

A telemedicine model for abortion in South Africa: a randomised, controlled, non-inferiority trial

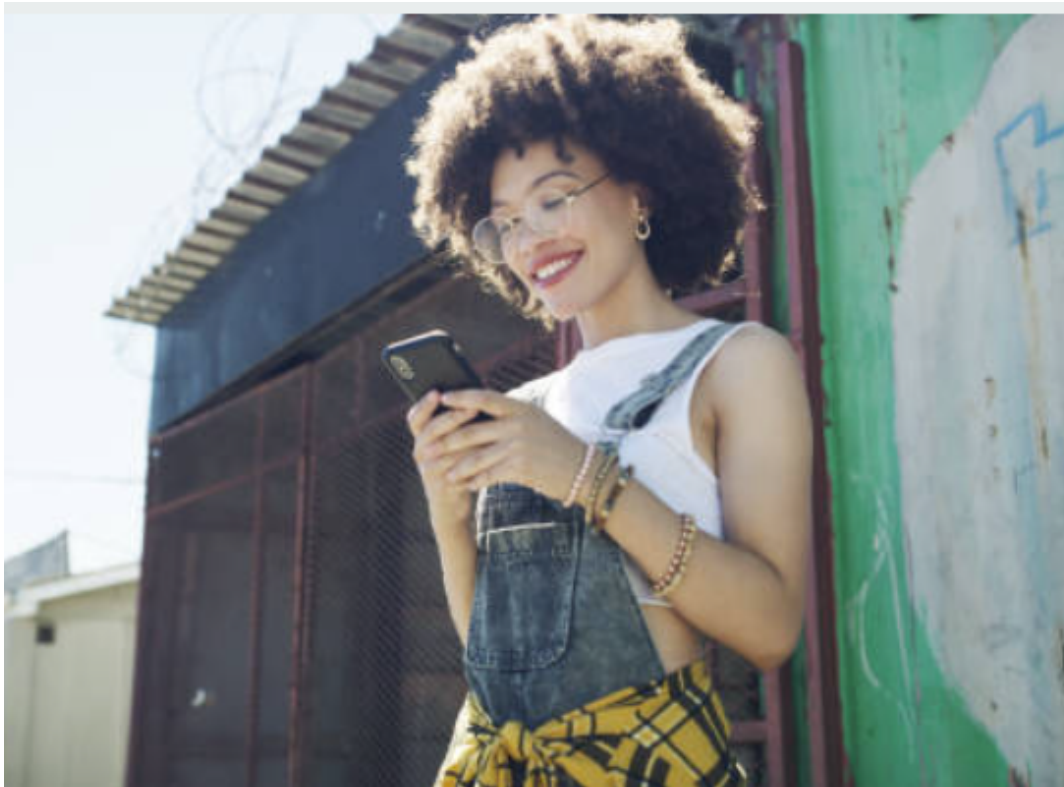
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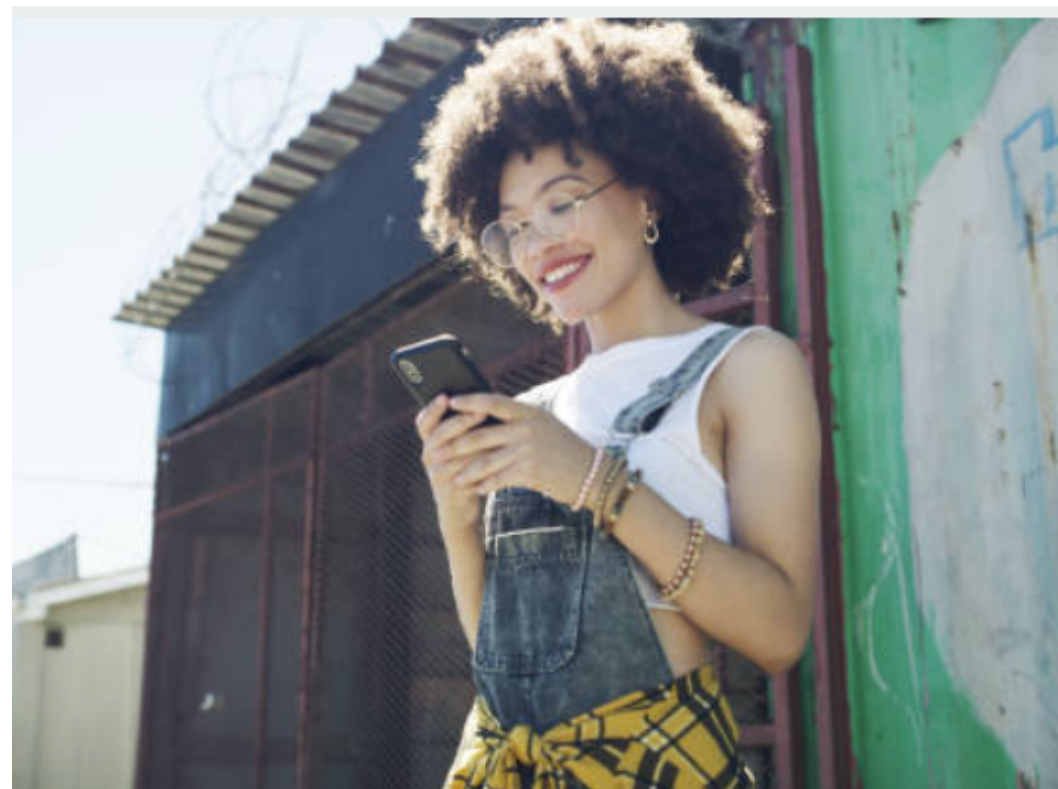
Premise for abortion through telemedicine in south africa



- Persistent barriers to access
- Home abortion safety
- Mobile phones
- The value of remote medicine

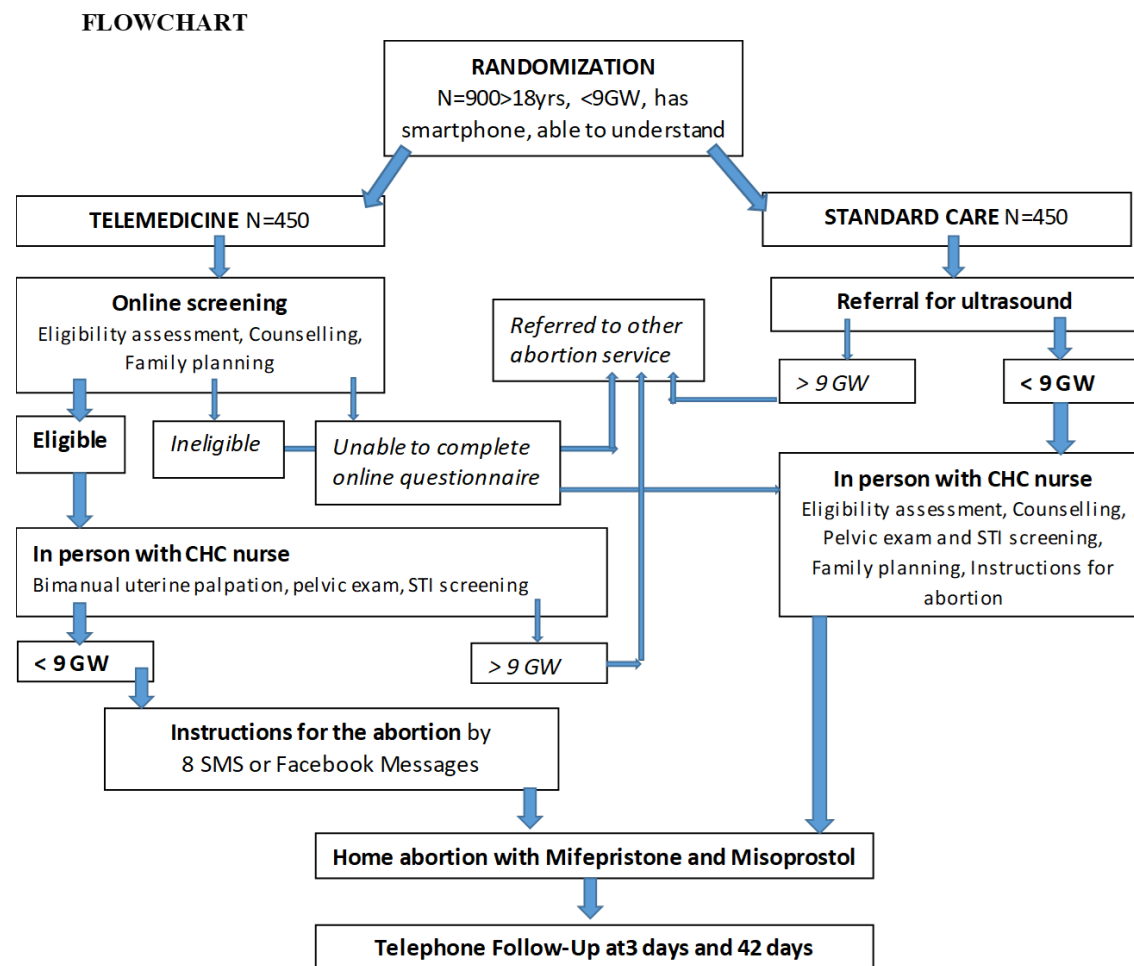
AIM

To determine if consultation and instruction for early medical abortion provided **online**, combined with a **simplified physical exam**, is equally effective, safe and acceptable to women in South Africa, as standard medical abortion care.



What was new about the intervention

1. The eligibility screening, counselling and instructions for the abortion **take place asynchronously online** and not face to face.
2. The physical exam does **not include a routine ultrasound**.
3. The telemedicine model is set in a **low-resource setting**



| | Telemedicine (n=450) | Standard care (n=450) |
|--------------------------------|---------------------------------------------------------------------|---------------------------------------------------------------------|
| Age | 28 (24-32) | 28 (25-33) |
| Gestational age | 6 weeks and 6 days (6 weeks and 0 days to 7 weeks and 6 days) | 6 weeks and 5 days (6 weeks and 0 days to 7 weeks and 5 days) |
| Parous | 358 (83.8) | 369 (85.4) |
| Previous abortion | 80 (17.9) | 82 (18.3) |
| Food scarcity | | |
| Sometimes | 209 (46.4%) | 212 (47.1%) |
| Never | 241 (53.6%) | 238 (52.9%) |
| House type | | |
| Shack-type housing | 120 (26.7%) | 145 (32.2%) |
| Internet use for communication | | |
| Seldom or never | 25 (5.6%) | 28 (6.2%) |
| Sometimes or often | 425 (94.4%) | 422 (93.8%) |
| Internet use for information | | |
| Seldom or never | 28 (6.2%) | 37 (8.2%) |
| Sometimes or often | 422 (93.8%) | 413 (91.8%) |

Data are n (%) or median (IQR).

Table 1: Background characteristics

Background characteristics



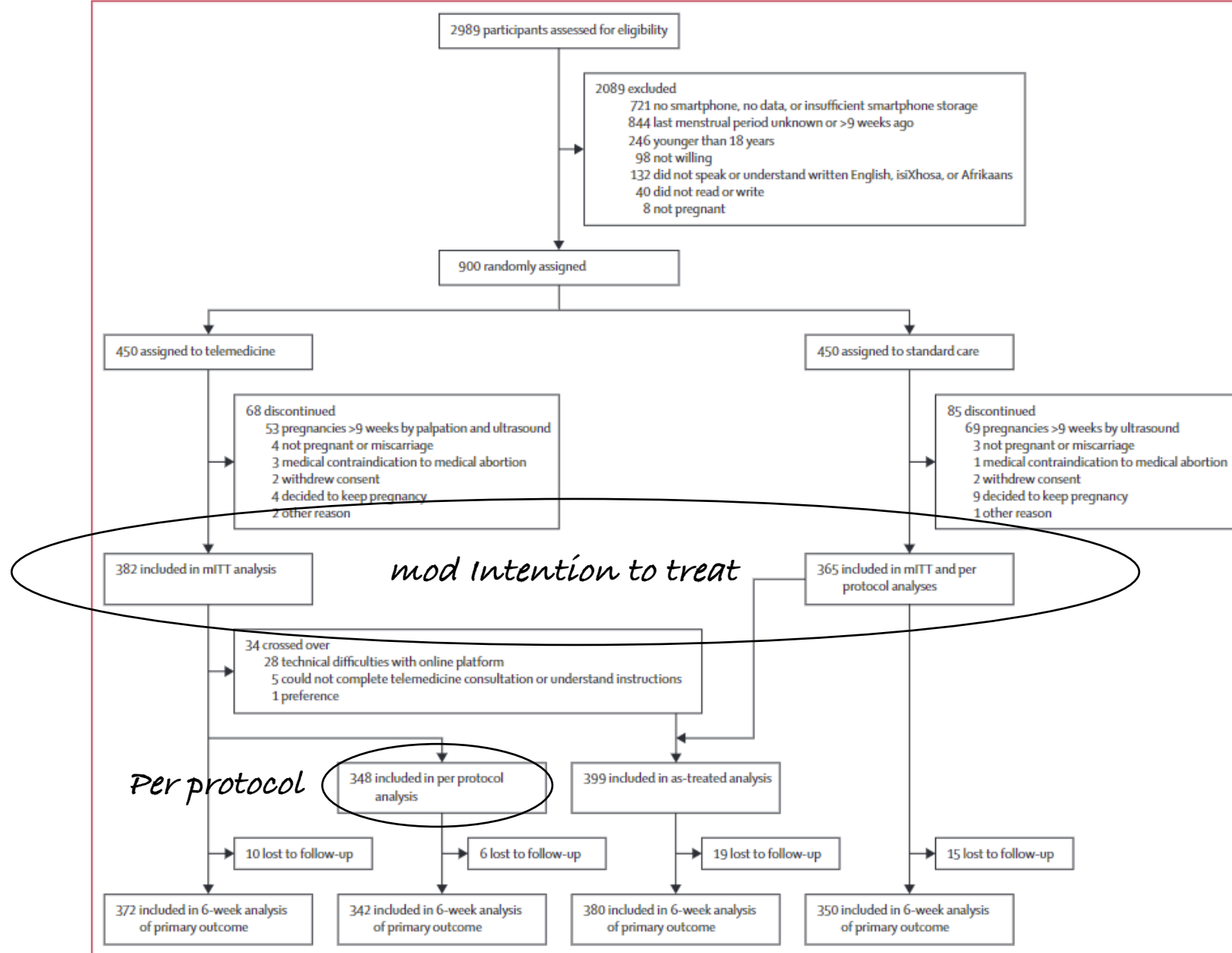


Figure 1: Trial profile
mITT=modified intention to treat.

EFFECTIVENESS

How many women had a successful abortion without needing any additional intervention?

ADHERENCE

How many women could follow the program and take the abortion pills correctly?

SAFETY

How many women had a complication to the abortion that put their health or life in danger?

ACCEPTABILITY

How many women expressed preference for telemedicine vs standard care?



Main outcomes

| | Modified intention to treat | | | | Per protocol | | | |
|------------------------------|-----------------------------|--------------------------|----------------------|---------------------|-------------------------|--------------------------|----------------------|---------------------|
| | Telemedicine (n=382) | Standard care (n=365) | Odds ratio (95% CI) | Risk difference | Telemedicine (n=348) | Standard care (n=365) | Odds ratio (95% CI) | Risk difference |
| Primary outcome | | | | | | | | |
| Complete abortion* | 355/372 (95.4%) | 338/350 (96.6%) | 0.74 (0.35 to 1.57) | -1.1% (-4.0 to 1.7) | 327/342 (95.6%) | 338/350 (96.6%) | 0.77 (0.36 to 1.68) | -1.0% (-3.8 to 1.9) |
| Secondary outcomes | | | | | | | | |
| Continuing pregnancy† | 6/372 (1.6%) | 3/350 (0.9%) | 1.90 (0.47 to 7.64) | .. | 5/342 (1.5%) | 3/350 (0.9%) | 1.72 (0.41 to 7.24) | .. |
| Adherence‡ | 358/378 (94.7%) | 340/354 (96.1%) | 0.74 (0.37 to 1.48) | .. | 324/344 (94.2%) | 340/354 (96.1%) | 0.67 (0.33 to 1.34) | .. |
| Admission to hospital | 3/377 (0.8%) | 2/359 (0.6%) | 1.43 (0.36 to 8.62) | .. | 3/345 (0.9%) | 2/359 (0.6%) | 1.57 (0.45 to 9.43) | .. |
| Blood transfusion | 2/377 (0.5%) | 1/359 (0.3%) | 1.91 (0.17 to 21.15) | .. | 2/345 (0.6%) | 1/359 (0.3%) | 2.09 (0.19 to 23.13) | .. |
| Emergency visits§ | 6/373 (1.6%) | 5/350 (1.4%) | 1.13 (0.34 to 3.74) | .. | 3/347 (0.9%) | 5/359 (1.4%) | 0.62 (0.15 to 2.60) | .. |
| Satisfaction¶ | 369/370 (99.7%) | 342/347 (98.6%) | 5.39 (0.63 to 46.41) | .. | 340/341 (99.7%) | 342/347 (98.6%) | 4.97 (0.58 to 42.77) | .. |
| Preference | | | | | | | | |
| Telemedicine | 259/370 (70.0%) | 149/347 (42.9%) | 5.21 (3.31 to 8.21) | .. | 242/341 (70.8%) | 149/347 (42.9%) | 6.04 (3.71 to 9.83) | .. |
| Standard care | 31/370 (8.4%) | 93/347 (26.8%) | Ref | .. | 25/341 (7.7%) | 93/347 (26.8%) | Ref | .. |
| Mixed model or no preference | 80/370 (21.6%) | 105/347 (30.3%) | 2.29 (1.39 to 3.37) | .. | 74/341 (21.7%) | 105/347 (30.3%) | 2.62 (1.54-4.46) | .. |

Data are n/N (%), unless otherwise indicated. Denominators are total sample excluding missing data. *Terminated pregnancy without need of additional medical or surgical intervention to complete the abortion. †Six continuing pregnancies occurred in the telemedicine group when no ultrasound was done. Four were later deemed to be before 9 gestational weeks and two were between 10 and 11 gestational weeks at the time of consultation. ‡Correct intake of medication with respect to dose, dose interval, mode of administration, and gestational age limits. §Unscheduled visit to a clinic within 2 days of the abortion for heavy bleeding, severe pain, or signs of infection. ¶Reporting being satisfied or very satisfied with model of care received. ||Reported preferred model of care for consultation and instructions if need of another abortion.

Table 2: Primary and secondary outcomes

Non-inferiority analysis

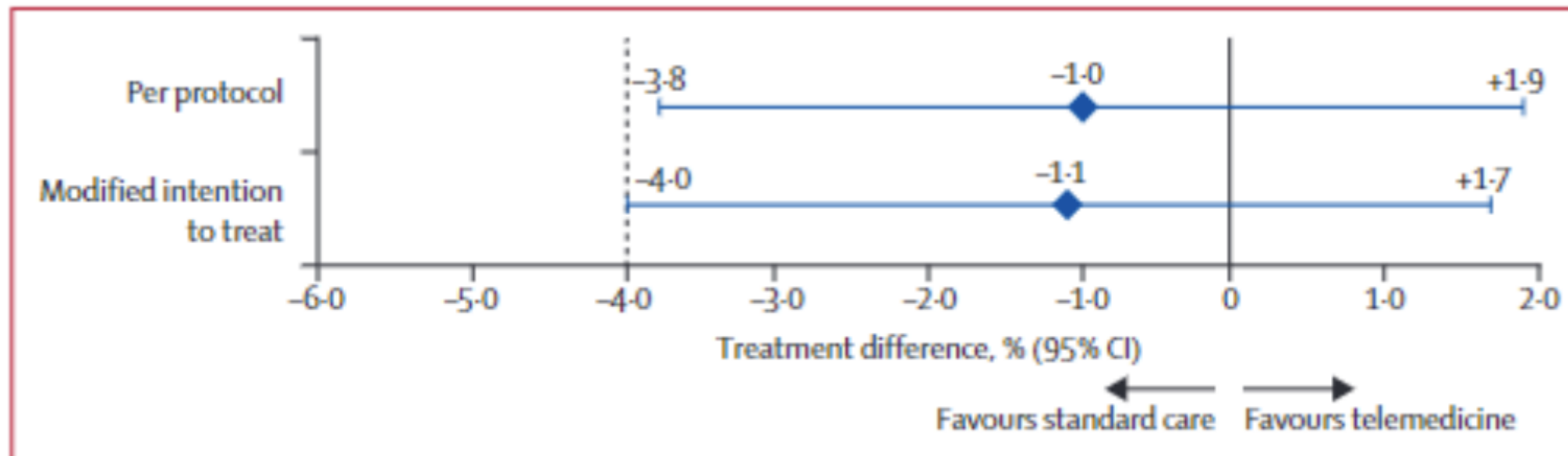


Figure 2: Non-inferiority diagram

Diamonds represent the risk difference (%), the wings represent the 95% CIs for the risk difference, and the dashed line is the predefined inferiority margin stipulated by the study.

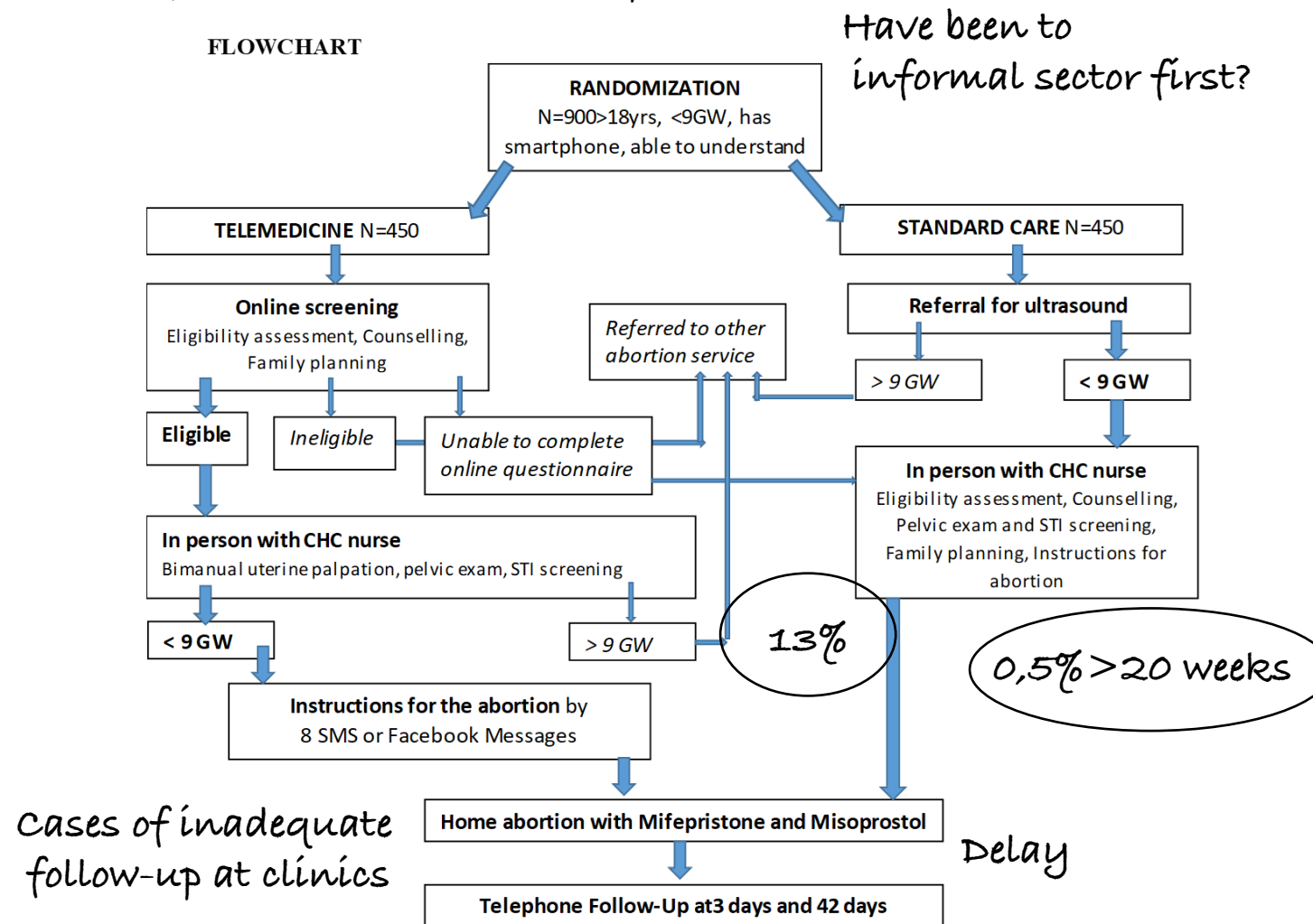
Conclusion

Asynchronous online consultation and instruction for medical abortion, with uterine palpation as the only in-person component, followed by home self-medication, is:

- Non-inferior to standard care with respect to rate of complete abortion.
 - Does not affect safety, adherence, or satisfaction.
-

Unsure of their LMP, no data, no phone

Questions that arose



Benefits and opportunities

Increase access for women

Reduce pressure on clinics

Increase autonomy in SRH

Meet demand

Data-competent women

Integrated care

Safe effective and acceptable to women

Challenges

Gestational age accuracy

Confidentiality

Connectivity / space on phones

Integration of IT into non-digitalized systems

Parallel illegal abortion services

Higher risk of ectopic pregnancy

Delays

Overburdened systems

Silos of care

Final thoughts

With selection of low risk women and a functioning back-up clinic telemedicine abortion is **safe and effective**.

In settings with little access to abortion both **need and risk** of TM or "no-test" abortion may be higher.

The implementation of TM for abortion must not absolve governments from acknowledging abortion as an essential part of public health services.



Thank
you!

