An innovative network-based approach to study and enable well-inFormed dEcision-Making among TurkIsh- and MoroccaN-Dutch women regarding cervIcal caNcer scrEening: the FEMININE study

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20819

Source
NTR

Brief title
FEMININE

Health condition

Cervical cancer (baarmoederhalskanker)

Sponsors and support

Primary sponsor: ZonMw (nr. 531002030)
Source(s) of monetary or material Support: ZonMw (nr. 531002030)

Intervention

Outcome measures

Primary outcome

The primary outcome measure will be the change in IDM level after receiving the intervention.

Secondary outcome

Secondary outcome measures will be changes in levels of decision-relevant knowledge, attitude, (intentional) screening participation, and other IDM influencing factors after receiving the intervention. We will also estimate the baseline IDM level using the RDS estimators (if the sociodemographic characteristics stabilise through two consecutive waves, which is in case of a change of less than 2%).

Study description

Background summary

To detect cervical cancer (CC) in an early treatable stage, every five years women in the Netherlands (aged 30 to 60 years) are invited to participate in the national screening programme. Since 2017, the Netherlands switched from cytology-based to human papillomavirus (HPV)-based screening because of substantial evidence that the latter is more effective in reducing the incidence of cervical (pre)cancer. An important advantage of HPV-based screening is that HPV testing can be done on a sample collected by women themselves (i.e., 'self-sampling'). Despite the availability of a national free of charge CC screening programme, participation is very low among migrant women, in particular among Turkish- and Moroccan-Dutch. Based on data in the period of 2005-2010, CC screening participation is 64% among Turkish- and 53% among Moroccan-Dutch women, much lower compared to the participation of 79% of Dutch women. It is crucial to investigate whether this participation is based on informed decision-making (IDM), since every women is entitled to individually consider the pros and cons of the screening in order to make an autonomous decision regarding her participation.

An informed decision can be defined as one that is based on decision-relevant knowledge while the decision-maker's attitude is consistent with her (intended) screen behaviour. Our focus group study (FEMININE Phase I) showed that women were aware of the pros (except the possibility to perform self-sampling), but could not name the cons of the screening. Women stated that it is a personal decision, where some shared the difficulties they experience with making this decision "right" and have doubts about what to choose. Furthermore, preliminary results of our quantitative study (FEMININE Phase II, n = 482) show that 53% of the women made an informed decision. For self-sampling, only 25% ever heard of self-sampling and also only 25% of the women made an informed decision regarding self-sampling. This indicates an overall limited IDM among Turkish- and Moroccan-Dutch women. This is especially worrying

as the CC incidence is higher among these women and more than half of the CCs occur in women who have not participated in screening.

Culturally Sensitive Educational Films (CSEFs) have been proven successful in improving IDM for prenatal screening, showing great potential for CC screening. As family, friends, and acquaintances influence health behaviour, spreading CSEFs through a social network approach can help strengthen the effect of this intervention.

We, therefore, aim to develop and use an innovative peer-driven social network intervention using CCEFs to improve IDM among Turkish- and Moroccan-Dutch women.

Our main research question is:
To what extent is CC screening (non)participation based on an informed decision and to what extent can CCEFs, tailored to their information needs, distributed through their social networks improve the IDM of Turkish- and Moroccan-Dutch women, aged 30-60 years?

Our proposed intervention:
We will develop three CSEFs. These are equal content-wise, but differ in the actresses (Moroccan, Turkish) and the spoken language. The CSEFs will be filmed at a setting where women feel the comfort to talk about this sensitive topic. These films will focus on one woman (in doubt about whether or not she should go to the screening) in interaction/dialogue with other women (W2 and W3, daughters and/or friends) discussing the decision whether or not to participate in CC screening through multiple scenes. W1 has a positive screening intention and W2 has a negative screening intention. The duration of each film will be maximally 2.5 minutes. Since all women will either receive the leaflet or the leaflet and CSEF, we chose to predominantly incorporate the emotional side of their reasoning (e.g. experiences and fears) in the CSEF and the rational side in the (already existing) current leaflet.

We will collaborate with Turkish and Moroccan actresses to develop CSEFs in Turkish, Moroccan-Arabic, and Moroccan-Berber (these actresses will be recruited by Zouka Media). Abdelkarim and Asma El-Fassi (founder and production leader of Zouka Media resp., see www.zouka.nl) will develop the CSEFs in close consultation with the researchers and with Prof. dr. Martine Bouman (Centrum Media & Gezondheid). They developed similar documentaries about their first-generation Moroccan mother and father. These documentaries are called “Mijn vader, de expat” and “Toen ma naar Mars vertrok”, of which more information can be found on https://www.2doc.nl/documentaires/series/2doc/2015/maart/mijn-vader-de-expat.html and https://www.2doc.nl/documentaires/series/2doc/2018/oktober/toen-ma-naar-mars-vertrok.html. To validate the content of these CSEFs, meetings will be organised with experts on language, culture, and CC. The CSEFs will be pilot tested in a small sample, as well as with representatives of our target populations in order to verify whether the prototype’s feasibility, content, and layout match their needs and requirements. To ensure our questionnaire is understandable for women (with limited (Dutch) literacy), the questionnaire will be extensively tested among low-literate native Dutch women by Pharos (these women will be also recruited via Pharos).

Turkish- and Moroccan-Dutch women aged 30 to 60 years old will be recruited via several

online communities, such as LinkedIn, SGAN (Stichting Gezondheid Allochtonen Nederland), and AMAN (Associatie Marokkaanse Artsen Nederland). Thereafter, a randomised intervention study with online respondent-driven sampling (RDS) will be conducted with a control group and an intervention group. Each 'seed' and her following study participants represent a recruitment tree. Each individual will be randomised to the intervention group or control group via an automated functionality already present in our existing online RDS platform.

Self-reported questionnaires in the language of choice (Dutch, Turkish, and Arabic) will be used before and after to measure the effect of the intervention:
- The control group will first receive a questionnaire to measure the baseline IDM and its influencing factors. Thereafter, the information leaflet that nowadays is being sent with the invitation letter, and directly afterwards the same questionnaire. By an already existing functionality in our RDS platform, we can assess whether or not they studied the leaflet by their time spend per page (and thus with reading the leaflet).
- The intervention group will first receive a questionnaire to measure the baseline IDM and its influencing factors. Subsequently, participants in this group will receive the information leaflet and CCEF, and directly afterwards the same questionnaire. By an already existing functionality in our RDS platform, we can assess whether or not they studied the leaflet and watched the CSEF by their time spend per page (and thus with reading the leaflet and watching the CSEF).

Turkish-Dutch women will be offered the CSEF in Turkish, and Moroccan-Dutch women will be offered the CSEF in Moroccan-Arabic and Moroccan-Berber. Both groups are asked to fill in the questionnaires and to invite 2 of their social contacts (other Turkish- and/or Moroccan-Dutch women aged 30 to 60 years) to do the same. It may be possible to have crossover between the two groups if for example a participant in the control group recruits someone already included in the intervention group. To prevent this, we will limit the number of invitations allowed (2 based on the results of our previous research).

At the end of the questionnaire, all participants will be asked whether or not they want to fill in the follow-up questionnaire after 4 weeks. Through this short follow-up with limited questions, we will measure the long-term effect of having read the leaflet (control) or having read the leaflet and watched the CSEF (intervention). At the end of the study, information will be given about the way the screening is organised and when birth cohorts are scheduled for screening.

With our randomised before and after design, we will be able:
- To evaluate the effect of an information leaflet (the current communication method) on IDM and its influencing factors regarding CC screening for these specific target populations, which has never been investigated.
- To evaluate the effect of an information leaflet combined with a CSEF on IDM and its influencing factors regarding CC screening.
- To compare IDM and its influencing factors for those intervened with an information leaflet versus an information leaflet combined with a CCEF, which results in an evaluation of the CSEF effect.

Study objective

A 10% point difference between the intervention group and control group in IDM is expected.

The sample size calculation is based on a worst-case scenario with regard to precision. For a binomial distribution, the widest distribution and thus largest needed sample size is around 50%. Therefore, the IDM increase was set and expected from 48% to 58%.

Study design

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Intervention

The interventions consist of a Culturally Sensitive Educational Film in Turkish, Moroccan-Arabic, or Moroccan-Berber (subtitled in Dutch) for the intervention group and the current information leaflet sent with the invitation for CC screening for the control group.

Contacts

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Eligibility criteria

Inclusion criteria

- Turkish-Dutch women aged 30-60 years: women born in Turkey and having at least one parent born in Turkey (first-generation migrants) or women born in the Netherlands and having at least one parent born in Turkey (second-generation migrants).
- Moroccan-Dutch women aged 30-60 years: women born in Morocco and having at least one parent born in Morocco (first-generation migrants) or women born in the Netherlands and having at least one parent born in Morocco (second-generation migrants).

Exclusion criteria

No Turkish- or Moroccan-Dutch woman aged 30-60 years.

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2020

Enrollment:	1930
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	11-03-2020
Application type:	First submission

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
NTR-new	NL8453
Other	METC Utrecht : WAG/mb/19/013070

Study results