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**by**

Nicola Esther Stanczyk

Effects of two web-based computer-tailored interventions for smoking cessation: Comparing text and video delivery of messages.

**TITLE****1a-i) Identify the mode of delivery in the title**

YES:

Effects of two web-based computer-tailored interventions for smoking cessation: Comparing text and video delivery of messages

**1a-ii) Non-web-based components or important co-interventions in title**

YES:

Effects of two web-based computer-tailored interventions for smoking cessation: Comparing text and video delivery of messages

**1a-iii) Primary condition or target group in the title**

n/a

**ABSTRACT****1b-i) Key features/functionalities/components of the intervention and comparator in the METHODS section of the ABSTRACT**

Objective: The results of video computer tailoring (VCT) and text computer tailoring (TCT) were compared with the results of a control condition (CC). Main effects and differential effects for subgroups with different educational levels and different levels of readiness to quit were assessed.

**1b-ii) Level of human involvement in the METHODS section of the ABSTRACT**

During a blind randomized controlled trial, smokers willing to quit within 6 months were assigned to VCT (N=670), TCT (N=708) or CC (short generic text advice) (N=721). After 6 months, effects on 7-day point prevalence abstinence (PPA) and prolonged abstinence (PA) were assessed using logistic regression analyses. Analyses were conducted in two samples:

**1b-iii) Open vs. closed, web-based (self-assessment) vs. face-to-face assessments in the METHODS section of the ABSTRACT self-assessment****1b-iv) RESULTS section in abstract must contain use data**

VCT was more effective in increasing 7-day PPA than CC in both samples (OR= 1.45, p= .010; OR= 2.29, p= .000). TCT was only more effective than CC in increasing 7-day PPA in sample 2. VCT resulted in significantly higher PA rates than CC among smokers with high (ready to quit within 1 month) and low (ready to quit within 4-6 months) readiness to quit, in sample 2 (OR= 4.49 p= .008; OR= 9.35, p= .001). No differential effects were found for level of education. Complete case analyses and multiple imputation yielded similar results.

**1b-v) CONCLUSIONS/DISCUSSION in abstract for negative trials**

Results suggest that video-based messages with personalized feedback adapted to the smoker's motivation to quit might be effective in increasing abstinence rates for smokers with diverse educational levels.

**INTRODUCTION****2a-i) Problem and the type of system/solution**

A wide range of different smoking cessation interventions have been developed and implemented but in spite of this smoking rates remain high, especially among people with a lower level of education [1-4]. This illustrates the need to improve smoking cessation intervention strategies for this group.

**2a-ii) Scientific background, rationale: What is known about the (type of) system**

Although web-based CT smoking cessation interventions have been shown to be potentially effective [15, 16], they often report problems in attracting, engaging and retaining smokers and quitters [8, 17-20].

**METHODS****3a) CONSORT: Description of trial design (such as parallel, factorial) including allocation ratio**

We expected video computer tailoring (VCT) to be more effective in smokers with a lower level of education, whereas text computer tailoring (TCT) was expected to be more effective in smokers with a higher level of education. As the interventions included different routings tailored according to the smokers' readiness to quit, we furthermore expected less motivated smokers to be successful in their quit attempt.

**3b) CONSORT: Important changes to methods after trial commencement (such as eligibility criteria), with reasons**

n/a

**3b-i) Bug fixes, Downtimes, Content Changes**

n/a

**4a) CONSORT: Eligibility criteria for participants**

Respondents were eligible for participation when they were motivated to quit smoking within the following 6 months, when they were 18 years or older and when they had access to the Internet.

**4a-i) Computer / Internet literacy**

n/a

**4a-ii) Open vs. closed, web-based vs. face-to-face assessments:**

Of the 2551 potential respondents assessed for eligibility, overall 49 declined to participate, 138 did not meet inclusion criteria and 265 did not complete the baseline questionnaire or had no baseline quit date (within routing 1). Finally, 2106 respondents were randomized to the VCT condition (N=670), TCT condition (N=708) and the CC (N=721).

**4a-iii) Information giving during recruitment**

First, a random sample of about 150 general practitioners (GPs) was asked to refer smoking patients to the intervention website. GP practices were provided with recruitment materials (flyers, business cards etc.) for this purpose.

Second, respondents were also recruited to participate via advertising campaigns in local newspapers, newspaper websites and health fund websites. At last, we used several national and international online social networking websites such as Hyves and Facebook to invite smokers to participate in our smoking cessation study. All advertisements provided a link to the intervention website that enabled people to find more information about the intervention and participation.

**4b) CONSORT: Settings and locations where the data were collected**

n/a

**4b-i) Report if outcomes were (self-)assessed through online questionnaires**

self-assessed

**4b-ii) Report how institutional affiliations are displayed**

**5) CONSORT: Describe the interventions for each group with sufficient details to allow replication, including how and when they were actually administered**

**5-i) Mention names, credential, affiliations of the developers, sponsors, and owners**

This work was supported by ZonMw, the Netherlands Organisation for Health Research and Development (grant number: 20011007).

**5-ii) Describe the history/development process**

n/a

**5-iii) Revisions and updating**

no

**5-iv) Quality assurance methods**

**5-v) Ensure replicability by publishing the source code, and/or providing screenshots/screen-capture video, and/or providing flowcharts of the algorithms used**

**5-vi) Digital preservation**

[www.steunbijstoppen.nl](http://www.steunbijstoppen.nl)

**5-vii) Access**

Participants did not had to pay for the intervention.

**5-viii) Mode of delivery, features/functionalities/components of the intervention and comparator, and the theoretical framework**

video versus text messages

The content of the feedback messages was exactly the same in both the text and video condition. In the text condition, respondents received multiple sessions of CT text-based advice without any graphics or animations. In the video condition, the same tailored advice were presented by adults in a video message. Five different adult presenters (two males, three females) were selected out of a screening test of 20 persons and delivered the tailored advice in a TV 'news program' format. We used a mix of adults during the different sessions who presented the different tailored advices.

**5-ix) Describe use parameters**

**5-x) Clarify the level of human involvement**

The MREC decided that no MREC approval was necessary because respondents were not required to undertake any particular action.

**5-xi) Report any prompts/reminders used**

Respondents in the text and video condition received tailored feedback over three months (see Intervention and Figure.1 for details). After 6 months follow-up, all respondents were sent an email invitation with a link to the intervention website to fill out the 6-month follow-up measurement. Respondents who did not complete the follow-up measurement after one week were reminded by email to fill out the online questionnaire. A further reminder was sent after two weeks if necessary. Respondents who did not respond to the email invitation or the two reminders received another email, inviting them to briefly indicate their current smoking status. This email requested completion of a shortened version of the 6-month follow-up measurement, consisting of 10 (instead of 95) important smoking related questions, which they could return by email. Lastly, if this abbreviated email assessment was still not completed, respondents were called for a short telephone interview, asking the same questions as in the shortened online questionnaire.

**5-xii) Describe any co-interventions (incl. training/support)**

n/a

**6a) CONSORT: Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed**

At the 6-month follow-up measurement,

7-day point prevalence abstinence (PPA)

was self-assessed by one item asking respondents whether they had refrained from smoking during the last seven days (0=no; 1= yes) [48, 49].

In addition, prolonged abstinence (PA) was

self-assessed by one item asking respondents

whether they had refrained from smoking since

their last quit attempt (allowing for a two-week grace period during

which the respondent could smoke 1-5 cigarettes) (0=no;1=yes) [48, 49].

In line with the definition of PA, those who reported that they had

quit less than three months before the follow-up measurements

were not included as quitters in the PA measurement [49].

**6a-i) Online questionnaires: describe if they were validated for online use and apply CHERRIES items to describe how the questionnaires were designed/deployed**

see study protocol

**6a-ii) Describe whether and how “use” (including intensity of use/dosage) was defined/measured/monitored**

See Figure 1 in paper

**6a-iii) Describe whether, how, and when qualitative feedback from participants was obtained**

n/a

**6b) CONSORT: Any changes to trial outcomes after the trial commenced, with reasons**

no

**7a) CONSORT: How sample size was determined**

**7a-i) Describe whether and how expected attrition was taken into account when calculating the sample size**

**7b) CONSORT: When applicable, explanation of any interim analyses and stopping guidelines**

n/a

**8a) CONSORT: Method used to generate the random allocation sequence**

n/a

**8b) CONSORT: Type of randomisation; details of any restriction (such as blocking and block size)**

n/a

**9) CONSORT: Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned**

n/a

**10) CONSORT: Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions**

n/a

**11a) CONSORT: Blinding - If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how**

**11a-i) Specify who was blinded, and who wasn't**

They did not know to which study group they were allocated.

**11a-ii) Discuss e.g., whether participants knew which intervention was the “intervention of interest” and which one was the “comparator”**

n/a

**11b) CONSORT: If relevant, description of the similarity of interventions**

n/a

**12a) CONSORT: Statistical methods used to compare groups for primary and secondary outcomes**

Third, logistic regression analyses were conducted to investigate

the effectiveness of the intervention on the outcome measures

assessed at the 6-month follow-up measurements.

The analyses were performed adjusting for potential confounders,

including demographic variables (e.g. age, educational level, gender

and ethnicity) and variables with a theoretically expected disturbing

effect (e.g. addiction level, recruitment strategy, readiness to quit smoking,

depression, smoking related illnesses, self-efficacy, preparatory planning and coping planning), baseline differences, drop-out predictors and two

interaction terms (readiness to quit smoking by condition and educational level by condition). Where significant interaction terms were found,

stratified analyses were performed separately for each group.

**12a-i) Imputation techniques to deal with attrition / missing values**

Intention to treat: negative scenario & multiple imputation

**12b) CONSORT: Methods for additional analyses, such as subgroup analyses and adjusted analyses**

Where significant interaction terms were found, stratified analyses

were performed separately for each group.

## RESULTS

**13a) CONSORT: For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome**

We added an attrition diagram in which these results are shown.

**13b) CONSORT: For each group, losses and exclusions after randomisation, together with reasons**

We added an attrition diagram in which these results are shown.

**13b-i) Attrition diagram**

**14a) CONSORT: Dates defining the periods of recruitment and follow-up**

n/a

**14a-i) Indicate if critical "secular events" fell into the study period**

**14b) CONSORT: Why the trial ended or was stopped (early)**

n/a

**15) CONSORT: A table showing baseline demographic and clinical characteristics for each group**

See our flow chart

**15-i) Report demographics associated with digital divide issues**

see table 1

**16a) CONSORT: For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups**

**16-i) Report multiple "denominators" and provide definitions**

See table 3 & 4

**16-ii) Primary analysis should be intent-to-treat**

**17a) CONSORT: For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)**

See Table in paper

**17a-i) Presentation of process outcomes such as metrics of use and intensity of use**

**17b) CONSORT: For binary outcomes, presentation of both absolute and relative effect sizes is recommended**

See table 2 & 3 & 4

**18) CONSORT: Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory**

We also compared the effects of the intervention between low and high motivated smokers.

**18-i) Subgroup analysis of comparing only users**

**19) CONSORT: All important harms or unintended effects in each group**

No intended harms were reported.

**19-i) Include privacy breaches, technical problems**

**19-ii) Include qualitative feedback from participants or observations from staff/researchers**

## DISCUSSION

**20) CONSORT: Trial limitations, addressing sources of potential bias, imprecision, multiplicity of analyses**

**20-i) Typical limitations in ehealth trials**

First, some degree of recall bias may have occurred when respondents were asked to indicate their smoking status at the 6-month follow-up measurement. For financial reasons, we were unfortunately not able to make a biochemical validation of participants' self-assessed smoking status. Although future web-based intervention studies might be recommended to verify smoking status through the use of biochemical cotinine test as part of a more detailed follow-up assessment, it is also argued that this might be irrelevant, e.g. if anonymity has been guaranteed [54]. It may be that web-based interventions are attractive because they enable people to participate anonymously. This topic requires further elaboration in future studies. Second, we assessed smoking status after 6 months; however it might be valuable to replicate these findings and investigate whether these results persist over a longer follow-up period.

**21) CONSORT: Generalisability (external validity, applicability) of the trial findings**

**21-i) Generalizability to other populations**

**21-ii) Discuss if there were elements in the RCT that would be different in a routine application setting**

**22) CONSORT: Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence**

**22-i) Restate study questions and summarize the answers suggested by the data, starting with primary outcomes and process outcomes (use)**

Our study revealed several important findings. First, in both samples, the web-based video-based multiple CT smoking cessation intervention was effective in increasing 7-day PPA. The text-based multiple CT smoking cessation intervention however was only significantly effective in increasing 7-day PPA in people who adhered to minimal one session. The VCT condition was also more effective compared to the TCT condition, regarding 7-day PPA in people who adhered to minimal one session. Secondly, with regard to PA our study revealed only a differential effect of the intervention for people with a low or high readiness to quit.

**22-ii) Highlight unanswered new questions, suggest future research**

#### Other information

**23) CONSORT: Registration number and name of trial registry**

Netherlands Trial Register (NTR3102).

**24) CONSORT: Where the full trial protocol can be accessed, if available**

n/a

**25) CONSORT: Sources of funding and other support (such as supply of drugs), role of funders**

This work was supported by ZonMw, the Netherlands Organisation for Health Research and Development (grant number: 20011007).

**X26-i) Comment on ethics committee approval**

The current study was submitted for approval to the Medical Research Ethics Committee (MREC) of Atrium Medical Centre Heerlen. The MREC decided that no MREC approval was necessary because respondents were not required to undertake any particular action. The study was registered at the Dutch Trial Register (NTR3102).

The study was in line with the ethical codes of conduct of the APA [38].

**x26-ii) Outline informed consent procedures**

Online informed consent

**X26-iii) Safety and security procedures**

**X27-i) State the relation of the study team towards the system being evaluated**

Hein de Vries is scientific director of Vision2-Health, a company that licences evidence-based computer-tailored health communication tools.