



ANRS | MIE Scientific Days in Vietnam

Towards ending epidemics

15th to 16th of November, 2023

From research to implementation: from Ipergay to real life

Bruno SPIRE

INSERM, AIDES, COALITION PLUS



The ANRS IPERGAY study



- **The ANRS-IPERGAY trial was the first prevention randomized trial in France**
- **Need of new tools to reduce the risk of acquisition of HIV**
- **Need of a strong research study to move forward**
- **PreP research was the right opportunity**

The ANRS-IPERGAY trial: intermittent PreP on demand



■ Hypothesis

- **Better adherence thanks to on demand scheme: 40% of MSM interested**
- **Better cost-efficacy**
- **Better tolerance**

 LORENTE, AIDS CARE 2011

■ Sexual health intervention

- **condoms + STI treatment+ coaching + Truvada® on demand**
- **condoms + STI treatment+ coaching + Placebo on demand**

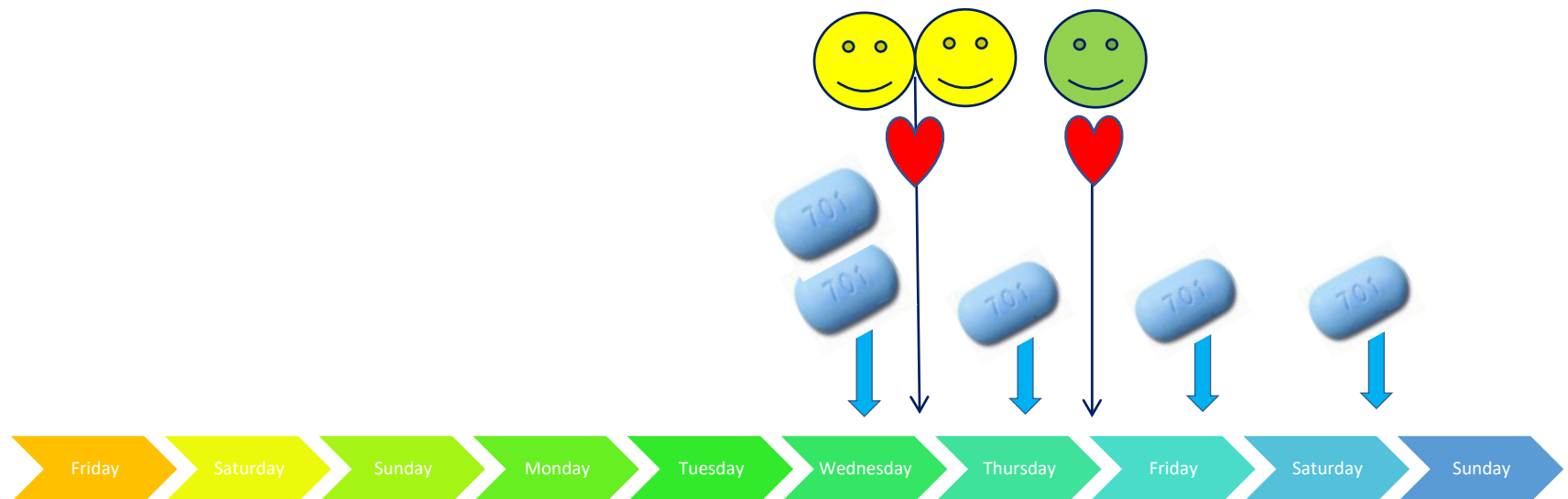
■ Aim : to test the efficacy of such scheme

Sex-driven IPERGAY 2+1+1 scheme



■ Sexual health intervention

- condoms + STI treatment+ coaching + Truvada® on demand
- condoms + STI treatment+ coaching + Placebo on demand



■ **The IPERGAY trial was planned with the users to fit as close as possible to the real life conditions:**

→ **Role of non-medical AIDES stakeholders in the trial**

→ **Enrolment and promotion**

→ **Coaching**

→ **A global sexual health intervention**

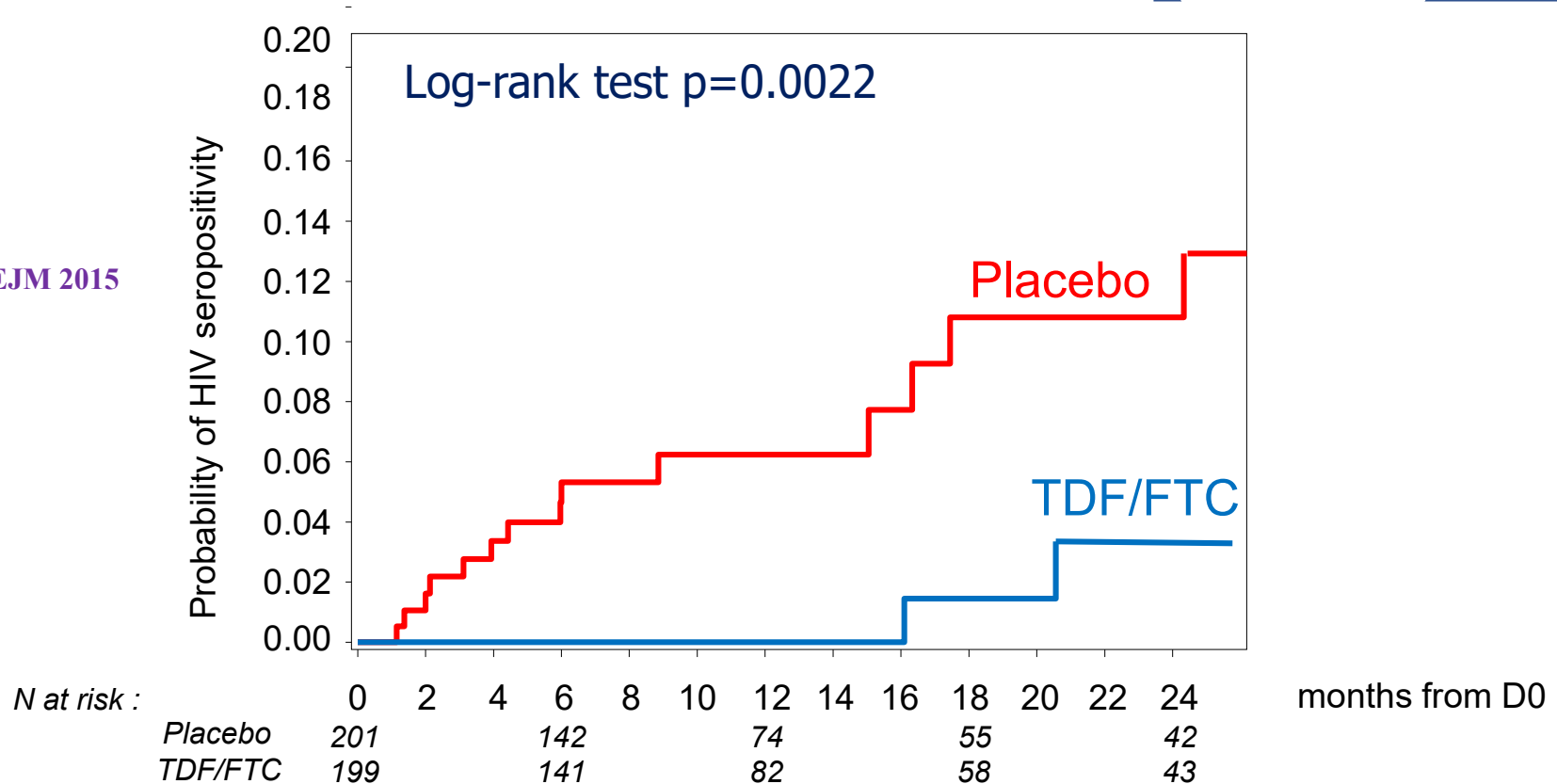
→ **Enrolment and promotion**

→ **Coaching**



KM Estimates of Time to HIV-1 Infection (mITT Population)

MOLINA, NEJM 2015



Median follow-up of 9.3 months: 16 subjects infected

14 in placebo arm (incidence: 6.60 /100 PY) and 2 in Truvada® arm (0.91 /100PY)

86% relative reduction in the incidence of HIV-1 (95% CI : 40-99)

France was the 1st country in Europe to adopt et reimburse PrEP in the frame of a holistic sexual health offer



PreP implementation in France : increasing coverage

■ Promotion

- Communication and PrEP awareness
- Attracting non-MSM KP

■ Prescription

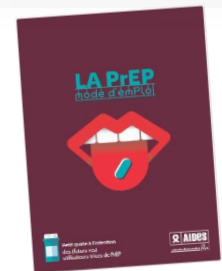
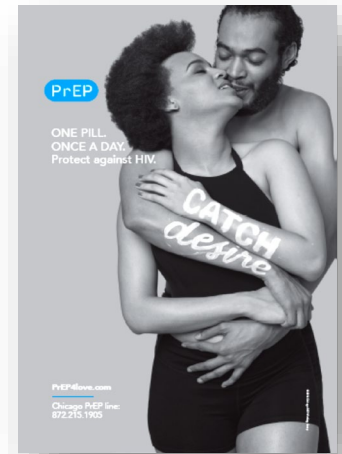
- Hospital : in Infectious disease departments
- In VCT centers
- In some CBOs
- Through GPs++++

■ Procedure

- quite similar as in research but choice between daily and on demand
- a comprehensive sexual health consultation
- Mobilization of CBOs to promote PrEP and support PrEP users

■ Limitation : health socioeconomic inequalities

- A study of the National Insurance System data estimated around 56% the efficacy of PrEP in real life
- Factors associated with failure were age < 30 years old and socioeconomic deprivation



Impact on HIV Incidence



Global HIV Incidence: 0.11/100 PY (95% CI: 0.04-0.23) (6 cases)

Mean Follow-up of 22.1 months and 5633 Person-Years

Rate of study discontinuation: 14.4/100 PY

Treatment	Follow-Up Pts-years	HIV Incidence per 100 Pts-years (95% CI)	IRR (95%CI)
TDF/FTC Daily	2583.25	0.12 (0.02 – 0.34)	0.99 (0.13-7.38)
TDF/FTC On Demand	2553.68	0.12 (0.02 – 0.34)	

- The 30-month discontinuation rate was 32% (95% CI: 29-35) : PrEP fatigue
- Good safety profile but high prevalence of psychiatric events and chemsex use
- High incidence of bacterial and viral STIs

MOLINA, LANCET HIV 2021



- How to deal with STIs? Doxy PEP trial in process
- How to deal with PrEP fatigue? Cabotegravir implementation in process within the study
- How to deal with Chemsex? : a web-app based intervention will be evaluated very soon