FÆLLES ANSØGNINGSSKEMA
TIL KVALITETS- OG UDVIKLINGSMIDLERNE UNDER KEU

REGION: Midtjylland	DATO: 31/7/2018	LØBENR.: (udfyldes af regionen)

STAMOPLYSNINGER

ANSØGERS NAVN, MAIL,TLF mm. Mette Tranberg, post doc, ph.d.,mettrani@rm.dk, 784 20264, Afdeling for Folkeundersøgelser, Regionshospitalet Randers. Mette Tranberg har været projektleder på et tidligere forskningsprojekt, hvor kvinder i alderen 30-64 år, som var bosiddende i Region Midtjylland fik tilbudt mulighed for hjemmeopsamlet prøve.

PROJEKTANSVARLIG: Mette Tranberg

ØVRIGE DELTAGERE: Berit Andersen, ledende overlæge, ph.d., professor, Afdeling for Folkeundersøgelser, Regionshospitalet Randers og Institut for Klinisk Medicin, Aarhus Universitet og Patologisk Institut, Regionshospitalet Randers.

PROJEKTBESKRIVELSE

PROJEKTETS TITEL: Forebyggelse af livmoderhalskræft hos ældre kvinder ved at udvide nuværende screeningsalder

PROJEKTETS (ANSØGNINGENS) EMNE: Screening for livmoderhalskræft hos ældre kvinder

OPDATERING VEDR. TIDLIGERE AFHOLDT PROJEKT (sæt x):

NYOPRETTET PROJEKT (sæt x):x

FORMÅL:
Projektets overordnede formål er at:

- Undersøge gennemførbarheden og effekten af at udvide screeningsalderen i det danske livmoderhalskræftscreeningsprogram til at omfatte kvinder i alderen 65-69 år, således at denne aldersgruppe tilbydes samme vilkår som yngre kvinder.
- Undersøge om udvidelse af screeningsalderen kan have samme positive betydning for forekomsten og dødeligheden af livmoderhalskræft, som indførsel af screeningsprogrammet har haft for aldersgruppen 23-64 årige.

I projektet gives tilbud om screening ved besøg hos egen læge eller hjemmeopsamlet prøve (efter eget valg) til kvinder bosiddende i Region Midtjylland, og effekten – herunder både fordele og ulemper - sammenlignes med kvinder bosiddende i andre regioner, som ikke får tilbuddet.

PROJEKTBESKRIVELSE (kort resumé) – selve projektbeskrivelsen vedlægges som bilag, der kan linkes til.

Screening for forstadier til livmoderhalskræft tilbydes i dag kvinder i alderen 23-64 år, hvilket har ført til et bemærkelsesværdigt fald i både forekomst og dødelighed. Set i lyset af den stadig højere forventede levetid, og en høj forekomst af livmoderhalskræft samtidig med høj dødelighed hos de ældste kvinder anbefaler Sundhedsstyrelsen, at der iværksættes projekter, der kan understøtte,

om der kan opnås lignende resultater med fald i forekomst og dødelighed ved at medtage gruppen 65-69 årige i screeningsprogrammet. I 2017 blev der som led Kræftplan IV taget politisk initiativ til, at kvinder født før 1948 (dvs. 69 år eller ældre) blev tilbudt screening. Denne mulighed var dog ikke gældende for kvinder under 69 år, der samtidig var for gamle til at indgå i det eksisterende screeningsprogram.

Det eksisterende screeningsprogram er udfordret af en deltagelse på kun 65 %, og at 45 % af alle livmoderhalskræfttilfælde forekommer hos kvinder, som ikke har deltaget regelmæssigt i screening. Undersøgelser har vist, at en barriere for deltagelse er, at screening normalvis kræver en gynækologisk undersøgelse, men et nyt studie fra Afdeling for Folkeundersøgelser, Regionshospitalet Randers har vist, at tilbud om hjemmeopsamlede prøver til undersøgelse for høj-risiko human papillomavirus (HPV) øger screeningsdeltagelsen især blandt tidligere ikke-deltagere i alderen 30 til 64 år. Effekten ses hos alle sociale grupper, men effekten er størst blandt socialt udsatte grupper. Studiet viste også, at kvinderne var gode til at tage de hjemmeopsamlede prøver, da kun 0,3 % af de returnerede prøver var uegnet til HPV testning. Desuden har Afdeling for Folkeundersøgelser i et andet studie dokumenteret, at en hjemmeopsamlet prøve er lige så god til at påvise om kvinden har en HPV infektion som en celleprøve taget hos egen læge.

Det er muligt, at en kombination af tilbud om hjemmeopsamlede prøver, særlig målrettet de kvinder, som ikke har deltaget tidligere, og den sædvanlige mulighed for at søge egen læge for en undersøgelse, kan give den bedst mulige effekt af et eventuelt initiativ om at udvide screeningsalderen.

Derfor igangsætter Afdeling for Folkeundersøgelser et populationsbaseret kohorte-studie, som inkluderer alle kvinder i Danmark i alderen 65-69 år, som ikke har fået foretaget en screeningsundersøgelse inden for de sidste 5 år og ikke er frameldt programmet.

Kvinder, som opfylder disse inklusionskriterier og er bosiddende i Region Midtjylland på rekrutteringstidspunktet udgør interventionsgruppen (20.000 kvinder). Kvinder i de øvrige regioner fungerer som kontrolgruppe (ca. 80.000 kvinder) og modtager intet tilbud om screening, men hvor der som vanligt vil forekomme enkelte opportunistiske undersøgelser (celleprøver taget udenfor det organiserede screeningsprogram).
Der vil blive tale om to delstudier:
1. delstudie: Vil fungere som et catch-up studie inkluderende kvinder, hvor der er gået mere end 5 år siden seneste screeningsundersøgelse
2. delstudie: Løbende inklusion af kvinder, hvor der er gået 5 år siden seneste screeningsundersøgelse. Rekrutteringen af disse kvinder forventes at forløbe over 2 år.

For begge delstudier vil kvinder i interventionsgruppen (Region Midtjylland) bliver tilbudt at få taget en celleprøve fra livmoderhalsen hos egen læge eller at bestille et prøvesæt, som tillader kvinden selv at tage en vaginal prøve hjemme og sende prøven til laboratoriet, hvor den bliver undersøgt for HPV (hjemmeopsamlet prøve). En hjemmeopsamlet prøve påviser kun om kvinden er smittet med HPV, men siger intet om hvorvidt infektionen har medført celleforandringer, der kan være forstadier til livmoderhalskræft. Således skal kvinder med en HPV positiv hjemmeopsamlet prøve gå til egen læge og få taget en opfølgende celleprøve, der kan påvise om HPV infektionen har medført forstadier til livmoderhalskræft. Konkret forventer vi, at cirka 350-375 kvinder henvises til egen læge for at få foretaget en sådan opfølgningsprøve.

Identifikation af læger der skal modtage honorering varetages af Afdeling for Folkeundersøgelser og sker via kobling af listen over screeningsdeltagere i alderen 65-69 år med registerudtræk fra

Patologidatabanken, som indeholder data om antallet af celleprøver og lægens yder-nr. Egen læge vil derfor ikke skulle bruge ressourcer på manuel registrering af prøverne. Vi forventer i alt ca. 5000 undersøgelser hos egen læge og ca. 350-375 opfølgende prøver, og fordelt over 800 praktiserende læger, så vil der blive tale om 6-7 undersøgelser hos hver læge. Honoreringen vil være samme takst (175,11 kr.) som tilsvarende prøvetagning af en celleprøve i det eksisterende screeningprogram og vil blive udbetalt på en gang ved projektets afslutning.

EVALUERING (metode og tidsramme samt plan for implementering og formidling) (1)

For at kunne afgøre om udvidelse af screeningsalderen kan bidrage til højnet sundhedstilstand i den ældre danske kvindelig population måles der på følgende effektmål:

- Andelen af kvinder, der tager imod tilbuddet i Region Midtjylland, og som bliver undersøgt enten via hjemmeopsamlet prøve eller hos egen læge sammenlignet med andelen af kvinder i andre regioner, som undersøges opportunistisk (Region Midtjylland i forhold til øvrige regioner).
- Diagnosticering af forstadier til livmoderhalskræft hos kvinder, der får tilbuddet og sammenlignet med kvinder, der ikke får tilbuddet (Region Midtjylland i forhold til øvrige regioner).
- Andelen af undersøgte kvinder med behov for opfølgning, som gennemfører denne opfølgning (Region Midtjylland)
- Screeningshistorik og socioøkonomisk status hos kvinder, der tager imod tilbuddet sammenlignet med øvrige kvinder (Region Midtjylland)

Kvinderne vil blive fulgt i 5 til 10 år med henblik på observation af forekomst og dødelighed af livmoderhalskræft. Effektmålene bliver undersøgt i registerudtræk fra Patologidatabanken. Desuden vil der blive udført sundhedsøkonomiske analyser, der kan afgøre om tilbuddet er omkostningseffektivt og om et lignende tilbud bør implementeres i de øvrige regioner.

Forskningsprojektet kan implementeres direkte i almen praksis, og rekvirering, og prøvetagning samt indsendelse af celleprøverne til Patologisk Institut (PAI), Regionshospitalet Randers vil foregå som i det eksisterende screeningsprogram for de 23-64 årige. Ved ankomst til PAI vil prøverne blive registeret i Patologidatabanken som vanligt.

Kvinden modtager selv svar på prøven, og samtidig sendes kopisvar til egen læge, hvilket er standard procedure for det eksisterende screeningsprogram i Region Midtjylland. Information om projektet vil blive bragt på praksis.dk, og i kopisvaret vil der ligeledes blive henvist til denne information.

Organisatorisk vil projektet være forankret i Afdeling for Folkeundersøgelser, der er en regional funktion, der har lokalitet på Regionshospitalet Randers. Afdelingen planlægger, koordinerer og administrerer kræftscreeningsprogrammerne i Region Midtjylland.

Vurdering/overvejelse om efterfølgende udbredelse og implementering i almen praksis

START- OG SLUTTIDSPUNKT (evt. forventet):
Delstudie 1:
Oktober 2018: Studiet påbegyndes og invitationerne udsendes
December 2019: Evaluering af studiet og studiet afsluttes
De første videnskabelige publikationer forventes klar indenfor 18 måneder efter opstart af studiet.
Delstudie 2:
December 2018: Studiet påbegyndes og invitationerne udsendes hver anden måned i en periode

på cirka 2 år.
Februar 2022: Evaluering af studiet og studiet afsluttes
De første videnskabelige publikationer forventes klar indenfor 4 måneder efter studiets afslutning. Afhængigt af rekrutteringens varighed kan studieperioden udvides, og i så fald vil en supplerende KEU ansøgning blive indsendt.

Effektmålene vedr. forekomst og dødelighed af sygdommen forventes først klar om 5-10 år efter studiernes afslutning.

Projektet bliver det første af sin slags, og har potentiale til at forebygge livmoderhalskræft blandt ældre kvinder, og vil være en vigtig brik i en generel beslutning om, hvorvidt screeningsalderen i Danmarks livmoderhalskræftprogram bør udvides til at inkludere ældre kvinder. Det vil også give mulighed for beslutning om, hvorvidt hjemmeopsamlet prøve skal være en del af tilbuddet. Også på internationalt niveau vil projektet have stor nyhedsværdi og få en vigtig betydning, da der mangler evidens for effekten af et sådant tiltag. Da projektet er efterspurgt bl.a. af Sundhedsstyrelsen forventes eventuelle positive resultater at kunne danne baggrund for nye anbefalinger i Danmark.

BUDGET

ANSØGT BELØB (2): 941.216 kr. Der ansøges om støtte til honorering af praktiserende læger, som tager en konventionel celleprøve hos projektets deltagere (forventeligt n=5000) samt tager en opfølgende celleprøve hos kvinder med en HPV positiv hjemmeopsamlet prøve (n=375).

BEVILLING (indeværende år og evt. efterfølgende år): 2018: 300.000 kr., 2019: 641.216 kr.

ANSØGT MIDLER SPONSERET FRA ANDRE SIDER: Helsefonden (200.000 kr.) og Roche Diagnostics (1.375.000 kr.). Der udarbejdes en juridisk bindende kontrakt mellem Roche Diagnostics og Afdeling for Folkeundersøgelser, således at Roche Diagnostics ingen indflydelse har på projektets design, resultater og konklusion. Kontrakten udarbejdes af Aarhus Universitet. Desuden planlægges at ansøge Region Midtjyllands Sundhedsvidenskabelig forskningsfond.

BUDGET FORDELT PÅ ÅR: 2018: 1.464.751 kr., 2019: 2.980.407 kr., 2020: 624.956 kr.

TOTALBUDGET: 5.070.114 kr., hvoraf 1.848.800 kr. er skaffet.

AFSLUTTENDE RAPPORT/ARTIKEL SENDES TIL DET REGIONALE SEKRETARIAT: Projektet forventes at resultere i minimum fem videnskabelige artikler, som alle vil blive forsøgt publiceret i internationale peer-review tidsskrifter og efterfølgende sendt til det regionale sekretariat.

SUPPLERENDE OPLYSNINGER:

BILAGSFORTEGNELSE: uddybet projektbeskrivelse (bilag 1) og udspecificeret budget (bilag 2)

(1) I forbindelse med evaluering skal projektet forholde sig til mulighederne for at anvende Triple Aim .
(2) Et udspecificeret budget vedlægges, hvor det er markeret præcist, hvilke midler der ansøges om hos KEU.

Bilag 1:

Reducing the burden of cervical cancer among older women by expanding current screening age

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Purpose

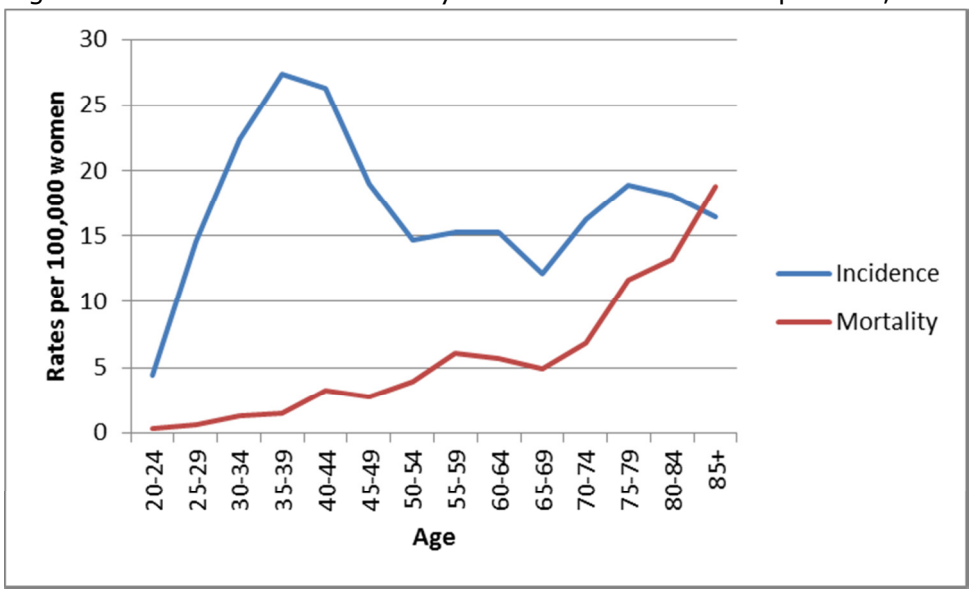
The overall purpose of this study is to evaluate the feasibility and outcome of expanding the target population in the Danish national cervical cancer uteri (CCU) screening programme to include women aged 65 to 69. The women will be invited to choose between a newly developed self-sampling procedure for high-risk human papillomavirus (hrHPV) detection or conventional obtainment of a screening sample at the general practitioner (GP).

Background

CCU screening was introduced in parts of Denmark in the 1960s and reached national coverage in the late 1990s (1). Until 2007 the screening age was 23 to 59 and hereafter it expanded to include all women aged 23 to 64 (2). The early CCU screening era lead to a remarkable decrease in morbidity and mortality, but this trend has stagnated (3) at approximately 400 new cases and 100 deaths annually over the past 5-10 years (4).

The CCU incidence is especially high in younger and older women (Figure 1). Among older women CCU is further associated with a relatively high mortality, indicating more advanced stages at diagnosis:

Figure 1: Incidence and mortality of cervical cancer uteri per 100,000 Danish women (2010-2014)



NORDCAN© Association of the Nordic Cancer Registries (15.9.2017)

The adverse trend among the youngest women will in the Danish society be met by the introduction of HPV vaccination among girls and female adolescents, but the older women cannot benefit from this initiative. Therefore, and as part of the Danish National Cancer Plan IV, a political decision was made to make a one-time screening offer in 2017 to women born before 1948 (by then aged 69 years or older). However, women below 69 years were not covered by this one-time screening offer and extending the age limit in general remains on the agenda and needs further evaluation to appraise feasibility, reduction of disease burden and socioeconomic consequences.

The participation in CCU screening within 1 year after an invitation in the Danish CCU screening programme is approximately 65% (5). Participation usually requires a gynaecological examination during which a cytology sample is obtained from the cervix. Subsequently, the sample is analysed in a pathology department. However, the gynaecological examination and difficulties in the planning of the screening visit at the GP are well-known barriers to participation (6,7).

HrHPV infection is a well-established causal agent for the development of cervical cancer and its precursors (8,9).

Compared with cytology-based screening, hrHPV DNA based-screening has a higher sensitivity for detection of underlying cervical intraepithelial neoplasia grade 2 (CIN2) (90%) and CIN3 and cancer (95%) at baseline, although it is less specific (92%) (10,11). Moreover, a negative hrHPV test result at baseline offers greater reassurance against CCU than a negative cervical cytology test result (12). HrHPV is widespread in the youngest part of the population (13) and since only few of the infections develop into CCU precursors (14), primary hrHPV screening should not be introduced in younger age groups (15) . In the current Danish CCU programme only women aged 60 to 64 undergo primary hrHPV screening (16).

Self-sampling of cervico-vaginal material may be an alternative for women to overcome certain barriers to participate in CCU screening. Through self-sampling, women can obtain the samples themselves at home using a brush device and return them directly to the laboratory for hrHPV testing (hrHPV self-sampling). In Danish studies, hrHPV self-sampling has been shown to increase participation (17,18) and especially encourage previous non-participants to submit a sample (17). A recently Danish study showed that Western immigrants and some lower socioeconomic groups benefitted the most from the self-sampling offer (19). Most studies found moderate to good concordance for hrHPV detection between self-sampling and clinician-sampling (20,21). A meta-analysis has shown that the clinical test performance of a hrHPV test on a self-sample and a clinician-collected sample (gold standard) for the detection of underlying CIN2+ is comparable if using certain clinically validated PCR-based HPV DNA tests (22,23).
Due to the lower specificity of HPV-based screening, HPV-positive women require cytology-triage testing before referral to colposcopy to avoid overtreatment (24). As self-samples do not allow for cytology-triage, all women who have hrHPV detected in their self-sample will need to a have a GP-collected sample for further triaging. An efficient self-sampling strategy depends on a high level of compliance with follow-up among HPV-positive self-samplers (23). In a recent study from Central Denmark Region (CDR) among non-participating women aged 30-64 years, the follow-up rate was 95% measured at 180 days (17).

Implementation of CCU screening in older age groups could be done by conventional gynaecological examination at a GP, but the optimal intervention would also allow women usually not following the CCU screening programme to overcome previously identified participation barriers by giving the opportunity to submit a self-sample.

Material and methods

Population

The study cohort consists of Danish women aged 65-69 years (i.e. above the current screening age) who have not participated in CCU screening within the past five years and are not unsubscribed from the programme. The women will be divided into two populations: 1) Catch-up population including women with no screening sample registered in more than 5 years, 2) screening population including women with no screening sample registered within 5 years. For the screening population the recruitment will be on-going, whereas for the catch-up population, the recruitment will be performed only one time. Women in both populations residing in the CDR (covering 22% of the Danish population) will receive the intervention.

Intervention

Women targeted in the intervention will be identified in the administrative database and will be invited to CCU screening by either seeking a GP for an examination or request a hrHPV self-sampling kit. Thus, the intervention works in the same way as the current CCU screening

programme, except for an older target population and a supplementary possibility to choose a self-sampling kit over usual procedure. The women can request the self-sampling kit by telephone, SMS message, e-mail or via an electronic link in the digital mail that takes them to an external web page.

Obtainment of samples at the GP follows routine procedures, and the samples will as per routine be mailed and primary analysed for hrHPV in the Department of Pathology, Randers Regional Hospital by using the Cobas 4800 HPV DNA test (Roche Diagnostics) (25).

Any woman requesting a self-sampling kit will receive a written instruction and a pre-paid, pre-addressed return envelope for returning the sample to the laboratory. She will be informed that the result of the self-sampling will be passed to her GP and to herself. She will also be informed that in case of a positive hrHPV test result, she must see a GP for a gynaecological examination to have a cytology-triage sample obtained. Women who had no cytology-triage sample registered within 120 days post the date of the test result are automatically identified through lists provided by the Danish Pathology Databank. These women will receive a telephone call from the Department of Public Health Programmes ensuring that the letter has been received and understood. If no telephone number is identified, the woman is sent an electronic message (e-boks). In all cases, the woman´s GP will be contacted by letter and encouraged to offer her a cervical cytology sample if she consults primary care for whatever reason.
The intervention will make use of standard procedures that have been thoroughly tested and used in the CDR in a previous self-sampling study (17).

The test kit that we expect to use is an endocervical brush (Evalyn Brush) (26), which was recently tested in the CDR (17,21) and in the Capital Denmark Region (18). We will, however, consider using a less expensive alternative if so justified by the results of a local project comparing different self-sampling devices. All self-samples will be analysed for hrHPV using the Cobas 4800 HPV DNA test (Roche Diagnostics) (25) at Department of Pathology, Randers Regional Hospital, which already has a set-up for analysis of similar tests.

Study designs
The project is a nation-wide cohort study in which all women in the CDR target population will receive the screening offer, while the remaining part of the country will receive usual care, which in this age group is low-level opportunistic testing. We will use a cohort design (rather than a randomised controlled trial design) in which one region is running the intervention as it will allow for better mass communication to the target population without influencing non-targeted women. Outcomes in the cohort receiving the intervention will be compared with outcomes among women from regions not receiving the intervention.

Outcomes measured in the intervention population:

- Proportion of targeted women in the CDR participating by visiting a GP or using hrHPV self-sampling, respectively
- The hrHPV prevalence among participants
- Screening history of participating and non-participating women
- Comparison of socio-economic factors of participants and non-participants
- Proportion of hrHPV-positive women using self-sampling procedure who have appropriate follow-up testing by their GP
- Results of cervical cytology specimens and cervical biopsy among those referred for further examinations

Outcomes measured and compared within the whole cohort:

- Detected cervical precursors (CIN2+) among the CDR cohort compared with cervical precursors detected by opportunistic testing in the other regions
- Conisation procedures in the CDR cohort compared with other regions
- Incidence and stage of cervical cancers developed within 5 and 10 years among the included women in the CDR compared with women in similar cohorts in other regions without a screening offer.

A cost-effectiveness analysis based on data from the study will be performed. Supplementary data in terms of questionnaires and qualitative interviews in the studies population will be considered. Women participating in the study will be asked if their sample may be stored for future research.

The study cohort will be managed in RedCap; and data on participation, HPV test results, cervical cytology results, histological diagnoses and screening history will be obtained from the nationwide Danish Pathology Databank (27). We expect that data on conisation procedures will be drawn from the Danish National Patient Registry (LPR). Data on socio-economic will be obtained from Statistics Denmark. STATA version 14 will be used for statistical analyses.

Sample size
There are approximately 167,000 Danish women aged 65-69 years of whom 37,000 are living in CDR (intervention group) (28). It is anticipated that approximately 55% of these have not participated in CCU screening within the past five years. Thus, the study cohort consists of a total of 91,850 women including 20,000 women in the intervention group. Based on the assumption that 50% of the targeted women will accept the offer of a CCU screening and the incidence of CIN2+ is around 0.3% in the targeted age-group, this study will detect around 30 out of 60 women with CIN2+ compared to roughly 180 undetected cases in the control group. We do not expect to detect statistically significant difference in CCU incidence, but is anticipated that it will be possible to uncover trends during the 5 and 10 years follow-up.

Approvals
The project has been approved by the Danish Data Protection Agency (j. no.: 1-16-02-158-18). Furthermore, the project received clearance at the Central Denmark Region Committees on Health Research Ethics (j.no.: 73/2018) and according to Danish Law this project should not be notified to the Committees. Approval from the Danish Patient Safety Authority to obtain data from the Danish Pathology Databank is ongoing.

Organisation and collaborators

The project will be administered by the Department of Public Health Programmes in CDR which is responsible for the planning, administration, development and research related to population-based cancer screening programmes in the CDR. The project will be embedded into the daily work in the department and - when applicable - it will follow current routines. The staff in the department has substantial experience from previous research projects relating to the organisation of self-sampling in cancer screening, direct mailing of invitations, requisition of self-sampling kits, user-friendly self-sampling kit instruction, dissemination of results to GPs and screening participants, and suitable follow-up procedures for hrHPV-positive women who refrain from attending a GP for a gynaecological examination.

The person in charge of the intervention and scientific evaluation of the project in the Department of Public Health Programmes will be Post doc Mette Tranberg, who has substantial experience on interventions related to hrHPV self-sampling (17,19,21,29) and CCU screening in general (30).

The project will be conducted in collaboration with the Department of Pathology, Randers Regional Hospital, which has substantial expertise with the analysis of self-sampled tests. The collaboration will be a continuation of previous collaborative efforts in other projects (17,21) about the effect and use of self-sampling in the context of the CCU screening programme.

Communication and dissemination

Initiation of the intervention will be communicated in mass media targeting Central Denmark Region. Results will be communicated in scientific journals continuously and the press will be informed on national level by eq. press releases when results are published.
Professor Berit Andersen and the Department of Public Health Programmes is deeply involved in planning of CCU screening on national and regional level, and the results – positive or negative - will easily be disseminated to other regions and the Danish Health Authorities in relevant forum for potential political decision.

Timeline

For population 1, the intervention is expected to be established from October 2018, and the invitations will be mailed out. It is expected that results on participation, follow-up, cytology- and histology results as well a conisation procedures will be in place within 18 months from initiation of the study. For population 2, the first women will be invited in December 2018 and the invitations will be mailed out over 2 years. For this population, the first publication is expected to be submitted June 2022. However, long-term follow-up data will be available only after 5 to 10 years and cannot be included in the primary evaluations.

Perspectives

This study has the potential to increase health and reduce burden of a preventable disease in a cost-effective way among women not usually targeted in CCU screening.

The study fills a knowledge gap and will generate important new knowledge about the effects and cost-effectiveness of expanding current CCU screening age to include women aged 65 to 69 by including the newly developed possibility of hrHPV self sampling. The possibility to include the use of Danish registers, which enjoy high validity, do further add to the quality of the outcome data, and the results will add substantially to the international knowledge of the effect of CCU screening in this age group.

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Bilag 2: Projektets budget: Forebyggelse af livmoderhalskræft hos ældre kvinder ved at udvide nuværende screeningsalder

		Forudsætninger		Udgifter				Finansiering				
		Antal	Pris pr. enhed	2018	2019	2020	Ialt	Søges KEU	Haves fra Region Midtjylland	Bevilliget af andre fonde	Søges andre fonde*	Ialt
Løn												
VIP	Post doc - Mette Tranberg	3	495.156	495.156	495.156	495.156	1.485.468			200.000	1.285.468	1.485.468
	Statistiker/datamanager	0,2	504.000		50.400	50.400	100.800		100.800		0	100.800
	Projektsekretær	0,5	396.000	99.000	49.500	49.500	198.000		198.000		0	198.000
TAP	Bioanalytikertimer (HPV-analyser)	2.500	165	103.125	309.375		412.500				412.500	412.500
	Bioanalytikertimer (frysning af prøver)	1.000	165	41.250	123.750		165.000				165.000	165.000
	Ialt løn			**738.531**	**1.028.181**	**595.056**	**2.361.768**	**-**	**298.800**	**200.000**	**1.862.968**	**2.361.768**
Øvrig drift												
Vareindkøb - hjemmeopsamlede prøver												
	Køb af plastic børste til hjemme-opsamling (max pris)**	5.000	25	31.250	93.750		125.000				125.000	125.000
	Returkuverter (bobbel kuvert), label mv.	5.000	2,5	3.125	9.375		12.500				12.500	12.500
	Papir og kuverter (vejledning m.v.)	5.000	2,5	3.125	9.375		12.500				12.500	12.500
	Utensiler mv. til HPV-analyse (max pris)**	10.000	135	337.500	1.012.500		1.350.000			1.350.000	0	1.350.000
	Prøvetagning af celleprøver hos egen læge***	5.375	175,11	300.000	641.216		941.216	**941.216**			0	941.216
												-
Forsendelse												-
	Invitation - digital post (70%)	14.000	0,38	1.330	3.990		5.320				5.320	5.320
	Invitation - fysisk post (30%)	6.000	8	12.000	36.000		48.000				48.000	48.000
	Porto returkuverter (USF)	5.000	12	15.000	45.000		60.000				60.000	60.000
	USF-aftale (årligt gebyr)		1.225	1.225	1.225		2.450				2.450	2.450
	Svarbreve**** - digital post (70%)	7.000	0,38	665	1.995		2.660				2.660	2.660
	Svarbreve - fysisk post (30%)	3.000	8	6.000	18.000		24.000				24.000	24.000
Data												-
	Dataudtræk fra registre				35.000		35.000				35.000	35.000
Formidling												-
	Konferencedeltagelse			15.000	15.000	15.000	45.000				45.000	45.000
	Sproglig revision af artikler	3	3.500		7.000	3.500	10.500				10.500	10.500
	Publikation af artikler	3	11.400		22.800	11.400	34.200				34.200	34.200
	I alt øvrig drift			**726.220**	**1.952.226**	**29.900**	**2.708.346**			**1.550.000**	**417.130**	**2.708.346**
Totalt				**1.464.751**	**2.980.407**	**624.956**	**5.070.114**	**941.216**	**298.800**	**1.550.000**	**2.280.098**	**5.070.114**

* Region Midtjyllands sundhedsvidenskabelig forskningsfond planlægges at søge om lønudgifter
** Leverandører vil blive søgt om nedsat pris på kit og utensilier til projektet
***) Det forventes, at ca. 5000 kvinder går til egen læge for at få taget en celleprøve, og at ca. 375 kvinder skal have taget en opfølgende celleprøve som følge af en HPV positiv hjemmeopsamlet prøve.
Prisenhed for celleprøve: takst 0101 (svt. ca. 140,67 kr.) og 2102: (svt. ca. 34,44 kr.) (i alt: 175,11 kr.)
****Der sendes direkte svar til alle kvinder, uanset om prøven er taget hos læge eller hjemme
Bevilliget af andre fonde: Helsefonden og Roche Diagnostics (endeligt tilsagn fra Roche forventes i august måned)