Could routine pregnancy self-testing facilitate earlier recognition of unintended pregnancy? A feasibility study among South African women

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ABSTRACT

Introduction We explored whether routine pregnancy self-testing is feasible and acceptable to women at risk of late recognition of pregnancy as a strategy to facilitate early entry into either antenatal or abortion care.

Methods A feasibility study among South African sexually active women not desiring pregnancy within 1 year, and not using long-acting or injectable contraceptives. At recruitment, we provided five free urine pregnancy tests for self-testing on the first day of each of the next 3 months. We sent monthly text reminders to use the tests with requests for no-cost text replies. Our main outcome was the proportion of participants self-testing within 5 days of the text reminder over three consecutive months. Other outcomes were ease of use of tests, preference for self-testing versus clinic testing, acceptability of routine self-testing (all binary responses followed by open response options) and response to text messages (four-point Likert scale).

Results We followed up 71/76 (93%) participants. Two confirmed new pregnancies at the first scheduled test and completed exit interviews, and 64/69 (93%) self-reported completing all three monthly tests. Self-testing was easy to do (66/71, 93%); advantages were convenience (21/71, 30%) and privacy (18/71, 25%), while the main disadvantage was no nurse present to advise (17/71, 24%). Most would recommend monthly testing (70/71, 99%). Text reminders were generally not bothersome (57/71, 80%); 35/69 (51%) participants replied with test results over all three months.

Conclusion Providing free pregnancy tests to women at risk of late recognition of pregnancy is feasible to strengthen early confirmation of pregnancy status.

Key messages

- Providing free pregnancy tests for routine monthly self-testing is a promising strategy to strengthen early confirmation of unintended pregnancy among at-risk women.
- Text message reminders to self-test are acceptable, but frequency of no-cost replies is variable.
- Routine monthly self-testing for unintended pregnancy is a feasible intervention to evaluate in a randomised controlled trial.

INTRODUCTION

In South Africa, 61% of first and 46% of second pregnancies are unintended.[1] Delays in obtaining safe legal abortion care are common with more than 25% of women undergoing abortion in the second trimester, compared with 10%–15% in the UK and United States (US), respectively.[1 2] Among women continuing a pregnancy to term, fewer than 7% of women attending public sector antenatal care in South Africa do so in the first trimester, as recommended by the South African National Department of Health and the World Health Organization (WHO).[3 4]

Abortion later in pregnancy is associated with a higher risk of complications compared with first-trimester termination.[5 6] Second-trimester abortion on socioeconomic grounds is legal and safely performed in South Africa;[7] however, providers are scarce[8] and later gestational age is the most common reason for denial of legal, safe abortion care.[9] Similarly, antenatal screening and treatment programmes aimed at reducing perinatal and maternal morbidity and mortality are rendered less effective when initiated at advanced gestation, particularly in high HIV prevalence settings where it is

recommended to start antiretroviral treatment early in pregnancy.[10 11]

Reasons for delay in seeking either abortion or antenatal care are multidimensional, and include absence or failure to recognise pregnancy symptoms, stigma, fear, and denial, as well as health system barriers.[8 12–18] Research from diverse settings has shown that, on average, time to confirmation of unintended pregnancy is the longest interval in the care-seeking process,[13 16 17 19 20] and there is a need for interventions to strengthen prompt recognition of pregnancy.[17 21 22] There is some evidence that women are more likely to suspect and self-test for pregnancy if tests are readily available.[19 23]

Further research is needed to better understand the benefits of providing readily available, free pregnancy tests to women as a public health strategy to improve timely care-seeking for women with unintended pregnancy.[16 22] To address this need, this study explored whether routine pregnancy testing is feasible and acceptable to women, and whether this approach lends itself to testing in a larger randomised controlled trial (RCT).

METHODS

Study procedures

We purposively sampled younger women (at least 50% ≤25 years, all ≤35 years) who were sexually active and not using longer-acting contraceptive methods and women seeking abortion from three distinct settings in South Africa: a university student wellness centre, an urban reproductive healthcare non-governmental organisation (NGO) providing abortion care (combined in analysis as the 'healthcare facility' group), and a peri-urban, economically disadvantaged community 50 km outside of Cape Town. Specific sites were selected for logistical reasons. Eligible women were aged 18–35 years, able to speak English, Afrikaans or isiXhosa, sexually active, not desiring pregnancy within 1 year, owned and had a working mobile phone with them at enrolment and were willing to receive monthly text messages and send replies (at no cost) over three consecutive months. Women using the implant, intrauterine contraception, or the 2- or 3-month injectable contraceptive were ineligible as the study follow-up period was limited to 3 months, and were excluded. In the healthcare facilities, a trained research assistant (RA) approached women in the reception area for interest and eligibility. Outside of facilities in the community, a community liaison officer informed local women about the study and where to meet for screening for participation. After the first group of community participants were enrolled, we used snowball sampling whereby participants encouraged acquaintances to join the study. We estimated a sample size of 76 was needed, assuming 80% of participants would test within 5 days of each monthly test date, with alpha set at 0.05, a margin of error of 10%, and loss-to-follow-up of 25%. We did not power the study to detect differences between groups.

Following eligibility screening, the RA obtained informed consent and conducted a structured baseline interview in private. We gathered sociodemographic information, reproductive history, current and expected sexual activity for the next 3 months, and regularity of menses. We established fertility awareness by asking if women knew about the fertile window, and categorised this as (1) unaware, (2) aware but with incorrect timing or (3) aware with correct timing.[17] The RA then provided participants with five midstream urine pregnancy tests, and explained how to use them and interpret results. She showed participants prescripted text messages they would receive on scheduled test days (first day of the next three consecutive months) and how to reply. After their third test date, the RA administered exit questionnaires in-person or by telephone. If a participant tested positive and confirmed with a second test, the RA advised them to seek healthcare and completed an exit interview, as the participant was discontinued. Participants were reimbursed South African Rand (ZAR) 100 (~US$7) for their time at baseline and ZAR100 airtime after their exit interview.

We used a text messaging system to send monthly reminders the evening before the test date and requests for test results the following morning. The reminder read "The PT Study reminds you to do your pregnancy test first thing tomorrow morning. Do not reply to this SMS". The test result request read "The PT study asks: Did you do your pregnancy test? Please reply ASAP Yes/No and the date you tested and the result if Pos or Neg. Or say why you didn't test". We developed messages for non-responders and for those who replied with a positive test result, which were used as needed.

Outcomes

Our primary outcome was the proportion of participants conducting self-testing within 5 days of the text reminder (the 'test window') over three consecutive months. Secondary outcomes were pregnancies identified, number of tests used and response rate to text messages; participant experience with self-testing (were tests easy to do/understand, was privacy a concern); preference for self-testing (advantages/disadvantages of self-testing vs clinic testing); acceptability of routine self-testing (interest in continuing to test every month, would recommend monthly testing to a friend, best/worst aspects of monthly testing; satisfaction with reminder text messages (how bothersome, four-point scale); and frequency and rationale for repeat testing. Group outcomes were compared using chi-square or Fisher's exact tests where appropriate.

Patient and public involvement

Patients and the public were not directly involved in the design or conduct of this study.

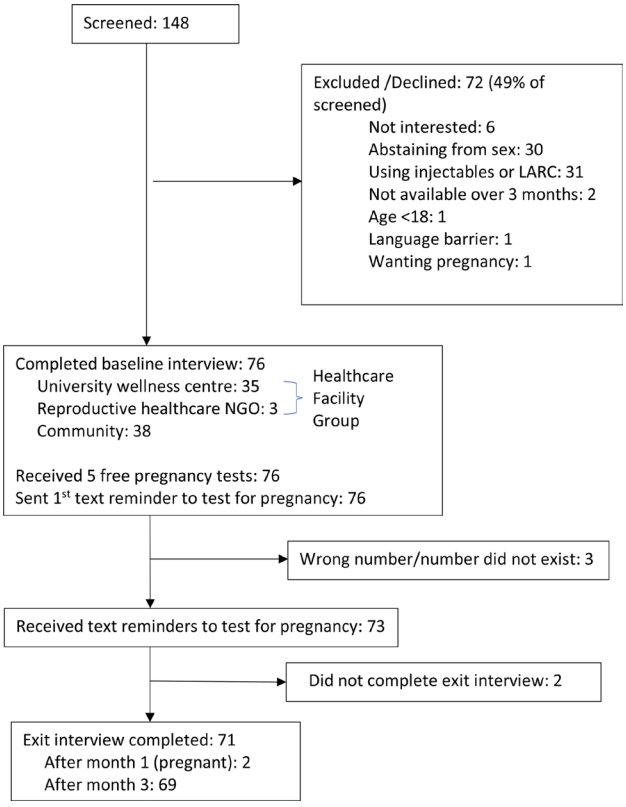

Figure 1 Participant flow through each stage of a feasibility study on routine self-testing for early recognition of unintended pregnancy.

RESULTS

Between March and May 2018, we screened 148 women. Of these, 66 were excluded, six declined and 76 were recruited (figure 1). We completed 71 (93%) exit interviews between April and September 2018; five participants were lost to follow-up.

Healthcare facility (HCF) and community participants had diverse sociodemographic backgrounds, reproductive characteristics and fertility awareness (table 1), significant at $p \leq 0.05$. Community participants were older, none had post-secondary education and nearly a quarter lived in informal dwellings. Community participants had more prior pregnancies, no prior abortions and most (36, 95%) were not currently using contraception. In contrast, 30 (79%) HCF participants were using contraception, either the pill and/or condoms. Most community participants (33, 87%) were unaware of the 'fertile period' while most HCF participants (29, 76%) knew of and correctly identified 'fertile period' timing. The majority of HCF (26, 68%) but few community (8, 21%) participants reported prior experience with pregnancy testing ($p < 0.001$).

Overall, 71/76 (93%) participants completed follow-up, comprising 36 (95%) HCF and 35 (92%) community participants (table 2). Two pregnancies were confirmed in the first month of testing (1 HCF, 1 community) and 64/69 (93%) reported testing within the test window for all 3 months (either as text replies and/or in exit interviews). There was some drop-off over the 3 months with 67 (97%) testing at month 2 and 64 (93%) testing at month 3. The response rate for text replies with test results was high among the HCF attendees, but relatively poor from community participants. Overall, the majority (58/71, 82%) responded to at least one message, but only half responded to all three messages.

Repeat testing for various reasons in any month was common with nearly a third repeat testing in month 1; this dropped slightly in months 2 and 3 (table 3).

The experience of monthly self-testing was similar for both groups. Most found tests easy to do and understand and few had privacy issues (online supplemental table S1). Most (69, 97%) agreed that doing the pregnancy tests was helpful in confirming their pregnancy status for the following reasons: no need to wait for symptoms (45, 65%), a negative result despite suspecting an unplanned pregnancy (10, 14%) and that routine testing gave reassurance (9, 13%), increased familiarity and trust with the tests (6, 9%) and because it was convenient and avoided stigma (6, 9%). A third of participants found a test result surprising. Of the 24 participants surprised by the test result, 15 (63%) had suspected they might be pregnant, and others (7, 29%) said they were sexually active but not using contraception. Of the four participants with a positive first test, two were false positives; two confirmed their pregnancies, both of whom had not suspected pregnancy. Most commonly reported advantages of home versus clinic testing included convenience (21, 30%) and privacy (18, 25%). Disadvantages were that there was no nurse to give advice (17, 24%), privacy problems in communal living situations (2, 3%) and uncertainty about reading the test results (4, 6%).

The most valued aspects of routine home testing were improved awareness of pregnancy status (51, 72%), convenience of having home tests kits and avoiding stigma and stress (32, 45%), a sense of autonomy emerging from repeat self-testing (11, 15%) and the benefit of receiving the intervention overall – both test kits and reminders (10, 14%). Approximately half (33, 47%) could not identify any particular unpleasant aspect of routine home testing. Some (18, 25%) mentioned that performing the test and anticipating the result provoked anxiety. Others (19, 27%) found the monthly testing process problematic for them in some way, for example, integrating this into their early morning routine, or urinating on a stick.

Many (63, 89%) were interested in continuing monthly testing (online supplemental table S1). Of these, the most common reasons were assurance of pregnancy status (30, 48%) and convenience – if tests were at hand and free (21, 33%). Others thought they would likely seek care earlier if pregnant (7, 11%). Those undecided or not interested in routine home testing (8, 11%) said they did not want to test every

Table 1 Baseline sociodemographic and reproductive characteristics among study participants according to study site

Characteristic	All participants (n=76) n (%)	Healthcare facility participants (n=38) n (%)	Community participants (n=38) n (%)	P value
Age (years)				0.003
18–20	21 (27.6)	12 (31.6)	9 (23.7)	
21–25	30 (39.5)	21 (55.3)	9 (23.7)	
26–30	14 (18.4)	3 (7.9)	11 (29.0)	
31–35	11 (14.5)	2 (5.3)	9 (23.7)	
Education completed				<0.001
Primary or some secondary school	28 (36.8)	0 (0.0)	28 (73.7)	
Secondary school	13 (17.1)	3 (7.9)	10 (26.3)	
Some post-secondary education	35 (46.1)	35 (92.1)	0 (0.0)	
Housing				0.001
Informal dwelling (shack)	9 (11.8)	0 (0.0)	9 (23.7)	
Formal dwelling (brick)	67 (88.2)	38 (100)	29 (76.3)	
Paid work	14 (18.4)	6 (15.8)	8 (21.1)	0.554
Prior pregnancies (n)				<0.001
0	36 (47.4)	27 (71.1)	9 (23.7)	
1	25 (32.9)	8 (21.10	17 (44.7)	
≥2	15 (19.7)	3 (7.9)	12 (31.6)	
Prior abortion (Yes)	8 (21.1)	8 (10.5)	0 (0.0)	0.003
Period regularity				0.014
Regular (every 21–35 days)	58 (76.3)	34 (89.5)	24 (63.2)	
Not regular (can be <every 21 days or >every 35 days)	18 (23.7)	4 (10.5)	14 (36.8)	
Awareness of period				0.622
Very aware – always knows when it will come	52 (68.4)	25 (65.8)	27 (71.1)	
Not very aware – some or no idea about when it will come	24 (31.6)	13 (34.2)	11 (28.9)	
Fertility awareness				<0.001
Aware, right timing	30 (39.5)	29 (76.3)	1 (2.6)	
Aware, wrong timing	9 (11.8)	5 (13.2)	4 (10.5)	
Unaware	37 (48.7)	4 (10.5)	33 (86.8)	
Current contraception				<0.001
No method	44 (57.9)	8 (21.1)	36 (94.7)	
Pills	14 (18.4)	14 (36.8)	0 (0.0)	
Condoms only	16 (21.1)	14 (36.8)	2 (5.3)	
Pills and condoms	2 (2.6)	2 (5.3)	0 (0.0)	

month, were on contraception anyway or were not having sex regularly.

DISCUSSION

This study aimed to determine the feasibility of evaluating routine pregnancy testing in an RCT in South Africa and other settings. We showed that participants adhered well to a schedule of monthly pregnancy testing over three consecutive months when given free home tests and monthly text reminders. A large RCT with approximately 2000 participants would be needed to determine whether the intervention was effective in facilitating earlier recognition of pregnancy and entry to care; our findings suggest that we would need to recruit from many more sites to obtain the desired sample size in a reasonable period of time. Text reminders and requests for results were successfully delivered to participants' mobile phones over the study duration with few failures, but with a diminishing return rate of replies over 3 months and from older women; in a future trial we would likely do quarterly follow-up telephone interviews to ensure complete data collection.

Other interventions aiming at strengthening timely use of sexual and reproductive healthcare include providing test kits for use when pregnancy

Table 2 Use and results from routine pregnancy testing among study participants followed up over 3 months

	All participants (n=71) n (%)	Healthcare facility participants (n=36) n (%)	Community participants (n=35) n (%)	P value
Performed test in month 1 within 5-day window	71 (100.0)	36 (100.0)	35 (100.0)	0.984
Test result in month 1				
Negative	69 (97.2)	35 (97.2)	34 (97.1)	0.984
Positive	2 (2.8)	1 (2.8)	1 (2.9)	
Did not test/missing	0 (0.0)	0 (0.0)	0 (0.0)	
Performed test in month 2 within 5-day window*	68 (98.5)	34 (97.1)	34 (100.0)	0.358
Test result in month 2*				
Negative	67 (97.1)	33 (94.3)	34 (100.0)	0.493
Positive	0 (0.0)	0 (0.0)	0 (0.0)	
Did not test/missing	2 (2.9)	2 (5.7)	0 (0.0)	
Performed test in month 3 within 5-day window*	64 (92.8)	34 (97.1)	30 (88.2)	0.327
Test result in month 3*				
Negative	64 (92.7)	34 (97.1)	30 (88.2)	0.198
Positive	0 (0.0)	0 (0.0)	0 (0.0)	
Did not test/missing	5 (7.3)	1 (2.9)	4 (11.8)	
Total number of study pregnancy tests used (n)				
≤1	0 (0.0)	0 (0.0)	0 (0.0)	0.450
2	7 (9.9)	2 (5.6)	5 (14.3)	
3	29 (40.9)	15 (41.7)	14 (40.0)	
4+	35 (49.3)	19 (52.8)	16 (45.7)	
Response to text messages				
Responded to ≥1 message	58 (81.7)	34 (94.4)	24 (68.6)	0.005
Responded to all 3 messages*	35 (50.7)	27 (77.1)	8 (23.5)	<0.01

Numbers performing test is based partly on contemporaneous text responses and also on patient recall at 3 months.
*Denominator excludes participants who tested positive in month 1 (both continued with their pregnancy).

is suspected, or having community health workers provide and conduct testing.[23 24] These have been tested in well-powered RCTs or follow-up studies; however, their findings are not necessarily generalisable as they were either limited to English-speaking US women[19] or were conducted in poor and rural settings with limited access to healthcare[23 24] or no access to abortion care.[23] Our study explored the feasibility of routine self-testing in urban and peri-urban settings in a middle-income country where abortion is legal but access is challenging, and has laid the groundwork for efficacy testing in a large-scale trial. Large RCTs offering free self-testing kits for HIV are instructive in this regard and report significant improvements in frequency of testing and prompt recognition of HIV-positive status.[25 26]

Although testing provoked anxiety among some women who anticipated a positive result, most did not

Table 3 Reasons reported for repeating the pregnancy test done at month 1, month 2 and month 3

Reason	Month 1 n (%)	Month 2 n (%)*	Month 3 n (%)*
Repeated the pregnancy test	20/71 (29.6)	15/69 (21.7)	15/69 (21.7)
Reason to repeat test†			
Thought I might be pregnant (pregnancy symptoms, unprotected sex, late period)	6 (30.0)	6 (40.0)	6 (40.0)
To be sure/check that I did it right	6 (30.0)	6 (40.0)	6 (40.0)
First test positive	3 (15.0)	1 (6.7)	0 (0.0)
First test invalid	2 (10.0)	0 (0.0)	1 (6.7)
First test unclear	2 (10.0)	2 (13.3)	2 (13.3)

*Two participants testing positive in month 1 were discontinued in months 2 and 3.
†One missing response.

delay performing their routine test. For women not using contraceptives, with short-term or intermittent sexual relationships or using contraceptives irregularly, routine testing may address the problem of delay in confirming pregnancy and heighten awareness of risk of pregnancy more effectively than risk-driven testing. Generally, behavioural practices that mitigate risk are hard to sustain, especially when the risk is not considered likely. However, familiar and routine practices are more easily carried out than unaccustomed ones. Reminders are likely needed to maintain monthly testing, and there are numerous mobile phone applications with reminders systems that are suitable for this purpose. The use of mHealth in Africa shows promise, and has become widespread during the COVID-19 pandemic; however, older people and those living in rural areas may experience challenges using mobile phones.[27 28]

Making pregnancy testing freely available and a commonplace experience has been repeatedly recommended to policymakers by researchers and advocacy groups,[17 19 23 24] and with the cost of pregnancy tests now as low as US$0.10 becomes a feasible public health strategy. Free and readily available pregnancy tests for women to routinely self-test is well-aligned with the WHO conceptual framework for self-care interventions.[29]

Strengths of this study are the novel intervention and promising evidence it provides for future scaled research. Our purposive sampling approach included a diverse study sample of women at risk of unintended or unwanted pregnancy, we had good retention over the study duration and few system failures occurred. The intervention is timely and well-aligned with current self-care approaches recommended by the WHO[28] and recent South African policy.[30]

Study limitations were possible selection bias from the preselected study sites and initial recruitment approach, and potential reporting and recall bias as the main outcomes were self-reported and based on recall at exit interview for those not sending text replies for all the study months (49%). The numbers performing pregnancy testing is based partly on contemporaneous text responses and also on patient recall at 3 months, which may be less accurate. The free reply message system was not well-used by older women and those living on low incomes. The study duration was limited to 3 months due to resource restraints necessitating exclusion of women using (and possibly discontinuing) an injectable contraceptive, the most common method used by South African women attending public sector services. Finally, it should be noted that the study data are from 2018.

In conclusion, this study demonstrated that providing free pregnancy test kits to sexually active women at some risk of unintended pregnancy is a feasible approach to strengthen early confirmation of pregnancy status, and that future research needs to test the effectiveness of this approach in an RCT.

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Contributors DC and DG were involved in the study design, and drafting and finalising the manuscript. DC conducted the study and did the analysis. SL managed the data, assisted with analysis, and reviewed the final manuscript.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

Patient consent for publication Not required.

Ethics approval The study protocol was approved on 14 February 2018 by the University of Cape Town Human Research Ethics Committee (HREC 013/2018); permission was obtained from the student wellness clinic and the non-governmental organisation providing abortion care.

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement Deidentified participant data is available from the corresponding author upon reasonable request. Reuse is permissible following the authors' agreement to the proposed study protocol. (ORCID ID: 0000-0002-7176-9963)

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