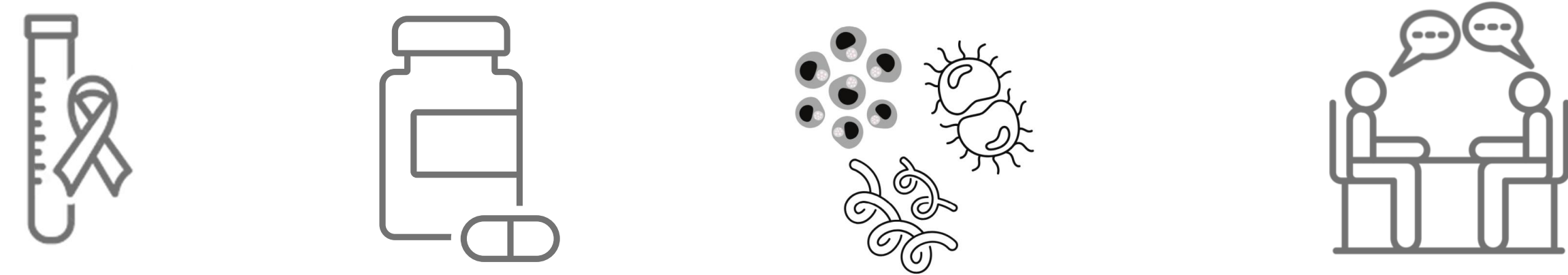


Marije Groot Bruinderink^{1,2}, Anders Boyd^{1,3}, Lotte Werner¹, Vita W. Jongen^{1,3,4}, Laura Blitz⁵, Colette van Bokhoven⁶, Joey Woudstra¹, Sophie Boers⁷, Hannelore M. Götz^{7,8}, Allard R. Feddes², Frenk van Harreveld², Maria Prins^{1,4,9,11}, Elske Hoornenborg^{1,4,9,11}, Udi Davidovich^{1,2*}, Maarten Schim van der Loeff^{1,4,9,11*} * These authors contributed equally

1. Department of Infectious Diseases, Public Health Service Amsterdam, Amsterdam; 2. University of Amsterdam, Department of Psychology, Amsterdam; 3. Stichting hiv monitoring, Amsterdam; 4. Amsterdam Institute for Immunology and Infectious Diseases (All), Amsterdam; 5. Public Health Service of Haaglanden, Department of Sexual Health, The Hague; 6. Public Health Service of Gelderland-Zuid, Department of Sexual Health, Nijmegen; 7. Public Health Service of Rotterdam-Rijnmond, Department of Infectious Diseases, Rotterdam; 8. Department of Public Health, Erasmus MC, University Medical Center, Rotterdam; 9. Amsterdam UMC location University of Amsterdam, Department of Internal Medicine, Meibergdreef 9, Amsterdam; 10. Amsterdam Public Health Research Institute (APH), Amsterdam; All in the Netherlands.

BACKGROUND

Standard-of-care oral HIV PrEP monitoring:
Every 3 months, in a clinical setting



Testing for HIV PrEP provision Screening for bacterial STIs Counselling PrEP intake and sexual health

Standard-of-care under debate:

- Burdensome for some PrEP users (discontinuation PrEP)
- Costly and labor intensive (unsustainable)

Viable alternatives for sustainable oral PrEP care:

- Online PrEP monitoring
- Less frequent PrEP monitoring

However:

- Less intensive counselling may lower PrEP adherence
- Evidence needed for alternative PrEP care efficacy

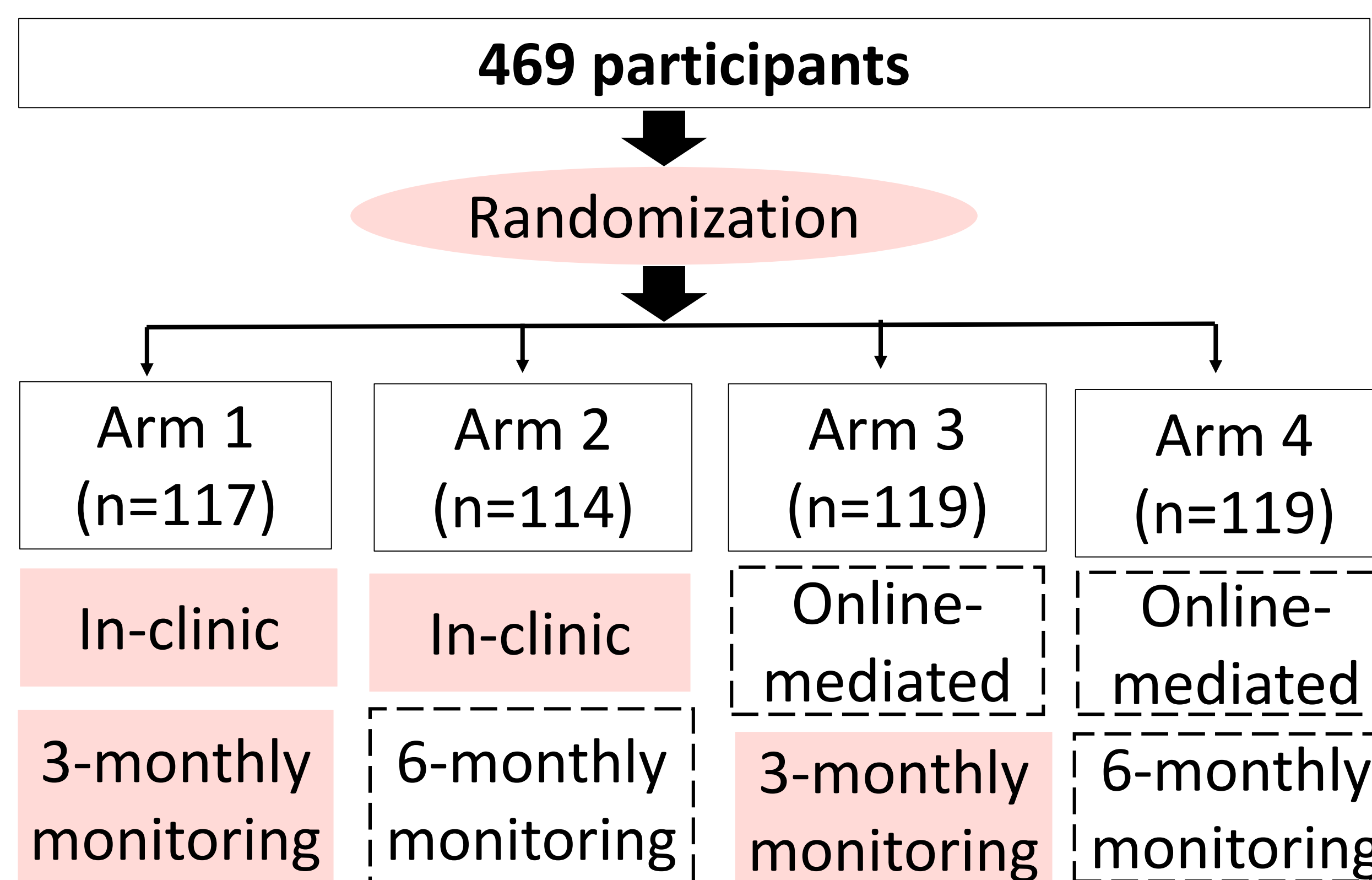
OBJECTIVE EZI-PrEP STUDY

Establish non-inferiority in terms of unprotected sex acts of two PrEP care alternatives:

- PrEP monitoring every 6 months vs. every 3 months
- Online-mediated vs. in-clinic PrEP monitoring

STUDY DESIGN

2x2 factorial, open-label, multi-center, randomized, controlled, noninferiority trial, conducted at 4 sexual health centers in the Netherlands.



PrEP monitoring every 6 months is non-inferior to PrEP monitoring every 3 months

Online-mediated PrEP monitoring is non-inferior to in-clinic PrEP monitoring

METHODS

Primary outcome measure: Unprotected sex act (UA)
condomless anal sex with a casual partner, not covered by PrEP

Data used:

- Daily diary data (EZI-PrEP study app)
- Until month 18 PrEP monitoring consultation
- Until last day of contact (if dropout/LTFU)

Comparing Incidence Rates (IR) of UA:

- comparing IR of 6-monthly with 3-monthly monitoring arms
- comparing IR of online-mediated with in-clinic monitoring arms

Non-inferiority if upper limit of 97.5%CI of IR ratio <1.8.

PARTICIPANT CHARACTERISTICS

All eligible for the Dutch National PrEP pilot Programme

RESULTS

Figure 1. Incidence rate ratio and 97.5% CI of unprotected sex acts.

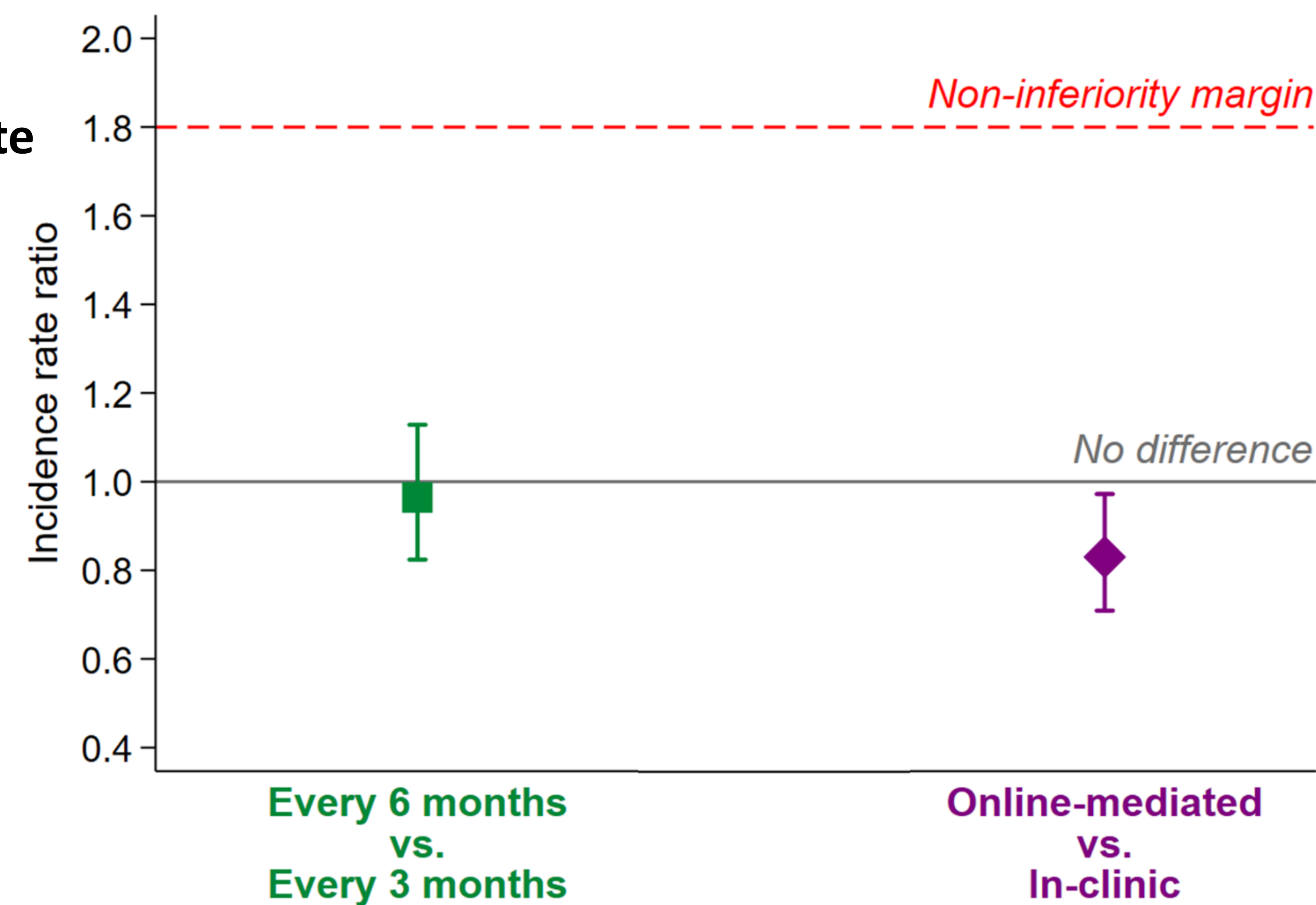


Table 1. No. of participants (N), no. of Unprotected sex Acts (UA), total follow-up (f-u) time, Incidence Rates (IR) and IR Ratios

	Total	Monitoring frequency		Monitoring modality	
		3-monthly (Arm 1 + Arm 3)	6-monthly (Arm 2 + Arm 4)	In-clinic (Arm 1 + Arm 2)	Online-mediated (Arm 3 + Arm 4)
N	469	236	233	231	238
f-u time (years)	605	305	300	307	298
No. UA	816	419	397	452	364
IR [95% CI] p/py	1.3 [1.2 - 1.4]	1.4 [1.2 - 1.5]	1.3 [1.2 - 1.5]	1.5 [1.3 - 1.6]	1.2 [1.1 - 1.4]
IR ratio [95% CI]		0.96 [0.84 - 1.11]		0.83 [0.72 - 0.95]	

CONCLUSION

6-monthly and online-mediated monitoring do not negatively impact unprotected sex acts in MSM and can be implemented

Email: mgrootbruinderink@ggd.amsterdam.nl

