Personalized Mobile Pregnancy Program (PMPP): development and evaluation.

Published: 03-10-2008
Last updated: 07-05-2024

This project aims to finalize the development (Study A) and to evaluate the efficacy (Study B) of a personal, individually tailored PMPP with interventions directed to stop smoking by 30% and/or alcohol consumption by 20% for women who are planning...

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

Summary

ID

NL-OMON31953

Source
ToetsingOnline

Brief title
Personal Mobile Pregnancy Programme (PMPP).

Condition

- Other condition

Synonym
pregnancy complications

Health condition

zwangerschapscomplicaties en ziekten tgv roken en of alcoholgebruik

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: zonmw

Intervention

Keyword: Health_benefits, Intervention, Lifestyle, Mobile_phone

Outcome measures

Primary outcome

Study A

-Content evaluation. The content evaluation consists of the following: opinions on the number and length of the questions and messages, (technical) usability, readability, comprehensibility, attractiveness and convenience and ease of navigating through the PMPP, perceived personal relevance, individualization, accuracy and persuasiveness of the feedback. A debriefing interview with each woman to gain additional information about usability, applicability and acceptance will be held.

- Process evaluation: Type of mobile phone, for what services they use their mobile phone (e.g. calling, SMS, WAP, MMS), frequency of use of these services are measures of feasibility (% of a sample owning a mobile phone and using specific mobile phone services) and acceptance (% of those owning a mobile phone and agreed to provide their mobile phone number to participate). Server registrations of the number of sent and returned questions and messages and the speed of response delivers quantitative information on usability and applicability.

Outcome measures of process and content are compared for different groups of

participants (e.g. socio-economic status, ethnic groups).

Study B

- short term primary outcome: proportion of women who smoke, the proportion of women who use alcohol, as measured at 1 and 6 months after the start of the intervention

- long term primary outcome: proportion of women who smoke, the proportion of women who use alcohol, as measured at +13 months and +18 months after the start of the intervention (= +1 month and +6 months after the PMPP-interventions has ended).

Secondary outcome

Study B

(1) if case of no cessation: the amount of reduction in smoking and/or a reduction in alcohol use;

(2) outcomes of biomedical measurements and blood sampling; both assessed at baseline, +1, +6, +13 and +18 months after start of the intervention.

For analytical purposes, participants who both smoke and use alcohol are considered a primary success if at least one of these risk factors is stopped.

Differential effects according to the interventions on smoking and/or alcohol in the same person, pregnancy, ethnicity, and SES will be further explored.

Study description

Background summary

In The Netherlands around 30% of women in reproductive ages smoke and more than 80% consume alcohol. Often these risk factors coincide, approximately 90% of smokers also consume alcohol. Besides the contribution to cardiovascular disease and cancer, smoking and alcohol use also detrimentally effect fertility, pregnancy course and birth outcomes. Therefore, women planning pregnancy are recommended to stop smoking and alcohol already in the preconception period. Nevertheless, Dutch studies show that during pregnancy approximately 25% of women still smoke and >35% still use alcohol. Therefore, there is plenty room for improvement. Despite current preconception care initiatives, in which women planning pregnancy are informed and advised to stop smoking and using alcohol, changing these behaviors is very difficult. In this context, new e-health communication channels enabling interactive and personalized health communications are very promising. The mobile phone, in particular the short message service (SMS), has the potential to reach many individuals at any desired time and place in order to provide personally tailored information that can contribute to a healthier lifestyle. The development of lifestyle programs on the mobile phone (PMPP) supported by (mobile) Internet, however, is still in its infancies and absent for women planning pregnancy. Furthermore, research on its usability and efficacy is scarce. Therefore, the PMPP directed to stop smoking and alcohol consumption can be an important first step towards more comprehensive interactive lifestyle interventions in these highly motivated young women that are planning pregnancy.

Study objective

This project aims to finalize the development (Study A) and to evaluate the efficacy (Study B) of a personal, individually tailored PMPP with interventions directed to stop smoking by 30% and/or alcohol consumption by 20% for women who are planning pregnancy. The harmful effects of these unhealthy behaviors on reproduction are regarded the strongest *motivation*, and the preconception period as *the window of opportunity* to reach this goal.

Study design

The project is divided in three phases.
In Study A (Development,7 months) the PMPP will be tested for usability, appreciation, acceptance and feasibility in a step-wise formative evaluation in 100 women of the target group. After screening on folic acid use, vegetable and fruit intake, smoking and alcohol use, baseline information on demographics, health status, cognitive determinants and other lifestyles will be obtained by questionnaires. After 1 and 3 months intervention, questionnaires for post-test evaluation will be filled out. Blood samples will be taken for compliance.
In Study B (Efficacy, 34 months), efficacy on smoking cessation by 30% and reduction of alcohol consumption by 20% will be tested in a randomized

controlled trial with the PMPP intervention (tailored feedback aimed at motivation, action initiation and maintenance advice through 12 months And conventional preconception care)and one control intervention (conventional preconception care only). The same target group will be enroled and screened on smoking and alcohol use. Next, the participants are allocated to either the PMPP intervention (n=219) or to the control intervention (n=219. In both groups, base line information will be obtained on demographics, health status, pregnancy, smoking, alcohol, cognitive determinants and other lifestyles by questionnaires. Questionnaires to evaluate efficacy will be filled out 1, 6 (short-term), 13 and 18 months (long-term) after study entry. Blood samples will be taken for compliance, e.g., cotinine.

Intervention

PMPP: Intervention on the lifestyle factors (folic acid, vegetables, fruits, alcohol, smoking) is based on (mobile) internet and SMS

Study burden and risks

Besides the very small risk of standard venapuncture there are no significant risks to be expected from the intervention with PMPP.
It is very likely that a significant contribution to the future primary and secondary prevention of subfertility and adverse pregnancy course and birth outcomes by preconception smoking cessation and reduction of alcohol use in women planning pregnancy can be gained.
When the PMPP turns out to be unsuccessful (proof of principle), it is questionable whether it has to be further developed for the general population to reduce cardiovascular disease and cancer in later life.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Dutch language in word, reading and understanding
pregnancy wish
alcohol use
smoking

Exclusion criteria

Not familiar with the Dutch language
no pregnancy wish

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-05-2008
Enrollment:	538
Type:	Anticipated

Ethics review

Approved WMO Date:	03-10-2008
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	03-01-2011
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL22724.078.08