MARS – Cash payment and counseling during pregnancy

MARS

Study protocol

Number of the Ethical Approval: BB 154/20
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1. Background

Smoking constitutes a risk of disease regardless of the dosage. Nevertheless, smoking is common among women in childbearing age and especially among those with a lower socio-economic status. Meta-analyses have shown that psychosocial interventions for quitting smoking have positive effects on both mother and child. Further, there is evidence from international studies on the efficacy of rewards in combination with psychosocial counseling. However, there is a lack of German studies on incentives to achieve smoking cessation among pregnant women. Therefore, in our current study, we ask how rewards are most effective in supporting smoking cessation in pregnancy.

2. Objectives

The primary outcome of this pilot study is the adherence of initially smoking pregnant women to the monitoring of the smoking status up to the birth of the child / children. Secondary outcomes are (1) differences in number of cigarettes per day by self-report, (2) number of attempts to stop smoking by self-report, (3) number of attempts to stop smoking by carbon monoxide measurement. All outcome data are collected between baseline and up to pregnancy week 36.

3. Methods/ Study design

The study region is Schwerin, a city with approximately 95.000 inhabitants in Northeast of Germany. MARS is a pilot study consisting of up to three assessments for the completion of a standardized survey at three time points (baseline, pregnancy week 36 , and 8 weeks after the delivery, as well as participation in the evaluation of the smoking status twice a week using breath carbon monoxide (CO) monitor piCObaby™ Smokerlyzer (Bedfont Scientific). After an initial survey, the participating women are scheduled twice a week for counseling and evaluation of the smoking status.They will receive cash payment of 25 Euro if her CO reading does not exceed value "3" on two consecutive dates per week.

Study population

The study population consists of pregnant women who meet the following inclusion criteria:
(1) Current pregnancy between pregnancy week 15 and 23,
(2) Current smoking of at least one cigarette per day

Recruitment

Pregnant women will be recruited by the staff of a counseling center for pregnant women in Schwerin. A short personal screening is performed to assess the inclusion criteria. For women who meet the inclusion criteria, an initial survey is conducted and data on socio-demographic variables (age, partnership, number of children, education), current pregnancy, smoking, alcohol consumption, physical activity, fruit and vegetable consumption are collected. The participating women are scheduled twice a week for counseling and evaluation of the smoking status. They will receive cash payment of 25 Euro if their CO reading does not exceed value "3" on two consecutive dates per week. A second survey will be conducted in pregnancy week 36 and a third survey, eight weeks after the delivery.

Documentation, data storage, and data security

All participants receive a study ID at the first visit in the examination center to ensure their correct assignment over time. Data from the self-administered questionnaire and data from the breath carbon monoxide examination will be stored in a central data base. Personal data (name, address, telephone number) will not be entered in the data base. The data storage is managed according to the standards for data security and data privacy. Only the staff members of the project team have access to personal data during the study.

Data analysis

Adherence to the study protocol will be investigated using drop-out analysis. Descriptive statistics of (1) differences in number of cigarettes per day by self-report, (2) number of attempts to stop smoking by self-report, and (3) number of attempts to stop smoking by carbon monoxide measurement will be calculated. The software package STATA (version 15.1) will be used.