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Effectiveness of the Addressing Reproductive Coercion in Health Settings (ARCHES) intervention among abortion clients in Bangladesh: a cluster-randomized controlled trial

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Summary

Background The Addressing Reproductive Coercion in Health Settings (ARCHES) intervention trains existing providers to address reproductive coercion (RC) and intimate partner violence (IPV) within routine family planning counseling. This study evaluated the effectiveness of a single ARCHES counseling session as adapted for use with abortion clients in Bangladesh.

Methods In this cluster-randomized controlled trial conducted between January 2019 and January 2021, health facilities with an abortion clinic with infrastructure for private counseling and onsite violence support services were eligible. Six facilities in Bangladesh met inclusion criteria, and matched pairs randomization with parallel assignment and a 1:1 allocation ratio was used to randomize three facilities to ARCHES and three facilities to control, which implemented standard counseling. Blinding was not possible as providers in intervention facilities participated in a three-day ARCHES training. Participants were abortion clients aged 18–49 years who could provide safe recontact information and be interviewed privately. The primary outcome was past three-month modern contraceptive use without interruption or interference. The trial was registered on clinicaltrials.gov (NCT03539315) on 29 May 2018.

Findings A total of 1492 intervention participants and 1237 control participants were enrolled. Available data were analyzed at each follow-up period: 1331 intervention and 1069 control participants at the three-month follow-up, and 1269 intervention and 1050 control participants at the twelve-month follow-up. ARCHES was associated with higher likelihood of modern contraceptive use at the three-month follow-up (adjusted RR = 1.08, 95% CI: 1.06–1.10) and the twelve-month follow-up (adjusted RR = 1.06, 95% CI: 1.02–1.10). ARCHES was also associated with decreased incident pregnancy, decreased IPV, and increased knowledge of IPV support services.

Interpretation The ARCHES intervention is effective in increasing post-abortion modern contraceptive use and decreasing incident pregnancy and IPV among abortion clients in Bangladesh. Implementation of ARCHES should be considered in facilities with sufficient privacy for counseling.

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Keywords: Reproductive coercion; Intimate partner violence; Abortion; Bangladesh; South Asia

Introduction

Intimate partner violence (IPV) negatively impacts women's health and well-being and is strongly associated with poor reproductive health and unintended pregnancy.[1–3] Reproductive coercion (RC) includes male partner behaviors that interfere with women's reproductive decision-making and autonomy.[4] In Bangladesh, RC has not previously been measured, but IPV is prevalent with an estimated 50–60% of women having experienced physical and/or sexual IPV in their lifetimes and 30% having experienced such violence in the past year. IPV experience is associated with a 50–60% increase in unwanted pregnancy and over two times higher odds of abortion (AOR = 2.60).[5] Bangladesh has

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Research in context

Evidence before this study

Despite the high prevalence of intimate partner violence (IPV) globally and the negative impact of IPV and reproductive coercion (RC) on women's health and well-being, few effective interventions to address IPV and RC in clinical contexts currently exist. Interventions addressing IPV in clinical settings, including routine IPV screening, the World Health Organization's LIVES (Listen, Inquire, Validate, Enhance safety, Support) approach, and the Healthcare Responding to Violence and Abuse (HERA) intervention have been tested with mixed results. Fewer interventions exist to address RC, and the Addressing Reproductive Coercion in Health Settings (ARCHES) intervention is the most widely adapted and tested intervention with contraception clients in both U.S. and low- and middle-income country contexts. In the U.S., ARCHES demonstrated effectiveness in reducing pregnancy coercion and increasing the likelihood that a woman will leave a violent relationship, but a larger trial of ARCHES found no impact on RC in intent-to-treat analyses, only among women who were experiencing multiple forms of RC. In Kenya, ARCHES was associated with short-term increases in modern contraceptive use and increased awareness of IPV support services.

Added value of this study

This trial is the first, to our knowledge, to test an intervention addressing RC and IPV with abortion clients in a South Asian setting. The ARCHES Bangladesh adaptation was a brief counseling intervention providing universal education on RC and IPV, counseling on RC coping strategies, offering family counseling, and referring for IPV support services. Findings demonstrate that ARCHES, delivered within the context of abortion care, can improve post-abortion contraceptive use twelve months post-abortion and reduce incident pregnancy and intimate partner violence.

Implications of all the available evidence

There is growing evidence that a single ARCHES counseling session in the context of clinical contraceptive and abortion services improves reproductive health and violence outcomes. Interventions such as ARCHES that address RC and IPV should be tested with contraceptive and abortion clients in additional settings and considered for scale-up.

among the highest abortion rates in the region with an estimated 35 abortions per 1000 women in 2015–2019.[6] Abortion is legal only to save a woman's life in Bangladesh, but menstrual regulation (MR)[d] is widely available in the public and private sectors to induce a menstrual cycle and establish non-pregnancy up to 12 weeks' gestation.[7] Postabortion care (PAC) services are also widely available to treat incomplete abortion.[8] In the context of MR/PAC (abortion) services, women reporting IPV are more likely to access abortion outside the health system and less likely to access post-abortion contraception, especially if accompanied to the facility by their partner, which suggests additional intervention is needed to support abortion clients' reproductive autonomy.[9]

The Addressing Reproductive Coercion in Health Settings (ARCHES) intervention was initially developed in the U.S. and involves training existing health providers to identify RC and IPV during standard facility-based contraceptive counseling. The intervention seeks to empower women with harm reduction strategies that minimize their risk for unintended pregnancy by providing counseling on contraceptive methods that are difficult for a male partner to detect or block. ARCHES also facilitates access to violence support services by connecting women with existing IPV services. Two cluster-randomized controlled trials of the ARCHES intervention in the U.S. demonstrated that a single exposure to the ARCHES intervention resulted in a 71% reduction in incidence of pregnancy coercion, increased self-efficacy to use a form of contraception that would minimize male partner interference, and a four-fold increase in knowledge of community-based IPV services at three months post-intervention.[10,11] The ARCHES intervention has also been adapted and tested in the Kenyan context to address RC and IPV among women and girls seeking contraceptive services.[12]

This study is the first to assess the efficacy of ARCHES adapted for use with abortion clients in a South Asian context, and this manuscript presents the impact of ARCHES counselling on abortion clients' post-abortion contraceptive use, experience of reproductive coercion, and other reproductive health and violence outcomes.

Methods

Trial design

A cluster-randomized controlled trial (clinicaltrials.gov: NCT03539315) with parallel assignment using a 1:1 allocation ratio was conducted to assess the effectiveness of the ARCHES intervention in six health facilities in urban areas of Bangladesh, three randomized to the intervention group (providers received training on ARCHES counseling) and three randomized to the control group (providers received no additional training and implemented standard counseling). The cluster-randomized design was selected to reduce potential

[d]Though pregnancy may not be confirmed prior to an MR procedure, for the purposes of this manuscript, MR will be considered equivalent to induced abortion. The term "abortion clients" will be used throughout in reference to MR and PAC clients.

contamination by asking providers working in the same clinic to offer the same counselling intervention to all of their clients. The study received ethical approval from the Bangladesh Medical Research Council (protocol number: BMRC/NREC/2016-2019/570) and the University of California, San Diego Human Research Protections Program (protocol number: 171903SX).

Participants

Facilities were eligible for inclusion in the trial if they had both a Reproductive Health Services Training and Education Program (RHSTEP) clinic providing abortion services and an onsite One-Stop Crisis Center (OCC) providing violence support services. RHSTEP clinics are private, NGO-run reproductive health clinics that were selected because they have sufficient infrastructure to privately conduct ARCHES counseling, including counseling rooms with audio and visual privacy. The study team required co-located violence support services due to the sensitive nature of the intervention, which was being conducted for the first time with abortion clients in the South Asian context. OCCs are government-run centers that provide medical, legal, and psychological support for violence survivors. Only six facilities in the country met these eligibility requirements at the time of the study, and all agreed to participate.

Trained female research assistants were posted at study facilities during available clinic hours to recruit abortion clients. RHSTEP staff referred potential study participants to the research assistants to assess eligibility and conduct informed consent procedures. Eligibility criteria included: 1) aged 18–49 years, 2) received MR or PAC (abortion) services, 3) were able to provide a safe phone number or address for recontact, and 4) were able to speak privately with the research assistant and/or provider without their husband/partner or other family members present. Those who were eligible and consented to participate completed interviewer-administered surveys at baseline before they met with the provider or counselor, at exit after they received their abortion service, and at three-months and twelve-months post-abortion (conducted in person or via phone after providing a password established at baseline). Participants who felt unwell after leaving the recovery room could complete their exit survey within seven days of enrollment. Data were collected using pre-programmed surveys in CommCare (Dimagi).

Interventions

The ARCHES intervention is a facility-based harm reduction intervention that empowers women to implement strategies that mitigate the impact of reproductive coercion on their reproductive health,[10,11] originally developed in the U.S. and adapted for use in Kenya, Nigeria, and Mexico. The ARCHES Bangladesh adaptation was based on a qualitative formative phase[13] and developed in partnership with providers from RHSTEP clinics through a participatory three-day workshop to determine how ARCHES counseling could be incorporated in RHSTEP's existing abortion and post-abortion contraceptive counseling. The intervention was piloted for two months in the three intervention facilities and finalized based on pilot findings and input from the study's technical advisory group. Key aspects of the ARCHES intervention in Bangladesh included: 1) provider/counselor establishing privacy and assuring client of confidentiality, 2) counseling all clients on RC and IPV, 3) counseling all clients on strategies for using contraception and abortion covertly, if desired, 4) screening all clients for RC and IPV within the context of counseling, 5) providing a warm referral for IPV support services to those screening positive for IPV, 6) offering family counseling on abortion and/or post-abortion contraception, and 7) providing a mini-booklet with key messages and resources for RC and IPV that clients could take home if it was safe for them to do so. Ipas Bangladesh conducted a three-day training of providers and counselors in the intervention facilities, which included information on RC and IPV, training on integrated ARCHES counseling including a full day of role play practice, and a meeting with OCC staff to learn about available violence support services and discuss referral processes. For six months post-training, trainees received mentorship and support to implement ARCHES, including a monthly in-person visit for coaching on counseling skills and a weekly phone check-in for sharing performance data and discussing any challenges. At six months post-training, Ipas Bangladesh shifted to bi-weekly phone check-ins, which continued through study recruitment. In control facilities, providers received no additional training and implemented standard abortion and post-abortion contraceptive counseling.

Outcomes

The primary outcome was past three-month use of modern contraception without interruption or interference, defined as continuous use of oral contraceptive pills, condoms, injectables, implant, intrauterine device, emergency contraception, sterilization, or lactational amenorrhea over the past three months. Interference included discontinuation because the husband/partner wanted her to become pregnant, the method had side effects he did not like, he was concerned about future infertility, he pressured her to stop using the method, he made it difficult for her to access or use the method, or he destroyed, hid, or took away her method. Interruptions or method switching with less than a one-month gap were considered continuous use.

Secondary outcomes included past three-month experience of RC, unintended pregnancy, and unsafe abortion within 12 months of the index abortion. Past three-month experience of RC was defined as

responding affirmatively to any of the types of RC in the Reproductive Coercion Scale (RCS)[14] adapted for the Bangladesh context based on formative findings,[13] and stating that the last time they experienced the event was within the past three months. The original RCS focused only on pregnancy-promoting RC[14] and excluded abortion-related measures; the Bangladesh adaptation added the following measures: husband/partner pressured her to keep a pregnancy she wanted to terminate, husband/partner pressured her to terminate a pregnancy she wanted to keep, and husband/partner forced or pressured her to use a contraceptive method she did not want to use. Unintended pregnancy was defined as pregnancy since the abortion that was not wanted at that time. Unsafe abortion was defined as pregnancy since the index abortion that was terminated using a method other than those considered safe (i.e., surgical procedure in a health facility or medication abortion in any setting). Past three-month use of modern contraception without interruption or interference and past three-month RC were assessed at the three-month and twelve-month follow-up surveys. Unintended pregnancy and unsafe abortion were assessed at the twelve-month follow-up.

We were underpowered for our secondary outcomes given lower than anticipated prevalence, and three outcomes with higher prevalence in the data were added *post hoc* to assess intervention effects: incident pregnancy within 12 months of the abortion (ascertained at the twelve-month follow-up), past three-month physical or sexual IPV (ascertained at the three-month and twelve-month follow-ups), and knowledge of IPV support services (ascertained at the three-month and twelve-month follow-ups). Incident pregnancy was defined as pregnancy since the index abortion, regardless of intendedness. IPV was measured using the same questions used in the 2014 Bangladesh Demographic and Health Survey (DHS),[15] which are based on the conflict tactics scale.[16] Past three-month physical or sexual IPV was defined as responding positively to any of the IPV experiences and stating that the last time they experienced the event was within the past three months. Knowledge of IPV support services was defined as knowing about any services a woman experiencing physical or sexual violence could go to for help. We also present data on outcomes of quality of care and acceptability of the ARCHES intervention collected during the exit survey, including whether the provider counseled her privately, whether she disclosed RC or IPV experiences to the provider, whether the provider offered a referral to IPV support services (among those disclosing IPV), whether she accepted the referral, and whether her family (accompanying male partner and/or other family members) was counseled on abortion and/or post-abortion contraception. We also assessed use of IPV services at the three-month and twelve-month follow-up surveys among participants who reported IPV over the follow-up period. Finally, we present data on reach of the ARCHES intervention beyond the facility setting, including sharing information with others about RC, strategies for covert contraceptive use, and available IPV support service information, all assessed on the three-month and twelve-month follow-up surveys.

Sample size

The study was powered to detect a 10 percentage point increase in past three-month modern contraceptive use without interruption or interference, assuming 50% modern contraceptive use at the twelve-month follow-up in the control group based on the modern contraceptive prevalence rate in the 2014 Bangladesh DHS in the divisions (administrative geographic areas) where study recruitment took place.[15] We assumed six clusters (facilities) of equal cluster size, an intraclass correlation coefficient (ICC) of 0.005 to account for clustering at the facility level, and 20% loss to follow-up over the twelve-month follow-up period, in line with previous studies.[9] The required sample size to achieve 80% power using a two-sided alpha of 0.05 for the primary outcome was 3044 participants, n = 1522 in the treatment arm and n = 1522 in the control arm.

Randomization and masking

The six eligible facilities were matched in pairs based on average monthly abortion caseload in 2017 and assigned a random number using Stata/SE. Within each matched pair, the facility with the higher random number was assigned to the intervention group. There was no masking of treatment assignment given that providers in intervention facilities were invited to attend the ARCHES training.

Implementation

Ipas Bangladesh staff approached each facility in-charge who provided permission for data collection. All six facilities (clusters) agreed to participate in the study before the principal investigator generated the random allocation sequence and assigned treatment groups. All abortion clients in study facilities who met eligibility criteria and provided informed consent were able to participate. Study enrollment was not required to receive ARCHES counseling in intervention facilities.

Statistical methods

We conducted intent-to-treat analysis using modified poisson regression models accounting for facility-level clustering using the clustered sandwich estimator, which are appropriate for correlated binary outcomes from cluster-randomized trials.[17] The primary outcome, past three-month use of modern contraception without interruption or interference, was assessed at each individual follow-up timepoint, comparing the intervention and control groups at the three-month, twelve-month,

and combined follow-up periods (three-month or twelve-month follow-up). We selected potential confounders to include in the analysis model based on known prognostic covariates associated with modern contraceptive use in South Asia, including number of living children,[9] living with the husband,[9] abortion service type,[9] and baseline report of past three-month RC.[18] This approach to confounder adjustment is recommended in Kahan et al., 2014 to increase power.[19]

We used multiple imputation to account for missing data. Item non-response was low in this study, and data were missing for only one prognostic covariate, baseline report of past three-month RC, for 11 participants (0.4% of the analytic sample). However, loss to follow-up resulted in missing outcome data, especially at the 12-month follow-up, making multiple imputation an appropriate approach to reduce bias in intent-to-treat analyses.[20] Multiple imputation was also used for four characteristics that were not used as covariates: age (n = 2 participants), baseline report of past three-month IPV (n = 12 participants), baseline report of knowledge of IPV services (n = 2 participants), and report of contraceptive uptake at exit (n = 2 participants). We used multiple imputation by chained equations (MICE) and performed 20 imputations for each variable with missing data, which was expected to be sufficient given that the number of imputations exceeded the percentage of missing data in the analytic sample (15.0% missing data at the 12-month follow-up).[21] All missing outcomes were binary, and a logit model was used to impute missing values with the following predictors: treatment group, the analysis covariates (living with husband, number of living children, MR or PAC service, and baseline report of past three-month RC), and auxiliary variables that were expected to predict the missing outcomes (age, marital status, religion, employment status, urban or rural residence, contraceptive uptake at exit, baseline knowledge of IPV services, and baseline report of past three-month IPV). A linear regression model was used to impute age and a logit model was used to impute baseline report of past three-month RC, baseline report of past three-month IPV, baseline report of knowledge of IPV services, and report of contraceptive uptake at exit. Imputation models for missing baseline and exit data included socio-demographic variables as predictors.

The secondary outcomes of unintended pregnancy and unsafe abortion were pre-specified as assessed at the twelve-month follow-up (single timepoint analysis), and the effect of ARCHES was measured using the same model described above for past three-month modern contraceptive use. The effect of ARCHES on past three-month RC was measured using a difference-in-difference approach, which assessed the difference in the change in past three-month RC at baseline and each follow-up timepoint between the intervention and control groups. Difference-in-difference models have four underlying assumptions: 1) consistency, which is met in the present study by having a well-defined intervention (ARCHES) implemented only in intervention facilities that were geographically distant from control facilities where no intervention was implemented; 2) parallel trend assumption, which assumes that the change in the primary outcome (past three-month contraceptive use without interruption or interference) occurs among women in the treatment and control facilities at the same rate in the absence of intervention, a reasonable assumption in the present study; 3) strict exogeneity; and 4) positivity, both of which are satisfied by randomized assignment of facilities to a treatment group.[22] The difference-in-difference models adjusted for the same set of prognostic covariates listed for the primary outcome with the exception of baseline RC, which was already taken into account by the difference-in-difference model, and the model accounted for individual-level and facility-level clustering. Incident pregnancy was assessed at the twelve-month follow-up (single timepoint analysis), and experience of past three-month IPV and knowledge of IPV services were assessed using the difference-in-difference approach described above. We also present bivariate statistics comparing the intervention and control groups on quality of care at exit and reach of the ARCHES intervention over the combined follow-up period. Statistical significance was assessed at $p < 0.05$ for all analyses. Analyses were conducted in Stata/SE 18.0 (Stata Corp, College Station, TX).

Role of the funding sources

Funders had no involvement in the study design, collection, analysis or interpretation of data, or the publication.

Results

Participant flow

The six facilities meeting inclusion criteria were randomized, three to the intervention group and three to the control group (Fig. 1). A total of 3187 abortion clients (1686 intervention, 1501 control) were screened for study eligibility, 2954 were eligible (92.7%), and 2729 consented to participate (92.4% of eligible clients). A total of 43 participants withdrew and 1 participant was excluded due to incomplete outcome data, leaving a baseline sample of 2685 participants. Loss to follow-up was similar across arms; 83 intervention and 91 control participants could not be recontacted for either the three-month or twelve-month follow-up survey (6.5% of the baseline sample). The three-month analytic sample was 2400 participants (89.4% of the baseline sample), and the twelve-month analytic sample was 2319 participants (86.4% of the baseline sample). A total of 2511 participants

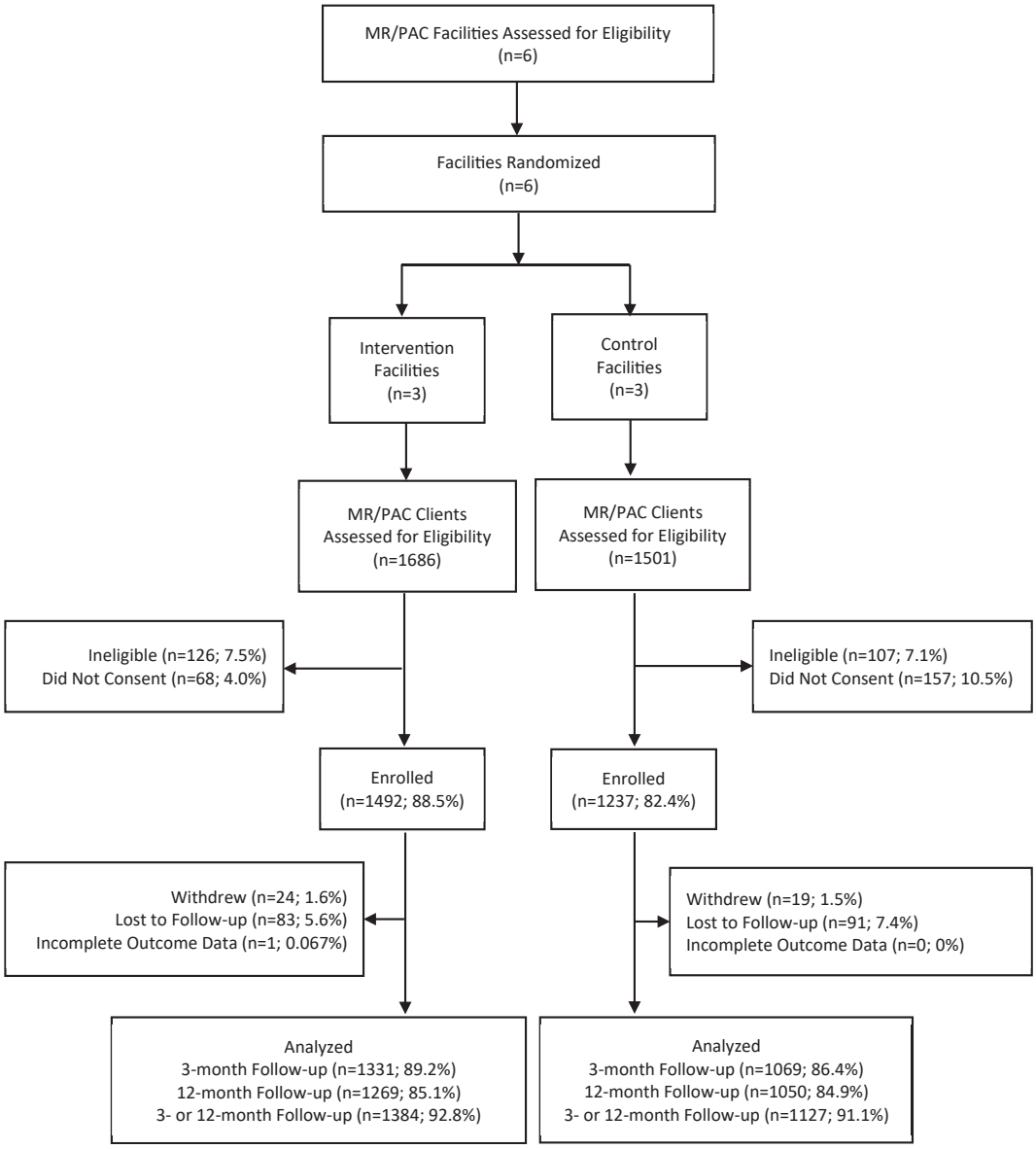

***Fig. 1*: CONSORT flow diagram.**

completed either follow-up survey (93.5% of the baseline sample) and were included in the combined follow-up analysis.

Recruitment

Participants were recruited from January to December 2019 when study facilities requested that we complete recruitment. Three-month follow-up surveys were collected July 2019–June 2020 and twelve-month follow-up surveys were collected February 2020–January 2021. Due to the COVID-19 pandemic, follow-up data collection was conducted via phone for 37.9% of participants in three-month follow-up surveys and 90.5% of participants in twelve-month follow-up surveys.

Baseline data

Table 1 presents the socio-demographic characteristics of abortion clients in the sample. The average age was approximately 29 years, half lived in rural areas, and two-thirds had less than secondary education. Almost all were married, and over 80% were living with their husbands. There was evidence of baseline imbalance between treatment groups on religion, residence, and number of living children. Ninety-five percent of participants in the intervention group were Muslim compared to 88.3% in

	Control Group (n = 1218)		Intervention Group (n = 1467)	
	n	(%)[a]	n	(%)[a]
Age in years, *mean (SD)*	*28.9*	*(6.13)*	*28.5*	*(6.23)*
Age				
18–19 years	64	(5.2)	97	(6.6)
20–24 years	253	(20.8)	327	(22.3)
25+ years	901	(74.0)	1043	(71.1)
Education				
None/less than primary	318	(26.1)	270	(18.4)
Primary	527	(43.3)	674	(45.9)
Secondary or higher	373	(30.6)	523	(35.7)
Religion				
Islam	1075	(88.3)	1398	(95.3)
Another religion	143	(11.7)	69	(4.7)
Residence				
Rural	461	(37.8)	744	(50.7)
Urban	757	(62.2)	723	(49.3)
Worked in past 12 months	314	(25.8)	358	(24.4)
Married	1196	(98.2)	1448	(98.7)
Living with husband	1085	(89.1)	1264	(86.2)
Number of living children				
None	138	(11.3)	185	(12.6)
1	259	(21.3)	360	(24.5)
2	406	(33.3)	641	(43.7)
3+	415	(34.1)	281	(19.2)
Index abortion procedure type				
Induced abortion/menstrual regulation (MR)	1032	(84.7)	1289	(87.9)
Postabortion care (PAC)	186	(15.3)	178	(12.1)
Ever experienced reproductive coercion	122	(10.0)	190	(13.0)
Past 3-month experience of reproductive coercion	75	(6.2)	107	(7.4)
Ever experienced physical or sexual intimate partner violence	539	(44.3)	677	(46.1)
Past 3-month experience of physical or sexual intimate partner violence	102	(8.4)	145	(10.0)

[a]Imputed % shown.

Table 1: **Baseline sample characteristics by treatment group (n = 2685).**

the control group, reflecting the population in the geographic regions where facilities were located, and the control group had a higher proportion of women living in urban areas and with three or more living children. The index abortion was induced for 84.7% of control and 87.9% of intervention participants. At baseline, rates of RC and IPV were similar across groups. Ten percent of control and 13.0% of intervention participants had ever experienced RC, including 6.2% and 7.4% in the past three months, respectively. Almost half of participants (44.3% control, 46.1% intervention) ever experienced physical or sexual IPV, including 8.4% and 10.0% in the past three months, respectively.

Numbers analyzed

Intent-to-treat analyses (Table 2) included available data at each timepoint analyzed by the original assigned treatment group (three intervention facilities: n = 1331 at three-month follow-up, n = 1269 at twelve-month follow-up, n = 1384 in the combined follow-up; three control facilities: n = 1069 at three-month follow-up, n = 1050 at twelve-month follow-up, and n = 1127 in the combined follow-up).

Outcomes and estimation

Intent-to-treat analyses demonstrated 1.08 times more likely (95% CI: 1.06–1.10) to use modern contraception without interruption or interference at the three-month follow-up (89.6% intervention, 83.7% control) and 1.06 times more likely (95% CI: 1.02–1.10) at the twelve-month follow-up (83.2% intervention, 79.7% control) (Table 2). The combined follow-up analysis had similar results (92.9% intervention, 90.6% control, adjusted risk ratio (RR) = 1.03, 95% CI: 1.01–1.06). The ICC for the primary outcome was 0.008 at the three-month follow-up and 0.005 at the twelve-month follow-up, demonstrating decreasing facility-level clustering of post-abortion contraceptive use over time.

	3-month follow-up survey (n = 2400)							12-month follow-up survey (n = 2319)							3- or 12-month follow-up survey (n = 2511)						
	Intervention (n = 1331)		Control (n = 1069)		Adjusted RR	p-value	(95% CI)	Intervention (n = 1269)		Control (n = 1050)		Adjusted RR	p-value	(95% CI)	Intervention (n = 1384)		Control (n = 1127)		Adjusted RR	p-value	(95% CI)
	n	(%)[c]	n	(%)[c]				n	(%)[c]	n	(%)[c]				n	(%)[c]	n	(%)[c]			
Primary outcome																					
Past 3-month use of modern contraception without interruption or interference[a]	1194	(89.6)	897	(83.7)	1.08	<0.0001	(1.06–1.10)	1064	(83.2)	845	(79.7)	1.06	0.0030	(1.02–1.10)	1289	(92.9)	1024	(90.6)	1.03	0.018	(1.01–1.06)
Secondary outcomes																					
Past 3-month reproductive coercion[b]	21	(1.6)	21	(2.0)	0.67	0.22	(0.36–1.27)	27	(2.3)	15	(1.6)	1.23	0.56	(0.61–2.49)	45	(3.3)	32	(3.0)	0.94	0.81	(0.57–1.57)
Unintended pregnancy in the past 12 months[a]	–	–	–	–	–	–	–	33	(2.7)	34	(3.5)	0.76	0.48	(0.36–1.61)	–	–	–	–	–	–	–
Unsafe abortion in the past 12 months	–	–	–	–	–	–	–	1	(0.1)	2	(0.2)	–	–	–	–	–	–	–	–	–	–
Additional outcomes of interest																					
Incident pregnancy in the past 12 months[a]	–	–	–	–	–	–	–	90	(7.1)	103	(10.2)	0.68	0.025	(0.49–0.95)	–	–	–	–	–	–	–
Past 3-month physical or sexual intimate partner violence[b]	27	(2.1)	25	(2.3)	0.76	0.33	(0.44–1.33)	48	(3.9)	45	(4.3)	0.76	0.19	(0.50–1.15)	63	(4.6)	64	(5.7)	0.68	0.038	(0.47–0.98)
Knowledge of intimate partner violence support services[b]	946	(71.2)	336	(31.6)	2.53	<0.0001	(2.17–2.94)	1128	(88.8)	730	(69.2)	1.44	<0.0001	(1.26–1.65)	1277	(92.2)	809	(71.6)	1.44	<0.0001	(1.26–1.66)

[a]Single timepoint analysis adjusted for baseline RC, living with husband, number of living children, and MR or PAC service, accounting for facility-level clustering. [b]Difference-in-difference analysis adjusted for living with husband, number of living children, and MR or PAC service, accounting for facility-level and individual-level clustering. [c]Imputed % shown.

Table 2: **Effect of ARCHES Bangladesh intervention on outcomes of interest at the 3-month, 12-month, and combined follow-up surveys.**

No statistically significant differences were observed in the secondary outcomes, which were rare at follow-up (Table 2). Past three-month incidence of RC was approximately 2% at follow-up in both treatment groups. Unintended pregnancy was somewhat lower in the intervention group compared to the control (2.7% intervention, 3.5% control), and only three unsafe abortions were reported (1 intervention, 2 control).

Ancillary analyses

Incident pregnancy over the twelve-month follow-up was lower in the intervention group (7.1%) compared to the control group (10.2%, adjusted RR = 0.68, 95% CI: 0.49–0.95) (Table 2). IPV was rare at follow-up, but difference-in-difference analyses demonstrated that there was a larger reduction in past three-month IPV in the intervention group compared to the control group in the combined follow-up analysis (4.6% intervention, 5.7% control, adjusted RR = 0.68, 95% CI: 0.47–0.98). The change in knowledge of available IPV support services was higher in the intervention group at the three-month follow-up (71.2% intervention, 31.6% control, adjusted RR = 2.53, 95% CI: 2.17–2.94), the twelve-month follow-up (88.8% intervention, 69.2% control, adjusted RR = 1.44, 95% CI: 1.26–1.65), and in the combined follow-up analysis (92.2% intervention, 71.6% control, adjusted RR = 1.44, 95% CI: 1.26–1.66).

Fidelity of implementation was high with 81.4% of participants exposed to core ARCHES intervention components (data not shown). Quality of care was higher in ARCHES intervention facilities compared to control facilities. Almost all participants (98.8%) in intervention facilities were counseled privately compared to 65.3% in control facilities (data not shown). In intervention facilities, disclosure of RC and IPV to the provider or counselor was high among those who reported RC or IPV at baseline (80.3% and 55.4%, respectively), in contrast to control facilities where disclosure was minimal (2.4% and 0.2%, respectively). Three-quarters of participants disclosing IPV in the intervention group were offered a referral for IPV support services, but only 2.2% accepted the referral. Despite high rates of IPV experience, disclosure, and offer of referrals, use of IPV support services was also rare among participants experiencing IPV over the follow-up period. Use of IPV support services was somewhat higher in the intervention group compared to the control among those reporting IPV over the follow-up period (11.1% intervention, 6.3% control, p = 0.67). Family counseling was available in all RHSTEP facilities, but explicitly offering family counseling through the ARCHES intervention led to higher uptake (54.1% intervention, 2.6% control). There was also evidence for reach of the ARCHES intervention beyond the facility setting with approximately half of intervention group participants sharing information about RC (47.8% intervention, 0.1% control), about strategies for covert use of contraception (53.7% intervention, 0.4% control), and about IPV support services (51.1% intervention, 1.6% control) over the follow-up period (data not shown).

Discussion

The ARCHES intervention was effective in increasing modern contraceptive use without interruption or interference, and this effect persisted to 12 months post-intervention. ARCHES was also associated with a decrease in incident pregnancy at the 12-month follow-up. Recent RC and IPV were rare at follow-up. The decline in RC from baseline to follow-up was similar across treatment groups, but ARCHES was associated with a decline in recent IPV experience in the combined follow-up analysis and with large increases in knowledge about available IPV support services. Core ARCHES components were implemented with over 80% of participants, suggesting feasibility and acceptability of the intervention. Providing counseling on RC and IPV in a single session during abortion services led to high rates of disclosure of RC and IPV experiences, increased use of family counseling, and increased sharing of information on RC and IPV services, suggesting reach of ARCHES beyond the facility setting.

Results of the ARCHES Bangladesh trial are similar to the ARCHES trial in Nairobi, Kenya, which identified effects on contraceptive use and knowledge of IPV support services.[12] Increases in post-abortion contraceptive use suggest that ARCHES is effective in supporting women to find the post-abortion contraceptive method that is best aligned with their personal preferences and violence experiences. Despite increased contraceptive use, we did not find a reduction in RC. ARCHES has mixed results on RC with one study in the U.S. demonstrating a reduction in pregnancy coercion[11] and a larger trial finding reduced RC only among women experiencing multiple forms of RC.[10] In the initial U.S. study, ARCHES may have reduced pregnancy coercion through women leaving violent relationships.[11] The Bangladesh trial had more married women, and the costs of leaving a violent relationship may be higher compared to the U.S. context. In the Bangladesh context, ARCHES is expected to work primarily through helping women cope with RC within their existing relationship, which improves their ability to use contraception but does not affect RC perpetration by their partners. Community-based interventions to change social norms around male control of reproductive decisions should be considered to reduce women's RC experiences. We found that past three-month RC and IPV decreased over time in both groups, suggesting that violence may be related to the unwanted pregnancy, which mirrors findings in the U.S. that access to abortion is associated with reductions in IPV.[23] Though rates of recent RC and IPV were low at follow-up, we did

observe a larger relative decrease in IPV in the ARCHES intervention group compared to the control, suggesting that ARCHES reduced IPV beyond the impact of receiving the abortion service.

Like the Nairobi trial[12] and studies from other settings,[24,25] we found that use of IPV support services was rare despite high rates of disclosure and offer of referral. Coping with IPV occurs along a continuum,[26] and women seeking abortion services may be in early stages of change. The ARCHES intervention may primarily support women in moving from the precontemplation stage where IPV is not recognized as a problem to the contemplation stage where IPV is acknowledged as a problem in their relationships.[26] The stages of change are non-linear, and women may spend significant time in the precontemplation and contemplation stages before moving to the preparation and action stages due to high perceived risks of utilizing support services (e.g., breakup of the family unit, lack of confidentiality, and police involvement).[26] Despite low uptake of IPV support services, results demonstrate that ARCHES increases long-term awareness of available services, which may enable women who transition into the preparation and action stages to access services when they are ready. Future ARCHES adaptations should consider facilitating informal IPV support, which may be more acceptable to women in earlier stages of change.

The trial results should be viewed in light of the study's limitations. Participants were recruited from six NGO-run facilities located in urban areas of Bangladesh. Facilities were located in six of the eight divisional capitals throughout the country and approximately half of participants resided in rural areas, but results may not generalize to abortion clients in the public sector or those seeking services in other parts of Bangladesh. Implementation of the ARCHES intervention at the facility level was important to prevent contamination, but this approach reduced the study's power compared to individual randomization given the small number of clusters (facilities) that were eligible for the study. We were underpowered to assess significant differences in secondary outcomes due to the lower prevalence than anticipated when planning the trial. In addition, random confounding is more likely in trials with a small number of clusters,[27] and in the present trial we found baseline imbalances on religion, residence, and number of living children, which may have compromised the trial's internal validity. Unmeasured confounding in the imputation model and the primary and secondary analysis models may also have biased the results. Due to the COVID-19 pandemic, most twelve-month follow-up surveys were conducted via phone rather than in-person. Research assistants asked participants to confirm privacy and provide their password (established at baseline) before proceeding with follow-up surveys to ensure the correct person was surveyed, but it is possible privacy was not maintained throughout the phone survey, which may have resulted in response bias. Finally, the study did not collect sustainment data to understand whether implementation of the ARCHES intervention continued after study recruitment was completed. Future studies should assess the scalability and sustainability of the ARCHES intervention.

The ARCHES intervention was successful in increasing post-abortion contraceptive use and reducing incident pregnancy over a twelve-month time horizon, in decreasing IPV, and in increasing knowledge of available IPV support services. Program implementers should consider integrating ARCHES within abortion services in health facilities that have infrastructure for private counseling. Scale-up of the ARCHES intervention to other settings, including public sector facilities and expansion to those seeking other contraceptive services, including interval and postpartum contraceptive services, may require additional adaptation.

Contributors

EP, DP, JM, and JGS adapted the ARCHES intervention for use in Bangladesh. JU and JGS created the ARCHES Kenya adaptation that served as the basis for ARCHES in Bangladesh. EP and JGS designed the trial. All authors contributed to study protocol and tool development, and DP, MAHS, and RAK oversaw ARCHES implementation by RHSTEP and trial data collection by our partners at BAPSA with support from EP and JM. EP, DP, JM, MAHS, and RAK verified the data underlying the trial results. EP and JU developed the statistical analysis plan, and EP, DP, JM, MAHS conducted the analysis. DP organized and led the technical advisory group meetings. All authors had full access to the study data and have contributed to the manuscript.

Data sharing statement

De-identified data and supporting documentation will be made available on request with no end date. Due to the sensitive nature of the data, a data use agreement with Ipas will be required to access data.

Declaration of interests

EP and DP have received research grants from Elrha as principal investigators to conduct ARCHES research; JM has had time funded through these grants. JGS has received research grants from the Bill & Melinda Gates Foundation and the National Institutes of Health as principal investigator to conduct ARCHES research, and EP, JM, and JU have had time funded through these grants. Other authors declare no competing interests.

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Appendix A. Supplementary data

Supplementary data related to this article can be found at https://doi.org/10.1016/j.eclinm.2024.102699.

References

1 Silverman JG, Raj A. Intimate partner violence and reproductive coercion: global barriers to women's reproductive control. *PLoS Med.* 2014;11(9):e1001723.

2 Miller E, Jordan B, Levenson R, Silverman JG. Reproductive coercion: connecting the dots between partner violence and unintended pregnancy. *Contraception*. 2010;81(6):457–459.
3 World Health Organization. *Responding to intimate partner violence and sexual violence against women: WHO clinical and policy guidelines*. Geneva: World Health Organization; 2013 [cited 2022 Aug 12]. Available from: https://apps.who.int/iris/handle/10665/85240.
4 Tarzia L, Hegarty K. A conceptual re-evaluation of reproductive coercion: centring intent, fear and control. *Reprod Health*. 2021;18(1):87.
5 Pallitto CC, García-Moreno C, Jansen HAFM, et al. Intimate partner violence, abortion, and unintended pregnancy: results from the WHO multi-country study on women's health and domestic violence. *Int J Gynecol Obstet*. 2013;120(1):3–9.
6 Bearak J, Popinchalk A, Ganatra B, et al. Unintended pregnancy and abortion by income, region, and the legal status of abortion: estimates from a comprehensive model for 1990–2019. *Lancet Glob Health*. 2020;8(9):e1152–e1161.
7 Singh S, Hossain A, Maddow-Zimet I, Vlassoff M, Bhuiyan HU, Ingerick M. The incidence of menstrual regulation procedures and abortion in Bangladesh, 2014. *Int Perspect Sex Reprod Health*. 2017;43(1):1–11.
8 Mridha MK, Anwar I, Koblinsky M. Public-sector maternal health programmes and services for rural Bangladesh. *J Health Popul Nutr*. 2009;27(2):124–138.
9 Pearson E, Biswas KK, Andersen KL, et al. Correlates of contraceptive use 4 months postabortion: findings from a prospective study in Bangladesh. *Contraception*. 2017;95(3):279–287.
10 Miller E, Tancredi DJ, Decker MR, et al. A family planning clinic-based intervention to address reproductive coercion: a cluster randomized controlled trial. *Contraception*. 2016;94(1):58–67.
11 Miller E, Decker MR, McCauley HL, et al. A family planning clinic partner violence intervention to reduce risk associated with reproductive coercion. *Contraception*. 2011;83(3):274–280.
12 Uysal J, Boyce SC, Undie CC, et al. Effects of a clinic-based reproductive empowerment intervention on proximal outcomes of contraceptive use, self-efficacy, attitudes, and awareness and use of survivor services: a cluster-controlled trial in Nairobi, Kenya. *Sex Reprod Health Matters*. 2023;31(1):2227371.
13 Pearson EE, Aqtar F, Paul D, et al. 'Here, the girl has to obey the family's decision': a qualitative exploration of the tactics, perceived perpetrator motivations, and coping strategies for reproductive coercion in Bangladesh. *SSM Qual Res Health*. 2023;3:100243.
14 McCauley HL, Silverman JG, Jones KA, et al. Psychometric properties and refinement of the reproductive coercion scale. *Contraception*. 2017;95(3):292–298.
15 National Institute of Population Research and Training - NIPORT/ Bangladesh, Mitra and Associates, ICF International. Bangladesh demographic and health survey 2014. In: *Dhaka, Bangladesh: NIPORT, Mitra and Associates, and ICF International*; 2016. Available from: http://dhsprogram.com/pubs/pdf/FR311/FR311.pdf.
16 Straus MA, Hamby SL, Boney-McCoy S, Sugarman DB. The revised conflict tactics scales (CTS2): development and preliminary psychometric data. *J Fam Issues*. 1996;17(3):283–316.
17 Zou GY, Donner A. Extension of the modified poisson regression model to prospective studies with correlated binary data. *Stat Methods Med Res*. 2013;22(6):661–670.
18 Tomar S, Dehingia N, Dey AK, Chandurkar D, Raj A, Silverman JG. Associations of intimate partner violence and reproductive coercion with contraceptive use in Uttar Pradesh, India: how associations differ across contraceptive methods. *PLoS One*. 2020;15(10):e0241008.
19 Kahan BC, Jairath V, Doré CJ, Morris TP. The risks and rewards of covariate adjustment in randomized trials: an assessment of 12 outcomes from 8 studies. *Trials*. 2014;15(1):139.
20 Groenwold RHH, Moons KGM, Vandenbroucke JP. Randomized trials with missing outcome data: how to analyze and what to report. *CMAJ*. 2014;186(15):1153–1157.
21 White IR, Royston P, Wood AM. Multiple imputation using chained equations: issues and guidance for practice. *Stat Med*. 2011;30(4):377–399.
22 Caniglia EC, Murray EJ. Difference-in-Difference in the time of cholera: a gentle introduction for epidemiologists. *Curr Epidemiol Rep*. 2020;7(4):203–211.
23 Roberts SC, Biggs MA, Chibber KS, Gould H, Rocca CH, Foster DG. Risk of violence from the man involved in the pregnancy after receiving or being denied an abortion. *BMC Med*. 2014;12(1):144.
24 Chang JC, Cluss PA, Ranieri L, et al. Health care interventions for intimate partner violence: what women want. *Womens Health Issues*. 2005;15(1):21–30.
25 Haggerty LA, Goodman LA. Stages of change-based nursing interventions for victims of interpersonal violence. *J Obstet Gynecol Neonatal Nurs*. 2003;32(1):68–75.
26 Reisenhofer S, Taft A. Women's journey to safety – the Transtheoretical model in clinical practice when working with women experiencing Intimate Partner Violence: a scientific review and clinical guidance. *Patient Educ Couns*. 2013;93(3):536–548.
27 Greenland S, Mansournia MA. Limitations of individual causal models, causal graphs, and ignorability assumptions, as illustrated by random confounding and design unfaithfulness. *Eur J Epidemiol*. 2015;30(10):1101–1110.