Bilaga till rapport

Utvärdering av att ta det första läkemedlet (mifepriston) utanför vårdinrättning vid medicinsk abort/ Evaluation of taking mifepristone at home during a medical abortion
Rapport 363 (2023)

Bilaga 4 Tabell över inkluderade studier/

Appendix 4 Tabel of included studies

Author	**Aiken**
Year	**2021**
Country	UK
Ref #	[1]
Study design	**Retrospective register study**
Group allocation	Date of abortion (before or after corona restrictions were implemented)
Setting	The three largest abortion provider organizations in England (BPAS, MSUK and NUPAS)
Population	Women who accessed medical abortion
Gestational age	Up to 10 weeks gestation
Method to determine gestational age	I: LMP, when needed ultrasound C: in person assessment and ultrasound
Inclusion criteria	All women who accessed an early medical abortion at the providers 2 months before and after the service model change.
Treatment (drugs, dose and route)	Mifepristone 200 mg orally Misoprostol 800 µg sublingually, buccally or vaginally plus 400 µg 3–4 hours later if expulsion did not occur, at home
Time between drugs	24–48 h
Intervention	**Mifepristone at home** Assessment by telemedicine (telephone/video) if LMP<10 weeks and low risk of ectopic pregnancy (61%), otherwise in person assessment and ultrasound (39%) Medicines received by mail or in clinic, additional dose of 400 µg misoprostol included with other drugs
Participants (n)	29 984
Mean age (SD)	28.5 (6.7) years
Had previous abortion	13 243 (44.2%)

Drop-outs (n)	0
Comparison	**Mifepristone in clinic** Assessment in person and ultrasound Medicines received in clinic, additional dose of 400 µg misoprostol if needed received if returned to clinic
Participants (n)	22 158
Mean age (SD)	27.8 (6.6) years
Had previous abortion	9 060 (40.9%)
Drop-outs (n)	0
Follow up	Self-assessment with pregnancy test 3 weeks after the abortion Collection of data from patient records 6 weeks after end of study period.
Outcomes included in the review	Successful abortion: Complete abortion, Incomplete abortion, Ongoing pregnancy Safety: Adverse events
Risk of bias	Overall: Moderate Domain 1: Some differences at baseline but confounders have been accounted for. Domain 2: Data collected retrospectively. Domain 3: Gestational length determined differently between groups. Domain 5: Not clear if blinded analysis. Domain 6: No pre-published protocol.

BPAS=British Pregnancy Advisory Service, C=Control group, mifepristone in clinic, I=Intervention group, mifepristone at home, LMP=last menstrual period, MSUK=MSI Reproductive Choices, NUPAS=National Unplanned Pregnancy Advisory Service

Author	**Chong**
Year	**2015**
Country	USA
Ref #	[2]
Study design	**Prospective non-randomized controlled clinical trial**
Group allocation	Woman's choice
Setting	Six Planned Parenthood centres in Vermont, New York City and Washington State
Population	Women aged 18 years or older seeking medical abortion
Gestational age	Up to 63 days (≤9+0 weeks)
Method to determine gestational age	No information
Inclusion criteria	In general good health. Assessed by a clinician to have an intrauterine pregnancy of correct gestational length. Eligible for medical abortion.
Treatment (drugs, dose and route)	Mifepristone 200 mg orally Misoprostol 800 µg buccally at home
Time between drugs	24–48 h
Intervention	**Mifepristone at home**
Participants (n)	128
Mean age (range)	27.8 (18–44) years
Had previous abortion	45 (35.2%)
Employed	101 (78.9%)
Student	29 (22.7%)
Drop-outs (n)	1 (0,8%) dropped out from treatment 19 (14,8%) lost to follow-up
Comparison	**Mifepristone in clinic**
Participants (n)	272
Mean age (range)	26 (18–43) years
Had previous abortion	108 (39.7%)
Employed	185 (68%)
Student	68 (25%)
Drop-outs (n)	0 dropped out from treatment 43 (15,8%) lost to follow-up
Follow up	1–2 weeks after mifepristone administration

Outcomes included in the review	Successful abortion: Complete abortion, Incomplete abortion, Ongoing pregnancy Safety: Adverse events, Medical treatment needs Contact with healthcare: Telephone, Visits Compliance: Within stated gestational age, Within recommended interval between drugs Women's experience: Place of mifepristone in future Practical consequences: Missed work, Missed school
Risk of bias	Overall: High Domain 1: Allocation to study arm depended on women's own choice. Domain 3: Unclear if there were differences in treatments as information is lacking. Domain 4: Lack of information about the participants lost to follow-up and not accounted for missing data in analysis. Domain 5: Time to follow-up may be too short for efficacy, adverse events and acceptability. Not stated if assessment was blinded.

Author	**Conkling**
Year	**2015**
Country	Nepal
Ref #	[3]
Study design	**Prospective non-randomized controlled clinical trial**
Group allocation	Woman's choice
Setting	Two tertiary university hospitals
Population	Women aged 18 years or older seeking abortion
Gestational age	Up to 63 days (≤9+0 weeks)
Method to determine gestational age	No information
Inclusion criteria	Good general health and no contra-indications to medical abortion
Treatment (drugs, dose and route)	Mifepristone 200 mg orally Misoprostol 400 µg sublingually at home
Time between drugs	24–72 h
Intervention	**Mifepristone at home**
Participants (n)	144
Mean age (range)	27.6 (16–41) years
Had previous abortion	29 (20.1%)
Employed	54 (37.5%)
Student	46 (31.9%)
Drop-outs (n)	0 dropped out from treatment 8 (5.6%) lost to follow-up
Comparison	**Mifepristone in clinic**
Participants (n)	56
Mean age (range)	27.3 (16–49) years
Had previous abortion	17 (30.4%)
Employed	6 (10.7%)
Student	46 (82.1%)
Drop-outs (n)	0
Follow up	Within 14 days of mifepristone administration
Outcomes included in the review	Successful abortion: Complete abortion, Incomplete abortion, Ongoing pregnancy Contact with healthcare: Telephone, Visits Compliance: Within stated gestational age, Within recommended interval between drugs

	Women's experience: Place of mifepristone in future
Risk of bias	Overall: High Domain 1: Allocation to study arm depended on women's own choice Domain 5: Time to follow-up may be too short for efficacy, contact with clinic and acceptability. Not stated if assessment was blinded. Domain 6: Pre-published protocol does not include all outcomes and data for participants in Moldova not reported.

Author	**Endler**
Year	**2022**
Country	South Africa
Ref #	[4]
Study design	**Prospective randomized clinical trial**
Group allocation	Randomization
Setting	Four public health clinics in the Cape Town metropolitan area that served people living on low incomes
Population	Women aged 18 years or older seeking medical abortion
Gestational age	≤9+0 weeks
Method to determine gestational age	I: LMP+nurse palpated the uterus. Ultrasound if palpation indicated pregnancy >9 weeks or if uterus could not be felt or if the woman reported irregular bleeding, pain, previous ectopic pregnancy or sterilisation C: Ultrasound to date pregnancy
Inclusion criteria	In possession of a smartphone, able to speak and understand written English, isiXhosa or Afrikaans
Treatment (drugs, dose and route)	Mifepristone 200 mg orally Misoprostol 800 µg sublingually at home
Time between drugs	24–48 h
Intervention	**Mifepristone at home**
Participants (n)	450 totally/382 included in mITT analysis
Median age (IQR)	28 (24–32) years
Had previous abortion	80/450 (17,9%)
Drop-outs (n)	68 discontinued before intervention 10/382 (2,6%) lost to follow-up
Comparison	**Mifepristone in clinic**
Participants (n)	450 totally/365 included in mITT analysis
Median age (IQR)	28 (25–33) years
Had previous abortion	82/450 (18,3%)
Drop-outs (n)	85 discontinued before intervention 15/365 (4,1%) lost to follow-up
Follow up	I: Self pregnancy test after 3–4 weeks, Phone interview after 5 days (safety, compliance) and 6 weeks (successful abortion, safety, contact with healthcare, experience)

Outcomes included in the review	C: Follow-up appointment at clinic after 6 weeks or self pregnancy test, Phone interview after 5 days (safety, compliance) and 6 weeks (successful abortion, safety, contact with healthcare, experience) Successful abortion: Complete abortion, Ongoing pregnancy Safety: Adverse events, Medical treatment needs Contact with healthcare: Visits Compliance: Combined measure of adherence Women's experience: Satisfaction with abortion procedure, Place of mifepristone in future
Risk of bias	Overall: Moderate Domain 1: Unblinded allocation. Some differences between groups at baseline. Domain 3: Participants not blinded. Domain 4: High proportion discontinued before intervention, higher in comparison group. Domain 5: Outcome assessors not blinded. Outcomes measured differently between groups. Domain 7: One author is director of Women on Web, the telemedicine service platform used in the study.

C=Control group, mifepristone in clinic, I=Intervention group, mifepristone at home, IQR=Interquartile range, LMP=last menstrual period, mITT=modified intention to treat

Author	**Platais**
Year	**2016**
Country	Kazakhstan
Ref #	[5]
Study design	**Prospective non-randomized controlled clinical trial**
Group allocation	Woman's choice
Setting	Two perinatal centres and one polyclinic in two cities
Population	Women seeking medical abortion
Gestational age	Up to 70 days (≤10+0 weeks)
Method to determine gestational age	Menstrual history, clinical examination and/or ultrasound
Inclusion criteria	Eligible for medical abortion and able to contact study staff or a medical centre in an emergency
Treatment (drugs, dose and route)	Mifepristone 200 mg orally Misoprostol 600 µg sublingually at home
Time between drugs	24–48 h
Intervention	**Mifepristone at home**
Participants (n)	185
Median age (range)	29 (19–44) years
Had previous medical abortion	35 (18,9%)
Had previous surgical abortion	72 (38.9%)
Employed	101 (54.6%)
Student	24 (13%)
Drop-outs (n)	1 dropped out from treatment
Comparison	**Mifepristone in clinic**
Participants (n)	105
Median age (range)	28 (16–42) years
Had previous medical abortion	21 (20%)
Had previous surgical abortion	41 (39%)
Employed	56 (53.3%)
Student	11 (10.5%)
Drop-outs (n)	0

Follow up **Outcomes included in the review**	12–15 days after mifepristone administration Contact with healthcare: Telephone, Visits Compliance: Within stated gestational age Women's experience: Satisfaction with abortion procedure, Place of mifepristone in future Practical consequences: Missed work, Missed school
Risk of bias	Overall: High Domain 1: Allocation to study arm depended on women's own choice Domain 3: Gestational length determined differently at different sites, no information if different between groups. Domain 5: Time to follow-up may be too short for contact with clinic and acceptability. Not stated if assessment was blinded.

Author	**Swica**
Year	**2013**
Country	USA
Ref #	[6]
Study design	**Prospective non-randomized controlled clinical trial**
Group allocation	Woman's choice
Setting	Four urban, demographically diverse clinical sites in New York City, Philadelphia and Atlanta
Population	Women seeking abortion
Gestational age	Up to 63 days (≤9+0 weeks)
Method to determine gestational age	Two sites by ultrasound, one site by LMP plus bimanual examination and one site by either or both methods
Inclusion criteria	No information
Treatment (drugs, dose and route)	Mifepristone 200 mg orally Misoprostol 800 µg, route of administration per site's medical abortion protocol, at home
Time between drugs	6–48 h
Intervention	**Mifepristone at home**
Participants (n)	139
Mean age (range)	28 (16–42) years
Had previous abortion	71 (51.4%)
Employed	95 (68.3%)
Student	44 (31.9%)
Drop-outs (n)	0 dropped out from treatment 13 (9.4%) lost to follow-up
Comparison	**Mifepristone in clinic**
Participants (n)	162
Mean age (range)	27.4 (14–48) years
Had previous abortion	65 (40.1%)
Employed	113 (69.8%)
Student	58 (35.8%)
Drop-outs (n)	0 dropped out from treatment 25 (15.4%) lost to follow-up
Follow up	1–2 weeks after mifepristone administration
Outcomes included in the review	Successful abortion: Complete abortion Safety: Medical treatment needs

	Contact with healthcare: Telephone, Visits Compliance: Within stated gestational age, Within recommended interval between drugs Women's experience: Place of mifepristone in future Practical consequences: Missed work, Missed school
Risk of bias	Overall: High Domain 1: Allocation to study arm depended on women's own choice. Domain 3: Determination of gestational length and route of administration for misoprostol may differ between sites, no information if different between groups. Domain 4: Difference in proportion lost to follow-up between groups. Lack of information about the participants lost to follow-up and not accounted for missing data in analysis. Domain 5: Time to follow-up may be too short for efficacy, adverse events and acceptability. Not stated if assessment was blinded. Domain 6: No pre-published protocol.

LMP= last menstrual period

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