

Impact of a DAART intervention on ART adherence in Mombasa: Results from an 18 month randomized controlled study

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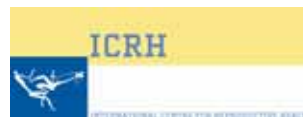
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Horizons

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Horizons is a global operations research program implemented by the Population Council in collaboration with the International Center for Research on Women, International HIV/AIDS Alliance, PATH, Tulane University, Family Health International, and Johns Hopkins University.

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Research Question

- Would a Directly-Administered ART (DAART or modified DOT) strategy result in improved adherence during the intervention period?
- Would DAART result in sustained high adherence in the post-intervention period?

Study Design

- Randomized controlled two-arm study
DAART vs. standard of care
 - Intervention for 24 weeks followed by routine follow up for 48 weeks
 - Intervention evaluated at:
 - 0-24weeks
 - 25-48 weeks
 - 72 weeks
- ART initiation and routine medical monitoring done monthly at treatment sites for all patients

DAART and Non-DAART Groups

- **Intervention: DAART**

- Twice weekly visit at clinic for first 24 weeks
 - ▶ One dose of medication observed, counseling and support
 - ▶ Used medication bottles collected
 - ▶ Medications dispensed for following 3 or 4 days
- Thereafter routine monthly follow-up for 48 weeks
- 6 Observation sites of choice

- **Control: Non-DAART**

- Routine monthly follow-up for 72 weeks
- Medications dispensed monthly

Measures of Adherence

- **Methods**

- Pill counts (clinic-based) every 4 weeks

- **Adherence**

Pills taken / Pills should have taken x100

- **Primary outcome indicator**

- % clients achieving $\geq 95\%$ adherence at 0-24, 25-48 and 72 weeks

Biomedical Measures

- Plasma viral load: 48, 72 weeks
- CD4 cell counts: 0, 24, 48, 72 weeks
- Body weight /BMI: every 4 weeks up to 48 weeks, 72 wks
- Depression (BDI ®): 0, 24, 48, 72 weeks
- Biomedical outcome indicator
 - % clients in each arm with undetectable virus (≤ 400 copies) at 48 and 72 weeks

Recruitment and Retention

Screened	249	
Refused	15	
Randomized	234	
Allocated to intervention	DAART 116	Non-DAART 118
Did not receive intervention	4 (1 refused DAART, 1 refused ART, 1 incapacitated, 1 death)	2 (2 deaths)
Received intervention	112	116
<u>24 weeks</u>		
Reached end point	97	101
Deaths	10	6
Lost to follow up	4	4
Discontinued intervention	1	5*
<u>72 weeks</u>		
Reached end point	89	94
Deaths	4	4
Lost to follow up	3	0
Discontinued intervention	1	4

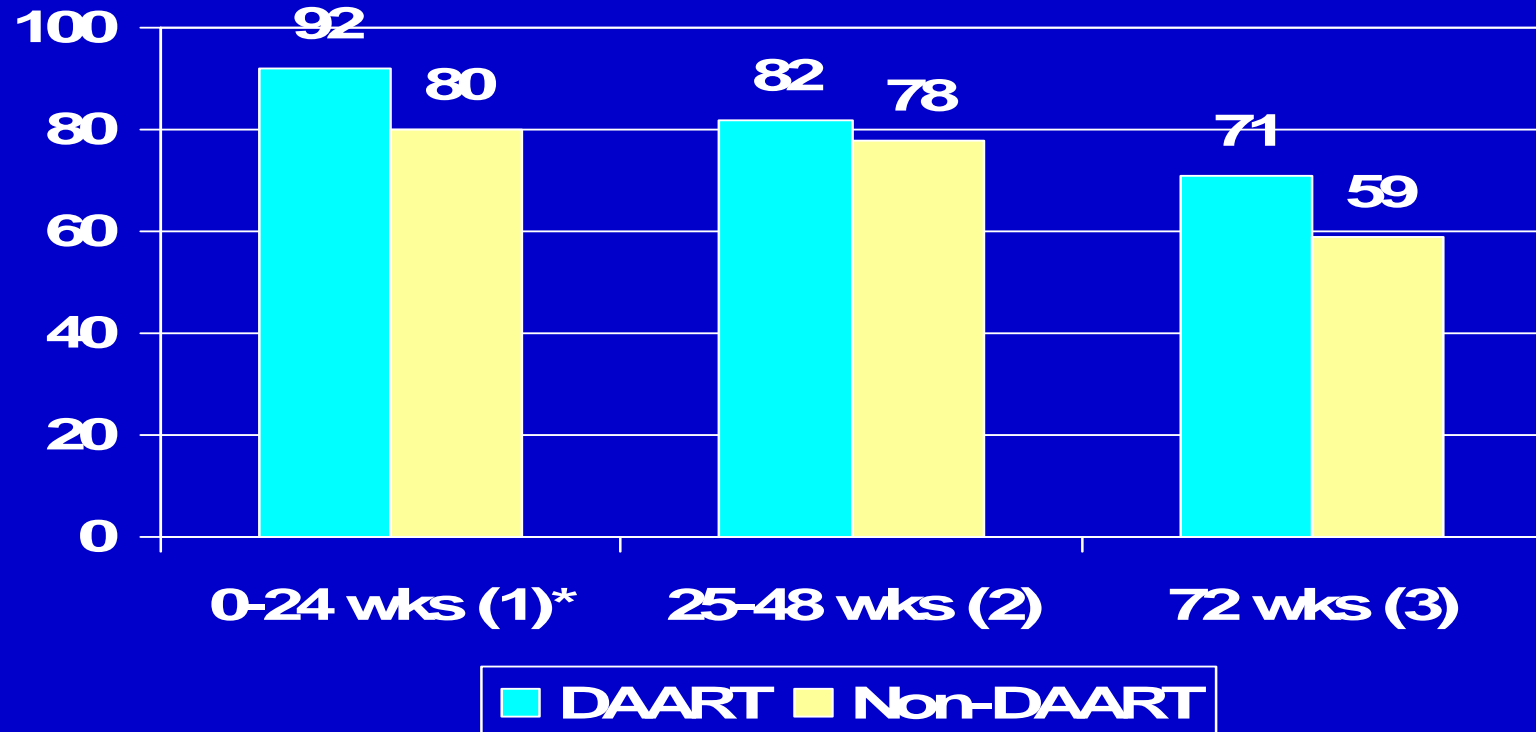
Baseline Characteristics (1)

		DAART % (n=116)	Non-DAART % (n=118)
Sex	Female	64	64
	Male	36	36
Age	Median years	(38)	(36)
Education	Never attended	5	6
	Primary	51	48
	Secondary	40	35
	Tertiary	20	23
Marital status	Never married	13	15
	Married/cohabiting	47	50
	Divorced/separated	13	16
	Widowed	27	19

Baseline Characteristics (2)

		DAART % (n=116)	Non-DAART % (n=118)
Living arrangement	Lives alone	10	15
Alcohol use	Within last month	3	6
Drug use	Ever used	16	16
Perceived stigma score	Minimal or low	34	28
	Moderate	58	57
	High	8	18
Depression	Minimal or none	32	35
	Mild	33	36
	Moderate/severe	35	29
Body Mass Index	Median kg/m ²	(20.6)	(20.8)
Hospitalizations	Last 12 months	17	18
CD4 Count	Median cells/mm ³	(106)	(96)

Proportion with Adherence $\geq 95\%$

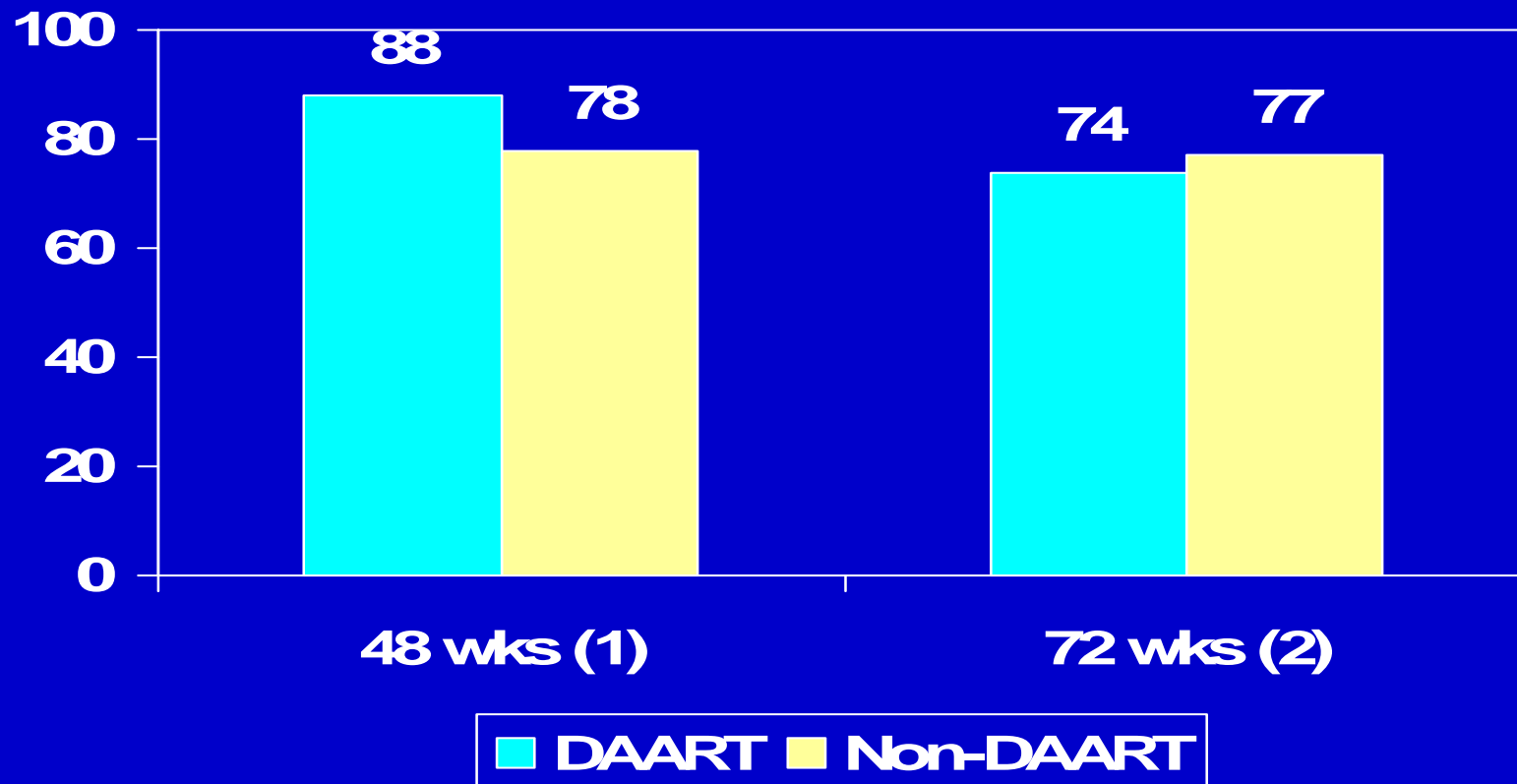


(1) $P=0.012$

(2) $P=0.47$

(3) $P=0.12$

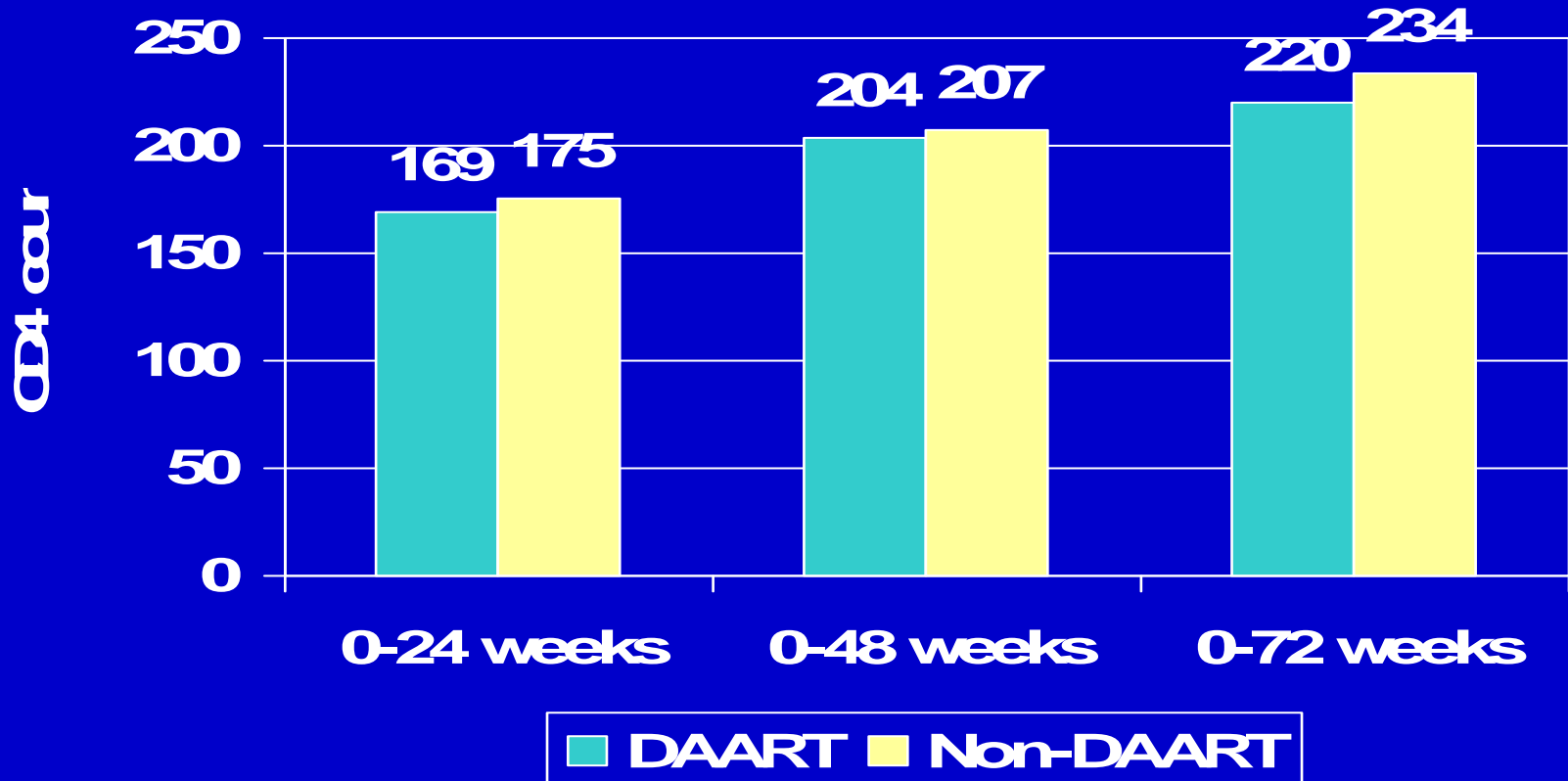
Proportion with Plasma Viral Load ≤ 400 copies/ml



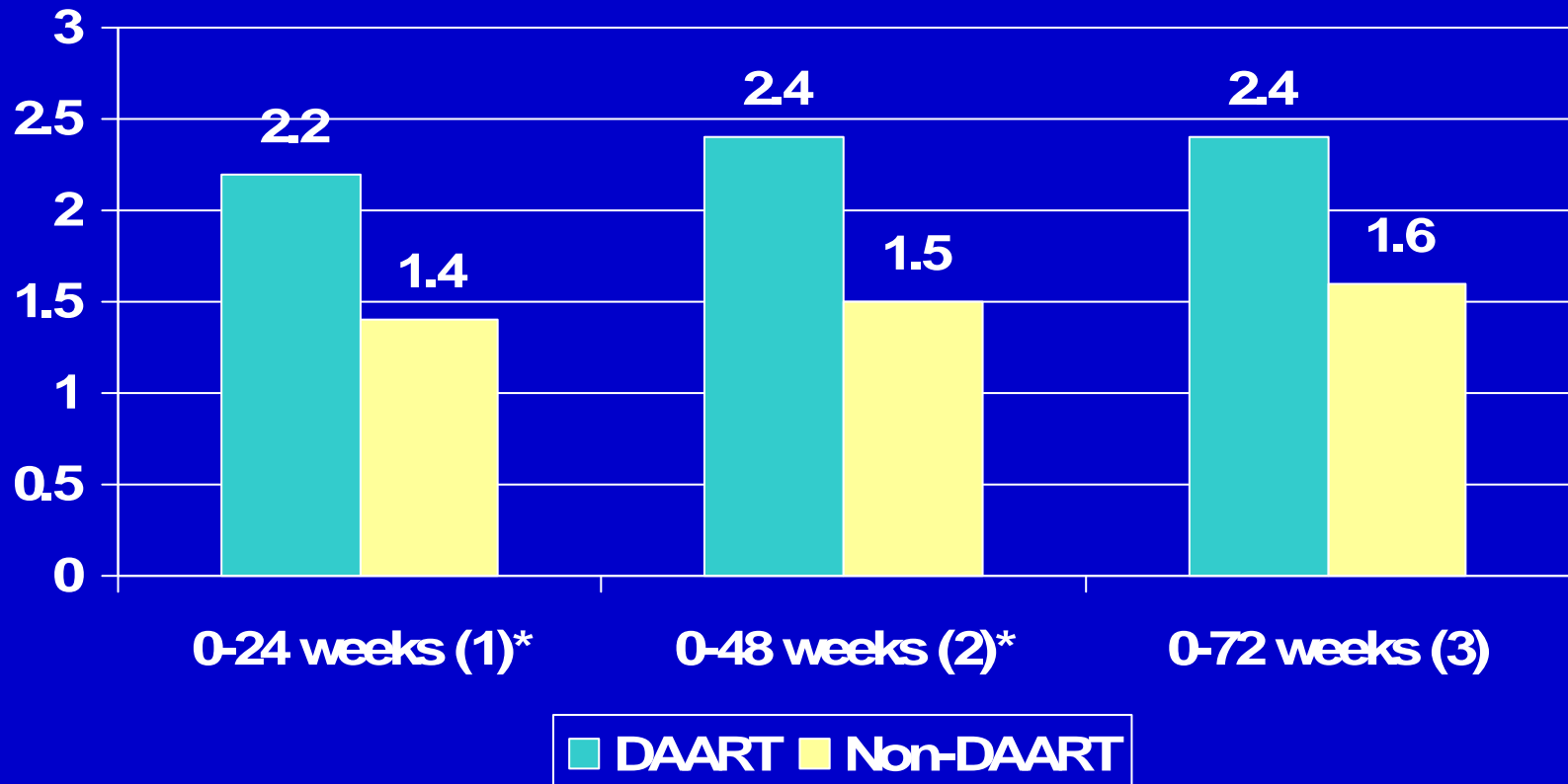
(1) $n=133$; $P=0.13$

(2) $n=180$; $P=0.55$

Median Change in CD4 cell counts



Median Increase in Body Mass Index

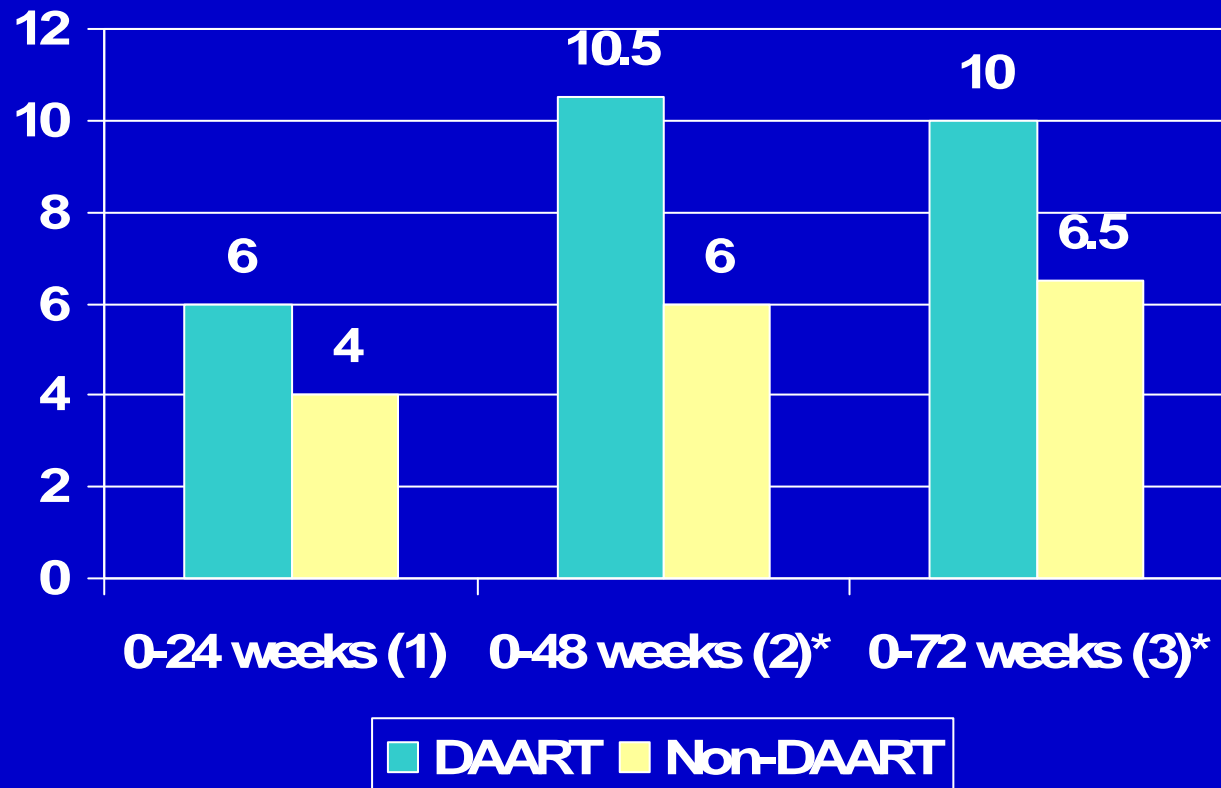


(1) $P=0.014$

(2) $P=0.047$

(3) $P=0.13$

Median Decrease in Depression Scores



(1) $P=0.13$

(2) $P=0.04$

(3) $P=0.024$

Intervention Effects in Subgroups

	0-24 weeks OR (95% CI)	
Depression		
No or minimal	1.3 (0.29-6.1)	0.7
Mild	1.7 (0.45-6.5)	0.43
Moderate to high	16.6 (1.6-174.7)	0.002

Conclusions (1)

- DAART was effective 0-24 weeks.
 - Significantly higher proportion of DAART patients achieved >95% adherence
- Effects of intervention not sustained in post-intervention period (25-48, 72 wks)
 - A higher proportion of patients achieved higher adherence, but not statistically significant
- Effectiveness of intervention supported by
 - Higher proportion of patients with undetectable viral load at 48 weeks
 - Greater increase in BMI (0-24 and 25-48 weeks)
 - Greater improvement in depression scores (25-72 weeks)
- Adherence decreased over time in the study population

Conclusions (2)

- DAART is particularly beneficial in patients with moderate to severe depression
- More research is needed:
 - To determine the optimum duration of DAART for the effects to be sustained in the post intervention period
 - To explore strategies to sustain long term adherence

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