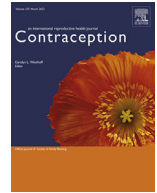




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A cross-sectional survey of U.S. abortion patients' interest in obtaining medication abortion over the counter

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ABSTRACT

Objective: To assess abortion patients' perspectives about a hypothetical option to access medication abortion over the counter without a prescription.

Study design: From October 2019 to March 2020, people ages 15 and over seeking abortion at 7 facilities across the United States completed a cross-sectional, self-administered survey regarding their personal interest in and general support for accessing medication abortion over the counter, including the advantages and disadvantages of over-the-counter access. We used multivariable logistic regression with generalized estimating equations to assess associations between experiencing barriers that led to delay in obtaining abortion care and personal interest in and general support for accessing medication abortion over the counter.

Results: Of the 1687 people approached, 1202 (71%) wanted to participate, and 1178 completed the survey. Most people were personally interested in (725/1119, 65%) and in favor of (925/1120, 83%) over-the-counter medication abortion. The most common advantages noted of the over-the-counter model included privacy (772/1124, 69%), earlier access (774/1124, 69%), and convenience (733/1124, 65%). The most common disadvantages noted included incorrect use (664/1124, 59%), not seeing a clinician beforehand (439/1124, 39%), and could be less effective (271/1124, 24%). In adjusted analyses, cost barriers that resulted in delays to the appointment, White race/ethnicity (vs Black), and higher educational attainment were significantly associated with greater personal interest in and support for over-the-counter medication abortion.

Conclusions: People accessing facility-based abortion care are very supportive of and interested in being able to access abortion over the counter. Those facing financial barriers obtaining facility-based care may benefit from allowing medication abortion to be available over the counter without a prescription.

Implications: Given people's interest in over-the-counter access to medication abortion, research is needed to assess whether people can use medication abortion appropriately without clinical supervision. Such research could help determine whether medication abortion is suitable for an over-the-counter switch.

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1. Introduction

While the United States (U.S.) Food and Drug Administration recently eliminated the in-person dispensing requirement for

mifepristone, the first drug used in the mifepristone/misoprostol medication abortion regimen, they still require a prescription by a certified healthcare professional who meets certain qualifications, and people living in states that restrict telemedicine continue to be unable to access medication abortion by mail [1]. This prescribing requirement is in place despite mifepristone's demonstrated safety, low toxicity profile, low potential for abuse [2–4], and even though

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people usually manage the entire abortion process on their own at home. Understanding people's interest in accessing medication abortion over the counter can help to demonstrate demand for an over-the-counter medication abortion product in the U.S., as well as to motivate the relevant stakeholders to conduct the necessary research to assess whether an over-the-counter switch for medication abortion is warranted.

However, there is limited evidence in the U.S. regarding people's interest in de-medicalized models of abortion care including accessing medication abortion over the counter. In 2017, findings from a national probability-based survey of people who self-identified as women demonstrated that 37% supported and 23% were personally interested in accessing medication abortion over-the-counter, noting its privacy and convenience, although people also noted concerns [5]. For example, among other concerns, people noted that women might take the pills incorrectly. Similarly, research with people accessing medication abortion through an online telemedicine service, where people receive the medication abortion pills by mail, along with online support and guidance from a clinician, indicated that users prefer the privacy and convenience of the telemedicine model [6,7]. The current study expands on previous research by gauging interest in an over-the-counter medication abortion model among people in the U.S. who might be most interested in this model: people accessing abortion.

2. Materials and methods

2.1. Study design

This analysis derives from a cross-sectional study of abortion patients' self-assessment of their pregnancy duration [8]. The present analysis focuses on patients' interest in and support for an over-the-counter medication abortion option. To develop the overall study design and survey items, we engaged an advisory board comprised of reproductive health and justice leaders and clinicians, who, in their professional roles, represent patients and people who may not have equal access to medication abortion. The survey included questions regarding people's pregnancy duration, barriers accessing abortion care, and interest in and support for an over-the-counter medication abortion provision model, and was pilot tested in English and Spanish.

From October 2019 to March 2020, we recruited people at 7 abortion-providing facilities located in 6 U.S. states (Alabama, California, Florida, Illinois, North Dakota, and Texas) and the District of Columbia. We selected recruitment sites to represent a wide range of U.S. regions and because their clinic flow allowed people to complete the survey prior to their ultrasound without disrupting clinical care provision. To be eligible, people needed to be pregnant, seeking abortion, ages 15 and older, able to speak and read English or Spanish, and not yet had an ultrasound for their current pregnancy at the recruitment facility. A research assistant approached potential participants prior to their appointment, verbally obtained informed consent among those interested, and handed them an iPad to complete an eligibility survey and had them self-administer an anonymous 15-minute survey on the iPad. Parental consent requirements varied by recruitment site according to state legal requirements and clinic preferences. We remunerated participants with a \$25 Amazon gift card for their participation. The Institutional Review Board at the University of California, San Francisco approved this study.

2.2. Analysis variables

Our primary outcome variables in multivariable analyses focused on people's 1) personal interest in and 2) support for over-the-counter medication abortion. These outcomes were based on

previous research [5] and included 2 questions preceded by a description of the hypothetical over-the-counter access model (see Box 1), that scored at an 11th grade reading level. We referred to medication abortion generically without referring to the specific medications. After presenting this description, we asked "Would you be personally interested in this option for yourself?" and "Even if you are not interested in this option for yourself, would you be in favor of *other women* being able to buy abortion pills in a drug store without a prescription?" with options presented in a 4-point Likert format, with additional options for "Don't know" and "Not sure." For logistic regression analyses, we dichotomized answer options: *Probably/definitely yes* vs *probably/definitely no/don't know* and *I am in favor/somewhat in favor* vs *I am somewhat opposed/opposed/not sure*. We also asked people to select advantages and disadvantages of an over-the-counter model from a list of options, including an open-ended "other" category. While we estimated a priori that a sample size of 1000 was required to answer the main study's research question regarding people's accuracy for self-assessment of pregnancy duration, post-hoc we calculated that for this analysis, a sample size of 1000 was sufficient to detect a ± 5 percentage point difference between our outcome and published estimates [5], with 90% power and an alpha of .05.

In multivariable regression analyses, we examined whether experiencing delays accessing abortion care was associated with interest in and support for an over-the-counter access model. Based on the question "Did any of the following delay you from getting your appointment today?" we grouped answer options to create 3 independent variables describing delays: (1) *finding a facility*, which included answering yes to any of 3 barriers "finding a place where I could get an abortion," "finding a place to do a procedure this far along in pregnancy," or "figuring out how to get a clinic"; (2) *financial barriers* included answering yes to "getting money to pay for the abortion" or "getting money to pay for travel," and; (3) *travel* which included barriers related to "transportation to the clinic or finding a driver" and "having multiple visits before today (at this clinic or elsewhere)." We also included a categorical variable describing the abortion policy environment of their state of residence, whether supportive, middle ground, or hostile to abortion rights, as defined by the Guttmacher Institute [9].

We selected additional model covariates a priori, based on the factors known to be associated with abortion attitudes [10]. As demographic characteristics we included age group, race/ethnicity, language spoken at home (English only, Spanish only, English and another language, other), highest level of education, currently employed full or part time, and experienced food insecurity in the past year [11]. As reproductive health covariates we included pregnancy duration based on ultrasound (recorded by clinic staff), parity, and history of abortion. For people with missing ultrasound data, we estimated their pregnancy duration according to self-reported last menstrual period.

2.3. Data analyses

We estimated frequencies for participant characteristics, interest and support for the over-the-counter medication abortion model, and its perceived advantages and disadvantages. For multivariable logistic regression models, we used generalized estimating equations to account for clustering by recruitment sites. We excluded 54 people who were missing both outcome variables from all analyses. We conducted all analyses in STATA 15. We report significance at $p \leq 0.05$.

3. Results

Of the 1687 people approached, 1202 were interested and eligible (71% response rate), 1178 started the survey, and 1124 re-

Table 1
 Characteristics of abortion patients enrolled in the pregnancy duration study (N = 1124)

	N (%)
Age in years, mean + standard deviation	26.5 + 5.9
15–17	26 (2)
18–19	90 (8)
20–24	350 (31)
25–29	331 (29)
30–46	314 (28)
Missing	13 (1)
Race / Ethnicity	
Black / African-American (non-Hispanic)	407 (36)
Hispanic / Latina	210 (19)
White (non-Hispanic)	363 (32)
Other (non-Hispanic)	92 (8)
More than one race	49 (4)
Missing	3 (<1)
Language spoken at home	
English only	965 (86)
Spanish only	33 (3)
English and Spanish or another language	100 (9)
Other	21 (2)
Missing	5 (<1)
Highest level of education	
Less than high school diploma	77 (7)
High school diploma or equivalent	665 (59)
Some college / Associate's degree	132 (12)
Bachelor's degree or higher	247 (22)
Missing	3 (<1)
Employment	
Not currently employed	350 (31)
Currently employed full or part-time	766 (68)
Missing	8 (1)
Experienced food insecurity in the past year	
No	684 (61)
Yes	430 (38)
Missing	10 (1)
Pregnancy duration based on ultrasound or date of last menstrual period	
Less than 10 wk	825 (73)
10 wk or more	293 (26)
Missing	6 (<1)
Number of live births	
None	495 (44)
One	255 (23)
Two or more	374 (33)
Ever had a prior abortion	
No	678 (60)
Yes	446 (40)
Missing	1 (<1)
Abortion policy environment in state of residence	
Hostile	528 (47)
Middle ground	362 (32)
Supportive	205 (18)
Missing	29 (3)
Delayed in accessing abortion care due to:	
Finding a facility to get an abortion for this pregnancy	237 (21)
Getting money to pay for the abortion and/or to pay for travel	370 (33)
Transportation to the clinic and/or multiple visits	161 (14)

sponded to one or both outcome variables, which came at the end of the survey. Participant characteristics and people's personal interest in and support for an over-the-counter medication abortion option are presented in [Tables 1](#) and [2](#), respectively. Most people indicated probable (253/1119, 23%) or definite (472/1119, 42%) personal interest in and being in favor (761/1120, 68%) or somewhat in favor (164/1120, 15%) of other women being able to buy abortion pills over the counter ([Table 3](#)). The most common advantages selected included privacy (772/1124, 69%), being able to end the pregnancy earlier (774/1124, 69%), and convenience (733/1124, 65%). The most common disadvantages selected included concerns that people might take the pills incorrectly (664/1124, 59%), not

Table 2
 Interest and support for an over-the-counter medication abortion option among U.S. abortion patients enrolled in the pregnancy duration study (N = 1124)

	n (%)
Would you be personally interested in this option (buying abortion pills in a drugstore without a prescription) for yourself?	
Definitely yes	472 (42)
Probably yes	253 (23)
Probably no	135 (12)
Definitely no	78 (7)
I don't know	181 (16)
Missing	5 (<1)
Would you be in favor of other women being able to buy abortion pills in a drug store without a prescription?	
I am in favor	761 (68)
I am somewhat in favor	164 (15)
I am somewhat opposed	41 (4)
I am opposed	43 (4)
Not sure	111 (10)
Missing	4 (<1)

Table 3
 Advantages and disadvantages of an over-the-counter medication abortion option selected by U.S. abortion patients enrolled in the pregnancy duration study (N = 1124)

	n (%)
Advantages selected	
Could help women get the abortion earlier in pregnancy	774 (69)
Could be more private	772 (69)
Could be more convenient	733 (65)
Could be less expensive	666 (59)
Could avoid going to a clinic	554 (49)
Could avoid having to see a doctor or nurse	334 (30)
Could be safer	196 (17)
Could be more effective	191 (17)
Other	11 (1)
I don't see any advantages	59 (5)
Disadvantages selected	
Women might take the pills incorrectly	664 (59)
Women might not see a doctor or nurse before they have the abortion	439 (39)
Could be less effective	271 (24)
Someone could find the pills at home	267 (24)
Could be too convenient	214 (19)
Could be more expensive	159 (14)
Could be less safe	154 (14)
Abortion should not be easy to access	78 (7)
Other	15 (1)
I don't see any disadvantages	136 (12)

Note: People could indicate one or more advantage or disadvantage.

seeing a clinician (439/1124, 39%), could be less effective (271/1124, 24%) and someone could find the pills at home (267/1124, 24%). Five percent (59/1124) of participants indicated that the over-the-counter model had no advantages whereas 12% (136/1124) indicated that it had no disadvantages.

In adjusted analyses, having experienced a financial barrier that led to delayed care was significantly associated with greater odds of having a personal interest in [adjusted Odds Ratio (aOR), 1.45, 95% Confidence Interval (CI), 1.06, 2.00] and being in favor of an over-the-counter option (aOR, 1.68, 95% CI, 1.09, 2.61) ([Table 4](#)). Personal interest in and support for an over-the-counter option was also significantly higher among non-Hispanic White respondents as compared to Black/African American respondents, and higher among people with a college degree than among those with a high school diploma or equivalent. People who indicated an "other" race/ethnicity that did not fit into our primary categories had significantly higher odds of expressing interest in (aOR, 1.82, 95% CI, 1.02, 3.25), but not support for, over-the-counter access than those who identified as Black/African American. When compared to people ages 20 to 24, people ages 30 or older had re-

Table 4

Proportions and adjusted odds ratios (aOR) of interest and support for medication abortion (MAB) being available over the counter without a prescription by participant characteristics.

	Personal interest in over-the-counter MAB (N=1,029)			In favor of over-the-counter MAB for others (N=1,030)		
	%	aOR	95% CI	%	aOR	95% CI
Age						
15 to 17 years	46%	0.96	(0.35,2.65)	76%	1.10	(0.24,4.94)
18 to 19 years	66%	1.08	(0.63,1.83)	81%	0.73	(0.37,1.43)
20 to 24 years	67%	Ref.		86%	Ref.	
25 to 29 years	65%	0.80	(0.56,1.15)	82%	0.68	(0.42,1.11)
30 to 46 years	65%	0.79	(0.53,1.18)	82%	0.52	(0.31,0.88)
Race/Ethnicity						
Black / African-American (non-Hispanic)	64%	Ref.		77%	Ref.	
Hispanic / Latina	60%	1.07	(0.65,1.76)	84%	1.21	(0.65,2.27)
White (non-Hispanic)	70%	1.42	(1.01,1.99)	90%	2.39	(1.51,3.80)
Other race (non-Hispanic)	70%	1.82	(1.02,3.25)	75%	0.96	(0.49,1.77)
More than one race	61%	1.00	(0.53,1.90)	86%	1.52	(0.64,3.60)
Language spoken at home						
English only	65%	Ref.		83%	Ref.	
Spanish only	61%	0.97	(0.39,2.40)	72%	0.53	(0.19,1.49)
English and Spanish or another language	69%	1.27	(0.70,2.33)	92%	2.73	(1.04,7.19)
Other	62%	0.61	(0.23,1.58)	62%	0.33	(0.12,0.90)
Highest level of education						
Less than a high school diploma	53%	0.65	(0.36,1.19)	83%	1.26	(0.56,2.86)
High school diploma or equivalent	64%	Ref.		81%	Ref.	
Some college / Associate's degree	72%	1.38	(0.90,2.14)	85%	1.54	(0.87,2.75)
Bachelor's degree or higher	69%	1.61	(1.09,2.38)	87%	2.44	(1.42,4.19)
Currently employed full or part-time	65%	0.89	(0.66,1.19)	82%	0.84	(0.57,1.24)
Experienced food insecurity in the past year	67%	1.15	(0.86,1.54)	85%	1.02	(0.69,1.49)
Pregnancy duration based on ultrasound						
Less than 10 weeks	65%	Ref.		82%	Ref.	
10 weeks or more	65%	0.93	(0.68,1.27)	84%	1.21	(0.80,1.85)
Missing	67%	0.82	(0.15,4.37)	83%	0.98	(0.12,7.99)
Number of live births						
None	63%	Ref.		83%	Ref.	
One	68%	1.29	(0.89,1.87)	85%	1.38	(0.84,2.27)
Two or more	65%	1.25	(0.86,1.80)	80%	1.21	(0.75,1.95)
Ever had a prior abortion	63%	1.05	(0.78,1.41)	82%	1.24	(0.85,1.83)
Abortion policy environment in state of residence						
Hostile	71%	Ref.		85%	Ref.	
Middle ground	61%	1.19	(0.75,1.88)	80%	0.85	(0.53,1.37)
Supportive	58%	0.66	(0.38,1.14)	83%	0.85	(0.48,1.49)
Missing	55%	0.58	(0.20,1.70)	72%	1.53	(0.30,7.89)
Delayed in accessing abortion care due to:						
Finding a facility to get an abortion for this pregnancy [§]	73%	1.32	(0.90,1.94)	86%	1.07	(0.64,1.81)
Financial barriers: Getting money to pay for the abortion and/or to pay for travel [§]	74%	1.45	(1.06,2.00)	89%	1.68	(1.09,2.61)
Travel barriers: Transportation to the clinic and/or multiple visits [§]	75%	1.29	(0.83,2.02)	89%	1.29	(0.70,2.39)

aOR=Adjusted Odds Ratio; Ref.= Reference group; Statistically significant differences ($p<.05$) are presented in **bolded** text; All variables were included in the same model

[§] People who did not report experiencing this barrier served as the reference group.

Box 1

Over-the-counter medication abortion provision model

In the future, it may be possible to access medication abortion pills differently from how they are accessed now, in a clinic. One option would be buying abortion pills legally in a drug store without a prescription. In this scenario, you could buy abortion pills without a prescription in a drug store or grocery, just like condoms or pregnancy tests. The pills would come with detailed information about how to take them and a 24-hour telephone number to call with questions. You could ask the pharmacist at the store any questions you might have, and you could go to a clinic to make sure the abortion was successful.

duced odds of support for over-the-counter access (aOR, 0.52, 95% CI, 0.31, 0.88) but age was not significantly associated with personal interest in over-the-counter access. Employment status, experiencing food insecurity, pregnancy duration, parity, history of abortion and living in a state with a hostile policy environment were not significantly associated with either outcome.

4. Discussion

This study assessed U.S. abortion patients' interest in and support for accessing medication abortion over the counter. We find high levels of support for the over-the-counter model presented (83%), markedly higher than the 37% previously reported among a nationally representative survey [5]. While we expected people seeking abortion to be interested in more accessible ways to obtain care, the high level of support observed may be indicative of a shift in preferences towards care outside of a facility, due to more experience with barriers accessing care, greater comfort with abortion, and/or an artifact of being surveyed in a clinic setting where clinic-level endorsement of an over-the-counter product may have been inferred.

Consistent with previous research [5], people who faced financial barriers that led to delay were most interested in an over-the-counter option. While there are many unknowns about the out-of-pocket costs of a future over-the-counter abortion product, most people assumed it would be less expensive. In the U.S., providers

have reported that the cost of the medications is under \$100, yet the average cost to obtain an in-clinic medication abortion is over \$500 [12,13]. This expense can be catastrophic for those living below their state's median household income [14]. While, the out-of-pocket costs of an over-the-counter medication abortion product would depend on insurance coverage and whether abortion funds offset the cost, the costs to the patient are likely to be lower than facility-based care [15]. At a minimum, the over-the-counter model could reduce travel-related costs; however, people might still incur the costs of any visits if they access facility-based care to confirm pregnancy completion or to treat any potential complications [16]. Given the high out-of-pocket costs for abortion care, people's desire for an inexpensive alternative should be prioritized [14,17,18]. Furthermore, people receiving care under an over-the-counter model of care may benefit from complete and accurate information of what to expect and how to manage the abortion process [16].

The majority of respondents selected several advantages of the over-the-counter model, with most appreciating not going to a clinic, as well privacy and convenience. Privacy preferences may stem from a desire to avoid negative reactions from others, including clinic protestors [19–22], and to avoid a clinic environment which may exacerbate abortion stigma [22].

People also highlighted a number of disadvantages of the over-the-counter model, mostly related to concerns about people's ability to take the pills correctly, lack of contact with a clinician, and effectiveness, although fewer reported concerns that the over-the-counter model would be less safe (14%) when compared to previous research in the general population (43%) [5]. People's view that not seeing a clinician would be a disadvantage to an over-the-counter model may be rooted in a preference for facility-based care, the desire or need for a clinical experience that provides support, affirmation [23], an environment that destigmatizes abortion and improves the overall abortion experience [24], and/or greater comfort and familiarity with the medicalized model of abortion care where clinicians serve as the gatekeepers of access [25]. A scenario where medication abortion is available over the counter will need to consider these perspectives and identify and develop the resources needed, if any, to support the abortion process (e.g., accompaniment, hotlines, written information, apps, etc.). However, to support an over-the-counter switch, there is also a need to conduct the necessary research demonstrating that people can take medication abortion safely without clinical supervision.

Across demographic characteristics, support for an over-the-counter model was high, although we also observed significant subgroup differences according to language group, race/ethnicity and educational level. Differences by those who spoke English vs another language at home (92% vs 62%) may be due to varied exposures to models of care in people's countries of origin [26,27]. The finding that college-educated and White respondents were most supportive and interested in over-the-counter access to medication abortion was unexpected, and possibly due their greater general support for abortion. A national study of people seeking abortion found that White and college-educated people were less likely to believe abortion is morally wrong and more likely to be in favor of the legal right to abortion than people who identified as Black, Hispanic/Latina or had less than a college education [28]. Other research has found that those identifying as White have significantly higher levels of perceived and internalized abortion stigma [21,29], which may partially explain their higher levels of interest in over-the-counter access to abortion. Another interpretation of this finding is that people of color may have more concerns about the out-of-pocket costs of an over-the-counter product, and/or greater mistrust in the quality or accessibility of over-the-counter medications. For example, one study examining the availability of progestin-only emergency contraception (EC) over-the-

counter found that pharmacies located in low-income neighborhoods were more likely to deny young people access to EC than those located in high-income neighborhoods [30]. Further research should examine the reasons for differing levels of interest in an over-the-counter model by subgroups. These varied levels of interest underscore the importance of offering a range of options to access abortion—whether over the counter, facility-based or other model of care— that match people's preferences, as well as the need to examine the potential impact of these models on disparities in access to abortion.

This study should be examined in the context of its limitations and strengths. First, our sample is limited to people accessing facility-based abortion care and only represents the perspectives of people who chose or had the resources to access in-person care. People with barriers accessing care and who consider abortion but do not reach a facility may be even more interested in an over-the-counter model. Furthermore, by being surveyed at a clinic, people may have assumed clinic-level endorsement of an over-the-counter model, thus biasing responses towards greater support. Another study limitation is that while the scenario describing our primary outcome has been previously used [5], the scenario itself was not cognitively tested and its reading level may have been too high for some of our study participants to understand, potentially limiting the validity of our findings. Moreover, we presented a hypothetical ideal over-the-counter scenario, covering a breadth of services—24-hour hotline, follow-up clinic-based care—that may not be available to people accessing a future over-the-counter medication abortion product. Furthermore, this study was fielded just before the COVID-19 pandemic, which forced people to minimize in-person clinical visits, potentially increasing interest in and demand for an over-the-counter option [6]. In this context, an over-the-counter option offers an approach to early abortion care that could decrease transmission of COVID-19 [31,32]. Also, we did not ask people whether they received counseling prior to completing the survey, whether they preferred a certain type of abortion—medication abortion or an in-clinic procedure—nor did we document the type of abortion people ultimately had, whether they had ever had a medication abortion, or if they lived in an urban or rural area. This information would have given us a better understanding of how people's interest in an over-the-counter model might differ by their abortion experiences, preferences for abortion type, or if counseling influenced their responses. Additionally, people selected advantages and disadvantages from a pre-specified list including an open-ended “other” category, which likely biased people to select from the list. Open-ended questions would have generated a broader range of responses. A study strength is our large sample size, which represented people accessing care across the U.S., and demographically similar to a national sample of people presenting for abortion care in terms of age, race/ethnicity and marital status [33].

Together, these findings highlight abortion patients' interest in an over-the-counter model of abortion care that they perceive has the advantage of being safe, convenient, affordable, and private. While it is unclear whether in practice an over-the-counter model of abortion care would be more affordable than facility-based care, our findings suggest that patients are interested in having more convenient and affordable choices. Together, our results have the potential to inform a public discourse and shift public perceptions surrounding medication abortion by highlighting the need for affordable options and normalized abortion access. The COVID-19 pandemic has spurred tremendous innovation in medication abortion care, including the implementation of a no-test protocol and the Food and Drug Administration removing the in-person dispensing requirement for mifepristone [34]. Furthermore, demand for an online telemedicine service increased during the pandemic, particularly

in areas that faced restrictions on in-clinic abortion access [6], and recent research suggests that most people understand key instructions found in a drug facts label prototype for medication abortion [37]. These innovations have brought medication abortion a step closer to over-the-counter status. Efforts to move medication abortion over-the-counter can be informed by strategies to move emergency contraception and oral contraceptives over-the-counter [35,36]. Given the documented interest in and potential benefits of over-the-counter access to medication abortion, it is essential to carry out the necessary research assessing the safety of an over-the-counter model.

Author contributions

DG conceived and designed the study and obtained funding. RB, KE, and NM participated in site recruitment, review of data collection instruments, programming study instruments, obtaining IRB approval, and overseeing data collection. NM conducted data cleaning, coding, and preliminary analyses. MAB conducted final data analyses and drafted the manuscript. All authors, including LR, JP, NK, KB, KW, participated in the study design, study planning, and review and approval of the final manuscript.

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Declaration of Competing Interest

All authors declare they have no financial conflicts of interest.

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