EARLY: An RCT of 3 Preconception Motivational Interventions to Reduce Alcohol-Exposed Pregnancy Risk

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Why Target Drinking __and__ Contraception?

- 50% of U.S. pregnancies are unintended
- Among women of childbearing age, 52% drink and 13% binge drink
- There is no known safe level of alcohol use during pregnancy

Why Target Drinking <u>and</u> Contraception?

- Harm can occur before pregnancy is recognized (typically 7 weeks)

- Even low doses (8+ standard drinks per week and/or binge drinking), are related to increased risk of:
    - Neurobehavioral deficits
    - Cognitive dysfunction
    - Learning and attention problems
    - ARND/ARBD

- AEP is a leading cause of preventable birth defects including FASDs

CHOICES Efficacy Study

- An RCT with 830 women from 6 settings in 3 states
- Compared a 4-session MI counseling intervention, plus a birth control visit delivered in self-identified, health care, addiction treatment, and correctional settings to Information only control condition
- PRIMARY OUTCOME: The intervention group was twice as likely to *not* be at risk for an AEP after 3, 6, and 9 months, compared with the control group
- More women in the intervention group changed both alcohol and birth control behaviors

CHOICES Efficacy Study Results

Not at risk (9 months)	Group Assignment	
	Intervention	Control
Reduced AEP risk	69%	54%
Reduced drinking risk	49%	40%
Effective contraception	56%	39%

*All group differences were statistically significant

Floyd et al., 2007, *Am J Prev Med, 32, 1-10*.

BALANCE: College RCT

- Modified CHOICES Intervention to fit college population
  - Single long motivational session containing all CHOICES elements
  - Feedback on risk behavior <u>and</u> personality
- BALANCE intervention compared to information only
- Mailed or emailed follow-ups (1- and 4-months)

BALANCE 4M Follow-up
N=208 (90%)

Variable		Controls N=107		Intervention N=101		Chi-Square Test
		N	%	N	%	
Risky Drinking No		24	22.4%	34	33.7%	X^2_{1df} =3.26, p<.08
Yes		83	77.6%	67	66.3%	
Contraception Effective		50	55.1%	68	68.7%	X^2_{1df} =3.99, p<.05
Ineffective		48	44.9%	31	31.3%	
AEP Risk No		69	64.5%	79	79.8%	X^2_{1df} =5.96, p<.02
Yes		38	35.5%	20	20.2%	

Logistic regression analysis showed that the **only independent predictor of remaining at risk for AEP at 4M follow-up was assignment to the control group (OR 2.2, 95% CI 1.2-4.1)**. Ceperich & Ingersoll, 2011, *J Beh Med, 34*, 381-395.

EARLY Study Design

Aim: to test single session interventions designed for community women at AEP risk

EARLY (MI + FB)

Video Information

Brochure Information

258 women randomly assigned (86 per group)

ℭℨFollow-ups at 3 and 6 months

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ELSEVIER

Preconceptional motivational interviewing interventions to reduce alcohol-exposed pregnancy risk

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Baseline Characteristics

Characteristics	Total (n=217)	EARLY (n=73)	Informational Video (n=70)	Informational Brochure (n=74)	Test
Age	**27.9** (7.4)	29.0 (7.3)	26.1 (6.8)	28.4 (7.9)	$F_{(2df)}=3.13$*
Race					$X^2_{(8df)}=4.3$
Black	104 (48.6%)	34 (46.6%)	35 (50.7%)	35 (48.6%)	
White	82 (38.3%)	29 (39.7%)	26 (37.7%)	27 (37.5%)	
Other	22 (10.3%)	9 (12.3%)	7 (10.1%)	6 (8.3%)	
Asian	6 (2.8%)	1 (1.4%)	1 (1.5%)	4 (5.6%)	
Rate of Ineffective Contraception	**71.6%** SD=29.7%	**74.6%** SD=29.2%	**72.2%** SD=27.6%	**68%** SD=32.3%	$F_{(2df)}=.87$
0% contraception	76 (35.7%)	27 (37.5%)	25 (36.2%)	24 (33.3%)	$X^2_{(188df)}=192.9$
Drinks per Drinking Day	**4.6** (4.0)	4.6 (3.9)	4.5 (3.2)	4.6 (4.7)	$F_{(2df)}=0$
# Risky Drinking Days in 90 Days	**19.1** (21.4)	18.7 (20)	21.5 (23.5)	17.1 (20.6)	$F_{(2df)}=.76$

Brochure Condition

- Eligibility Screening
- Informed Consent
- Enrollment
- Baseline Assessment
- Randomization
- Information Provision and Resource List
- Schedule 3 and 6 M follow-ups

Video Condition

- Eligibility Screening
- Informed Consent and Enrollment
- Baseline Assessment
- Randomization
- Video and debriefing
- Schedule 3 and 6 M follow-ups

EARLY MI + FB Condition

- Eligibility Screening
- Informed Consent and Enrollment
- Baseline Assessment
- Randomization
- Single session, using MI spirit and techniques
- Feedback on:
  - drinks/week, drinks/day, binging, BAC
  - $ of drinking
  - Pregnancy risk
  - Efficacy of contraception methods
- 10 minute video
- 1 activity to explore ambivalence, readiness, situations, or change planning.
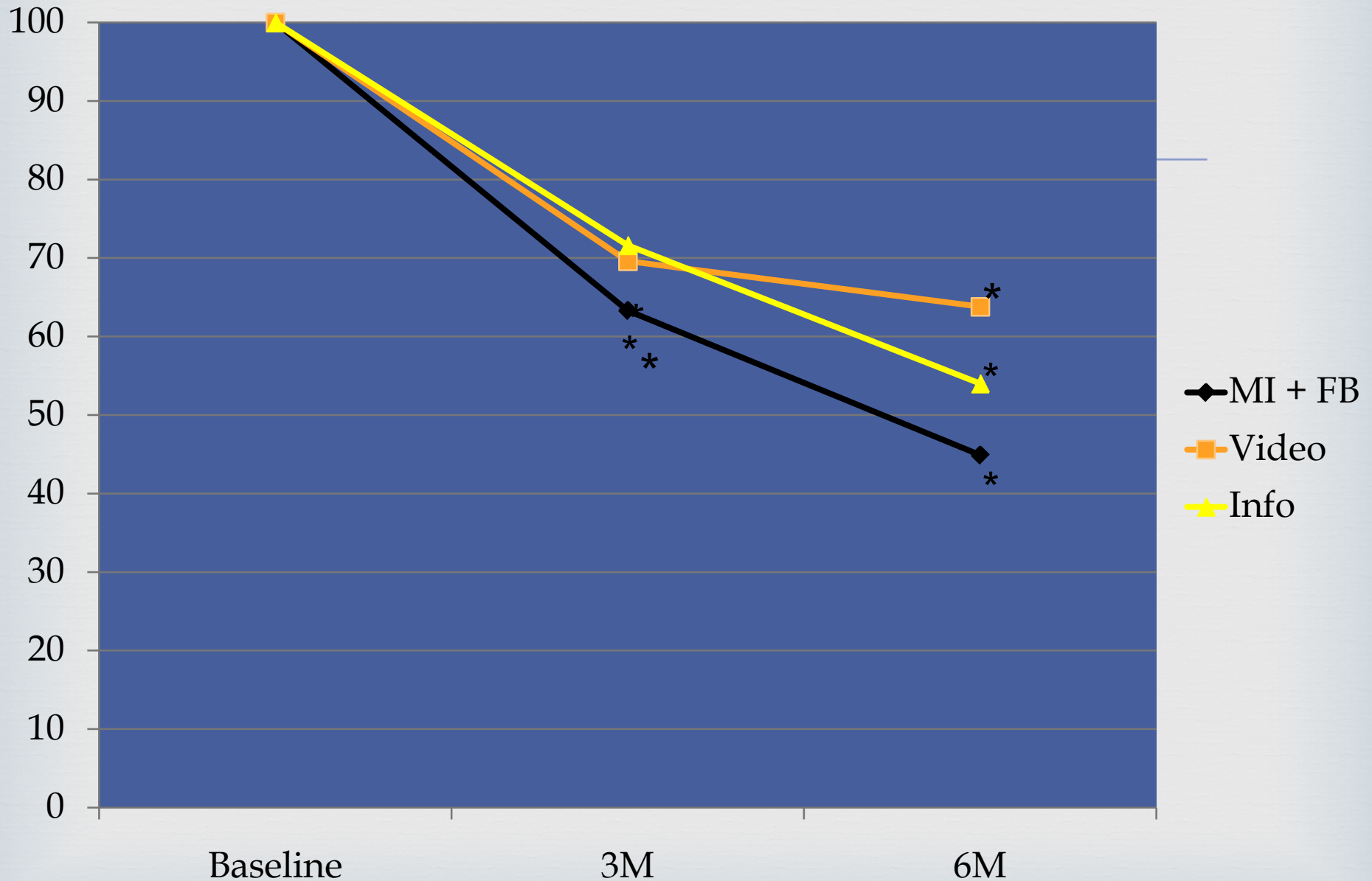- When needed, encourage a gyn visit
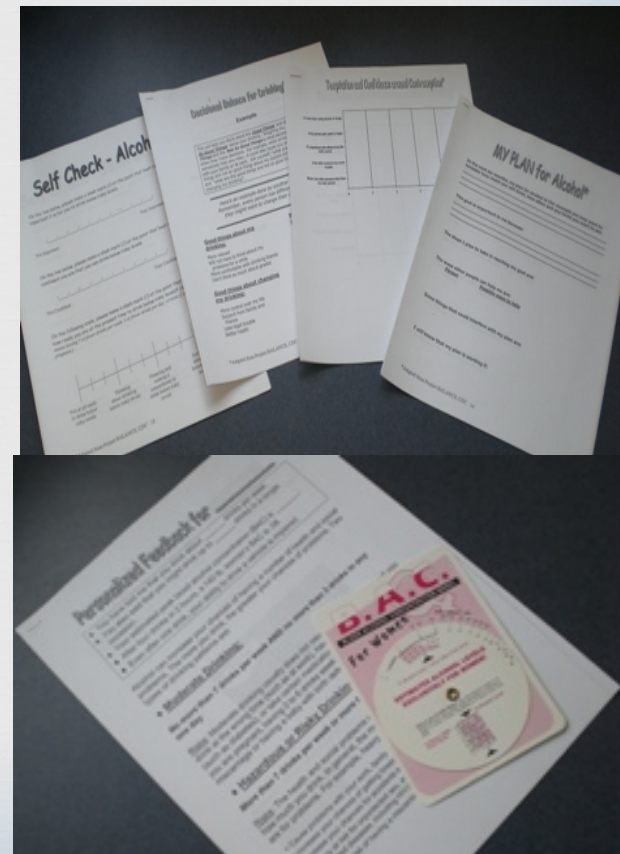
Outcomes: Drinks per Drinking Day
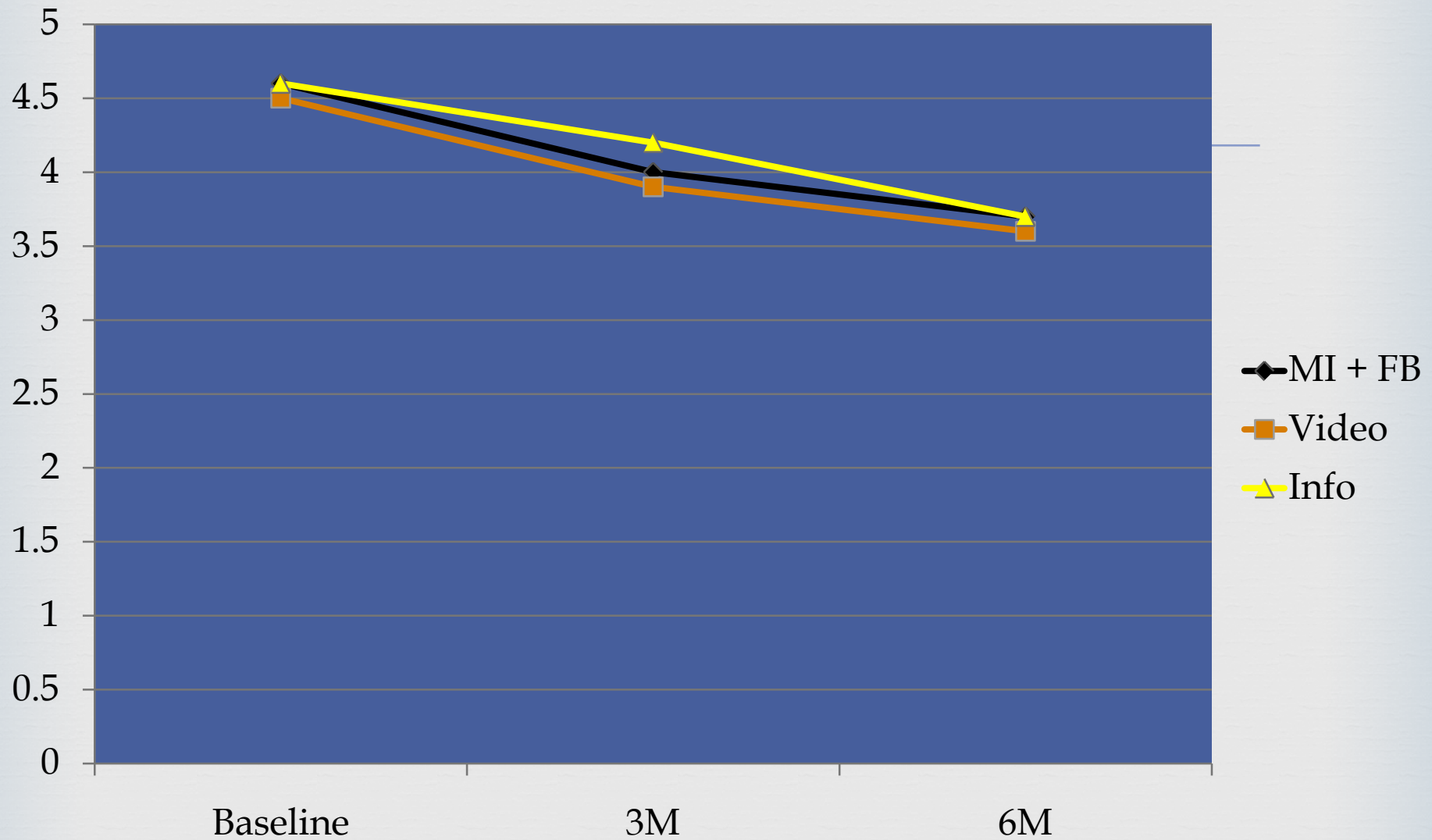
Outcomes:
Ineffective Contraception Rate
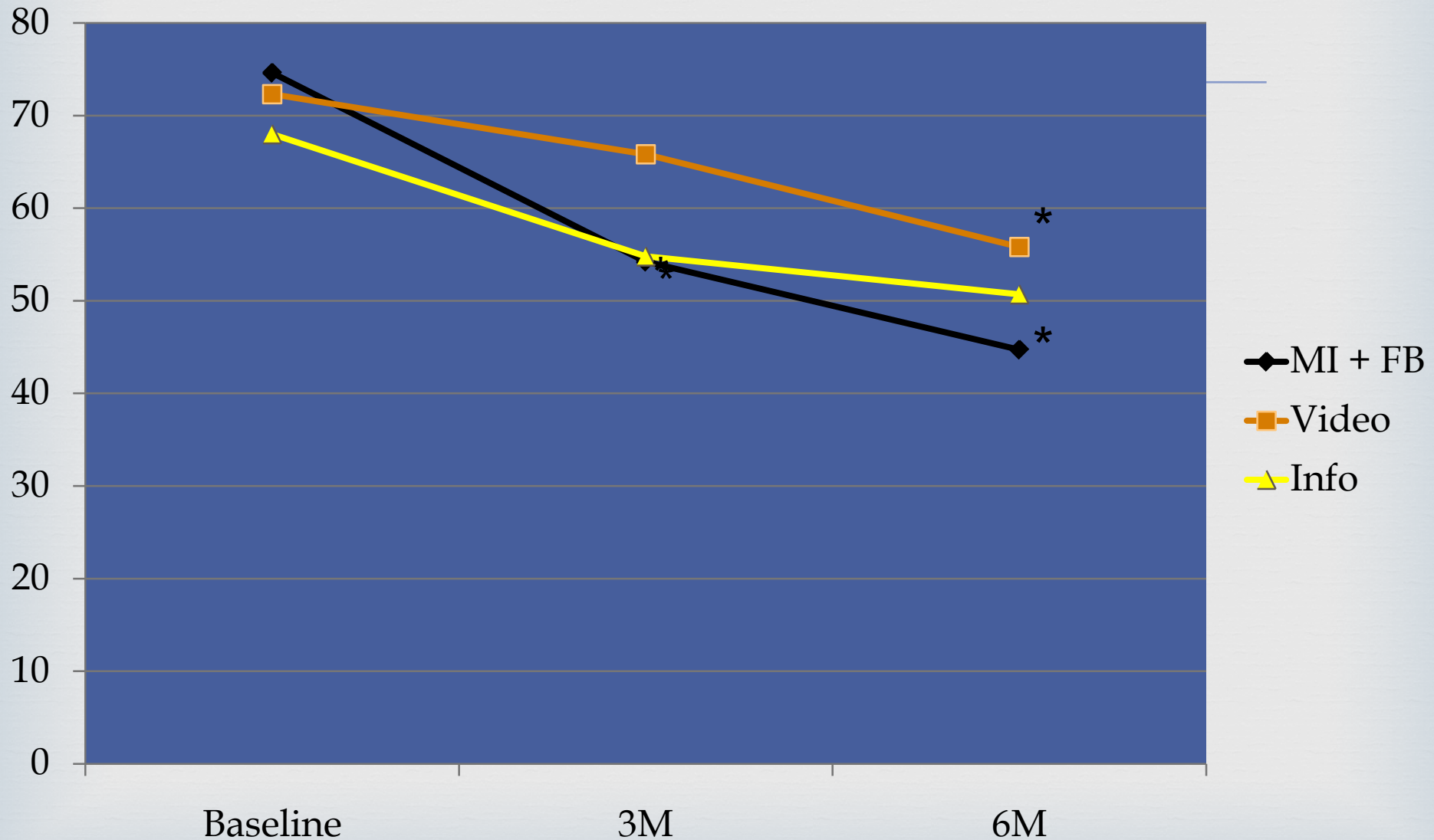
Outcomes: AEP Risk

Meta-analysis: EARLY, CHOICES, BALANCE

Comparison with other randomized controlled trials at 3* or 4** month follow-up.

	CHOICES			BALANCE			EARLY			
	CHOICES % at risk	Brochure % at risk	Effect size d (95%CI)	BALANCE % at risk	Brochure % at risk	Effect size d (95%CI)	EARLY % at risk	Video % at risk	Brochure % at risk	Effect size d (95% CI)
Ineffective contraception+	54.2%	71.6%	CHOICES vs. Brochure:	38.2%	45.2%	BALANCE vs Brochure	81.0% ($N=58$)	89.3%	86.4%	EARLY vs. video:
	($n=332$)	($n=333$)	$d=.43$	($n=76$)	($n=84$)	$d=.16$	$RR=19.0\%$	($n=56$)	($n=66$)	$d=.37$ ($-.22, .96$)
	$RR=45.8\%$	$RR=28.4\%$	(.26, .61) ARR=17.4%	$RR=61.8\%$	$RR=54.8\%$	($-.19, .51$) ARR=7.0%		$RR=10.7\%$	$RR=13.6\%$	ARR=8.3% EARLY vs. brochure: $d=.22$ ($-.31, .75$) ARR=5.4%
Risky drinking+	57.8%	69.7%	CHOICES vs. Brochure:	83.4%	87.0%	BALANCE vs. Brochure	80%	69.6%	73.1%	EARLY vs. video:
	($n=332$)	($n=333$)	$d=.29$ (.11, .47)	($n=97$)	($n=100$)	$d=.17$ ($-.26, .61$)	($n=60$)	($n=56$)	($n=67$)	$d=-.31$ ($-.78, .16$)
	$RR=42.2\%$	$RR=30.3\%$	ARR=11.9%	$RR=16.6\%$	$RR=13.0\%$	ARR=3.6%	$RR=11.8\%$	$RR=17.5\%$	$RR=17.4\%$	ARR=-10.4% EARLY vs. brochure: $d=-.02$ ($-.42, .38$) ARR=-6.9%
Risk for AEP+	36.4%	54.4%	$d=.41$	31.3%	37.5%	BALANCE vs Brochure	62.1%	60.7%	61.2%	EARLY vs. video:
	($n=332$)	($n=333$)	(.23, .58)	($n=80$)	($n=88$)	$d=.15$ ($-.18, .52$)	($n=58$)	($n=56$)	($n=67$)	$d=-.03$ ($-.45, .38$)
	$RR=63.6\%$	$RR=45.6\%$	ARR=18.0%	$RR=68.7\%$	$RR=62.5\%$	ARR=6.2%	$RR=29.7\%$	$RR=26.4\%$	$RR=29.3\%$	ARR=-1.4% EARLY vs. brochure: $d=-.02$ ($-.42, .38$) ARR=$-.9\%$

Notes: *CHOICES and EARLY **BALANCE + As explained in the text, not all participants in the EARLY study were defined as risky drinking at baseline when older definitions of risk were used to transform variables for comparison. Risky drinking and AEP risk rates were 91.8% for EARLY, 87.1% for informational video, and 90.5% for informational brochure in the present study. All other risk variables were 100% at baseline.

Summary of Findings

- Single session MI + FB, Video, and Info interventions all decreased DDD, Ineffective Contraception Rate, and AEP Risk

- No group differences on DDD

- MI + FB "EARLY" intervention had larger effects than Video or Info on contraception and AEP risk

- Effects of MI + FB in current study on contraception are smaller than those in CHOICES or BALANCE

- Overall rate of women still at risk for AEP in EARLY MI condition was 62.1%, compared to 36.4% in CHOICES and 31.3% in BALANCE

Conclusions: How Low Can You Go?

- The briefer MI+FB "EARLY" intervention had effects, but reduced AEP risk for a smaller proportion of women than CHOICES

- When greater resources exist, we recommend using CHOICES intervention

- Brief interventions targeting AEP risk are more practical and may be an appropriate option in a hypothetical continuum of AEP preventive care when resources are more limited