

A systematic review on the inclusion (or exclusion) of women in HIV research: from clinical studies of antiretrovirals and vaccines to cure strategies

Mirjam J Curno^{1,2*}, Samuela Rossi^{1,3}, Ioannis Hodges-Mameletzis^{1,4}, Rowena Johnston⁵, Matt A. Price^{6,7}, Shirin Heidari^{1,8}

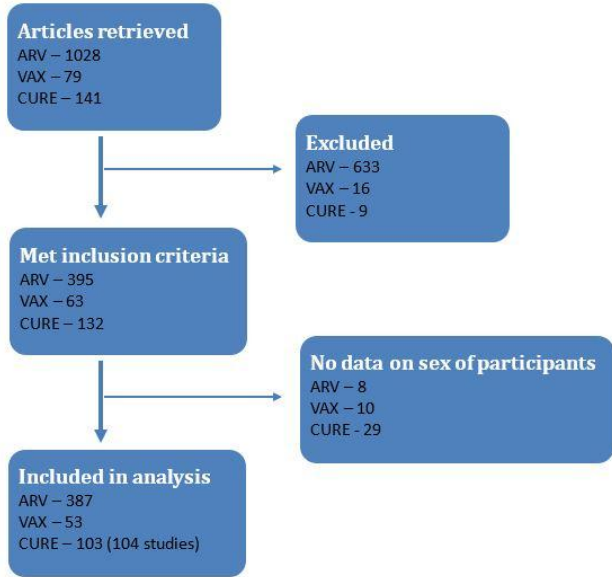
Table S1: Overview of the search characteristics across ARV, VACC and CURE clinical trials

HIV clinical trials	
National Library of Medicine Search Limits	
ARV	Clinical trial; Clinical trial, Phase I, Clinical Trial, Phase II, Clinical Trial, Phase III, Clinical Trial, Phase IV; Human; English; Male; Female; All Adult: 19+ years
VACC	Clinical Trials, Phase I, Phase II, Phase III, Phase IV, Controlled Clinical Trials, Randomized Controlled Trials
CURE	Human; English; Male; Female; All Adult: 19+ years; HIV
Terms and medical subject headings (MeSH) used (accessed April 2012)	
ARV	Antiretroviral agents, OR agents, antiretroviral OR highly active antiretroviral therapy OR antiretroviral therapy, highly active OR anti aids agents OR agents, anti aids OR anti hiv agents OR agents, anti hiv OR anti hiv drugs OR drugs, anti hiv OR aids drugs OR drugs, aids OR anti aids drugs OR drugs, anti aids
VACC	AIDS Vaccines AND Clinical Trial OR Clinical Trial OR Phase I Clinical Trial OR Phase II Clinical Trial OR Phase III Clinical Trial OR Phase IV Controlled Clinical Trial OR Multicenter Study OR Observational Study OR Randomized Controlled Trial OR Pragmatic Clinical Trial
CURE	HIV (MeSH) AND HIV cure (all fields), OR functional cure (all fields),OR sterilizing cure (all fields), OR intensification (all fields), OR virus latency (MeSH), OR viral reservoirs (all fields), OR histone deacetylase inhibitors (MeSH), OR HDACI (Title/abstract), OR vorinostat (MeSH), OR prostratin (MeSH), OR bryostatin (MeSH), OR panobinostat (MeSH),OR suberoylanilide hydroxamic acid (MeSH), OR SAHA (Title/abstract), OR valproic acid (MeSH), structured treatment interruption (all fields); OR STI (Title/abstract), OR analytic treatment interruption (all fields), OR ATI (Title/abstract), OR withholding treatment (MeSH), OR immune therapy (all fields), immune modulation (all fields), OR interleukin-2 (MeSH), OR IL-2 (Title/abstract), OR interleukin-7 (MeSH), OR IL-7 (Title/abstract), OR interleukin-12 (MeSH), OR IL-12 (Title/abstract), OR therapeutic vaccine (all fields), OR dendritic cell vaccine (all fields), OR immunization/therapeutic use (MeSH), OR immunization/therapy (MeSH), OR nuclease (all fields), OR gene editing (all fields), OR zinc finger nuclease (all fields), OR genetic therapy (MeSH),OR gene therapy (all fields), OR early treatment (all fields)

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Figure S1: Flowchart of systematic PubMed searches showing numbers of articles



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Table S2: Reasons for exclusion of articles. Articles could be excluded for more than one reason.

	Total excluded	Not a clinical trial	All participants <18 years	Single-sex study	Out of scope*	Duplicate study	No data on sex [§]
ARV	641	380	36 (+ 6 with no data)	146	151	67	8
VAX	26	0	3	4	0	9	10
CURE	38	n/a	0	0	9	0	29

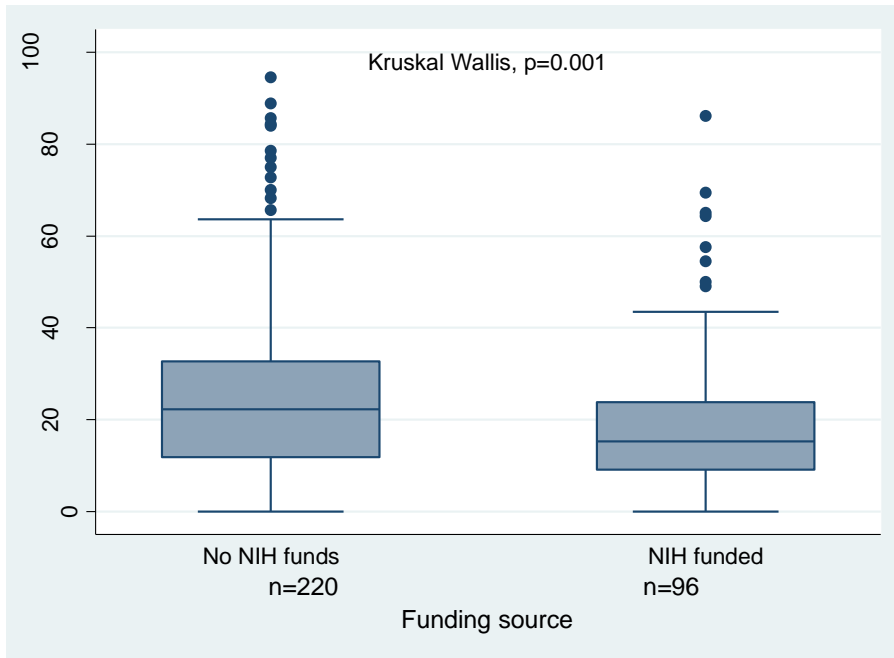
*ART: not an antiviral agent; VAX: not preventative vaccines; CURE: not an eradication strategy

[§]Included those where sex distribution was only available for the final, analysed sample.

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Figure S2: Percentage of female clinical study participants vs funding source divided into NIH-funded or not NIH-funded (horizontal bars are median values, box represents the IQR, whiskers the upper and lower adjacent values, and outliers shown as dots)



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Table S3: Multivariable analysis of square root transformed percent women enrolled in ARV studies (n=379)

Characteristic	Coefficient	SE	95% CI	P value
Year of study				
1995-1997	Ref.	--		
2001-2004	0.993	0.321	(0.361, 1.625)	0.002
2008-2012	1.275	0.325	(0.635, 1.914)	<0.001
Funding source				
Private (non-commercial)	Ref.	--		
Private (commercial) & mixed	-0.892	0.389	(-1.657, -0.127)	0.022
Public	-1.229	0.413	(-2.040, -0.418)	0.003
No data on funding source	-0.706	0.421	(-1.534, 0.121)	0.094
Country Income class				
Low, Middle, Low & Middle	Ref.	--		
High, High & other	-2.271	0.324	(-2.908, -1.633)	<0.001
Trial size				
>124 volunteers	Ref.	--		
<125 volunteers	-0.307	0.185	(-0.671, 0.057)	0.098

SE: Standard error, CI: Confidence interval