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eRegCom: communication strategies to healthcare providers and women from an electronic maternal and child health registry – a cluster randomized controlled trial

Submission date
18/10/2018

Recruitment status
Suspended

Registration date
06/12/2018

Overall study status
Completed

Last Edited
18/01/2023

Condition category
Pregnancy and Childbirth

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Antenatal (during pregnancy) and postpartum (after birth) care is recommended for a positive pregnancy experience and maternal and newborn survival. The timing and content of these visits are important. An electronic maternal and child health registry (MCH eRegistry) is an interactive health information system. It can use the data entered at the point of care to communicate to women and health care providers. The aim of this study is to assess if an eRegistry with targeted client communication by means of SMS messages to pregnant/postpartum women, and/or performance feedback to healthcare providers by means of a dashboard, can increase timely attendances and quality of care in Palestine.

Who can participate?
140 primary healthcare clinics in the West Bank and Gaza strip, Palestine

What does the study involve?
Participating clinics are randomly allocated to one of four groups. The first group continues to use standard care: an MCH eRegistry that provides interactive checklists with clinical decision support. In the second group women who are attending antenatal care also receive SMS messages from the clinic throughout their pregnancy and 6 weeks postpartum to remind them of appointments and improve their healthcare-seeking behavior. In the third group healthcare providers receive performance feedback for 12 months. In the fourth group clinics receive both the interventions described above. Information is collected from the MCH eRegistry monthly.

What are the possible benefits and risks of participating?
Clinics may benefit from timely feedback about their performance to better target their quality improvement efforts, and use SMS as a communication tool to better inform and remind their clients about the importance of timely attendance to care. Women attending these clinics may benefit from an overall improvement in the quality of care. The messages may empower them to take better-informed choices in their clinical care. Messages are reminders of appointments they

have agreed to, and the content built solely on guideline driven counseling in the Palestinian health system. The risk of harm from the interventions is therefore negligible.

Where is the study run from?
The study is run as a collaboration between the Palestinian National Institute of Public Health, World Health Organization, Ramallah, Palestine, and the Norwegian Institute of Public Health.

When is the study starting and how long is it expected to run for?
October 2016 to October 2019

Who is funding the study?
1. European Research Council (European Union)
2. Norwegian Research Council (Norway)
3. Center for Intervention Science in Maternal and Child Health (Norway)
4. Norwegian Institute of Public Health (Norway)
5. Palestinian National Institute of Public Health, World Health Organization (Palestine)

Who is the main contact?
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Study website
http://eregistries.org

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
eRegCom: the effectiveness of performance feedback to healthcare providers and/or targeted client communication to pregnant and postpartum women, from an electronic maternal and child health registry, on improving effective coverage of care - a cluster randomized controlled trial

Acronym
eRegCom

Study objectives
Performance feedback to healthcare providers or targeted client communication to pregnant and postpartum women, or the combination of the two, compared with standard care with no such communication strategies from an electronic maternal and child health registry, can impact the quality, utilization, continuity, and equity of antenatal and postnatal care.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval from the Palestinian Health Research Council (04/06/2018, ref: PHRC/HC/401 /18), and exemption from ethical review from the Regional Committee for Health Research Ethics (REK) - Section South East B, from Norway (05/06/2018, ref: REK sør-øst 2018/1148) as health systems research falls outside of the mandate for ethical review in Norway.

Study design
Cluster randomized controlled trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
GP practice

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Antenatal and postpartum care in public health services in Palestine, particularly the quality of care, the timely utilization of care, and the combination of the two, defined as effective coverage. To this end, five sentinel conditions, complications, and events in pregnancy are studied: anemia, hypertensive disorders in pregnancy, gestational diabetes mellitus, fetal growth restriction, and maternal attendance to care.

Interventions
The unit of randomization is public primary healthcare centers. All included public primary healthcare centers use the electronic maternal and child health registry system (MCH eRegistry). Details of the MCH eRegistry have previously been reported with a previous trial ISRCTN18008445. The new features in the MCH eRegistry are available the day care providers receive training and their clinic is enrolled in the study. Only data from new pregnancies are included in the trial. The period of recruitment is 6 months. The four arms of the trial are:

1. Performance Feedback (PFB) to a healthcare provider: a dashboard in the MCH eRegistry to the healthcare providers. It is weekly updated and includes their clinical performance indicators and recommended actions to facilitate their quality improvement efforts. Healthcare providers will have access to their dashboard for a total duration of 12 months (6 months recruitment + 6 months follow-up), in order for the two interventions to have the same timeline
2. Targeted client communication (TCC): automated SMS messages to pregnant and postpartum women signed up to the service at booking for antenatal care. The SMS is individualized by the women's gestational age and risk profile, and aims to remind them of appointments and improve their healthcare-seeking behavior. Pregnant women will receive phone text messages throughout their pregnancy and 6 weeks postpartum. The average period from the first antenatal care visit to postpartum care in Palestine is approximately 6-7 months
3. The combination of the two above (PFB + TCC)
4. Control (CTR) - standard care, continue to use the MCH eRegistry without any of the interventions described above

There is an expectation that the Palestinian MoH will incorporate both interventions into their national standard MCH eRegistry after the trial.

Intervention Type
Behavioural

Primary outcome measure
1. Comparison I: PFB arm vs Control arm:
Appropriate screening and management of anemia, hypertensive disorders of pregnancy (HDP), gestational diabetes mellitus (GDM), and fetal growth restriction (FGR)
2. Comparison II: TCC arm vs Control arm:
2.1. Timely attendance to antenatal care visits
2.2. Retention rate from antenatal care to postpartum care
3. Comparison III: PFB + TCC (arm 3) vs Control arm:
Timely attendance, appropriate screening, and management of anemia, hypertensive disorders of pregnancy, gestational diabetes mellitus, and fetal growth restriction.

All the outcome measurements will be obtained from the MCH eRegistry monthly throughout the trial, data needed for these outcomes are continuously entered by the healthcare professionals at the point of care as a routine part of their documentation of care in clinical records.

Secondary outcome measures
1. Comparison I: PFB arm vs Control arm:
1.1. Timely screening for anemia
1.2. Timely screening for HDP
1.3. Timely screening for GDM
1.4. Timely screening for FGR
1.5. Appropriate management of anemia
1.6. Appropriate management of HDP
1.7. Appropriate management of GDM
1.8. Appropriate management of FGR
2. Comparison II: TCC arm vs Control arm:
2.1. Timely attendance for anemia screening
2.2. Timely attendance for HDP screening
2.3. Timely attendance for GDM screening
2.4. Timely attendance for FGR screening
3. Comparison III: PFB + TCC (arm 3) vs Control arm:
3.1. Timely attendance, screening, and management of anemia
3.2. Timely attendance, screening, and management of HDP
3.3. Timely attendance, screening, and management of GDM
3.4. Timely attendance, screening, and management of FGR

All the outcome measurements will be obtained from the MCH eRegistry monthly throughout the trial, data needed for these outcomes are continuously entered by the healthcare professionals at the point of care as a routine part of their documentation of care in clinical records. The outcomes stated above will be stratified by equity quintiles.

Overall study start date
01/10/2016

Completion date
21/10/2019

Eligibility

Key inclusion criteria
1. Public primary healthcare centers providing antenatal and postnatal services; currently active users of the national MCH eRegistry
2. There are no inclusion criteria on an individual basis

Participant type(s)
Mixed

Age group
Adult

Sex
Both

Target number of participants

138 clusters (140 healthcare centers) with the cluster size ranging from 45 up to 3000 new pregnancies per year were randomized to one of the four arms. In total, approximately 23736 pregnant women will attend antenatal care in the healthcare centers included in the study during the six months recruitment.

Key exclusion criteria
There are no eligibility criteria by individual healthcare providers or their client population characteristics

Date of first enrolment
22/10/2018

Date of final enrolment
22/04/2019

Locations

Countries of recruitment
Palestine, State of

Study participating centre
Palestinian National Institute of Public Health, World Health Organization
Ministry of Health Building, 1st Floor Qadora Street
Ramallah/ Al-Bireh
Palestine, State of
PO Box 4284

Study participating centre
World Health Organization (Occupied Palestinian Territory)
UNDP Building, Rimal
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Sponsor information

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Sponsor type
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Funder(s)

Funder type
Government

Funder Name
European Research Council

Alternative Name(s)
ERC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

Funder Name
Norges Forskningsråd

Alternative Name(s)
Forskningsrådet, Norwegian Research Council, Research Council of Norway

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Norway

Funder Name
Center for Intervention Science in Maternal and Child Health

Results and Publications

Publication and dissemination plan
The trial protocol, developed according to the SPIRIT guidelines, the formative research of intervention development, and the main trial results will be published.

Intention to publish date
30/12/2018

Individual participant data (IPD) sharing plan
Data in the MCH eRegistry belongs to the Palestinian Ministries of Health in the West Bank and Gaza strip. The Palestinian National Institute of Public Health/WHO is the custodian of the MCH eRegistry (http://pniph.org/site/). To access data from the MCH eRegistry, a data request to the Palestinian MoHs together with a study protocol and ethical clearance is required. Replication of the trial results is possible because the trial uses routine data collected continuously, and syntaxes to create the indicators and the randomization code will be published together with the trial results. All outcomes are routine data collected continuously without consent. Women seeking care from clinics belonging to the “TCC to pregnant and postpartum women” intervention arm have to say yes to receive phone messages. The trialists have exemption for ethics review from the Regional Committees for Medical and Health Research Ethics (REC) in Norway, and ethics approval from the Palestinian Health Research Council.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	11/01/2021	01/03/2021	Yes	No
Other publications	descriptive study	01/07/2021	07/07/2021	Yes	No
Other publications	Intervention development	06/01/2020	18/01/2023	Yes	No
Other publications	Sub-study results	23/04/2021	18/01/2023	Yes	No