Quality improvement dashboard for health care providers and targeted client communication to pregnant women to improve timely attendance and quality of antenatal care: a multi-arm cluster randomized trial (the eRegCom trial)

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Abstract

Background: Digital health interventions can strengthen coverage and quality of care. Our aim was to assess the effectiveness of targeted client communication (TCC) to pregnant women via text messages, health care provider communication via a quality improvement dashboard (QID) and the combination of TCC and QID—generated and delivered from a digital maternal and child health registry (MCH eRegistry), running on the District Health Information Software 2 (DHIS2) platform in West Bank and Gaza. The control was the regular MCH eRegistry.
Methods: We included 137 clusters in a four-arm cluster randomized controlled trial. Primary outcomes were appropriate screening and management of anemia, hypertension and diabetes during pregnancy, and timely attendance to routine antenatal care (ANC).
Results: The COVID-19 pandemic interrupted the trial, which failed to achieve the estimated sample size. Between 1 December 2019 and 23 March 2020, 4138 women attended ANC in the TCC, 3553 in the QID, 4223 in the TCC & QID and 3324 in the control arm. In the TCC arm, 76.5% of the visits were attended timely versus 73.4% in the control arm, (adjusted odds ratio, 1.2; 95% confidence interval, 0.90–1.61). We found no difference between QID and control, or between TCC & QID control in the proportion of visits where anemia, hypertension and diabetes were appropriately screened and managed.
Conclusion: The routine individual-level data of the MCH eRegistry enabled the implementation of theory-driven TCC and QID. However, the COVID-19 pandemic interrupted this trial of TCC and QID, and we were unable to observe any significant effect.
Trial registration: ISRCTN Registry, ISRCTN10520687.

Keywords: antenatal care, digital health registry, eRegistry, mHealth, digital health, digital health intervention, targeted client communication, SMS, quality improvement dashboards, audit and feedback, DHIS2, timely attendance, quality of care, Palestine, cluster-randomized controlled trial

BACKGROUND

The goal of enhancing universal health coverage, central to the Sustainable Development Goal 3: *better health and well-being for all*, requires health systems strengthening and robust financing structures to close the gaps in coverage and quality. Audit and feedback is a quality improvement strategy intended to support health care providers in self-assessment and adjustment of their clinical practice to reduce the gap between recommended and actual clinical practices [1]. Clinical practice is also influenced by the interaction between the health care provider and client, and the client's level of knowledge [2–4]. Health care provider performance may therefore, in addition to strategies targeting themselves, be improved by strategies targeting clients that encourage

clients to be active in their care and to ask questions. Strategies targeting clients may also affect coverage by improving adherence and attendance to care [5].

Digital health interventions (DHIs), defined as discrete functionalities of digital technology to achieve health sector objectives, can facilitate the delivery of strategies intended to improve coverage and quality of health practices [6, 7]. DHIs can be essential in health systems strengthening, and the World Health Organization (WHO) has developed a standardized vocabulary to articulate functionalities of digital health implementations, which includes health care provider communication and targeted client communication (TCC) [5]. Health care provider communication is the transmission of, for example, performance feedback and alerts [8, 9]. TCC is the transmission of information to individuals or groups of people, based on their health or demographic status [10]. Health care provider communication and TCC are most commonly implemented in isolation; however, they have the potential to leverage one another [5].

The WHO guideline for DHIs for health systems strengthening specifically calls for research that applies robust study designs in the evaluation of the effectiveness of DHIs in low- and middle-income countries (LMICs) on health systems process improvements, and the synergies across combinations of DHIs [5]. In Palestine, the routine documentation tool for antenatal care (ANC) in governmental primary health care clinics is the maternal and child health (MCH) eRegistry [11], using the District Health Information System Software (DHIS2). It includes client identification and registration, client health records, and health care provider decision support [5]. The MCH eRegistry addresses the traditional lack of timely data to health care providers and clients [12], and its implementation has improved quality of ANC [13]. The uniform and longitudinal individual-level clinical data, entered by health care providers at the point of care, can also drive additional DHIs for potential further health systems strengthening. The system in Palestine, covering approximately half of the total pregnant population in the country, is unique and well-suited to address the knowledge gaps identified in the WHO guideline for DHI.

The need for innovative solutions to strengthen antenatal and postnatal care services in the Palestinian setting is high, and Palestinian health authorities prioritize improvements of coverage and quality of care. The fertility rate is 3.6 (2019), and ANC services are reported to have high coverage, but poor quality content. Furthermore, no more than 13% of the women use ANC within the recommended gestational age window as per the national guideline, which hampers timely screening and management, and thus the quality of care provided [14].

Our aim was to undertake a large trial to estimate the effectiveness of health care provider communication via a quality improvement dashboard (QID), TCC to pregnant women via text messages (SMS) and the combination of the QID and TCC on improving timely attendance to routine ANC contacts, as well as appropriate screening and management of diabetes, hypertension and anemia in pregnancy.

METHODS
Trial design and materials
This four-arm cluster randomized controlled, parallel-group superiority trial was carried out in public primary health care clinics offering ANC in the West Bank and Gaza, Palestine. The trial protocol is published elsewhere [15]. In short, 138 eligible clusters (136 clusters composed of one individual clinic, plus two clusters composed of two clinics with services offered by the same health care provider) were included. They were distributed in 14 districts in the West Bank (Bethlehem, Jenin, Nablus, Ramallah/Al-Bireh, Salfit, Hebron, Jericho, Jerusalem, North Hebron, South Hebron, Qalqiliya, Tubas, Tulkarm, Yatta) and the Gaza Strip. Each cluster enrolled 45–3000 new pregnancies in 2016. We excluded small clinics due to impracticalities in the evaluation, and big clinics because they were atypical. We stratified the randomization by the point in time the MCH eRegistry was implemented, and constrained on laboratory availability, ultrasound availability and the size of the clinic. The 138 clusters were equally allocated (1:1:1:1 ratio) to the TCC intervention, QID intervention, TCC & QID intervention or control arm.

Each user of the MCH eRegistry has an individual username and password that allow access to records and specific system features consistent with the user's assigned role [16]. The health care provider enters a woman's personal identity number to generate a new digital ANC record, and thereafter sociodemographic, obstetric and medical data at point of care. DHIs are generated by using the routinely entered individual-level clinical data.

The female literacy rate in Palestine is high (>94%). About 85% of the women listed in the MCH eRegistry are registered with a mobile phone number, and >85% have their individual mobile phone [17].

Intervention
The interventions targeted pregnant women and nurses, midwives, physicians, and community health workers, henceforth referred to as health care providers, and their clients.

Health care provider communication and performance feedback via quality improvement dashboard
The dashboard, integrated in the routine MCH eRegistry, presented quality performance indicators for their clinic to the care providers (Fig. 1). The indicators are presented in tables and graphs as an average over the last 3 months. The indicators are also benchmarked with clinics in the same district. The proportions of clients who were appropriately screened and managed according to guideline algorithms for anemia, hypertension, diabetes, as well as the proportion of clients with timely attendance to ANC, were presented. Each of these four domains (anemia, hypertension, diabetes and attendance) had a separate tab in the dashboard. Health care providers received weekly alerts in the MCH eRegistry with a prompt to visit that week's domain. Corresponding to the clinic's performance level, two screening and two management action items—recommendations for improvement in colors (green = good performance, yellow = room for improvement, red = large room for improvement) were presented with monthly updates.

Health care providers received in-person training on how to use the QID as a tool to improve quality-of-care practices between 10 February and 12 March 2019, and a refresher training video in October 2019. Health care providers received access to the QID at the trial start (December 2019). The regular in-person supervision to all clusters from MCH supervisors was not changed.

In line with audit and feedback best practice recommendations [1, 9, 18], the QID intervention featured timelines (frequent feedback); actionability (recommendations and clear goals); specificity (individualized); and non-punitively (friendly language, easy to understand) [19]. The development of the QID is described in detail elsewhere [19].
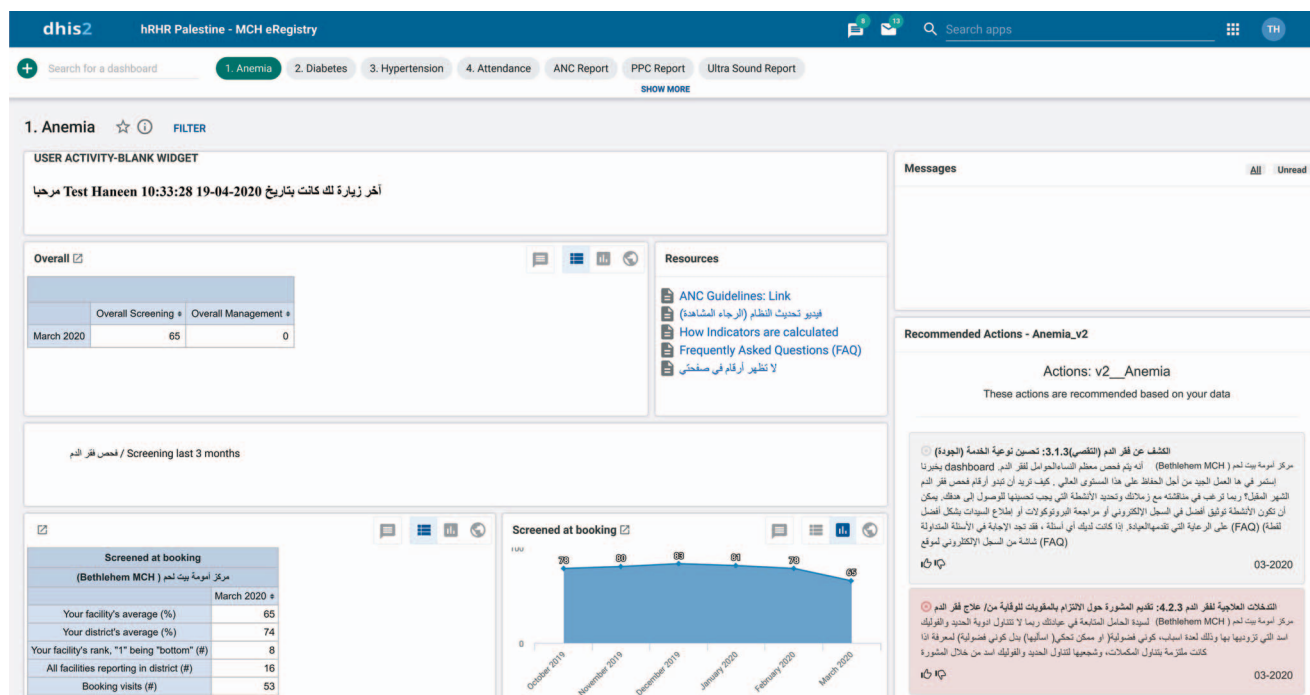
Figure 1. QID for anemia with tables, graphs and action items corresponding to the performance level.

Table 1. English translation of a text message series to a woman at risk of high blood pressure due to a high body mass index

Welcome, at registration	1 wk before a contact	3 d before a contact	24 h before a contact
Dear Aisha, Most women attend antenatal care for their own and baby's health. The health care provider will measure your blood pressure, hemoglobin and blood glucose level. You will receive text message appointment reminders. Please let us know if you do not want these messages. Tamoon clinic	Dear Aisha, The date of your upcoming appointment is 20 May 2022. One in 20 develop high blood pressure in pregnancy, and this may affect your health and the growth of your baby. The health care provider will measure your blood pressure and the amount of protein in your urine as they may be signs of high blood pressure. Tamoon clinic	Dear Aisha, 20 May 2020 is your next appointment, as agreed. High body weight before pregnancy may increase the risk of developing high blood pressure. The health care provider will measure your blood pressure and the amount of protein in your urine at your next visit. Tamoon clinic	Dear Aisha, This is a reminder that you have an appointment tomorrow, 20 May 2020, as agreed. Tamoon clinic

Targeted client communication via text messages

The TCC intervention consisted of individualized text messages sent to the client's mobile phone with reminders of care appointments, and information on pregnancy and ANC to motivate active participation in ANC. The content, timing and frequency of the text messages were informed by theory from the Health Belief Model [20]; Model of Actionable Feedback [18]; as well as nudging and enhanced active choice [21].

Women, invited by their health care provider, could register for the text message service at any time in gestation, preferably at the first contact. A reminder text messages that included the woman's and her clinic's name, and the date of her next contact, were sent 24 hours before any scheduled contact (Table 1). Information text messages, which in addition to the reminder information included health information, were sent 1 week before a timely scheduled (16, 18–22, 24–28, 32, or 36 weeks of gestation) routine contact, and for women with identified risk factors, also 3 days before a scheduled routine contact. Text messages were thus delivered at a scale and intensity proportional to the degree of need [9, 22].

Health care providers were trained on how to register and withdraw women from the text message service, and received a clear description of the text messages. The registration opened June 2019. The development of the text messages and the text message library is described in detail elsewhere [23].

Control

The control clusters used the routine MCH eRegistry functionalities (client identification and registration, client health records and health care provider decision support) without QID or TCC.

Outcomes

The outcomes—appropriate screening and management for anemia, hypertension and diabetes and timely attendance—are aligned with the key areas of quality concerns in Palestine [15] and our eRegQual trial (Table 2) [13].

The primary outcome for the assessment of QID versus control measured the health care providers' adherence to national clinical ANC guidelines for anemia, diabetes and hypertension. We only assessed the first step of management. For women

Table 2. Palestinian anemia, hypertension and diabetes ANC guidelines, and trial outcome definition

Condition	Time*	Screening	Results	Management**	Overall eRegCom trial outcome definition
Anemia during pregnancy	First visit	Hemoglobin test	Hb ≥11 g/dl (Normal)	No further action	**QID vs control:** Number of ANC visits, per time point, where anemia should have been screened for (denominator), AND among them – screened normal, OR – identified with mild/moderate anemia AND managed with repeated test, OR – identified with severe anemia AND managed with referral **QID & TCC vs control:** The number of timely scheduled routine ANC visits, per time point, where anemia should have been screened for (denominator) AND among them – screened normal, OR – identified with mild/moderate anemia AND managed with repeated test, OR – identified with severe anemia AND managed with referral
	24–28 wk		Hb 7–10.9 g/dl (mild/moderate anemia)	Repeat test within 4 wk	
	36 wk		Hb <7 g/dl (severe anemia)	Referral to hospital	
Hypertensive disorders of pregnancy	First visit before 23 wk	Blood pressure measurement	SBP <140 & DBP <90 mm Hg (normal)	No further action	**QID vs control:** Number of ANC visits, per time point, where hypertension should have been screened for (denominator), AND among them – screened normal, OR – identified with chronic hypertension AND referred – identified with mild gestational hypertension and managed with repeated test, OR – identified with moderate/severe hypertension AND referred **QID & TCC vs control:** The number of timely scheduled routine ANC visits, per time point, where hypertension should have been screened for (denominator), AND among them – screened normal, OR – identified with chronic hypertension AND referred – identified with mild gestational hypertension and managed with repeated test, OR – identified with moderate/severe hypertension AND referred
	16 wk		SBP ≥140 mm Hg, DBP ≥90 (chronic hypertension)	Refer to high-risk clinic	
	18–22 wk			No further action	
	24–28 wk	Blood pressure measurement	SBP <140 & DBP <90 mm Hg (normal)	Repeat test within 4 days	
	32 wk		SBP 140–149 mm Hg OR DBP 90–99 (mild gestational hypertension)	Referral to hospital	
	36 wk		SBP ≥150 mm Hg OR DBP ≥100 (moderate/severe gestational hypertension)		

Table 2. Continued

Condition	Time*	Screening	Results	Management**	Overall eRegCom trial outcome definition
Hyperglycemia in pregnancy	First visit before 24 wk	Urine OR blood glucose test	Negative glucose urine	No further action	**QID vs control:** Number of ANC visits, per time point, where diabetes should have been screened for (denominator), AND among them – screened normal, OR – identified with glucose in urine AND referred, OR – identified with diabetes and referred
			RBG <140, OR FBG <126 mg/dl		
			Positive glucose urine	Refer to laboratory for blood glucose test	
			RBG ≥140, FBG ≥126 mg/dl (diabetes)	Refer to diabetes or high-risk clinic	
	First visit after 28 wk	Blood glucose test	RBG <140, OR FBG <126 mg/dl	No further action	**QID & TCC vs control:** The number of timely scheduled routine ANC visits, per time point, where diabetes should have been screened for (denominator), AND among them – screened normal, OR – identified with glucose in urine AND referred, OR – identified with diabetes and referred
	24–28 wk		RBG ≥140, FBG ≥126 mg/dl (diabetes)	Refer to diabetes or high-risk clinic	

DBP indicates diastolic BP; FBG, fasting blood glucose; Hb, hemoglobin; RBG, random BG; SBP, systolic blood pressure *Results registered 1 week before or after the 16-, 32-, and 36-week visits were accepted. **Only the first step in the management is described.

with normal screening results, no further action was defined as correct and complete management. Pregnant women with documented ongoing anemia, hypertension or diabetes before the routine appointment were not included in the denominator for appropriate screening and management.

The primary outcome for the assessment of TCC versus control measured clients' timely attendance to scheduled routine ANC contacts (16, 18–22, 24–28, 32 and 36 weeks of gestation). The first ANC contact (booking visit), recommended to take place in the first trimester, is not included in the assessment of timely attendance because it is not amenable to change by the intervention.

The primary outcome for the assessment of QID & TCC versus control measured the combination of the health care providers' adherence to guidelines and the clients' timely attendance to scheduled routine ANC contacts.

Data collection and blinding

All data in the MCH eRegistry database are owned by the Ministry of Health in the West Bank and Gaza, respectively. In line with their ministries' legal framework and the standard operating procedures of the MCH eRegistry, blinded data analysts extracted predefined variables and prepared anonymous datasets to allow the evaluation of the effectiveness of the interventions. Individual-level clinical data entered by the health care providers in the MCH eRegistry during the consultation with women between 1 December 2019 and 23 March 2020, were used to assess the effectiveness of the interventions. No incentives were provided to women or health care providers. We did not identify any potential significant harm, and a data monitoring committee was considered unnecessary [15].

Health care providers were blinded to the outcomes, but it was not possible to blind them to the allocation. Women were blinded to the outcomes and the allocation of the QID intervention, but not to the allocation of the TCC intervention. We generated allocation codes and converted the codes to allocation groups after the completion of the primary analyses and unblinding. The statisticians were blinded to allocation until the primary analyses were completed. However, shortly after unblinding, we discovered a problem with the source code that led to highly implausible low attendance rates in a group of clinics across all arms. We identified and corrected the code for data retrieval and re-analyzed the corrected data. The statisticians were aware of allocation in the corrected dataset, but we did not change any of the analyses after unblinding.

Ethics

The health authorities in Palestine notified all study clinics about the research. Women had to provide consent to receive text messages. The trial was approved by the ethics committee in Palestine, the Palestinian Health Research Council (401/18 and 670/19), and received an exemption from review by the Regional Committee for Health Research Ethics - Section South East B, Norway (2018/1148C).

Statistical analysis

The sample size calculation is described in detail elsewhere [15]. Briefly, assuming an intra-cluster correlation coefficient of 0.05, an average of 344 deliveries per clinic-year, a coefficient of variation in cluster size of 1.69 and type I and II error probabilities of 0.05 and 0.2 (i.e. 80% power), we calculated that at least 138 eligible clusters would be necessary to detect a difference of 50% for outcomes with the lowest prevalence (e.g. improving anemia screening and management at 24–28 weeks of gestation from 30% to 45% of attending women).
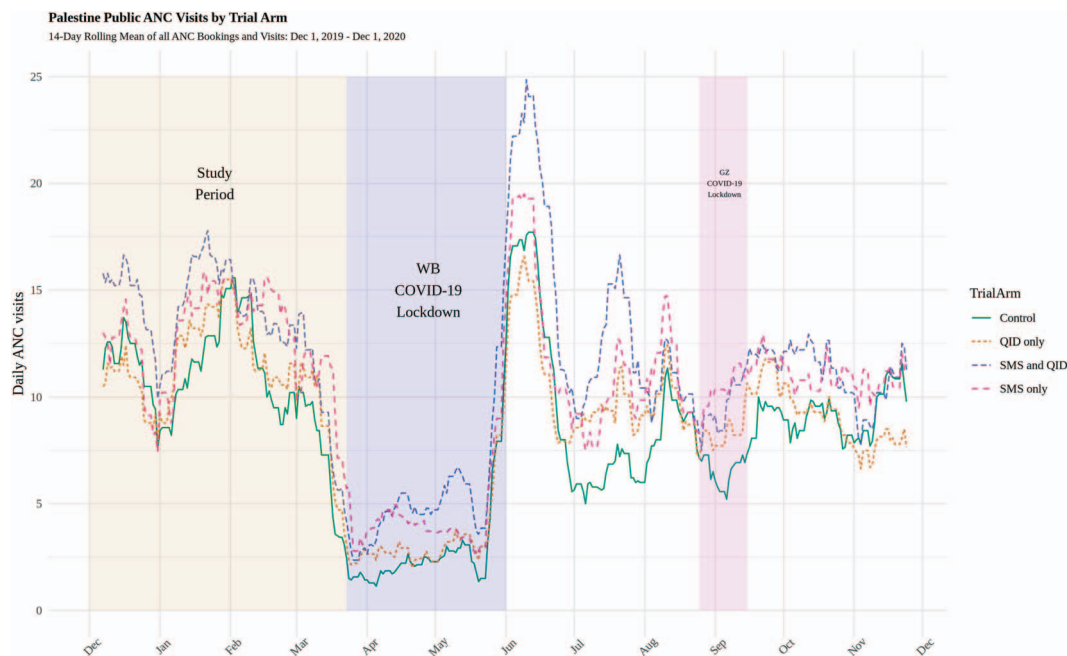
Figure 2. ANC booking and follow-up contacts between 1 December 2019 and 1 December 2020 presented as 14-day rolling mean.
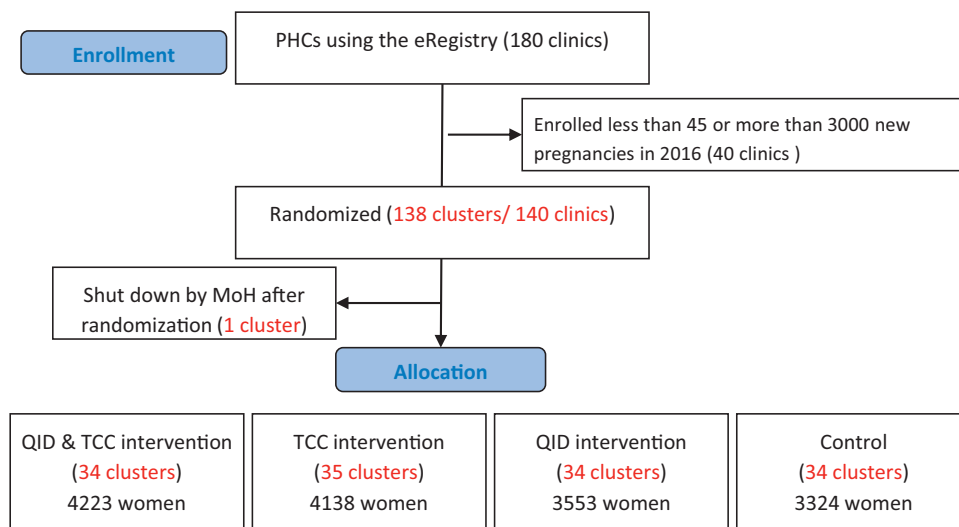

Figure 3. Flow diagram showing eligible clinics, allocation and number of women with an ANC contact.

We report descriptive statics at baseline and at the end of follow-up. We estimated treatment effect using mixed-effects logistic regression and report odds ratios (ORs), 95% confidence intervals (CIs), and two-sided *P*-values throughout. We accounted for the cluster-randomized design by computing cluster-robust standard errors. Where appropriate, we accounted for within-pregnancy clustering (repeat visits by the same woman) using random intercepts at the level of pregnancy. We adjusted for the stratification variable (cluster size) and for laboratory availability, ultrasound availability and the phase (time point at which the MCH eRegistry was implemented) as fixed effects [13, 24]. No data were missing. We performed all analyses according to the intention-to-treat principle: all randomized women were included and analyzed in the arms to which the clinics they attended were randomized. Analyses were performed using Stata 16 (StataCorp LLC, College Station, Texas, USA).

Modifications in extenuating circumstances

COVID-19 pandemic response measures, introduced by the Ministry of Health in the West Bank and Gaza, included restrictions on mobility, and clinics were closed for regular ANC. Some health care providers were transferred to other areas of the health care system to assist in the COVID-19 response. The trial was therefore put on hold for an indefinite period. The pause was registered in ISRCTN (ISRCTN10520687) 19 March, and executed from 23 March 2020. Women who had registered for the SMS service received an SMS with information about the pause in the SMS service. The team monitored the number of ANC contacts registered in the MCH eRegistry on a regular basis (Fig. 2). The number of ANC contacts in the study clinics revealed that it dropped continuously from mid-January throughout the original study period (1 December 2029 to 1 June 2020). The number of ANC contacts was lowest during the COVID-19 lockdown. The mobility restrictions lasted until the end of June 2020; however, reduced health care

Table 3. Women's and clinic's characteristics at the ANC booking contact across allocation

	Control N = 3324		TCC N = 4138		QID N = 3553		TCC & QID N = 4223	
	n	%	n	%	n	%	n	%
Maternal age								
≤20 y	559	16.8	623	15.1	619	17.4	702	16.6
21–25 y	1078	32.4	1448	35.0	1165	32.8	1379	32.7
26–30 y	944	28.4	1128	27.3	994	28.0	1209	28.6
31–35 y	478	14.4	623	15.1	493	13.9	604	14.3
36–40 y	235	7.1	259	6.3	235	6.6	267	6.3
>40 y	30	0.9	57	1.4	47	1.3	62	1.5
Missing	0	0	0	0	0	0	0	0
Parity								
Primiparous	806	24.3	883	21.3	795	22.4	1024	24.3
Missing	0	0	0	0	0	0	0	0
Gestational age								
0–14 gestational wk	2441	77.9	3120	78.7	2646	77.1	3146	79.4
>14 gestational wk	692	22.1	847	21.4	784	22.9	814	20.6
Missing	191	5.8	171	4.1	123	3.5	263	6.2
Body Mass Index								
<18.5 kg/m^2	97	3.7	126	4.1	133	4.8	130	4.2
18.5–24.9 kg/m^2	1188	45.4	1383	44.8	1281	45.8	1362	43.6
25–29.9 kg/m^2	858	32.8	993	32.2	883	31.6	991	31.7
≥30 kg/m^2	475	18.1	587	19.0	500	17.9	641	20.5
Missing	706	21.2	1049	25.4	756	21.3	1099	26.0
Average income								
<200 Israeli Shekel (ILS)	71	2.9	80	2.7	111	4.3	122	4.0
201–900 ILS	1260	52.2	1421	48.8	1294	49.7	1581	51.4
901–1820 ILS	827	34.3	1093	37.5	962	36.9	1071	34.8
1821–3050 ILS	231	9.6	290	10.0	223	8.6	264	8.6
>3050 ILS	25	1.0	31	1.1	15	0.6	38	1.2
Missing	910	27.4	1223	29.6	948	26.7	1147	27.2
Years of education								
<10 y	311	9.6	342	8.5	478	13.7	371	9.1
10–13 y	1590	48.9	1954	48.3	1749	50.2	1987	48.5
>13 y	1354	41.6	1752	43.3	1258	36.1	1741	42.5
Missing	69	2.1	90	2.2	68	1.9	124	2.9
Laboratory availability								
Yes	2551	76.7	3415	82.5	3106	87.4	3680	87.1
Ultrasound availability								
Yes	3148	94.7	3752	90.7	3293	92.7	3982	94.3
Implemented MCH eRegistry								
Phase I West Bank	874	26.3	1007	24.3	1110	31.2	959	22.7
Phase II West Bank	1810	54.5	2159	52.2	1773	49.9	2273	53.8
Phase III Gaza	640	19.3	972	23.5	670	18.9	991	23.5

usage continued for several months after. In the protocol, there were no contingency plans for the scenario that all routine ANC would close for several months. The continued effect of the pandemic on ANC, the limited external validity of results for routine ANC in LMICs, as well as depleted funding due to the delays, all informed the trial sponsors and independent trial monitors (Centre for Intervention Science in Maternal and Child Health, University of Bergen). Their decision not to re-open the trial was made on 1 November 2020. All research data until this date were preserved.

Role of the funding source

RESULTS

In total, 137 clusters (34 control, 34 QID, 35 TCC, 35 QID & TCC) were included, with 15 238 women booked for ANC (4138 in the TCC, 3553 in the QID, 4223 in the QID & TCC and 3324 in the control cluster) between 1 December 2019 and 23 March 2020 (Fig. 3).

The groups were balanced on women's and clinics' characteristics (Table 3).

There were no statistically significant effects of the QID intervention on appropriately screened and managed anemia, hypertension and diabetes separately (Table 4).

Approximately 730 per 1000 women randomized to the control arm attended timely follow-up contacts. An OR of 1.20 indicates the TCC intervention would increase timely attendance to 760 per 1000 women (an additional 30 per 1000 women); however, the CI is consistent with a decrease, increase and no difference in timely attendance (Table 4).

Table 4. Comparison between control and intervention arms for primary outcomes

	N events/ N contacts	%	N events/ N contacts	%	OR*	95% CI	P
Screening and management:	*Control*		*QID*		*QID vs Control*		
Anemia[a]	2030/4024	50.5	2306/4378	52.7	1.04	(0.75–1.44)	0.831
Hypertension[b]	9748/9959	97.9	10 319/10560	97.7	0.97	(0.67–1.42)	0.882
Diabetes[c]	2239/4849	45.8	2238/5263	42.5	0.84	(0.57–1.23)	0.361
Timely attendance to scheduled ANC	*Control*		*TCC*		*TCC vs Control*		
ANC contacts	2791/3803	73.4	3759/4916	76.5	1.20	(0.90–1.61)	0.213
Timely attendance to scheduled ANC contacts, & screening and management:	*Control*		*QID & TCC*		*QID & TCC vs Control*		
Anemia[d]	470/1222	38.5	727/1554	46.8	1.13	(0.63–2.03)	0.684
Hypertension[e]	1728/1781	97.0	2174/2239	97.1	0.83	(0.52–1.33)	0.436
Gestational Diabetes[f]	364/684	53.2	502/847	59.3	0.98	(0.58–1.64)	0.936

*Adjusted for cluster size, phase, laboratory and ultrasound availability (all as fixed effects), within-pregnancy clustering (random effects) and cluster-robust standard errors to account for the cluster design. [a]N = 301 (9.1%) women from control and N = 263 (7.4%) from QID arm did not have the opportunity to be screened for anemia. [b]N = 67 (2.0%) women from control and N = 67 (1.9%) from QID arm did not have the opportunity to be screened for hypertension. [c]N = 89 (2.7%) women from control and N = 75 (2.1%) from QID arm did not have the opportunity to be screened for diabetes. [d]N = 2234 (67.2%) women from control arm and N = 2840 (67.3%) from QID & TCC arm were not scheduled for anemia screening. [e]N = 1543 (46.4%) women from control and N = 1984 (47.0%) from QID & TCC arm were not scheduled for hypertension screening. [f]N = 2640 (79.4%) women from control and N = 3376 (79.9%) from QID & TCC arm were not scheduled for diabetes screening.

The combination of the QID and TCC intervention did not statistically significantly improve the health care provider's performance, when the women attended a timely scheduled contact (Table 4).

Secondary analyses revealed no statistical difference between the QID and control arms, nor between the QID & TCC and control arms, on timely attendance to scheduled ANC contacts. There were no differences between the TCC and control arms on appropriate screening and management, with the exception of a clinically insignificant improvement in appropriate screening and management of hypertension in the TCC arm with 98.5% (12 674 appropriate among 12 869 opportunities) versus 97.9% (9748 appropriate among 9959 opportunities) among controls (Table S1).

DISCUSSION

The multi-arm eRegCom cluster RCT was interrupted due to the COVID-19 pandemic, which resulted in reduced opening hours and care services provided. We were therefore not able to properly assess whether digital communication strategies to women and health care providers in isolation and/or combination are effective in improving timely attendance to, and quality of, ANC in an LMIC primary health care setting. The development and implementation of our theory-driven interventions and strong methods illustrate an example of how to develop and assess health systems-strengthening approaches in primary health care settings.

The eRegCom trial is a direct response to WHO's request for effectiveness studies of DHIs from LMIC settings [5]. Digital audit and feedback in primary health care is effective in various health domains and settings; however, limited evidence exists from ANC in LMICs [8]. Limited evidence exists also regarding the effect of TCC via text messages on improving ANC attendance [10, 25, 26]. Our messages ranged from simple appointment reminders to complex tailored messages that included information about the severity and potential consequences of the woman's identified risk factor. Tailored messages are reported to lead to behavior change [27, 28]. Health-seeking behavior and usage of ANC were also addressed by including awareness and education components, preferred by women [29, 30]. We have previously shown

that the tailored text messages based on individual-level risk factors did not trigger women's worries [17]. We did not formally assess or document other perspectives among users, although feedback from users in various encounters such as seminars or meetings was overwhelmingly that text messages were welcomed and viewed positively.

The eRegCom trial is also a direct response to WHO's request for research that assesses the synergies across combinations of DHIs [5]. We are not aware of any studies that have assessed the effect of digital communication strategies to pregnant women and health care providers in combination. Clients who understand their condition and think the health care provider is concerned about their well-being have improved client satisfaction, compliance and health outcomes [4, 31]. A potential leverage effect may be explained through an ecological perspective, where multiple levels interactively influence health-related behaviors and conditions [32]. In our case, the text message content could potentially influence the clients' perceptions of pregnancy-related adverse conditions including the risks and the benefits of attending ANC (individual level), the QID could potentially influence the health care providers' clinical practice and the interpersonal communication with the women (social level) and the possibility to send text message alerts via the system could potentially influence the scheduling of ANC appointments (organizational level).

The eRegCom trial was a follow-up of our eRegQual trial, assessing similar outcomes [13]. We targeted and assessed health system process improvements—appropriate screening and management, and timely attendance to ANC—as immediate results of the QID, the TCC and the TCC & QID interventions, instead of distal outcomes that are affected by a variety of factors beyond the interaction with our interventions [5]. The evidence on distal effects of DHI on maternal health behaviors and maternal-fetal health outcomes are limited [33, 34].

The first and foremost limitation is that the trial failed to achieve its sample size due to the COVID-19 pandemic. Several factors hindered access to maternal health care services during the pandemic [35] and most likely influenced the behavior of women and health care providers in our study before, during and after the lock down. The trial was first paused, but resource constraints forced us to stop the trial as the pandemic continued to evolve with disruptions in the provision of, and access to, health

care services. For technical reasons (the inability of the software to identify non-existing or lacking events at the time we developed the interventions), we were unable to introduce 24 hours after a missed appointment and recapture messages, as described in the protocol paper [15]. In addition for technical issues, because our software lacked features to deliver more active approaches at the time of our study [36], health care providers had to 'pull' or actively click and visit the QID. Even though, feedback that is 'pushed' to beneficiaries facilitate interaction to a greater extent compared with feedback that beneficiaries have to 'pull' [37].

The strengths are the rigor of the methodology of a cluster RCT with a large population-based sample, for women and clinics. In addition, we developed our theory-based interventions with stakeholders and users described in previous publications [19, 23]. The individual-level clinical data and user information in the MCH eRegistry enable us to automatically tailor DHIs without additional efforts, which may potentially improve the return of investments of comparable systems.

CONCLUSION

The eRegCom trial was conducted at the beginning of the COVID-19 pandemic, which influenced the number of scheduled and attended ANC contacts. The pandemic also influenced health care providers' tasks because many were transitioned to assist in the pandemic response. We therefore failed to achieve our target sample size and properly assess the effectiveness of our DHIs—the TCC, the QID and the QID & TCC—on timely attendance to, and the quality of, ANC in Palestine. Our approach of developing and implementing TCC and QID in a routine health information system, and rigorous methods of evaluation, will hopefully contribute to further learning for future evaluations of digital health interventions.

Supplementary Data

Supplementary data are available at *Oxford Open Digital Health* online.

Trial registration: ISRCTN, trial registration number: 10520687, registered 18 October 2018, http://www.isrctn.com/ISRCTN10520687.

Conflict of interest

The authors declare that they have no conflict of interest.

Authors' contributions

J.F.F. conceptualized the study and acquisitioned funding. J.F.F. was the principal investigator and led the supervision with K.M. K.M. and J.F.F. supervised PhD and master students, and B.G. supervised the team in Palestine. K.M., B.G. and J.F.F. led the project administration, and B.G. led the implementation of the MCH eRegistry in Palestine. K.M., B.G., B.B., M.V. and J.F.F. developed the methodology, and all authors contributed to the refinement of methods through protocol and/or analysis plan workshops. K.M., B.G., E.A., K.A.K., I.A.W., B.B., T.H., K.S.F., Z.N. and J.F.F. contributed to the investigation for the development of the interventions, and B.G., E.A. and I.A.W. contributed to the investigation of the outcomes. A.A., M.B., M.J.F., B.O. and Y.R. developed and implemented the software, with support from E.A., I.A.W., B.B., M.I., S.I. and S.E.Q. M.I. and S.I. were responsible for data curation. C.J.R. oversaw the formal statistical analysis, and E.P. conducted the formal analysis with assistance from M.V. B.O. contributed to the visualization. K.M. wrote the original draft. All authors contributed to the review and editing of the manuscript and approved the final version.

Declaration
Availability of data and materials

The data in the eRegistry are owned by the Ministry of Health in the West Bank and Gaza. The extraction code for the exact dataset used in this trial analysis and a data dictionary are stored at the Palestinian National Institute of Public Health. Access to the anonymized, individual-level data and the data dictionary can be provided by the Palestinian National Institute of Public Health on request, which includes a study protocol, a predefined list of variables, and appropriate ethics approvals, submitted to info@pniph.org. All codes used in this publication are available at GitHub (lila-papadopoulou/EregCom_Trial2). The latest version at the time of writing is archived at Zenodo (https://doi.org/10.5281/zenodo.7524399).

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