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**Online and less frequent monitoring
of oral HIV PrEP use
are non-inferior to standard of care**
Results from the EZI-PrEP randomized controlled trial

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Disclosure of speaker's interests

- **Marije Groot Bruinderink**

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 - Aidsfonds
 - Gilead Sciences
 - GGD Amsterdam Research Fund



Background



- **Monitoring of PrEP users:**
 - Every 3 months, in clinical setting
 - Monitoring includes:
 - HIV testing
 - Screening for bacterial sexually transmitted infections (STI)
 - Counselling on PrEP intake and other strategies to reduce risk of HIV infection
 - PrEP provision
- **Under debate because:**
 - Burdensome for some PrEP users (could lead to discontinuation)
 - Costly and labor intensive; unsustainable on the long term



Background



- **Viable options for sustainable PrEP care:**
 - Online PrEP care
 - Less frequent PrEP monitoring
- **However:**
 - Less intensive counselling may lower PrEP adherence
 - Evidence is lacking



Primary research objective

To establish the **non-inferiority in terms of PrEP adherence** of:

- Online-mediated PrEP monitoring versus in-clinic PrEP monitoring
- PrEP monitoring every 6 months versus every 3 months



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Methods



Methods – Study design

- **Randomized Controlled Non-Inferiority Trial**
- **4 study arms:**
 1. In-clinic PrEP monitoring, every 3 months
 2. In-clinic PrEP monitoring, every 6 months
 3. Online-mediated PrEP monitoring, every 3 months
 4. Online-mediated PrEP monitoring, every 6 months
- Implemented within Dutch National PrEP Pilot Program (NPP); 2019-2024
- **4 study sites:** Sexual Health Centers in Amsterdam, Rotterdam, The Hague and Nijmegen



Methods – Primary outcome measure



Unprotected act (UA):

condomless anal sex with a casual partner,
not covered by PrEP



Daily diary
EZI-PrEP app

■ Data used:

- Until month 18 PrEP consultation
- Until last day of contact (if dropout/LTFU)



Methods – Non-inferiority analysis

- Calculated the incidence rate ratio (IRR) of UA:
 - comparing online-mediated with in-clinic monitoring arms
 - comparing 6-monthly with 3-monthly monitoring arms
- Non-inferiority if upper limit of 97.5%CI of IRR <1.8.



Daily diary
EZI-PrEP app

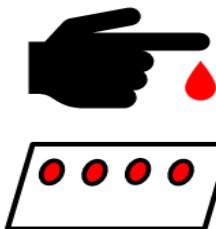


Methods – Secondary outcome measure



Intracellular Tenofovir diphosphate (TFV-DP) concentrations

- Indicates cumulative PrEP intake in preceding 6 weeks
- N=225 DBS from daily users, taken at month 6 and 12
- Analyses:
 - TFV-DP levels compared between modality and monitoring frequency
 - Tobit regression



Dried blood spots
(DBS)



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Results



Results – Participants

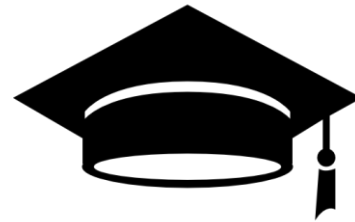
■ 469 participants; 99% MSM



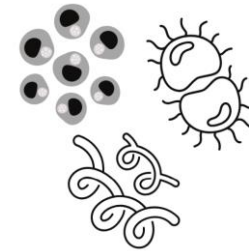
Median 36 yrs
(IQR 29-47)



68% born in
Netherlands



81% university or
university of
applied sciences
degree



19% had at least 1
bacterial STI at
baseline



Results – Allocation to modality and frequency



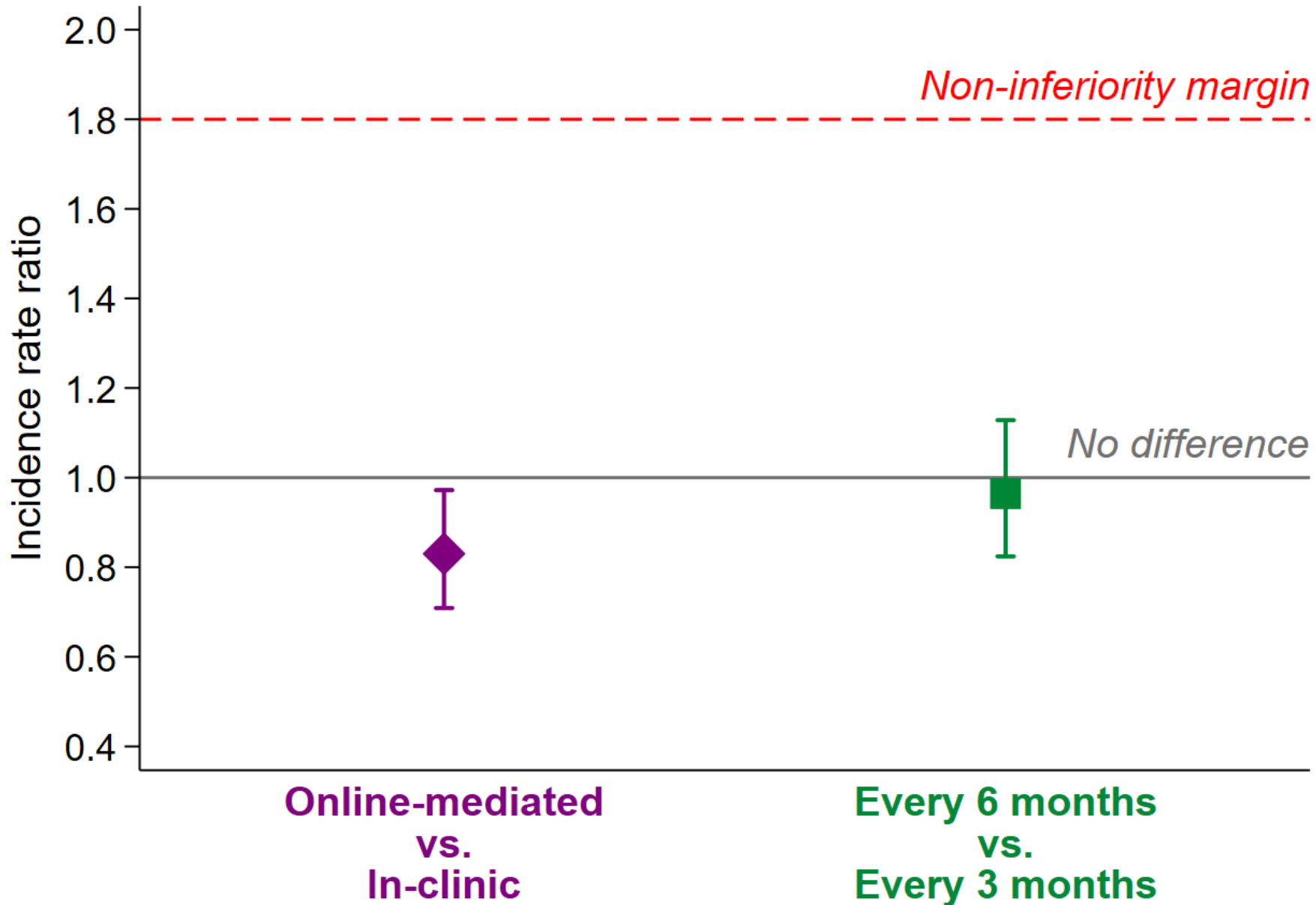
Study arm	Total	Monitoring modality		Monitoring frequency	
		Online-mediated	In-clinic	Every 6 months	Every 3 months
Arm 1	117	0	117	0	117
Arm 2	114	0	114	114	0
Arm 3	119	119	0	0	119
Arm 4	119	119	0	119	0
Total	469	238	231	233	236



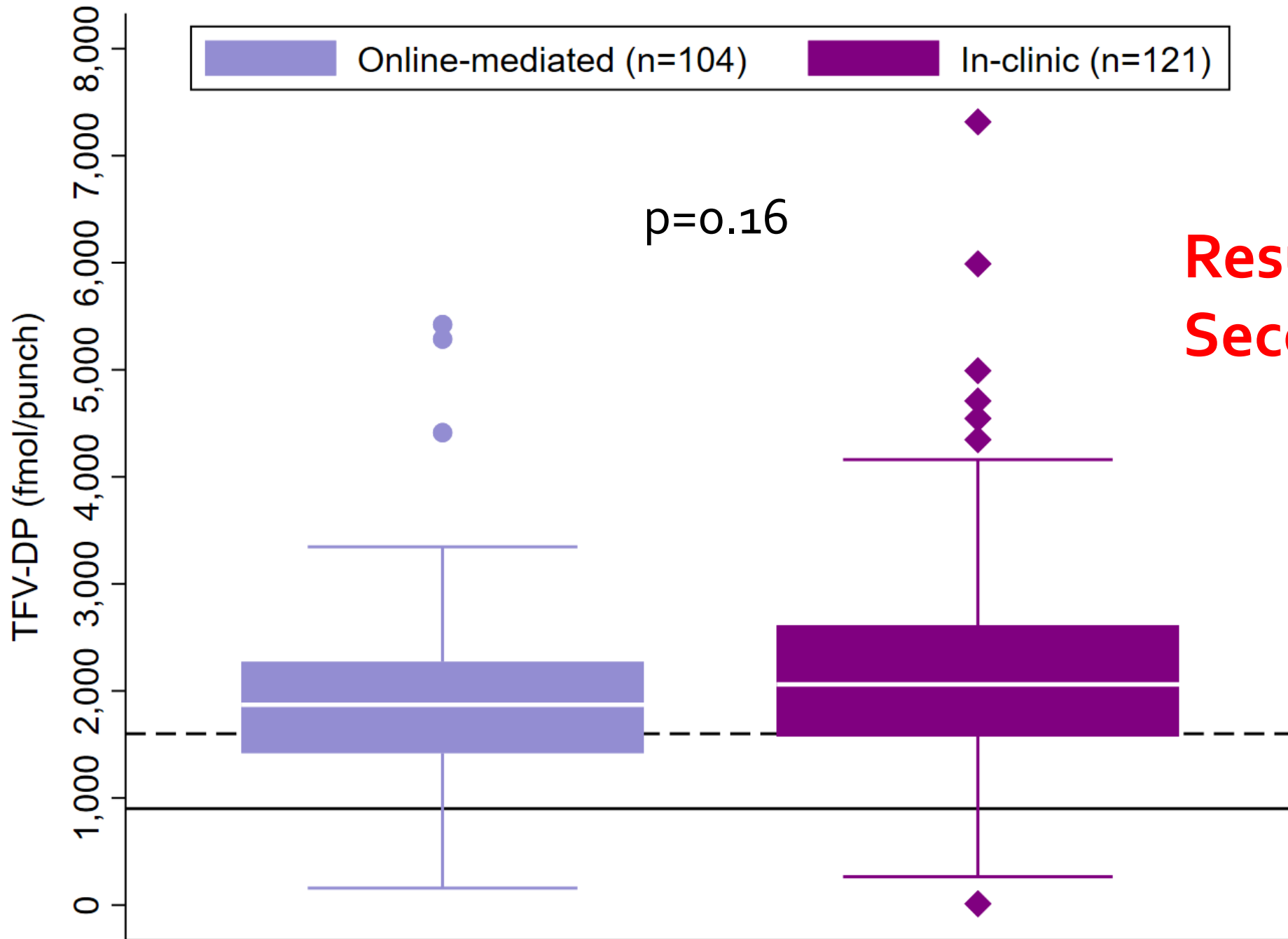
Results – Unprotected acts, all participants



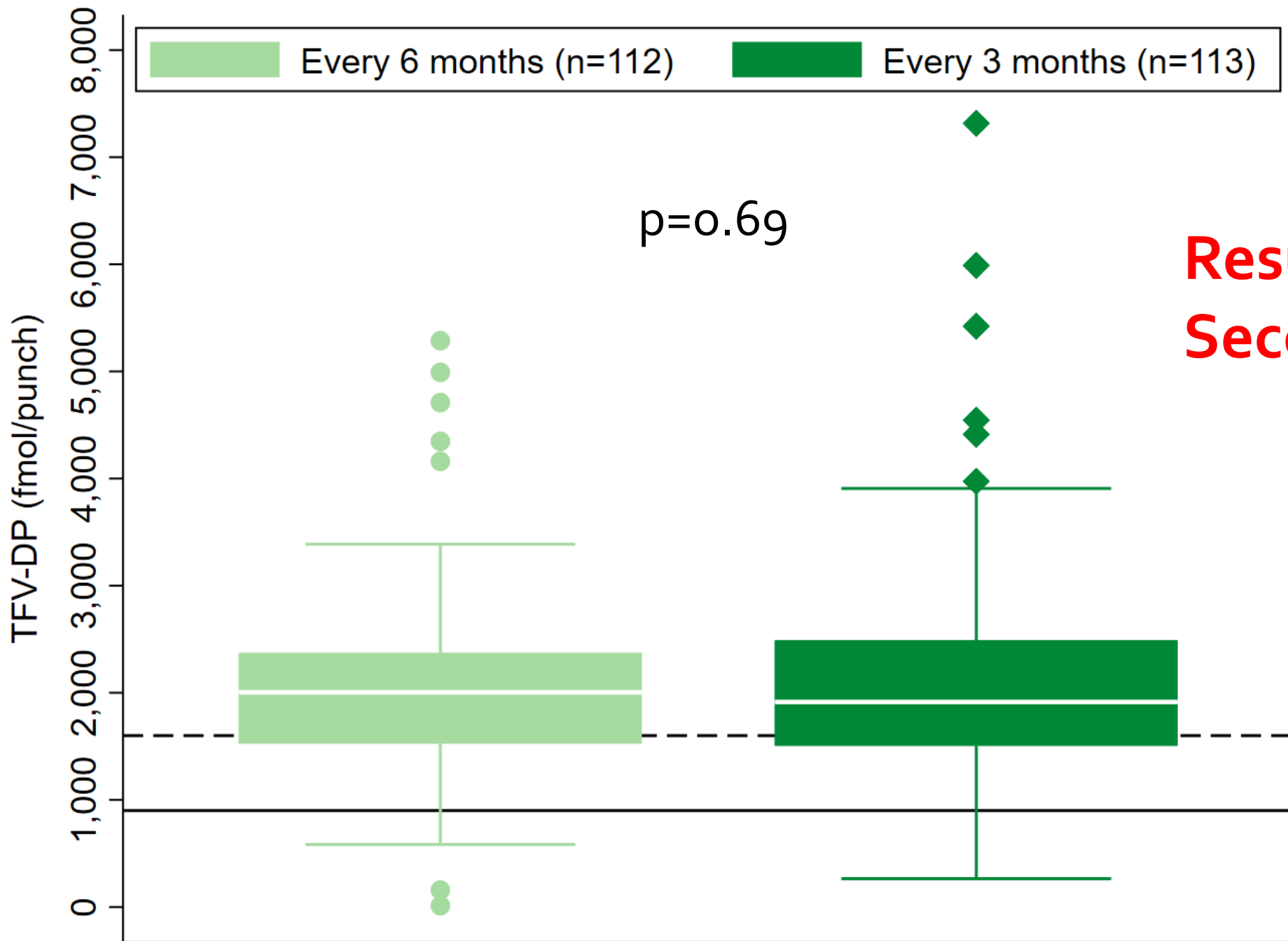
	Total
Number of participants	469
Number of unprotected acts	816
Follow-up time (years)	605
Incidence rate per py [95% CI]	1.3 [1.2 - 1.4]



**Results –
Non-inferiority
analysis**



Results – Secondary analysis



Results – Secondary analysis



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Conclusions



Conclusions



- **Based on unprotected acts analysis we conclude that:**
 - Online-mediated monitoring is non-inferior to in-clinic monitoring
 - 6-monthly monitoring is non-inferior to 3-monthly monitoring
- Secondary analysis of TFV-DP concentrations in daily users supports this conclusion

Online-mediated and 6-monthly monitoring do not negatively impact PrEP adherence in MSM and can be implemented



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Participants
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