Helping pregnant women stop smoking with a dual tasking treatment

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON48957

Source
ToetsingOnline

Brief title
Dual tasking with smoking, pregnant women

Condition

- Other condition
- Pregnancy, labour, delivery and postpartum conditions

Synonym
Nicotine dependency, smoking addiction

Health condition

rookverslaving

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit van Tilburg
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: craving, pregnancy, smoking cessation, working memory

Outcome measures

Primary outcome

Number of cigarettes smoked.

Secondary outcome

Smoking status (breathalyzer), Cigarette craving (The Obsessive Compulsive Drug Use Scale, OC-DUS, adapted for cigarette smoking). Nicotine dependence (Fagerstrom Test of nicotine dependence, FTND), social support (own questionnaire), perceived stress (Perceived Stress Scale, PSS-10/4), positive and negative affect (PANAS), self-reported loss of control.

Study description

Background summary

Smoking in pregnancy is associated with many adverse health outcomes for the unborn child including low birthweight (Shah & Bracken, 2000), stillbirth (Flenady et al., 2011), premature delivery (Pollack, Lantz, & Frohna, 2000), cardiovascular/heart defects, muscoskeletal defects, missing limbs/fingers, clubfoot, craniosynostosis, facial defects, eye defects, orofacial clefts, gastrointestinal defects, gastroschisis, anal atresia, hernia and undescended testes (Hackshaw, Rodeck, & Boniface, 2011). However, despite the adverse outcomes, fairly high smoking prevalences of 12*25% (US), 13*36% (Europe) and 13*31% (other countries) are reported in the period 1982-2001 (Schneider & Schütz, 2008). In a recent study done in the Netherlands, over the period 2001-2015 12,2% of pregnant women indicated having smoked during pregnancy (Lanting et al., 2015). A Dutch pregnant woman who was having trouble quitting smoking elaborates in a recent article from Nederlandse Omroep Stichting (NOS)

about the help she received: *I was sent home with a flyer and the advice I should do it on my own* (Nederlandse Omroep Stichting, 2017). The interview was done to advertise a recent Dutch campaign launched by state secretary Van Rijn to reduce the percentage of pregnant smokers (Nederlandse Omroep Stichting, 2017).

Several treatments to aid in smoking cessation during pregnancy have been researched. Lumley et al. (2009) found that all smoking cessation treatments (cognitive behavioural therapy/motivational interviewing, advice and counselling based on assessment of stages of change, interventions using feedback on fetal health status/mother*s health, provision of rewards and incentives, provision of pharmacotherapies and other therapies, for example hypnosis) compared to no treatment, show a small but statistically significant improvement in smoking cessation outcomes in late pregnancy (RR = 0.94, 95% confidence interval (CI) 0.93-0.96). Thus in the intervention condition 6% less women continued to smoke (Lumley et al., 2009). Because most smoking cessation programs offer multiple, partly overlapping modules in their treatment, main components were identified in Lumley*s study to allow for subgroup analyses. Subgroup analyses comparing the main intervention strategies showed that contingency management showed a significantly larger effect (RR = .76, 95% CI 0.71 to 0.81) than Cognitive Behavioural Therapy (CBT: RR = .95, 95% CI 0.93 to 0.97) and Nicotine Replacement Therapy (NRT) (RR 0.95, 95% CI 0.92 to 0.98). Interventions using a main component of *stages of change* showed a significant reduction in smoking outcomes in late pregnancy (RR = .99 95% CI 0.97 to 1.00). Interventions using feedback were found not to be significantly effective (RR = .92, CI 0.84 to 1.02). However, great heterogeneity makes it difficult to interpret the results of Lumley et al. (2009) at a general level. Two other meta-analyses have looked at NRT alone (Coleman, Chamberlain, Cooper, & Leonardi*Bee, 2011; Trivedi, 2013) and concluded that there were no significant treatment effects compared to placebo (respectively RR = 1.76, 95% CI: 0.92-3.36; RR = 1.33, 95% CI 0.93*1.91). A narrative review focusing on partner focused support (Hemsing, Greaves, O*Leary, Chan, & Okoli, 2012), found that 7 out of 9 trials found no effect of the intervention on smoking cessation. Lastly, Greaves et al. (2011) outlined the evidence for contingency based interventions and concluded the intervention to be effective on the short term. In conclusion, the evidence for successful smoking cessation interventions in a pregnant population is not very compelling.

In addition to most treatments not having the desired effect, the current array of treatments has significant drawbacks associated with them. For example, for NRT researchers have their doubts about safety for the unborn child (Coleman et al., 2011; Trivedi, 2013). Still, clinical guidelines in the Netherlands recommend using NRT when patient smoke more than 10 cigarettes a day, even when they are pregnant (Kwaliteitsinstituut voor de Gezondsheidszorg CBO, 2009). Drawbacks of other (effective) interventions are for example the need for specialized personnel, significant time investment (cognitive behavioural therapy), ethical and financial considerations, as well as societal acceptability (contingency management) (Greaves et al., 2011). Because of these drawbacks, the lack of efficacy within this population and the specific needs

within the (Dutch) healthcare system, there is need for a safe, acceptable and cost and time inexpensive new treatment.
As in most addictions, two mutually interconnected emotional and behavioural components can also be identified in smoking addiction: first there is the emotional aspect of wanting, or even needing the cigarette. If this component stays unanswered to long, the addicted subject experiences craving. The second aspect is the behavioural component: smoking cigarettes. Psychological anti-smoking interventions target either one of these components or both. The current study focuses on the first aspect of (cigarette) cravings, since research has shown that it*s an important pathway to smoking relapse (Zhou et al., 2009), especially post quit craving (Killen & Fortmann, 1997; Wray, Gass, & Tiffany, 2013).

Eye Movement Desensitation and Reprocessing (EMDR). One treatment which has received research attention in treatment of cravings and addictive behaviours is EMDR. Originally stemming from trauma research, EMDR is a treatment which is effective in treating traumatic memories. Currently, the best explanation for EMDR comes from working memory theory (Andrade, Kavanagh, & Baddeley, 1997). It states that by recalling a traumatic memory from long term memory, it becomes labile in the working memory. By engaging in a second task (in the traditional EMDR procedure fast horizontal eye movements by following the therapist*s hand) while simultaneously thinking of the traumatic memory, competition is created between the two tasks within the limited cognitive resources of the working memory. By repeating this process several times, emotionality and vividness of the traumatic memory are reduced. The implication is then that eye movements are not necessary, but that sufficient working memory load in general is critical for the intervention to be successful (Van den Hout & Engelhard, 2012). Therefore, procedures as EMDR and similar interventions taxing working memory can be referred to as dual tasking procedures (van den Hout & Engelhard, 2012).
Perhaps encouraged by the fact that craving is shown to take up cognitive resources (Kemps, Tiggemann, & Grigg, 2008) and its role in relapse (Killen & Fortmann, 1997; Wray et al., 2013) and smoking (American Psychiatric Association, 2013), researchers have tried using EMDR to treat memories associated with high feelings of craving. Littel, van den Hout, and Engelhard (2016) conducted a proof of principle study to research if EMDR has potential in both desensitizing addiction related memory representations and imagery. Students were asked to formulate a memory or emotional state in which they experienced craving and smoked a cigarette. While recalling their memory, the experimental group engaged in eye movements. Littel et al. (2016) found that eye movements has potential in attenuating craving and associated imagery. A second study conducting a proof of principle of EMDR in addiction was done by Markus, de Weert-van Oene, Woud, Becker, and DeJong (2016). In their study three specific personal memories were formulated that were ordered from high to low craving and treated with eye movements. Positive, short-term results were found on craving. However, these results were not contained at follow-up. In addition, no results were found on smoking outcomes. Markus et al. (2016) call

for dose response studies in which exposure is increased and daily measurements are made. Lastly, studies looking at interfering with craving by means of visuospatial interference showed that craving for cigarettes decreased compared to control in the lab (May, Andrade, Panabokke, & Kavanagh, 2010) and via digital delivery by playing Tetris (Skorka-Brown, Andrade, Whalley and May, 2015). However, all of these studies were carried out in non-help seeking groups.
The potential for a dual tasking treatment in smoking cessation in the short term shows promise. Firstly, because of the behavioral nature of the treatment, there is a minimization of adverse side effects (both to the unborn child and mother). In addition, the cost effectiveness of an automatized dual tasking treatment is of great significance in this population. Lastly, because this population is likely very motivated to stop smoking, it will serve as an ultimate test for the efficacy of a dual tasking intervention in smoking cessation.
Thus, the current study investigates whether a dual tasking treatment serves as a potential efficacious treatment for reduction of cigarette cravings and smoking cessation in pregnancy. First, the experimenter identifies a number of idiosyncratic situations memory which elicit high feelings of craving in the pregnant woman. These idiosyncratic situations are then used throughout the study to activate feelings of craving. While craving is activated, participants play a puzzle game on the tablet (dual tasking).

Study objective

Specifically, the first objective of the current study is to compare the efficacy of a dual tasking treatment versus treatment as usual in the treatment of smoking addiction in a pregnant population on smoking outcomes.

Secondary objectives:
Effect of the intervention on smoking (breathalyzer) nicotine dependence, and craving as a mechanism. Additionally, by looking at patient characteristics, such as perceived stress, social support and positive and negative affect, an attempt is made to be able to see which combination of treatment works for whom.

Study design

This study is an individual randomized controlled trail with 2 arms: Full dose condition and Treatment as Usual+ (TAU+) only. The two groups are compared on variables measured on T1 and T2 . This amounts to a 2x2 design with the between factor being *condition* and the within factor *time*.

Justification of design
Because of the vulnerability of the group of pregnant women and their unborn babies, the control group is set to an *upgraded* Treatment as Usual. Since the

gynecologists and midwives indicated that help is available but not included in the standard package of care, this was deemed appropriate. Moreover, this *upgraded* TAU controls for differing activation of the app between groups.

Because of the experimental nature of this intervention, it was deemed appropriate to compare a maximum dose intervention to the above mentioned control condition.

Intervention

All interventions will be performed by the first researcher (Tom IJdema) or by Master students Medical or Clinical psychology (from now on: test leaders). They are all trained by the senior, EMDR schooled therapist Kees Korrelboom).

Treatment as Usual+ (TAU+): control
All participants will receive TAU+ when enrolled in the study. The test leader will have a short talk about the downsides of smoking, one booklet (*Rookvrij ook jij*) is handed out with anti-smoking tips and additional resources which the pregnant woman may pursue. While the use of nicotine patches of gum and e-cigarettes is not an exclusion criterion, this use is not encouraged.
However, its use will be registered in advance of and during treatment.
Participants assigned to the *TAU+ only* condition will receive an app in which they receive facts about smoking. To ensure equal activation among conditions, the prompts filled with information will follow the same schedule as the prompts in the dual tasking app. Since the TAU folder contain mostly links and telephone numbers for additional resources rather than information, additional folders were used for the app. These are: "Rookvrij zwanger, dat bevalt beter" (rougly translated to: *Smokefree pregnant, that feels better' from TRIMBOS instituut) and "Wat je moet weten over Alcohol en Roken voor, tijdens en na de zwangerschap" (roughly translated to: *what you should know about alcohol and smoking before, during and after pregnancy* from TRIMBOS and STAP).

Full dose
In addition to receiving treatment as usual, participants assigned to the *full dose intervention* will also receive therapist-assisted dual tasking treatment during a f-t-f session. Treatment is given according to a standardized dual tasking protocol targeting the desensitization of craving. In line with the protocol, idiosyncratic memories and daily situations are targeted which are associated with high feelings of craving.
The dual task intervention consists of playing a puzzle game on a touch screen tablet. The researcher helps the patient to formulate three trigger situations which the patient associates with high feelings of craving. A short script is formulated. Next, three keywords are formulated to summarize the trigger situation and these words are put into the software. Then, the patient selects nine other general keywords associated with smoking from a list, which are then put in the software as well. Then, the patient is stimulated to visualize the memory and the associated craving as vividly as she can imagine.

Then, the participants fills in a manipulation check. Then she engages in completing the pictures on the tablet. While playing the puzzle game, the selected keywords appear in the top of the screen to keep stimulating the participant to think of their craving and thus emphasizing the dual tasking aspect of the intervention. After the participant has completed four sets of 45 seconds playing the puzzle game, the participant fills in the manipulation check. Thereafter, the interviewer assesses the next trigger situation in the same procedure described above and the puzzles are played in the same manner. This is repeated until 3 trigger situations have been completed. See below for a graphical representation of the intervention.
After the procedure, the mobile app (based on the same principles as in the session) is uploaded on the patient*s personal mobile phone. The personalized keywords are loaded into their app and instructions are given to practice at home. After four weeks of practicing with the dual tasking app at home, the patient will come to the hospital for an end evaluation. The app is closed off for more practice after that.

Study burden and risks

For the current study the benefits greatly outweigh the risks. With regard to burden: the participant is required to invest a minimum of 1 hour and 40 minutes (session 1: max 90 minutes, session 2: max 10 minutes). In addition, questionnaires are conducted for a total of 20 minutes. Lastly, it is advised to do the exercise on the app (for a total of 4 hours). The time investment is significant should the participant choose to do all the exercises on the mobile phone. However, these brief moments (3 minutes per exercise) are spaced out throughout the days and 4 weeks of the intervention. The sessions in the hospital are planned consecutively to a regular pregnancy consult at the hospital to minimalize burden on the participant.

The risks for participating in the study are considered low. Researchers are trained and supervised intensively by an experienced EMDR therapist. The protocol is highly standardized. Secondly, the research will take place in the hospital and midwive practices, where trained personnel is nearby should a calamity arise. Thirdly, inducing craving in participants without presence of a researcher could be considered a risk. However, previous research doesn*t report risk associated with this treatment (Littel et al., 2016; Markus et al., 2016). Lastly, the participants are free to stop with the study, or to seek out additional treatment, without consequences for treatment in the hospital.

With regard to benefits, it was shown in several studies that there were positive or buffering short term effects on smoking craving measures (Littel et al., 2016; Markus et al., 2016; May et al., 2010; Skorka-Brown et al., 2015). Combined with the fact that most existing treatments are neither safe, effective or cost-effective in pregnant women, we believe it to be justifiable to test the efficacy of the treatment in this population.

Contacts

Public
Universiteit van Tilburg

Warandelaan 2
Tilburg 5037 AB
NL
Scientific
Universiteit van Tilburg

Warandelaan 2
Tilburg 5037 AB
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1. Participants must be over 18 years
2. Pregnant
3. Smoker (smoked 1 or more cigarettes in the last 7 days)
4. In possession of an Android of iPhone smartphone
5. Comprehension of the Dutch language must be sufficient.
6. Willingness to try stop smoking
7. Informed consent

Exclusion criteria

- Due to deliver baby in 4 weeks of the start of the intervention

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-03-2018
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO Date:	04-12-2017
Application type:	First submission
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	20-03-2019
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL63161.028.17