to him/her.* |
| Do differently | Web-based sessions | The patient reacted to this email. |
| Action plan | Face-to-face sessions | The email containing the the form for filling-in the action plan was sent to the patient.* |
| Action plan | Web-based sessions | The patient filled-in at least one character in this form. |

Notes. * This email was indicative that a discussion between the patient and the counsellor concerning this particular issue (e.g. the setting of future goals, the use of measures for self-control etc.) has already been conducted in the face-to-face sessions, reg. = registered, sth = something.

2.3. Description of the systems used

For the adherence measurements three systems-sources of information were used. The first two systems were 'X-Care' and 'Digitaal status voering (DSV)'. X-Care is the electronic record of the patients of MST which contains basic information about each patient treatment status, such as when the patient started the treatment, which clinic is offering the treatment, time, day and type of appointments, time and day of telephone consults and which kind of treatment was offered in each appointment. DSV is another electronic record of MST which includes more detailed information about patient's treatment progress, such as notes from physicians or counsellors about how the patient is reacting to the treatment, examination results and prescribed medication. The third system used is Tactus Addiction Treatment website www.rokendebaas.nl where, using a counsellor account provided by Tactus, specific information about patients'-users' response to online sessions, such as which features were used, for how long and how intensely these features were used, was collected.

2.4. Adherence as a dichotomous variable

The adherence to the blended treatment was calculated by defining the patients who showed at least 60% adherence in both modes of delivery of the treatment as adherent. Considering the exploratory character of this study and the low number of participants, this cut-off score of 60% was selected because it divides the sample into two groups of sufficient size (i.e. adherent and non-adherent), allowing in this way several statistical analyses, such as the identification of predictors of adherence, to be performed. This data-driven approach is similar to often-used median-split procedures and allows exploratory between-subjects analyses with a low sample size.

More specifically, in the minutes-based measure, the patients who spent at least eighty minutes in face-to-face sessions (this equals to 60% of the total time offered in this mode of delivery) and at least sixty minutes in web-based sessions (this equals to 60% of the total time offered in this mode of delivery) were classified as adherent. Patients who spent less than 60% of the intended time in one of the two modes of delivery of the treatment were identified as non-adherent.

In the features-based measure, the patients who actively used at least five out of the eight features (i.e. this equals to 60% adherence) of the face-to-face sessions and at least six out of the ten features (i.e. this equals to 60% adherence) of the online

sessions were classified as adherent. Patients who showed less than 60% adherence in one of the two modes of delivery of the treatment were considered non-adherent.

2.5. The assessment of adherence in the minutes-based measure

To evaluate patients' adherence through the minutes-based measure, information from X-Care was used. In this platform, the counsellors report, in an encoded form, which type of sessions are completed, as well as some other actions performed by the patients which are indicative of their involvement in the treatment (see table 2). Each code represents a fixed number of minutes invested on face-to-face or online sessions, as shown in table 2.

Table 2

Description of the codes used to calculate time spent in the face-to-face and online sessions in the minutes-based measure

| Code reported | Description | Minutes spent |
|---------------|---|---------------|
| RSN | First individual ftf session | 50 minutes |
| RSAB | Individual ftf session visiting a patient in another department of the hospital. | 50 minutes |
| RSNS | First ftf session with two patients (e.g. husband and wife, mother and daughter etc.) | 35 minutes |
| RSC | Usual individual ftf session | 20 minutes |
| RSTC | Individual telephone consult | 20 minutes |
| RSAC | Additional consult (to add to RSN or RSC if more time is needed) | 20 minutes |
| RSIC | Online session via rokendebaas.nl | 20 minutes |
| RSEC | Email consult | 10 minutes |
| TC | Telephone call (administration, not consult) | 10 minutes |
| RSOC | Other consult | 10 minutes |

Notes. ftf = face-to-face, web. = web-based.

After receiving permission, these codes were used by the researchers to calculate the total number of minutes spent in the face-to-face and online sessions by the patients, as shown in table 3.

Table 3

The calculation of minutes spent in face-to-face and online sessions in the minutes-based measure

| Mode of delivery | Calculation of minutes spent |
|-----------------------|-------------------------------------|
| Face-to-face sessions | RSN/RSNS+RSAB+RSC+RSTC+RSAC+TC+RSOC |
| Online sessions | RSIC+RSEC |

As shown in table 4, considering that the blended treatment consists of five face-to-face (which equals to 130 minutes) and five online sessions (which equals to 100 minutes), adherence of at least 60% was requested for a patient to be classified as adherent to treatment (i.e. this equals to eighty minutes spent in face-to-face sessions and sixty minutes spent in online sessions), to face-to-face sessions (i.e. this equals to eighty minutes spent in face-to-face sessions) and to online sessions (i.e. this equals to sixty minutes spent in online sessions).

Table 4

The assessment of adherence in the minutes-based measure

| Adherence measurement | Description | Source |
|------------------------------------|---|--------|
| Adherence to face-to-face sessions | At least 80 minutes spent in ftf sessions | X-Care |
| Adherence to online sessions | At least 60 minutes spent in web. sessions | X-Care |
| Adherence to treatment | Adherence to ftf + adherence to web. sessions | X-Care |

Notes. ftf = face-to-face, web. = web-based.

2.6. The assessment of adherence in the features-based measure

In the features-based measure, adherent considered the patients who actively used at least five out of the eight features (i.e. this equals to 60% adherence) of the face-to-face sessions and at least six out of the ten features (i.e. this equals to 60% adherence) of the online sessions. In each one of these features a specific level of use was set as sufficient, as suggested by the researchers of the treatment. The criteria which defined sufficient level of use for each one of the features are shown in table 1.

2.7. Patients' baseline characteristics

The patients' baseline characteristics investigated in the present study were: demographic (i.e. gender, age, education, marital status, housing situation, main daily activity), health-related [i.e. depression (DASS-21), anxiety (DASS-21), stress (DASS-21), mental health (DASS-21) (Lovibond & Lovibond, 1995), medication

(general, physical, psychiatric, other) and health complaints (MAPHSS) (Darke, Ward, Zador, & Swift, 1991)], internet skills (Deursen, Courtois, & Dijk, 2014), quality of life (EQ-5D, VAS QL) (EuroQol, 1990), smoking-related factors [i.e. number of previous quit attempts, nicotine dependence (Heatherton, Kozlowski, Frecker, & Fagerstrom, 1991), health and smoking complaints (MAPHSS) (Darke et al., 1991)] and cognitive constructs [i.e. attitude (Ajzen & Fishbein, 1980; Vries & Mudde, 1998), self-efficacy (Ajzen & Fishbein, 1980; Vries & Mudde, 1998), social support (Ajzen & Fishbein, 1980; Vries & Mudde, 1998), social modelling (Ajzen & Fishbein, 1980; Vries & Mudde, 1998), motivation to quit (DiClemente, Prochaska, Fairhurst, Velicer, Velasquez, & Rossi, 1991) and readiness to quit (DiClemente et al., 1991)]. Additional information concerning the instruments used to collect the data about each characteristic can be found in the protocol article regarding the 'Livesmokefree' study (trial number: NTR5113) published by Siemer and others (2016).

2.8. Smoking abstinence assessment

In the current study, smoking abstinence was assessed mainly (i.e. in 33 out of 38 patients) through CO measurements, where, in accordance with literature, the presence of less than 5 parts per million (p.p.m.) of CO found in patients' breath indicates smoking abstinence (Siemer et al. 2016). This measurement was taken at three and at five months after the commence of the treatment. Each time (i.e. at three and at five months) the measurement of CO was taken three times and the average of these three measurements was recorded as the amount of CO found in patients' breath. To assess abstinence both measurements (i.e. at three and five months) were used. Provided that the average of those two measurements was less than 5 p.p.m, a patient was considered abstinent. When CO measurements of a patient were not available (i.e. in six out of the 38 patients), the assessment of smoking abstinence was based on self-reported abstinence, a measurement which was taken at three and six months after the beginning of the treatment.

2.9. Data analysis

The following statistical analyses were performed for both the minutes-based and the features-based measure of assessing adherence.

A univariate regression analysis was performed in which the baseline

characteristics between adherent and non-adherent patients were compared by applying independent T-tests (normally distributed) or Mann–Whitney U tests (non-parametric) for continuous variables. To compare categorical variables, Chi-square tests or Fisher's exact tests were used, as appropriate. Continuous variables are displayed as mean with standard deviation (SD) in case of normally distributed variables or as median with interquartile range (IQR) for non-parametric variables. Categorical variables are displayed as numbers with corresponding percentages.

Moreover, multivariate regression analysis was also conducted. In this analysis, the patients' baseline characteristics univariately associated with adherence ($p < .10$) were selected for a multivariate logistic regression analysis in order to identify independent predictors of adherence to the blended treatment. To achieve this, taking into account the low number of patients ($n = 70$), forward stepwise regression analysis was applied. During this analysis, variables were entered step by step to the multivariate model and only remained in this model if they significantly increased the model fit (based on -2 loglikelihood).

Furthermore, some additional analyses were performed or used in order to validate both measures. Precisely, to examine construct validity, and more specifically convergent validity, the outcomes of the univariate and multivariate regression analysis were used. Moreover, to evaluate divergent validity the association of several (expected) non-adherence-related patients' baseline characteristics with adherence was tested using Chi-square tests or Fisher's exact tests, as appropriate. Additionally, to assess content validity, the degree of agreement between the minutes-based and the features-based measure in terms of their classification of adherent and non-adherent patients was examined using Cohen's kappa test of agreement (Cohen, 1960). Finally, to examine criterion validity the correlation between two measures (i.e. concurrent validity) was tested using Spearman's rank correlation coefficient and the capability of each measure to predict smoking abstinence (i.e. predictive validity) was tested applying Fisher's exact test for the minutes-based measure and Chi-square test in case of the features-based measure.

3. Results

3.1. Results of the minutes-based measure

3.1.1. Adherence rates in the minutes-based measure

As shown in table 1, of the 70 patients, 33 (47.1%) were found adherent to the blended treatment. In the group of non-adherent patients ($n = 37$), there were 24 (64.9%) patients who adhered only to the face-to-face sessions and 13 (35.1%) who did not adhere to both face-to-face and online sessions of the treatment. Notably, there were no patients who adhered to the online sessions and did not adhere to the face-to-face sessions.

Table 1

Adherence to face-to-face and to online treatment in the minutes-based measure (N=70)

| | | <u>face-to-face treatment</u> | | |
|-------------------------|--------------|-------------------------------|--------------|-------|
| | | adherent | non adherent | total |
| <u>Online treatment</u> | adherent | 33 | 0 | 33 |
| | non adherent | 24 | 13 | 37 |
| | total | 57 | 13 | 70 |

3.1.2. The association between patients' baseline characteristics and adherence assessed though the minutes-based measure

Table 2 presents the univariate regression analysis of the patients' baseline characteristics regarding the minutes-based measure. Firstly, health-related complaints, as well as health and smoking-related complaints were significantly lower for adherent patients compared to the non-adherent patients (respectively $M = 10.6$ vs 14.9 , $p = .008$ and 30.4 vs 37.9 , $p = .030$). Moreover, adherent patients experienced fewer symptoms of stress ($Mdn = 6$ vs 12 , $p = .029$) and mental health issues ($Mdn = 14$ vs 24 , $p = .022$) and they showed a less negative attitude towards quitting smoking compared to the non-adherent patients ($Mdn = -1.3$ vs -1.5 , $p = .047$). In addition, there was a trend towards significance for a higher age of the adherent patients compared to the non-adherent ($M = 49.2$ vs 42.8 , $p = .053$). Finally, there were trends towards significance indicating less anxiety ($Mdn = 4$ vs 6 , $p = .062$) and better quality of life (EQ-5D) ($Mdn = .8$ vs $.8$, $p = .052$) of the adherent patients as opposed to the non-adherent.

Table 2

The association between patients' baseline characteristics and adherence in the minutes-based measure (N=70)

| User characteristic | adherent | non-adherent | p |
|---|-----------------|----------------|-------|
| Age, mean (SD) | 49.2 (12) | 42.8 (14.8) | .053+ |
| Gender, n (%) | | | .602 |
| men | 19 (67.6%) | 19 (51.4%) | |
| women | 14 (42.4%) | 18 (48.6%) | |
| Main daily activity, n (%) | | | .945 |
| work or studying | 14 (42.4%) | 16 (43.2%) | |
| private life | 19 (57.6%) | 21 (56.8%) | |
| Education, n (%) | | | .853 |
| university education | 18 (54.5%) | 21 (56.8%) | |
| other | 15 (45.5%) | 16 (43.2%) | |
| Internet skills, mean (SD) | 38.3 (5) | 37.3 (6.9) | .506 |
| Marital status, n (%) | | | .147 |
| having partner | 25 (75.8%) | 22 (59.5%) | |
| not having partner | 8 (24.2%) | 15 (40.5%) | |
| Housing situation, n (%) | | | .922 |
| living without children | 20 (60.6) | 22 (59.5%) | |
| living with children | 13 (39.4) | 15 (40.5%) | |
| Attitude positive, Median (IQR) | 2.5 (2-2.8) | 2.5 (2-2.9) | .830 |
| Attitude negative, Median (IQR) | -1.3 (-1.8,-.8) | -1.5 (-2.5,-1) | .047* |
| Self-efficacy, mean (SD) | -.08 (1) | -.3 (.9) | .381 |
| Social support, Median (IQR) | 4 (3-4) | 4 (3-4) | .618 |
| Social modelling, Median (IQR) | 1.5 (0-2.5) | 2 (1-3) | .122 |
| Readiness to quit, n (%) | | | .300 |
| "I have already stopped" | 1 (3%) | 2 (5.4%) | |
| "within 1 month" | 12 (36.4%) | 6 (16.2%) | |
| "within 2 months" | 6 (18.2%) | 9 (24.3%) | |
| "within 3 months" | 14 (42.4%) | 20 (54.1%) | |
| Motivation to quit, n (%) | | | .958 |
| extrinsic motivation | 10 (30.3%) | 11 (29.7%) | |
| intrinsic motivation | 23 (69.7%) | 26 (70.3%) | |
| Quality of life (VAS QL), Median (IQR) | 75 (60-82.5) | 70 (50-79) | .208 |
| Quality of life (EQ-5D), Median (IQR) | .8 (.7-1) | .8 (.6- .9) | .052+ |

| | | | |
|--|------------|-------------|--------|
| Nicotine dependence, mean (SD) | 5.4 (2.1) | 5.9 (1.8) | .261 |
| Health complaints, mean (SD) | 10.6 (6.8) | 14.9 (6.4) | .008** |
| Health and smoking complaints, mean (SD) | 30.4 (15) | 37.9 (13.4) | .030* |
| Depression, Median (IQR) | 2 (0-11) | 6 (2-12) | .270 |
| Anxiety, Median (IQR) | 4 (2-6) | 6 (2-16) | .062+ |
| Stress, Median (IQR) | 6 (2-11) | 12 (5-18) | .029* |
| Mental Health (DASS), Median (IQR) | 14 (7-28) | 24 (14-35) | .022* |
| Previous quit attempts, n (%) | | | .292 |
| yes | 29 (87.9%) | 29 (78.4%) | |
| no | 4 (12.1%) | 8 (21.6%) | |
| Medication in general, n (%) | | | .194 |
| yes | 22 (66.7%) | 19 (51.4%) | |
| no | 11 (33.3%) | 18 (48.6%) | |
| Psychiatric medication, n (%) | | | .676 |
| yes | 28 (84.8%) | 30 (81.1%) | |
| no | 5 (15.2%) | 7 (18.9%) | |
| Physical medication, n (%) | | | .518 |
| yes | 18 (54.5%) | 23 (62.2%) | |
| no | 15 (45.5%) | 14 (37.8%) | |
| Other medication, n (%) | | | .233 |
| yes | 26 (78.8%) | 33 (89.2%) | |
| no | 7 (21.2%) | 4 (10.8%) | |

Notes. independent samples T-test was performed for the variables: age, internet skills, self-efficacy, nicotine dependence, social modelling, health complaints and health and smoking complaints, Mann–Whitney U test was applied for the variables: positive attitude, negative attitude, depression, anxiety, stress, mental health, social support and quality of life (VAS QL) (EQ-5D), Chi-square test was performed for the variables: gender, marital status, housing situation, motivation to quit, main daily activity, education, previous quit attempts, medication in general, psychiatric medication, physical medication and other medication and Fisher's exact test was applied for the variable readiness to quit, SD= standard deviation, IQR= interquartile range, + $p < .1$, * $p < .05$, ** $p < .01$.

3.1.3. Validation of the minutes-based measure

3.1.3.1. Construct validity of the minutes-based measure

Multivariate logistic regression analysis showed that negative attitude and health complaints were the best predictors of adherence. Taken together, these two predictors accounted for the 20.8% of the variation of adherence (Nagelkerke's $R^2 =$

.208). As shown in table 3, an increase of one unit in negative attitude was associated with 2.1 increased possibility of adherence ($OR = 2.10$; 95% $CI = 1.05, 4.02$; $p = .035$), while, an increase of one unit in health complains was associated with 10% decreased likelihood of adherence ($OR = .90$; 95% $CI = .83, .97$; $p = .009$).

Table 3

Patients' baseline characteristics as predictors of adherence with the minutes-based measure (N=70)

| Predictor variable | OR | CI (95%) | p |
|--------------------|------|-----------|--------|
| negative attitude | 2.10 | 1.05–4.02 | .035* |
| health complaints | .90 | .83– .97 | .009** |

Notes. Negative attitude is a variable which fluctuates between 0 and -3, in which a score close to zero represents a less negative attitude, while a score close to -3 represents a more negative attitude, OR= odds ratio, CI= confidence interval. * $p < .05$. ** $p < .01$.

As shown in table 4, overall, this model managed to correctly classify the patients in 70% of the cases. More specifically 70.3% of the non-adherent patients and 69.7% of the adherent patients were classified correctly.

Table 4

Classification table in the minutes-based measure (N=70)

| | | Predicted | | Percentage correct |
|-----------------|--------------------|--------------|----------|--------------------|
| | | non-adherent | adherent | |
| <u>Observed</u> | non-adherent | 26 | 11 | 70.3% |
| | adherent | 10 | 23 | 69.7% |
| | Overall percentage | | | 70.0% |

Concerning divergent validity, as shown in table 5, adherence, evaluated through the minutes-based measure, was unrelated to non-adherence-related patients' baseline characteristics.

Table 5

*The association between (expected) non-adherence-related patients' baseline characteristics and adherence in the minutes-based measure (N=70)**

| User characteristic | adherent | non-adherent | p |
|---------------------|------------|--------------|---|
| Nationality, n(%) | | | 1 |
| Dutch | 31 (47%) | 35 (53%) | |
| Other | 2 (50%) | 2 (50%) | |
| Cultural heritage | | | 1 |
| Dutch | 31 (50.8%) | 30 (49.2%) | |

| | | | |
|--|------------|------------|------|
| Other | 2 (22.2%) | 7 (77.8%) | |
| Number of children | | | .937 |
| 0-2 children | 27 (47.4%) | 30 (52.6%) | |
| 3-5 children | 6 (46.2%) | 7 (53.8%) | |
| Medical referral | | | .243 |
| Pulmonary medicine | 6 (66.7%) | 3 (33.3%) | |
| Other department | 9 (39.1%) | 14 (60.9%) | |
| Cigarettes | | | .261 |
| Yes | 23 (51.1%) | 22 (48.9%) | |
| No | 10 (40%) | 15 (60%) | |
| Coarse shredded tobacco | | | .533 |
| Yes | 11 (42.3%) | 15 (57.7%) | |
| No | 22 (50%) | 22 (50%) | |
| Cigars or cigarillos | | | 1 |
| Yes | 2 (50%) | 2 (50%) | |
| No | 31 (47%) | 35 (53%) | |
| Supp. measures in prev. quit attempts: | | | |
| 1. Nicotine chewing gum | | | .647 |
| Yes | 9 (52.9%) | 8 (47.1%) | |
| No | 19 (46.3%) | 22 (53.7%) | |
| 2. Nicotine patch | | | .813 |
| Yes | 13 (50%) | 13 (50%) | |
| No | 15 (46.9%) | 17 (53.1%) | |
| 3. Nicotine lozenge | | | 1 |
| Yes | 3 (50%) | 3 (50%) | |
| No | 25 (48.1%) | 27 (51.9%) | |
| 4. Varenicline | | | .290 |
| Yes | 6 (66.7%) | 3 (33.3%) | |
| No | 22 (44.9%) | 27 (55.1%) | |

Notes. * N = 58 for the variables: nicotine chewing gum, nicotine patch, nicotine lozenge and varenicline and N = 32 for the variable: medical referral, Chi-square test was performed for the variables: number of children, cigarettes, tobacco, nicotine chewing gum and nicotine patch, Fisher's exact test was conducted for the variables: nationality, cultural heritage, medical referral, cigars or cigarillos and varenicline, supp.= supportive, prev.= previous.

3.1.3.2. Content validity of the minutes-based measure

The results of the Cohen's kappa test showed moderate agreement between the evaluation of adherence using the minutes-based and the features-based measure ($\kappa = .438$, $p < .001$). As shown in table 6, the two measures agreed in the classification of 37 patients as non-adherent and of 14 patients as adherent. Consequently, in sum, they

agreed in the classification of 51 (72.9%) out of the 70 patients and they disagreed in the classification of 19 (27.1%) patients. These 19 patients were all classified as adherent by the minutes-based measure, but as non-adherent by the features-based measure.

Table 6

The agreement between the two measures of assessing adherence (N=70)

| | | Features-based | | total |
|---------------|--------------|----------------|----------|-------|
| | | non-adherent | adherent | |
| Minutes-based | non-adherent | 37 | 0 | 37 |
| | adherent | 19 | 14 | 33 |
| | total | 56 | 14 | 70 |

3.1.3.3. Criterion validity of the minutes-based measure

Referring to concurrent validity, adherence assessed using the minutes-based measure was highly correlated with adherence evaluated through the features-based measure [$\rho(70) = .529$, $p < .001$].

Concerning predictive validity, as shown in table 7, adherence assessed through the minutes-based measure was not associated with smoking abstinence ($p = .471$). Contrary to the hypothesis, the percentage of adherent patients who quit was 37%, while more than half (i.e. 54.5%) of the non-adherent patients quit smoking.

Table 7

The association between adherence (assessed through the minutes-based measure) and abstinence (Fisher's exact test) (N=38)

| User characteristic | adherent | non-adherent | total | p |
|---------------------------|-----------|--------------|------------|------|
| Smoking abstinence, n (%) | | | | .471 |
| quitter | 10 (37%) | 6 (54.5%) | 16 (42.1%) | |
| non-quitter | 17 (63%) | 5 (45.5%) | 22 (57.9%) | |
| total | 27 (100%) | 11 (100%) | 38 (100%) | |

3.2. Results of the features-based measure

3.2.1. Adherence rates in the features-based measure

As shown in table 8, of the 70 patients, 14 (20%) were found adherent to the blended treatment. In the group of non-adherent patients ($n = 56$), there were 5 (8.9%) patients who adhered only to the face-to-face sessions and 3 (5.4%) who adhered only

to online sessions. Finally, 48 (85.7%) of the non-adherent patients did not adhere to both face-to-face and online mode of delivery of the treatment.

Table 8

Adherence to face-to-face and to online treatment in the features-based measure (N=70)

| <u>Online treatment</u> | | <u>face-to-face treatment</u> | | total |
|-------------------------|--------------|-------------------------------|--------------|-------|
| | | adherent | non adherent | |
| | adherent | 14 | 3 | 17 |
| | non adherent | 5 | 48 | 53 |
| | total | 19 | 51 | 70 |

3.2.2. The association between patients' baseline characteristics and adherence assessed through the features-based measure

Table 9 presents the univariate regression analysis of the patients' baseline characteristics concerning the features-based measure. First of all, health-related complaints, as well as health and smoking-related complaints were significantly lower for adherent patients compared to the non-adherent patients (respectively $M = 9.4$ vs 13.7 $p = .037$ and $M = 27$ vs 36.2 , $p = .033$). Moreover, adherent patients experienced less modelling of smoking in their social environment in comparison with the non-adherent patients ($Mdn = 1$ vs 2 , $p = .042$). In addition, the two groups also differed in terms of gender ($p = .041$), with the majority of the adherent patients being men (i.e. 78.6%), while less than half of the non-adherent patients were males (i.e. 48.2%). Finally, the two groups also differed in terms of marital status ($p = .026$), with almost all the adherent patients having a partner [i.e. 13 (92.9%) out of the 14 patients], compared to 34 (60.7%) out of the 56 non-adherent patients.

Table 9

The association between patients' baseline characteristics and adherence in the features-based measure (N=70)

| User characteristic | adherent | non-adherent | p |
|----------------------------|-------------|--------------|-------|
| Age, mean (SD) | 50.6 (11.9) | 44.6 (14.1) | .150 |
| Gender, n (%) | | | .041* |
| men | 11 (78.6%) | 27 (48.2%) | |
| women | 3 (21.4%) | 29 (51.8%) | |
| Main daily activity, n (%) | | | .227 |
| work or studying | 4 (28.6%) | 26 (46.4%) | |
| private life | 10 (71.4%) | 30 (53.6%) | |
| Education, n (%) | | | .630 |

| | | | |
|--|-----------------|----------------|-------|
| university education | 7 (50%) | 32 (57.1%) | |
| other | 7 (50%) | 24 (42.9%) | |
| Internet skills, mean (SD) | 37.9 (4.7) | 37.7 (6.2) | .912 |
| Marital status, n (%) | | | .026* |
| having partner | 13 (92.9%) | 34 (60.7%) | |
| not having partner | 1 (7.1%) | 22 (39.3%) | |
| Housing situation, n (%) | | | .807 |
| living without children | 6 (42.9%) | 22 (39.3%) | |
| living with children | 8 (57.1%) | 34 (60.7%) | |
| Attitude positive, Median (IQR) | 2.4 (2-2.6) | 2.5 (2-3) | .582 |
| Attitude negative, Median (IQR) | -1.3 (-1.5--.9) | -1.5 (-2.4--1) | .212 |
| Self-efficacy, mean (SD) | 0 (-.5-.9) | -.02 (.9) | .407 |
| Social support, Median (IQR) | 4 (3-4) | 4 (3-4) | .618 |
| Social modelling, Median (IQR) | 1 (0-2.1) | 2 (.5-3) | .042* |
| Readiness to quit, n (%) | | | .300 |
| "I have already stopped" | 0 | 3 (5.4%) | |
| "within 1 month" | 5 (35.7%) | 13 (23.2%) | |
| "within 2 months" | 3 (21.4%) | 12 (21.4%) | |
| "within 3 months" | 6 (42.9%) | 28 (50%) | |
| Motivation to quit, n (%) | | | .529 |
| extrinsic motivation | 3 (21.4%) | 18 (32.1%) | |
| intrinsic motivation | 11 (78.6%) | 38 (67.9%) | |
| Quality of life (VAS QL), Median (IQR) | 70 (62.5-80) | 70 (55.8-80) | .762 |
| Quality of life (EQ-5D), Median (IQR) | .8 (.7-1) | .8 (.7-1) | .188 |
| Nicotine dependence, mean (SD) | 5.4 (2) | 5.7 (1.8) | .361 |
| Health complaints, mean (SD) | 9.4 (4.7) | 13.7 (7.1) | .037* |
| Health and smoking complains, mean (SD) | 27 (11.4) | 36.2 (14.8) | .033* |
| Depression, Median (IQR) | 4 (1.5-13) | 6 (2-11.5) | .953 |
| Anxiety, Median (IQR) | 3 (2-6) | 6 (2-11.5) | .244 |
| Stress, Median (IQR) | 5 (1.5-13.5) | 9 (4-16) | .182 |
| Mental Health (DASS), Median (IQR) | 14 (4-32.5) | 22 (12-32) | .245 |
| Previous quit attempts, n (%) | | | 1.000 |
| yes | 10 (83.3%) | 35 (81.4%) | |
| no | 2 (16.7%) | 8 (18.6%) | |

| | | | |
|--------------------------------|------------|------------|------|
| Medication in general, n (%) | | | .903 |
| yes | 8 (57.1%) | 33 (58.9%) | |
| no | 6 (42.9%) | 23 (41.1%) | |
| Psychiatric medication , n (%) | | | .695 |
| yes | 11 (78.6%) | 47 (83.9%) | |
| no | 3 (21.4%) | 9 (16.1%) | |
| Physical medication, n (%) | | | .275 |
| yes | 10 (71.4%) | 31 (55.4%) | |
| no | 4 (28.6%) | 25 (44.6%) | |
| Other medication, n (%) | | | .212 |
| yes | 10 (71.4%) | 49 (87.5%) | |
| no | 4 (28.6%) | 7 (12.5%) | |

Notes. independent samples T-test was performed for the variables: age, internet skills, self-efficacy, nicotine dependence, social modelling, health complaints and health and smoking complaints, Mann–Whitney U test was applied for the variables: positive attitude, negative attitude, depression, anxiety, stress, mental health, social support and quality of life (VAS QL) (EQ-5D), Chi-square test was performed for the variables: gender, housing situation, main daily activity, education, medication in general and physical medication and Fisher's exact test was applied for the variables: marital status, motivation to quit, previous quit attempts, psychiatric medication, other medication and readiness to quit, SD= standard deviation, IQR= interquartile range, * $p < .05$, ** $p < .01$.

3.2.3. Validation of the features-based measure

3.2.3.1. Construct validity of the features-based measure

Multivariate logistic regression analysis showed that the factors marital status and social modelling were the best predictors of adherence. Taken together, these two predictors accounted for the 27.3% of the variation of adherence (Nagelkerke's $R^2 = .273$). As shown in table 10, patients who had a partner had 12.38 higher odds to be adherent than patients who did not have a partner ($OR = 12.38$; 95% $CI = 1.44, 106.18$; $p = .022$), while, patients who reported having more smoking-promoting models within their social environment had .52 lower odds to be adherent than patients who reported lower social modelling ($OR = .52$; 95% $CI = .30, .88$; $p = .016$).

Table 10

Patients' baseline characteristics as predictors of adherence with the features-based measure (N=70)

| Predictor variable | OR | CI (95%) | p |
|--------------------|-------|-------------|-------|
| marital status | 12.38 | 1.44–106.18 | .022* |
| social modelling | .52 | .30–.88 | .016* |

Notes. OR= odds ratio, CI= confidence interval. * $p < .05$.

As shown in table 11, overall, this model managed to correctly classify the patients in 81.4% of the cases. More specifically 92.9% of the non-adherent patients and 35.7% of the adherent patients were classified correctly.

Table 11

Classification table in the features-based measure (N=70)

| <u>Observed</u> | | <u>Predicted</u> | | Percentage correct |
|-----------------|--------------------|------------------|----------|--------------------|
| | | non-adherent | adherent | |
| | non-adherent | 52 | 4 | 92.9% |
| | adherent | 9 | 5 | 35.7% |
| | Overall percentage | | | 81.4% |

Concerning divergent validity, as shown in table 12, adherence, evaluated through the features-based measure, was unrelated to non-adherence-related patients' baseline characteristics.

Table 12

*The association between (expected) non-adherence-related patients' baseline characteristics and adherence in the features-based measure (N=70)**

| User characteristic | adherent | non-adherent | p |
|-------------------------|-------------|--------------|------|
| Nationality, n(%) | | | 1 |
| Dutch | 13 (19.7%) | 53 (80.3%) | |
| Other | 1 (25%) | 3 (75%) | |
| Cultural heritage | | | .675 |
| Dutch | 13 (21..3%) | 48 (78.7%) | |
| Other | 1 (11.1%) | 8 (88.9%) | |
| Number of children | | | .441 |
| 0-2 children | 13 (22.8%) | 44 (77.2%) | |
| 3-5 children | 1 (7.7%) | 12 (92.3%) | |
| Medical referral | | | 1 |
| Pulmonary medicine | 2 (22.2%) | 7 (77.8%) | |
| Other department | 5 (21.7%) | 18 (78.3%) | |
| Cigarettes | | | 1 |
| Yes | 9 (20%) | 36(80%) | |
| No | 13 (19.7%) | 53 (80.3%) | |
| Coarse shredded tobacco | | | .902 |
| Yes | 1 (25%) | 3 (75%) | |
| No | 9 (20.5%) | 35 (79.5%) | |
| Cigars or cigarillos | | | 1 |

| | | | |
|--|-----------|------------|------|
| Yes | 2 (50%) | 2 (50%) | |
| No | 31 (47%) | 35 (53%) | |
| Supp. measures in prev. quit attempts: | | | |
| 1. Nicotine chewing gum | | | .715 |
| Yes | 4 (23.5%) | 13 (76.5%) | |
| No | 7 (17.1%) | 34 (82.9%) | |
| 2. Nicotine patch | | | .738 |
| Yes | 4 (15.4%) | 22 (84.6%) | |
| No | 7 (21.9%) | 25 (78.1%) | |
| 3. Nicotine lozenge | | | .318 |
| Yes | 2 (33.3%) | 4 (66.7%) | |
| No | 9 (17.3%) | 43 (82.7%) | |
| 4. Varenicline | | | 1 |
| Yes | 2 (22.2%) | 7 (77.8%) | |
| No | 9 (18.4%) | 40 (81.6%) | |

Notes. * N = 58 for the variables: nicotine chewing gum, nicotine patch, nicotine lozenge and varenicline and N = 32 for the variable: medical referral, Chi-square test was performed for the variables: cigarettes, tobacco and nicotine patch, Fisher's exact test was conducted for the variables: nationality, cultural heritage, number of children, medical referral, cigars or cigarillos, nicotine chewing gum, nicotine lozenge and varenicline, supp.= supportive, prev.= previous.

3.2.3.2. Content validity of the features-based measure

Information regarding content validity is presented in paragraph 3.1.3.2.

3.2.3.3. Criterion validity of the features-based measure

Information regarding concurrent validity is presented in paragraph 3.1.3.3.

Concerning predictive validity, as shown in table 13, adherence was not significantly associated with smoking abstinence ($p = .152$). Nevertheless, in line with the hypothesis, more than half (i.e. 57.1%) of the adherent patients quit smoking, while one third (i.e. 33.3%) of the non-adherent patients managed to quit.

Table 13

The association between adherence (assessed through the features-based measure) and abstinence (Chi-square test) (N=38)

| User characteristic | adherent | non-adherent | total | p |
|---------------------------|-----------|--------------|------------|------|
| Smoking abstinence, n (%) | | | | .152 |
| quitter | 8 (57.1%) | 8 (33.3%) | 16 (42.1%) | |
| non-quitter | 6 (42.9%) | 16 (66.7%) | 22 (57.9%) | |
| total | 14 (100%) | 24 (100%) | 38 (100%) | |

4. Discussion

4.1. Interpretation of the main findings regarding adherence

The current study showed that a blended smoking cessation treatment for outpatients in a general hospital in the Netherlands had, compared to adherence rates reported in previous smoking cessation interventions, a rather low adherence rate of between 20% and 47.1% depending on the measure for adherence. Notably, most non-adherence occurred in the web-based components of this blended intervention. This study also revealed several participants' baseline characteristics that may be predictive of non-adherence in smoking cessation treatment in general, and in a blended program in particular. More specifically, non-adherence was predicted by a lower physical and mental health status (i.e. more health and smoking complaints, more symptoms of anxiety and stress, worse mental health and decreased quality of life), by some cognitive determinants of smoking cessation (i.e. more negative attitude towards smoking cessation and higher social modelling of smoking) and by some demographic variables (i.e. female gender, lower age and absence of a partner). Further, this study aimed to contribute to the validation of two adherence assessment measures, in particular suitable for this blended intervention. In sum, both measures exhibited good construct validity, good content validity and quite good criterion validity. Notably, features-based measure seemed to show better construct and predictive validity and better diagnostic accuracy than minutes-based measure.

The first aim of this study was to assess adherence to the blended treatment. For this purpose, two measures of evaluating adherence were developed, one enabling easy and time-saving evaluation (i.e. minutes-based measure), and one offering a more in-depth assessment of adherence (i.e. features-based measure). The minutes-based measure showed that 33 (47.1%) of the 70 patients adhered to the treatment, while the features-based measure classified only 14 (20%) patients as adherent. In both measures, adherence observed seems to be significantly lower in comparison with adherence rates reported in previous face-to-face smoking cessation interventions (Patterson et al., 2003; Taleb et al., 2015). In these two studies, adherence was defined as 100% attendance to face-to-face counselling sessions and adherence of 70.5% and 70% was reported respectively. The observed adherence in the current study (in which adherence was defined as at least 60% active use of both face-to-face and online modes of delivery of the intervention) appears lower even compared to the 50% adherence reported on average in various online interventions

applied in healthcare domain, in which adherence was mostly defined as the 100% completion of the online sessions provided (Kelders et al., 2012).

Given that non-adherence was found higher in the web-based part of this intervention in both measures (see tables 1 and 8), some possible explanations for the low adherence observed in this blended treatment might be technology-related. More specifically, the patients-users have to use their own electronic device to gain access to the online sessions, thus, some hardware damage or software malfunction could lead to non-adherence to these sessions. Moreover, in both cases, there is an decreased possibility for the patients-users to gain access to the online sessions through some other device which they may also use frequently (e.g. mobile phone), since the web-based sessions are only accessible through some Flash-compatible device. Another possible explanation for the low-adherence found, might be the potential low persuasiveness of the online mode of delivery of the treatment, as known persuasive elements applied in online interventions (e.g. praise, rewards, reminders, normative influence, third-party endorsements) (Kelders et al., 2012; Oinas-Kukkonen & Harjumaa, 2009) were not embedded consistently in the web-based sessions. Furthermore, some negative user experience of the patients while interacting with the online part of the intervention might be another reason leading to low adherence. Negative user experience might be caused, for instance, by too demanding or/and time-consuming features and features seemingly overlapping with each other.

Except technological issues, other potential explanations, for the low adherence found, might be treatment-related. For instance, assuming that the blended treatment was too intensive causing a higher burden to the patients than the treatment as usual, lower adherence would have been expected. Additionally, the low adherence might be sample-related. More specifically, since the sample of this study was patients of a hospital, their physical or/and mental health could be significantly lower than that of the general population and this might have led to the low-adherence observed. Finally, from a methodological perspective, the low adherence could be the outcome of too strict measures of assessing adherence. Even though the cut-off of 60% use of both parts of the treatment seems low and easy to be achieved, in comparison with the 100% attendance to sessions required in some face-to-face smoking cessation studies (Patterson et al., 2003; Taleb et al., 2015), the low

adherence found using both measures (i.e. 47.1% and 20% respectively) indicates that these measures of assessing adherence might have been too strict.

A secondary purpose of the study was to identify predictors of adherence. Regarding the minutes-based measure, adherent patients reported fewer health-related complaints, health and smoking-related complaints and symptoms of anxiety and stress, better mental health, less negative attitude towards smoking cessation, higher age and better quality of life compared to non-adherent patients. In agreement with some of these findings, in another study conducted by Taleb and associates (2015), which assessed adherence to face-to-face counselling sessions, adherent patients also had higher age and reported fewer health and smoking-related complaints than the non-adherent patients. Nevertheless, the interpretation of these findings should be considered carefully because of the fact that the population in which the latter study was conducted (i.e. outpatients of Syrian general hospitals), might be very different (e.g. socio-economic status, cultural differences, education) from the population where the current study was applied (i.e. outpatients of Dutch general hospital).

Concerning the features-based measure, adherence was associated with male gender, the presence of a partner, fewer health complaints, fewer health and smoking complaints and lower social modelling of smoking. Concluding, the only common predictors between the features-based and the minutes-based measure are health complaints and health and smoking complaints, two variables which could not be considered as autonomous constructs, since the questionnaires which were used to calculate their scores are overlapping. Nevertheless, a variable which might be closely related to health or/and smoking-related complaints is withdrawal symptoms, which are reported as predictors of adherence to smoking cessation intervention in another study (Taleb et al., 2015). Another interesting predictor of adherence found in the current study is social modelling. Based on self-reported data, the presence of smokers in recent ex-smokers' social environment is one of the main reasons for relapse (Cummings, Jaén, & Giovino, 1985; Shiffman, 1982). In an empirical study, Marlatt and Gordon (1980) found that the presence of a smoking model was as likely to result in relapse as a more direct smoking trigger, such as offering a cigarette to recent ex-smokers. Taken together, these findings indicate that the relationship between social modelling and low adherence, found in the present study, might be mediated by relapsing episodes as follows: the patients experiencing higher social

modelling of smoking might have increased probability to relapse and, consequently, drop-out from the blended treatment which, in turn, could result into low-adherence.

4.2. Interpretation of the main findings concerning validity

Regarding the validity of the two measures, overall, they both exhibited good construct and content validity and quite good criterion validity. More specifically, their construct validity was good since both the minutes-based and the feature-based measure were associated with adherence-related variables (see tables 2 and 9 respectively) and they were unrelated to non-adherence-related variables (see tables 5 and 12 respectively), as expected. Additionally, the content validity of the two measures was good, since moderate agreement was found between them in terms of their classification of adherent and non-adherent patients. More specifically, kappa test ($\kappa = .438$, $p < .001$). showed that the two measures agreed in the classification of 51 (72.9%) out of the 70 patients. In healthcare settings, agreement of a least 70% (equals to $\kappa = .400$) is considered supportive of the content validity of a test (Delgado-Rico, Carretero-Dios, & Ruch, 2012; Wynd, Schmidt, & Schaefer, 2003). Finally, referring to criterion validity, it seemed to be quite good in both measures. That is because the high positive correlation found between the two measures indicated good concurrent validity. On the other hand, none of the two measures showed good predictive validity, since they both failed to significantly predict smoking abstinence.

Comparing the two measures, the features-based measure seems more valid for the following reasons. First of all, considering that the predictive model of adherence assessed through the features-based measure showed higher model fit than the corresponding model of the minutes-based measure (Nagelkerke's $R^2 = .273$ vs $.208$, respectively), the former measure seems to illustrate higher construct validity than the latter. In addition, it seems to have better diagnostic accuracy since it appears to offer a more accurate categorisation of the patients into adherent and non-adherent than the minutes-based measure (see tables 11 and 4 respectively). Moreover, it seems to have better predictive validity. More specifically, even though adherence, assessed by the features-based measure, failed to significantly predict abstinence, this prediction approximated a trend towards significance ($p = .152$). Additionally, the direction of the observed relationship between adherence and abstinence was in line with the research hypothesis, since, a higher proportion of adherent patients (57.1%)

managed to quit smoking compared to the non-adherent (33.3%) (see table 13). The minutes-based measure showed poorer predictive validity because its predictive capability was poorer ($p = .471$) than that of the features-based measure ($p = .152$) and due to the fact that, in this measure, the direction of the relationship between adherence and abstinence was contrary to the research hypothesis, since a lower proportion of adherent patients (37%) managed to quit as opposed to the non-adherent (54.5%) (see table 7).

4.3. Advantages and downsides of the two measures

In the following lines some of the main benefits and setbacks of the two measures of assessing adherence are summarised. More specifically, a practical advantage of the minutes-based measure is that it provides a fast, easy and simple method to assess adherence. Additionally, neither much time nor much effort or expertise is needed to use this measure, something which means that anyone can, potentially, understand how to use it or/and how to interpret it. Last but not least, it produces objective outcomes. That is because minutes spent in treatment is a more objective factor than some debatable theoretical construct, the evaluation of which could be biased for various reasons (e.g. confirmation bias, ambiguity effect).

Nevertheless, this measure has some main downsides. The first is that it does not measure patients' real exposure time, but intended exposure time based on the protocol. Given that the amount of time intended to be spent during each type of session was fixed and that the funding received by the counsellors is dependent, to some extent, on the time they spend offering their services, the reported time spent in treatment might have been biased, with more time been reported than actually spent. Secondly, it seems to offer a less accurate classification of the patients into adherent and non-adherent than the features-based measure (i.e. respectively, 70% vs 81.4% correct classification), thus, by applying this measure more patients would be misclassified (i.e. respectively, 30% vs 18.6%). Another drawback of this measure is that not only does it fail to predict smoking abstinence, but it produces outcomes towards the opposite direction, since, according to this measure, a lower proportion of adherent patients (37%) achieved to quit compared to the non-adherent (54.5%), an outcome which contradicts what was expected based on literature (Alterman et al.,

1999; Fish et al., 2009; Westman et al., 1997). Taken together, these three arguments/findings are questioning the validity of this measure.

Regarding the features-based measure, its first advantage is that it seems to correctly classify the patients in 81.4% of the cases (see table 11). Moreover, it seems a very good measure in terms of specificity, since it produces 92.9% correct classification of the non-adherent patients (see table 11). Its second asset is that it produces outcomes in line with what the literature suggests, since a higher proportion of adherent patients (57.1%) managed to quit smoking as opposed to the non-adherent (33.3%). These two findings, along with the good construct and content validity of this measure are all supporting its validity.

Despite that, the features-based measure also has several disadvantages. Firstly, it is characterised by low sensitivity, since it correctly classifies the adherent patients in 35.7% of the cases (see table 11). Secondly, it is a much more complicated and time-consuming method to assess adherence than the minutes-based measure.

4.4. Strengths and limitations of the study

Generally, as a strength of this study can be considered the fact that it provides insight into the adherence to the blended treatment which is a new and promising approach in the field of smoking cessation interventions which has not been evaluated until now. In that essence, this study managed to address a knowledge gap.

A second contribution of this study, is that it achieved to identify predictors of adherence. This information could lead to the improvement of adherence, for instance by adding some persuasive features (e.g. similarity, expertise, normative influence, social facilitation, cooperation) in order to motivate patients with certain characteristics-predictors of adherence to remain in the treatment. For example, normative influence could be applied, by showing videos of their peers praising quitting attempts of others, to patients who report high social modelling of smoking in their social environment. An overview of all the persuasive elements which could be applied in online interventions is presented by Oinas-Kukkonen and Harjumaa (2009).

This study has some major limitations as well. First of all, in both measures adherence was assessed in an indirect way, using time spent or activities performed, such as replying to some emails, as indicative of patients' adherence. Nevertheless, it

could be preferable the adherence to be assessed in a more direct and objective manner, for instance by using log-data. This would require the recording of the patients-users online activity within the web-based part of the intervention in real-time. For example, using log-files information, such as when the patients log-in to *rokendebaas.nl*, for how long, how many features they use in each of their log-ins and how much time they spend in each feature, could be recorded. In a relevant study, in which adherence to a mobile phone smoking cessation application was assessed via log-data, fully adherent considered the patients who had completed the four key components of the intervention, while the depth of the patients adherence was determined by the number of uses within each component (Zeng, Heffner, Copeland, Mull, & Bricker, 2016).

A second limitation is that the cut-off score of 60% adherence, applied in both measures, to differentiate adherent from non-adherent patients is not supported in the literature. Even though the bibliography on blended smoking cessation treatment is very limited, in another study where adherence was defined as compliance to two distinct modes of delivery (i.e. counselling and pharmacotherapy) of the same intervention, a higher cut-off score was applied (i.e. 80% adherence in both modes of delivery) (Berg et al., 2013).

A further limitation is that, in the absence of a golden standard to compare each measure with it in order to assess validity, the conclusions that the features-based measure seems to show higher construct and predictive validity and increased diagnostic accuracy compared to minutes-based measure are based on the assumption that the predictive models of adherence, assessed through each measure, are indeed predicting adherence. This means, for instance, that the increased capability of the features-based measure to correctly classify the patients might have been caused of the fact that the factors marital status and social modelling are indeed predicting adherence, while the factors negative attitude and health complaints are not.

Another limitation is that fidelity (i.e. the extent to which the counsellors follow the intervention protocol) was not evaluated and, consequently, a lack of fidelity might be responsible for patients' low level of adherence. In this particular case, given that the blended treatment was recently introduced to the counsellors, their potential unfamiliarity with this treatment could have led them not to follow the

intervention protocol. For example, some counsellors might have chosen to replace a web-based session with a, more familiar to them, face-to-face session. The absence of examination regarding fidelity is a common omission in studies where adherence to treatments is investigated (Moncher & Prinz, 1991).

Finally, this study is also limited for two additional reasons. Firstly, because of the small sample size used, which might be responsible for non-detecting some meaningful but not statistically significant results (e.g. the potential good predictive validity of the features-based measure) and, secondly, due to the non-existence of testing of external validity which questions the generalisability of the outcomes found in this study.

4.5. Implications of the study and suggestions for further research

One of the main objectives of the current study was to assess adherence to the blended treatment using two new measures, the minutes-based and the features-based measure. Despite the setting of a low cut-off score (i.e. 60% adherence in both modes of delivery) in both measures, adherence was quite lower (i.e. 47.1% and 20% adherence respectively) than the 70% adherence reported, on average, in face-to-face smoking cessation interventions (Patterson et al., 2003; Taleb et al., 2015) and the 50% adherence reported, on average, in web-based interventions applied in healthcare domain (Kelders et al., 2012). In future studies, it could be fruitful the potential reasons responsible for this low adherence to be investigated. Such reasons, as mentioned in paragraph 4.1, might include characteristics of the technological means through them this treatment is offered, of the treatment itself, of the sample investigated or/and of the measures used to assess adherence.

The examination of the two measures showed an overall superiority of the features-based measure in terms of validity, as it has already been described. Considering that this measure seems to be characterised by high specificity (see table 11), it could be used for research purposes, where this property is often highly appreciated (Saah & Hoover, 1997; Wainer & Braun, 2013). For instance, it could be used to explore why people with certain characteristics tend to/not to adhere to the blended treatment or/and to test the generalisability of the results found in this study in different populations. Furthermore, the implementation of the features-based measure could be proven useful in clinical settings as well. More specifically, the

ability of this measure to identify patients' characteristics-predictors of non-adherence could be used to re-design the blended treatment in order to improve adherence. For example, by adding videos of people praising quit attempts of others as part of the web-based sessions, this could counteract the negative influence of social modelling of smoking on adherence.

Moreover, the evaluation of the predictive validity of both measures showed that none of them predicted smoking abstinence. Considering that the cut-off score for defining adherent and non-adherent patients was 60% adherence in both modes of delivery, which is a cut-off quite lower than what is mostly applied in other relevant studies (e.g. Patterson et al., 2003; Taleb et al., 2015), it would be interesting to set a higher cut-off score (i.e. at least 80%) and re-conduct this analysis.

Furthermore, another intriguing issue would be to investigate which are the effects of overuse of the blended treatment for the patients as well as for the healthcare providers. As far as the patients are concerned, it would be interesting to compare the abstinence rates of the patients who overuse the blended treatment with those of the patients who underuse it and those who use it as intended. From the healthcare providers point of view, it would be interesting to be tested how many patients overuse the blended treatment and how costly is this behaviour for the organisations involved (i.e. MST and Tactus).

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