



## Couple-focused support for improving HIV medication adherence

### CITATION

Remien RH, Stirratt MJ, Dolezal C et al. Couple-focused support to improve HIV medication adherence: a randomized controlled trial. *AIDS* 2005;19:807-814

### RESEARCH QUESTION

Does couple-focused support improve HIV medication adherence among patients with poor adherence?

### THE STUDY DESIGN

Randomized controlled trial

### STUDY SETTING

Two HIV/AIDS outpatient treatments clinics of St Luke's Roosevelt Hospital Center in New York City August 2000 – January 2004

Approved by the Institutional Review Boards of the New York State Psychiatric Institute and St Luke's-Roosevelt Hospital Center.

Written informed consent was obtained.

### PARTICIPANTS

Included: HIV-serodiscordant couple with a relationship duration of 6 months or more; partners were English-speaking adults (> 18 years of age); HIV-seropositive partner needed to be in primary care, taking ART for at least 1 month and had a baseline adherence level of < 80% of prescribed doses taken within specified time windows

Excluded: No mention of it was made

### INTERVENTIONS

Intervention Group: A four-session couple-focused adherence program. The intervention was individually administered to each couple by a nurse practitioner through four 45-60 min sessions held over 5 weeks. Intervention consisted of education about treatment and adherence, identifying adherence barriers, developing communication and problem-solving strategies, optimising partner support, and building confidence for optimal adherence

Control: Usual care through the medical provider of the HIV-seropositive partner  
Patients were followed up to 6 months after the intervention. Assessments took place 8 weeks after baseline, week 20 (3 months) and week 32 (6 months).

### OUTCOME

Primary: Medication adherence

Secondary: Viral load, CD4 cell counts

**RISK OF BIAS** (Risk Scale: Low – Moderate – High)

### SELECTION BIAS: Low - Moderate

Couples were randomly assigned. A randomisation table was constructed from a random numbers list and stratified by couple type. Allocation concealment not reported. There were no significant differences between the two study arms on socio-demographic variables (Raw data not provided). The only exception was that HIV-seropositive participants in the control arm reported a significantly higher annual income than those in the intervention arm.

**PERFORMANCE BIAS: Moderate**

(I.e what else happened that may have affected the result?)

Participants were unblind. Assessors and all other personnel (except for intervention facilitators) were blind to study arm assignment throughout the trial. Participants in the intervention group received additional payment for each intervention session.

**DETECTION BIAS: Low - Moderate**

Participants were unblind. Assessors and all other personnel (except for intervention facilitators) were blind to study arm assignment throughout the trial. Adherence was measured using the MEMS cap. Viral load and CD4 cell counts were measured. ACASI and CAPI were also used. Interviewers were trained and certified by the study team.

**ATTRITION BIAS: Low**

	Intervention	Control
Started	106	109
Completed trial	88	94
Loss to follow-up	18 (17.0%)	15 (13.8%)

All analyses were conducted according to the intention to treat.

**STUDY FINDINGS**

Out of 1014 pre-screened 215 randomised.

Medication Adherence

Time line	Treatment	Total Doses		Doses taken within specified time windows	
		Mean adherence [% prescribed doses taken (SD)]	Weighted mean difference (95% CI)	Mean adherence [% prescribed doses taken (SD)]	Weighted mean difference (95% CI)
Baseline	I	75 (25)	3 (-3.8; 9.8)	43 (21)	-2 (-7.8; 3.8)
	C	72 (26)		45 (22)	
8 week	I	76 (27)	16 (7.8; 24.2)	58 (29)	23 (15.75; 30.25)
	C	60 (34)		35 (25)	
3 month	I	73 (28)	7 (-1.0; 15.0)	52 (29)	13 (5.5; 20.5)
	C	66 (32)		39 (27)	
6 month	I	66 (28)	0 (-7.8; 7.8)	44 (25)	5 (-2.2; 12.2)
	C	66 (30)		39 (29)	

Viral load

As reported, Although viral load in the control group increased by an average of 12000 copies/ml and stayed relatively stable in the intervention group, the difference was not significant.

CD4 count

Reportedly, CD4 cell counts fell slightly for both groups.

**ADVERSE EVENTS**

No serious adverse events were identified.

**COMMENTS**

The SMART Couples program did improve medication adherence over usual care. However, the level of improved adherence for many participants was still sub optimal and the effect was attenuated over time.

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