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RU OK? The acceptability and feasibility of remote technologies for follow-up after early medical abortion☆,☆☆,★

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Abstract

Objectives: We tested the effectiveness and feasibility of remote communication technologies to increase follow-up after early medical abortion.

Study design: Women (n=999) were randomized to 'remote' follow-up incorporating a low-sensitivity pregnancy test and standardized symptom questionnaire administered online, by text message or telephone by a non-clinical call center operator 2 weeks after treatment, or to 'clinic-based' follow-up with ultrasound at 1 week. Women in the clinic-based group who could not return performed a high-sensitivity pregnancy test at 3 weeks and had a telephone call with clinic staff. The primary outcome was completion of follow-up. Rates of complications, acceptability and preferences were compared.

Results: The overall follow-up rate did not differ by group {clinic-based, 73% vs. remote, 69%; risk ratio (RR) 1.0 [95% confidence interval (CI) 0.9–1.2]}. In the clinic-based group, 83% did not return for an ultrasound scan and were followed up by phone. In the remote group, follow-up by phone or text was more successful than online (text: 75.4%; phone: 73.7%; online: 46.5%, p<.001). The proportion of women receiving additional care was 9% in the clinic-based group and was 4% in the remote group [RR 1.8 (95% CI 1.1–3.1)]. Most women found their follow-up method acceptable but would prefer follow-up by phone or text message if needed in future.

Conclusions: Follow-up after medical abortion using remote communication is feasible and, for most women, preferable to a clinic visit.

Implications: Medical abortion protocols typically use follow-up visits to ensure early identification of complications. This study demonstrates that follow-up can be achieved using remote communication technologies. This model may reduce the burden of multiple clinic visits on patients and providers.

Keywords: Mifepristone; Low-sensitivity pregnancy test; Text message; Telephone; Acceptability

1. Introduction

A follow-up visit remains an integral part of nearly all medical abortion protocols [1–3] to exclude ongoing pregnancy [4] or identify other problems. However, a model of care with multiple office visits is neither feasible nor desirable for all women [5]. Repeated visits are also expensive for providers, particularly when women do not attend scheduled follow-up appointments [6].

Promising alternatives to an in-person follow-up visit have been reported. These include self-administered symptom questionnaires, telephone follow-up with high- and low-sensitivity urine pregnancy tests and self-assessment with a semi-quantitative urine pregnancy test [7–12]. These new methods could make the process more acceptable while still giving providers and women reassurance that the treatment has succeeded.

The British Pregnancy Advisory Service (**bpas**) performs approximately 20,000 early medical abortions annually at 34 units spread throughout England and Wales. Organizational guidelines recommend follow-up with an ultrasound scan 1–2 weeks post-treatment or self-administration of a high-sensitivity pregnancy test and telephone follow-up with a

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clinic staff member 3 weeks after treatment. Compliance is low with both options and considerable resources are spent attempting to contact women to determine outcomes. In an effort to reduce the burden on clinics and to improve the follow-up rate, this study evaluated a system in which women self-administered a low-sensitivity pregnancy test 2 weeks post-treatment and were assessed via a standardized symptom questionnaire administered remotely from **bpas**' telephone contact center by text message, online survey or telephone. The study describes the proportion of women choosing different communication modalities, follow-up rates, detection of ongoing pregnancies and acceptability of this 'remote' system as compared to **bpas**' routine clinic-based follow-up.

2. Materials and methods

This study was conducted at **bpas** clinics in London, Chester, Birmingham and Swindon. Women with pregnancies ≤ 63 days gestation by ultrasound scan, desiring a medical abortion with mifepristone and misoprostol, ≥ 16 years old and willing and able to communicate in English, provide informed consent and comply with the study protocol were eligible for inclusion. All participants had to have access to a mobile phone, the internet or a telephone and be willing to use at least one of these for post-abortion assessment. Screening, enrollment and randomization occurred on the day of mifepristone administration. Women were randomized to either remote or clinic-based follow-up when a clinic research staff member opened the next sequential sealed opaque envelope indicating group assignment. The groups were created by Gynuity Health Projects using a computer-generated sequence in blocks of 8 and stratified by study site. The medical abortion regimen consisted of 200 mg oral mifepristone followed 6–72 h later by 800 mcg vaginal misoprostol administered in clinic, as required by law in Britain. Women were discharged after misoprostol administration to complete the medical abortion at home.

Women in the remote group followed a protocol undertaken by non-clinical telephone operators at the **bpas** contact center. Women indicated their first and second choices for follow-up (telephone call, SMS text message or online questionnaire). They were provided with a low-sensitivity urine pregnancy test (NADEL hCG-2000, 2000 mIU/mL) with instructions to perform the test in 2 weeks at which point they would be contacted by their chosen method. The following validated [8] questions were asked, regardless of method of contact:

- "Did you experience no or only one day of heavy bleeding during treatment?
- Do you have any of the following today: breast tenderness, nausea or morning sickness, frequent urination, or exhaustion or tiredness?
- Thinking of how you feel at this moment, physically and emotionally, would you say that you still feel pregnant?
- Is your pregnancy test positive?"

Women electing phone communication were called by an operator who administered the questionnaire. Women selecting SMS text messaging received and responded on their mobile phone. Women completing the questionnaire online were sent an email directing them to a secure site for submission of responses. The contact center operator then assessed the responses. If the answer to any of the questions was "yes," women were advised to call the contact center to schedule an appointment (SMS text message, online) or to do so with the operator with whom they were speaking (telephone). Women then completed a questionnaire regarding acceptability and preferences. If the woman failed to respond to advice to contact **bpas** for a follow-up appointment, three further attempts were made to contact her using both her first and second choice modality. All additional or unscheduled visits were documented.

Women in the clinic-based group were asked to return in 1 week for an assessment and ultrasound. A high-sensitivity urine pregnancy test (Clearview One Step, 25 mIU/mL) was provided to women in this group with instructions to perform the test in 3 weeks and to phone the clinic with the results if they could not return for their in-person visit. A nurse or a trained non-clinical staff member overseen by a nurse conducted the follow-up call but did not use a standardized script. If the woman reported a positive pregnancy test or any concerning symptoms, she was given a clinic appointment. Three attempts were made to contact women who failed to return or call in. Once follow-up was complete, women were asked about acceptability and preferences either in person or by phone depending on how their follow-up was conducted.

We hypothesized that the remote group would have a 20% higher rate of contact than those assigned to **bpas**' usual clinic-based regime (estimated at 50%) and thus required a sample size of 125 women per group (α=0.05; $1-\beta$=0.9, using a one-tailed test). To account for inter-site variations, we planned to enroll 250 women (125 per study arm) at each site for a total sample size of 1000.

The primary outcome was completion of follow-up. Women were considered to have completed follow-up if they made contact with the clinic and answered one or more of the follow-up questions. Women who were referred to the clinic after phone, text or email contact but did not return were considered lost to follow-up. Secondary outcomes included further treatment (including for ongoing pregnancy), acceptability and preferences. Two-tailed $p<.05$ was considered statistically significant. Binomial proportion confidence intervals (CIs) for follow-up and complication rates were calculated. We used Fisher's exact test to determine differences in proportions and Student's *t* test to determine differences in means for continuous variables.

Hierarchical logistic regression analyses were conducted to adjust for possible confounders using both forced entry of the term for group assignment and, separately, the backwards stepwise Wald method with probability of score statistic for variable removal of 0.05 and probability of the Wald statistic for variable of 0.10 for potential confounders (highest education completed, travel time>40 min, computer at home, site). Data were analyzed using SPSS 15.0.

The study was approved by the National Research Ethics Service–West Midlands Research Ethics Committee and the **bpas** Research and Ethics Committee. The protocol was registered with clinicaltrials.gov trial registry, NCT01362387.

3. Results

Between April 2011 and February 2012, 1405 women were screened and 999 women were enrolled [Birmingham (*n*=270); Swindon (*n*=270); London (*n*=179); Chester (*n*=280)]. Fourteen women were determined to be ineligible because they did not have access to a mobile phone or computer. Four hundred ninety-eight women were randomized to the remote follow-up group and 501 were randomized to clinic-based follow-up (Fig. 1). Twenty-one women withdrew after randomization (remote: 11; clinic-based: 10). Table 1 shows the sociodemographic characteristics of participants. Women in the remote group were significantly more educated (p=.004) and more likely to have a computer at home (p=.028) than those in the clinic-based group.

Overall, the medical abortion outcomes of the two groups were not statistically significantly different (Table 2). Among women with follow-up data, most had a complete abortion without surgical evacuation (clinic-based: 96.1%, 347/361; remote: 97.6%, 332/340). There was no difference in rates of surgical evacuation for ongoing or non-viable pregnancy or retained gestational sac between groups. Three women per group were hospitalized after administration of mifepristone or misoprostol for bleeding or pain management. One woman with excessive bleeding received a blood transfusion.

A few women in each group visited the clinic or hospital before their scheduled contact date (Fig. 1). Regardless of group assignment, most did not receive additional treatment at that interim visit (14/18 remote, 15/27 clinic-based).

The proportions of women that completed follow-up did not differ by group assignment (Table 3). In the clinic-based group, 72.6% (337/464) completed follow-up (Fig. 1) but

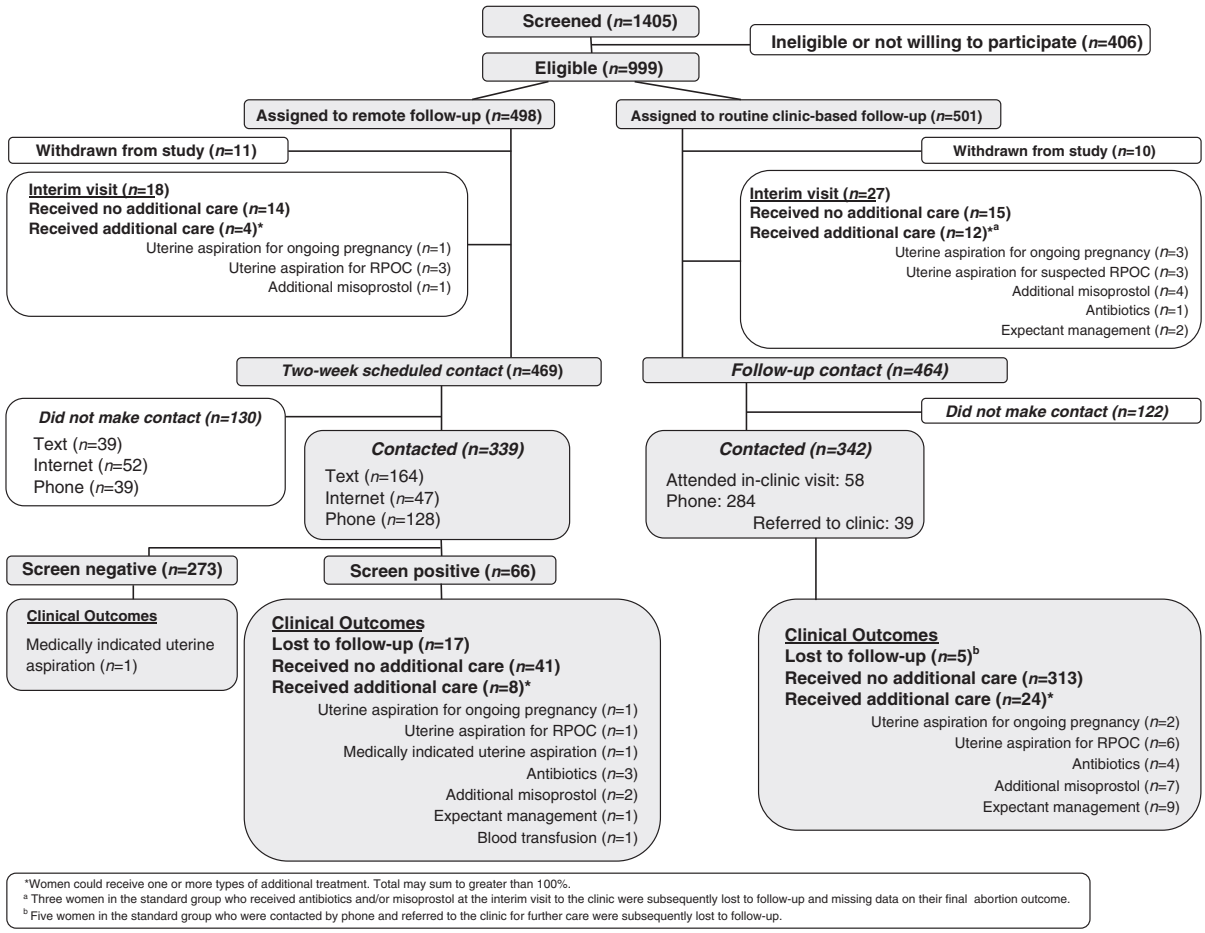

Fig. 1. Flowchart of participants by follow-up group.

Table 1
Participant characteristics by group assignment

	Clinic-based follow-up (*n*=491)	Remote follow-up (*n*=487)	p Value
Age, in years: mean±SD (range)	26.6±7.1 (16–48)	26.5±6.8 (16–44)	.726
Level of education: % (*n*)			.004
No education or primary school	0.8 (4)	2.3 (11)	
Secondary school/ GCSEs	28.3 (139)	28.3 (138)	
Sixth form college/ A levels	46.4 (228)	37.4 (182)	
University or postgraduate	24.4 (120)	32.0 (156)	
Ethnicity: % (*n*)			.318
White	83.9 (411)	81.5 (397)	
Mixed	3.1 (15)	3.5 (17)	
Asian or Asian British	5.1 (25)	6.2 (30)	
Black or Black British	7.3 (36)	6.6 (33)	
Chinese or other ethnic group	0.6 (3)	2.1 (10)	
Marital status: % (*n*)			
Single	28.5 (140)	24.6 (120)	.151
Partnered but not married	55.4 (272)	57.9 (282)	
Married	12.2 (60)	15.2 (74)	
Divorced/separated/ widowed	3.9 (19)	2.3 (11)	
Mean travel time to clinic (min)	38.2±23.7 (2–150)	35.5±23.2 (2–150)	.070
Previous medical abortion: % (*n*)	19.8 (97)	17.0 (83)	.274
Gestational age (days)			
≤42	24.8 (122)	22.1 (108)	.641
43–49	35.0 (172)	38.6 (188)	
50–56	26.3 (129)	26.1 (127)	
57–63	13.8 (68)	13.1 (64)	
Access to and use of technology: % (*n*)			
Own mobile phone	99.8 (490)	99.8 (486)	.995
Computer at home	84.1 (413)	88.9 (433)	.028
Internet at home	87.2 (428)	89.1 (434)	.346
Have landline	63.7 (313)	61.4 (299)	.447
Use email daily	57.6 (283)	58.9 (287)	.496
Use internet daily	75.4 (370)	78.9 (384)	.554
Use text/SMS daily	98.4 (483)	97.7 (476)	.873

most failed to return for their scheduled ultrasound scan and were followed-up by phone (83.0%; 279/337). In the remote group, 68.7% (322/469) completed follow-up by their method of choice administered by a call center operator [risk ratio (RR) 1.06 (95% CI 0.97–1.20)]. In this group, women who elected follow-up by phone or text had higher rates of contact than those who selected the online questionnaire (text: 75.4%; phone: 73.7%; online: 46.5%) (text vs. phone, p=.37; text vs. online, p<.001; phone vs. online, p<.001). The time between mifepristone administration and follow-up was shorter for women in the remote group (*n*=322) (mean: 15.3 days; median: 15 days; range: 11–36) compared to women assigned to the clinic-based group (*n*=336) (mean: 25.5 days; median: 25 days; range: 7–66). This difference was statistically significant (p<.05).

Table 2
Medical abortion outcome: % (*n*)

	Clinic-based follow-up (*n*=491)	Remote follow-up (*n*=487)	RR (95% CI)
Unknown, LTFU	26.5 (130)	30.2 (147)	0.88 (0.72–1.07)
	n=361	*n*=340	
Complete abortion without surgical evacuation	96.1 (347)	97.6 (332)	0.98 (0.96–1.01)
Surgical evacuation	3.9 (14)	2.4 (8)	
Ongoing pregnancy	1.4 (5)	0.6 (2)	2.48 (0.48–12.72)
Non-viable pregnancy or retained gestational sac[a]	2.5 (9)	1.2 (4)	2.12 (0.66–6.82)
Medically indicated[b]	0	0.6 (2)	–
Received any additional care[c]	9.1 (33)	3.5 (12)	1.88 (1.15–3.06)

[a] One woman was admitted to another facility and received an evacuation and blood transfusion.

[b] One woman was hospitalized for excessive bleeding. One woman underwent an evacuation for excessive bleeding and retained sac.

[c] Includes women who returned for follow-up and received an evacuation, additional misoprostol or expectant management for RPOC, antibiotics, and one woman who was hospitalized for pain management. Three women in the standard of care group received antibiotics and/or misoprostol at an interim visit and were subsequently lost to follow-up.

In the clinic-based group, 28% (97/342) either attended for an ultrasound scan as scheduled (*n*=58) or were referred to the clinic for further assessment after follow-up by phone (*n*=39), mainly due to a positive high-sensitivity pregnancy test (74.4%; 29/39). Two women were diagnosed with an ongoing pregnancy in this group and both reported a positive pregnancy test result at phone follow-up. The sensitivity and specificity of the clinic-based follow-up protocol for identification of ongoing pregnancy were 100% and 73.1%, respectively (Table 4). Five women who were

Table 3
Follow-up rate and method of contact: % (*n*)

	Clinic-based follow-up (*n*=464)	Remote follow-up (*n*=469)		RR (95% CI)
Completed follow-up[a]	72.6 (337)	68.7 (322)		1.06 (0.97–1.15)
		Text at 2 weeks[b] (*n*=203)	Phone at 2 weeks (*n*=167)	Online at 2 weeks (*n*=99)
Completed follow-up		75.4 (153)	73.7 (123)	46.5 (46)

[a] Excludes women who made an interim visit to clinic prior to scheduled contact (clinic-based: *n*=27; remote: *n*=18). In the clinic-based group, 17% of women (58/337) returned to the clinic and 83% (279/337) were contacted by phone by clinic staff.

[b] Text vs. phone (p=.371); text vs. online (p<.001); phone vs. online (p<.001).

Table 4
Sensitivity/specificity and positive/negative predictive values of clinic-based and remote protocols for detection of ongoing pregnancy after medical abortion [% (95% CI)]

Screen	Sensitivity	Specificity	Screened positive	Positive predictive value	Negative predictive value
Clinic-based follow-up[a]	100 (19.3–100)	73.1 (68.1–77.8)	27.3 (22.8–32.3)	2.2 (0.3–7.7)	100 (98.5–100)
High-sensitivity urine pregnancy test performed at 3 weeks	100.00 (19.3–100)	89.9 (85.7–93.2)	10.8 (7.6–14.9)	6.7 (1.0–22.1)	100 (98.5–100)
Remote follow-up[b]	100 (16.5–100)	85.5 (80.7–88.8)	15.2 (11.7–19.6)	2.04 (0.3–10.9)	100 (98.6–100.0)
Low-sensitivity test urine pregnancy test performed 10–14 days after mifepristone administration	100 (16.5–100)	94.1 (90.9–96.4)	6.2 (4.0–9.4)	5.0 (0.8–24.9)	100 (98.8–100.0)
Symptom checklist performed 10–14 days after mifepristone administration	100 (16.5–100)	85.1 (80.7–88.8)	15.2 (11.7–19.6)	2.0 (0.3–10.9)	100 (98.6–100.0)

[a] n=337; excludes women who withdrew from the study (n=10) made an interim visit to clinic (n=27) or were lost to follow-up (n=127). Includes two women with an ongoing pregnancy at follow-up.
[b] n=322; excludes women who were withdrawn from the study (n=11) or made an interim visit to clinic (n=18) or were lost to follow-up (n=147). Includes one woman with an ongoing pregnancy at follow-up.

referred to the clinic for further assessment failed to return (Fig. 1).

In the remote follow-up group, 19% (n=66) were referred for further assessment. More women were asked to return as a result of one or more positive responses on the symptom checklist (66/66) than due to a positive low-sensitivity pregnancy test (20/66).The sensitivity and specificity of the remote follow-up system (checklist and pregnancy test) were 100% and 85.1%, respectively. The sensitivity and specificity of the low-sensitivity pregnancy test alone were 100% and 94.1%, respectively (Table 4).

Most of the women in the remote group who were referred for an in-clinic assessment did not receive additional care (62.1%, 41/66) (Fig. 1). When all interventions were combined by group, women in the clinic-based group were 1.9 times more likely to receive some type of additional medical abortion-related care than women in the remote group (RR: 1.875; 95% CI 1.15–3.06). Seventeen women in the remote group who were referred to the clinic for follow-up (including two women with a positive pregnancy test) failed to return.

The probability of completing follow-up was assessed against study group, study site, education level, distance traveled to clinic and having a computer at home. Women at sites 3 and 4 were significantly more likely to complete follow-up than woman at site 1. This difference did not influence the likelihood of follow-up by group assignment in the full unadjusted or adjusted models [unadjusted odds ratio (OR)= 0.825 (0.622–1.095); fully adjusted OR=0.820, 95% CI 0.613–1.095]. The results of the backwards stepwise Wald model were identical to the full model and are not presented here.

At the start of the study, preferences for mode of contact among women in the remote group were text message (42.9%, 209/487), phone (35.7%, 174/487) and online (21.4%, 104/487). The majority of women in the clinic-based group reported an a priori preference for phone follow-up (87.2%, 328/491). After the study, most women reported that their follow-up method was acceptable or very acceptable (Table 5). When asked what method they would prefer in the future, most women indicated either a telephone call (54.8%, 373/681) or text message (25.6%, 174/681).

Table 5
Acceptability of follow-up method: % (n)

	Clinic-based follow-up (n=355)	Remote follow-up (n=326)		
		Phone (n=128)	Text (n=150)	Online (n=48)
Acceptability of follow-up method				
Very acceptable	61.4 (218)	41.4 (53)	63.3 (95)	62.5 (30)
Acceptable	37.5 (133)	50.8 (65)	27.3 (41)	31.3 (15)
Neither acceptable or unacceptable	0.8 (3)	4.7 (6)	7.3 (11)	2.1 (1)
Unacceptable	0.3 (1)	3.1 (4)	2.0 (3)	2.1 (1)
Very unacceptable	–	–	–	2.1 (1)
Preference for future follow-up				
At the clinic	14.4 (51)	6.3 (8)	4.7 (7)	16.7 (8)
At home with phone follow-up	67.3 (239)	75.0 (96)	18.0 (27)	22.9 (11)
At home with text messaging	15.5 (55)	7.0 (9)	68.0 (102)	16.7 (8)
At home using an online questionnaire	–	1.6 (2)	2.7 (4)	37.5 (18)
No preference	2.9 (10)	10.2 (13)	6.7 (10)	6.3 (3)

Includes women who returned for follow-up and completed questionnaire. Six women in the clinic-based group and 14 women in the remote group were missing acceptability data.

Only 10.8% of participants (74/681) would prefer in-clinic follow-up if needed in the future.

4. Discussion

We found that follow-up after medical abortion using standardized assessments administered remotely by non-clinical call center staff was a feasible alternative to clinic-based follow-up. Our study found no significant difference in rates of follow-up between groups, but the model employing remote technologies significantly reduced the number of women who utilized in-clinic resources and allowed for a shortened time between mifepristone administration and follow-up.

Consistent with other studies [9,10], telephone-based follow-up was popular among women in our trial regardless of group assignment. Women assigned to clinic-based follow-up overwhelmingly eschewed an in-person visit in favor of a telephone call despite having to wait 3 weeks to determine the outcome of their abortion. Almost all of the women in our study reported owning a mobile phone and using text messaging daily, so it was not surprising to find that many women chose this method of follow-up. A preference for follow-up by text message persisted for many but not all participants. The text service we used required sending up to five separate messages to ascertain outcomes and provide advice or reassurance. The use of a more streamlined system might result in greater acceptability and improved adherence.

Although also considered acceptable to most women who chose it, online follow-up was not as effective as phone-based methods. Less than half of women who chose online follow-up completed the symptom questionnaire. It is unclear why this method performed so poorly. One possible explanation is that the email that included a link to the survey was sent to "junk mail" and thus never received by participants.

Overall, the proportion of women who utilized clinic resources or received an intervention was lower in the remote group. This may have been due to the fact that fewer women in this group underwent ultrasound examinations thus avoiding the potential for unnecessary intervention for ultrasonographically diagnosed, but not clinically relevant, retained products of conception [13–15]. It could also have reflected the timing of follow-up if those in the in-clinic group had an in-clinic visit at 1 week. Symptoms such as continued bleeding consistent with normal recovery one week after treatment may have been incorrectly perceived to be due to a complication. Lastly, it is possible that some women who "screened negative" in the remote group sought care outside of a **bpas** clinic, for example, with a GP or in an NHS hospital, and underwent further treatment in those settings of which we were unaware.

This study was not powered to test the effectiveness of a low-sensitivity pregnancy test for detection of ongoing pregnancy, but we found that it performed well, albeit with wide CIs. The sensitivity of the test was comparable to that of a high-sensitivity test at 3 weeks [10] but with greater specificity and allowing for follow-up sooner after the abortion, which women appear to prefer. Although not as precise as a semi-quantitative urine pregnancy test [11,12] or serial serum β-hCG [7], a low-sensitivity test appears to be feasible alternative.

The standardized symptom checklist we used was an inadequate screening tool. The checklist was the trigger for referral for most women in this group and was associated with a high false-positive rate. When the remote group was compared to the subset of women in the clinic-based group who followed up by phone, referrals back to the clinic for an assessment were higher in the remote group (19% vs. 14%). The use of a standardized symptom checklist with a urine pregnancy test may therefore result in unnecessary referrals to clinic and increase lost to follow-up rates of women flagged to return.

One limitation of the study is that the standard of care at **bpas** may not reflect that of other facilities requiring universal clinic follow-up. The benefit of remote follow-up in terms of increasing follow-up rates is likely to be greater where the only option is an in-clinic visit for an ultrasound scan. In addition, the study was unable to test effectiveness of the system for identification of continuing pregnancy after medical abortion, the primary outcome of interest in any follow-up scheme. Seven ongoing pregnancies were identified of which four were diagnosed in women who self-referred for an interim visit. The remaining were identified in the remote group ($n=1$) or via phone follow-up in the clinic-based group ($n=2$). Reassuringly, of those who were contacted, no woman who screened negative by phone or other remote communication method presented at a later time with an ongoing pregnancy. As discussed, it is possible that some women who were lost to follow-up received care elsewhere. At present, **bpas** asks patients and GPs to relay information about complications but this is not always reliable [16].

Another limitation is that we were unable to assess what characteristics of the follow-up modalities impacted acceptability and preference or to understand what, if any, impact the use of non-clinical staff to undertake follow-up had on these outcomes or on inter-clinic variations in follow-up completion. Future research could explore these questions qualitatively.

In conclusion, this study demonstrates that follow-up can be achieved using remote communication technologies. This model may reduce the burden of multiple clinic visits on women and providers. More research is needed to identify the best way to deliver follow-up remotely, in particular, by SMS text messaging.

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