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# Pre-randomization analysis and cross-country differences among MSM enrolled in a trial aimed at reducing risk of HCV reinfection: an update from the ICECREAM study

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# Disclosure

None.



# Introduction

- WHO set ambitious targets to eliminate HCV as a public health threat (i.e. 80% reduction in new chronic infections and 65% reduction in mortality)
- MSM are a key population
- Re-infection rate among MSM with HIV remains high due to continuing risk behaviour<sup>1,2</sup>
- Widespread HCV treatment combined with behavioural interventions are crucial to curb the epidemic<sup>3,4</sup>

<sup>1</sup>Sacks-Davis et al. Lancet HIV, 2024. <sup>2</sup>Smit et al. Lancet HIV, 2021. <sup>3</sup>Salazar-Vizcaya et al. J Hepatol, 2016.

<sup>4</sup>Martin et al. J Infect Dis, 2019.



# Introduction

- **Behavioural interventions targeting HCV**
  - Modelling indicates that targeting high-risk behaviour would be the most effective intervention<sup>1</sup>
  - Lack of behavioural intervention studies
- **More frequent HCV testing**
  - Potential to change risk behaviour<sup>2</sup>
  - Early diagnosis and re-treatment



## Study objective

To investigate whether an online behavioural and testing intervention, alone or in combination, cause a reduction in sexual and drug use behaviours associated with HCV





# Methods

**12 study sites:** HIV treatment and STI/PrEP centres in the Netherlands and France

## Inclusion criteria

- MSM  $\geq$  18 years (HIV+ and HIV-)
- History of a cured or spontaneously cleared HCV infection
- Have internet access and an e-mail address

## Exclusion criteria

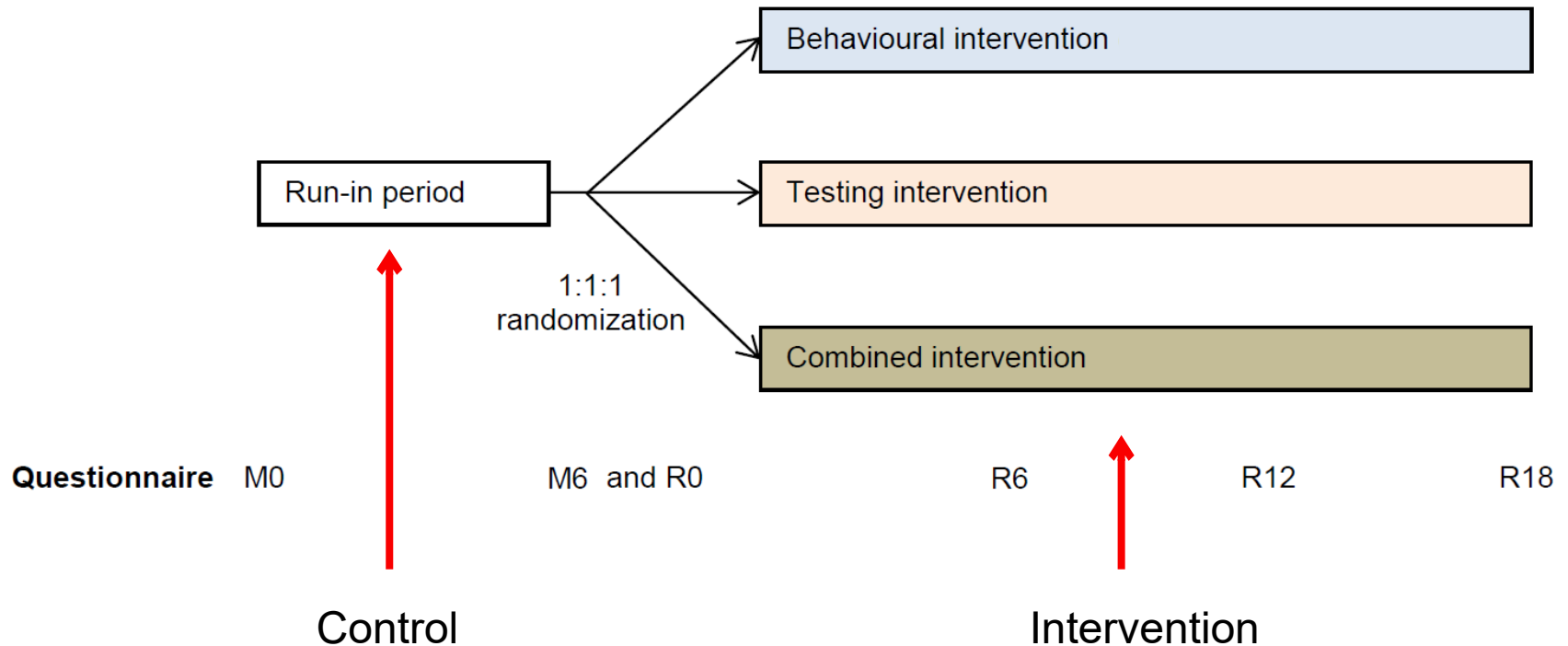
- HCV infection or HCV treatment at time of enrolment

**Primary endpoint:** % at risk of HCV infection (determined by the HCV-MOSAIC risk score<sup>1</sup>) during the run-in vs intervention periods



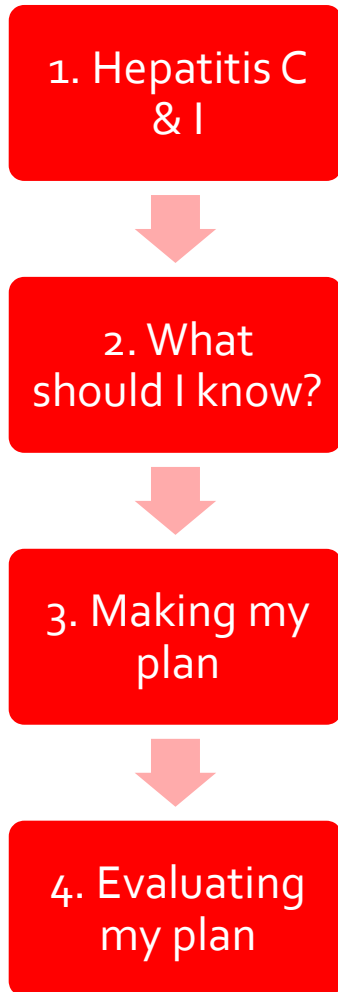
# Methods – Study design

Study design 3-arm randomized trial of interventions aimed at reducing risk behaviour in MSM. Total study period: 24 months (M)

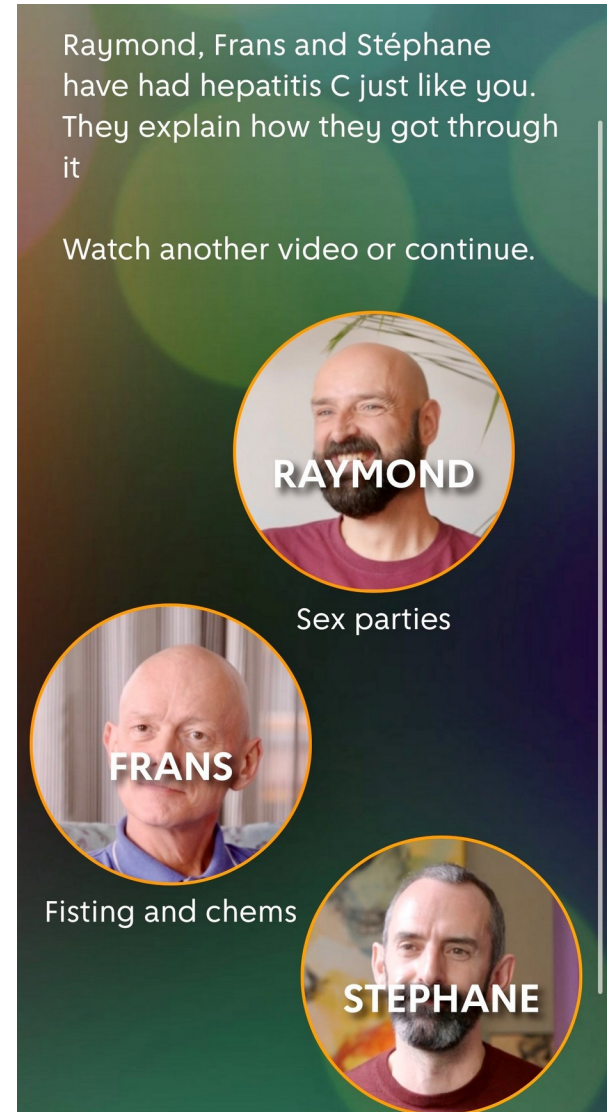




# Methods – Online behavioural intervention



- Self-reflection need/desire for change using filmed testimonials of peers
- General information
- Tailored self-risk assessment
- Tailored modules to set behavioural change goals
- Tailored modules to overcome barriers
- Reflect on change (follow-up)
- Adaptation of plans





# Methods – Testing intervention

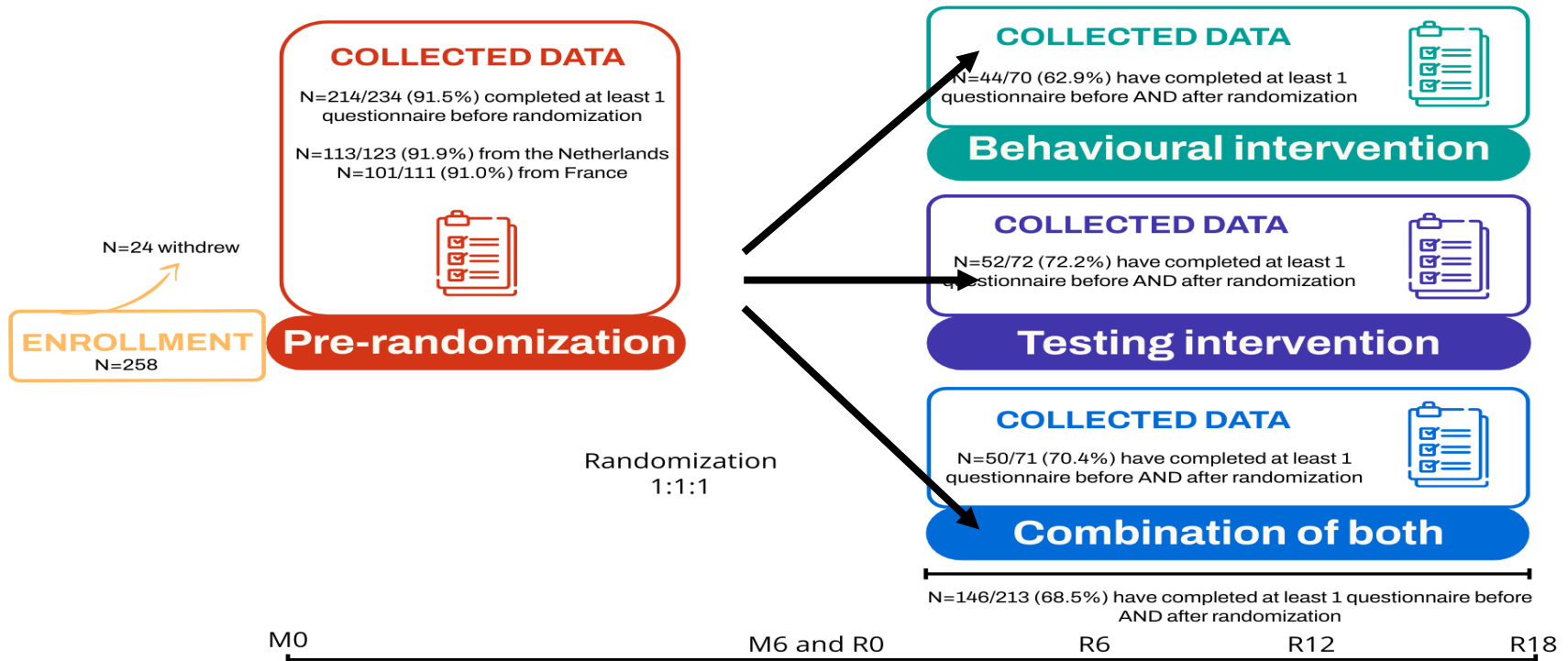
- 4 free of charge HCV-RNA self-sampling tests
- Performed on DBS
- Delivered along with paper instructions and an online demonstration video
- Results via secured mail (if negative) or phone (if positive), and immediately offered linkage to clinical care





# Study progress

- Inclusion period: September 2021 – February 2024



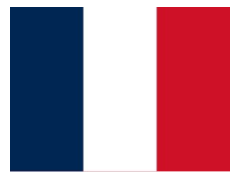


# Results – Participant characteristics

- **Inclusion period:** September 2021 – February 2024
  - n=258 consenting to participate
  - n=212 (82.2%) completed the baseline questionnaire



n=113 (53.3%)



n=99 (46.7%)



99.5% male  
gender



Median 51 yrs  
(IQR 44-58)



76.4% >high  
school degree



81.6% HIV  
diagnosis



# Results – Risk behaviour of participants at baseline

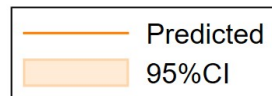
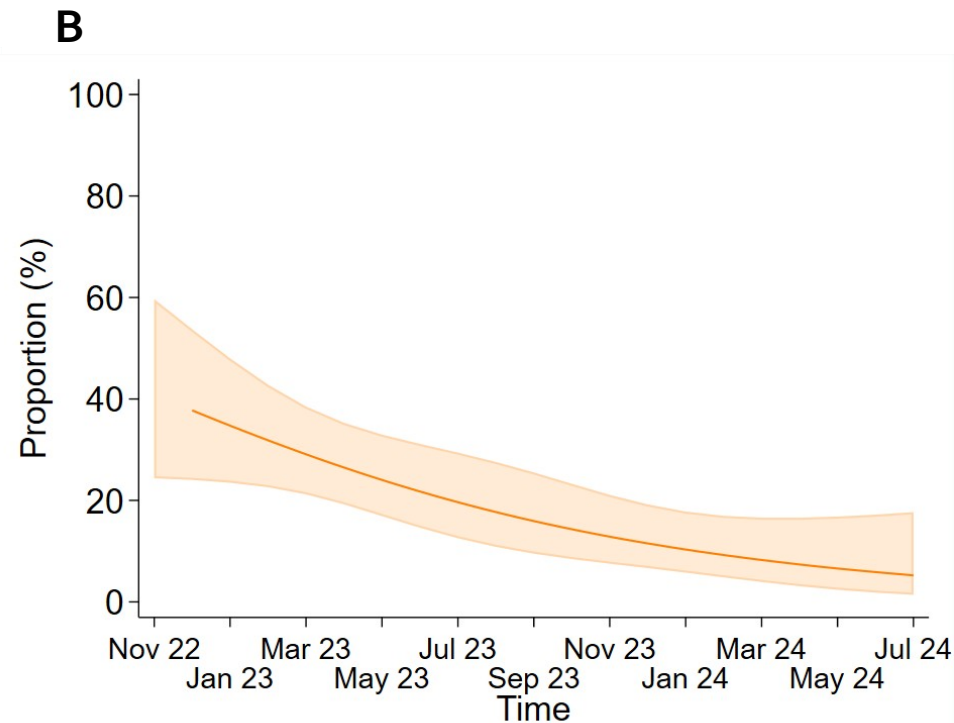
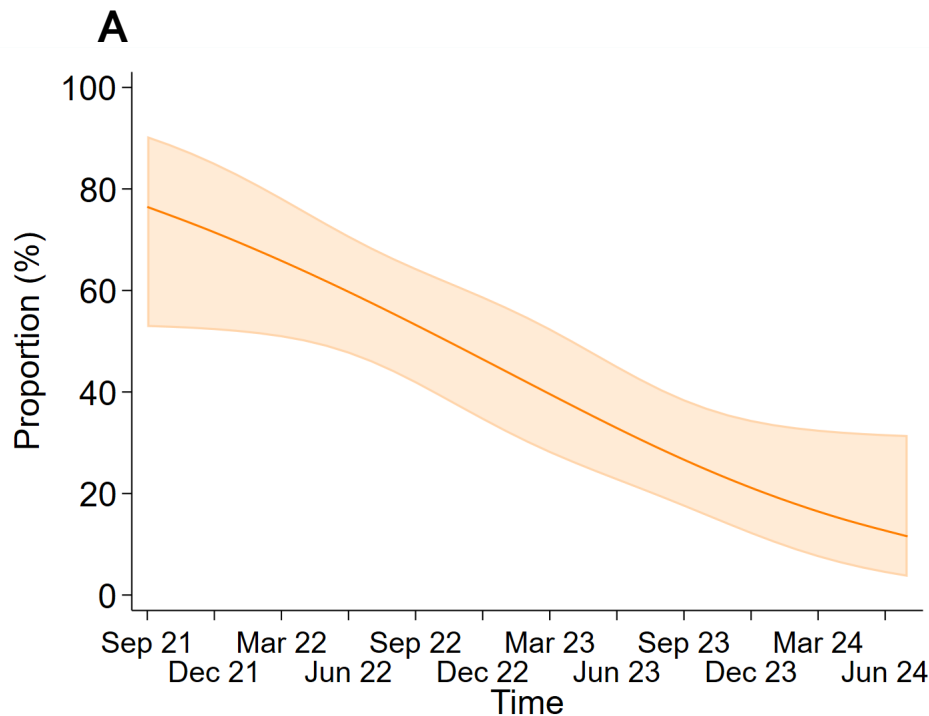
Risk behaviour <sup>a</sup>	Overall (n=212)	Enrolled in NL (n=113)	Enrolled in FR (n=99)
Casual partner	173 (81.6)	90 (79.7)	83 (83.8)
Receptive CAS	173 (81.6)	91 (80.5)	82 (82.8)
Unprotected fisting	82 (38.7)	42 (37.2)	40 (40.4)
IDU	37 (17.5)	19 (16.8)	18 (18.2)
Ulcerative STI	50 (23.6)	23 (20.4)	27 (27.3)
Chemsex	114 (53.8)	59 (52.2)	55 (55.6)
Group sex	119 (56.1)	47 (41.6)	72 (72.7)*
HCV-MOSAIC risk score <sup>b</sup>	2.2 (1.1-3.5)	2.3 (1.1-3.5)	2.1 (1.1-3.4)

Presented are n (%) or median (IQR), \* $p < 0.05$ , <sup>a</sup>Behaviours refer to those occurring in the previous 6 months, <sup>b</sup>HCV-MOSAIC risk score  $\geq 2.0$  indicates high HCV re-infection risk



# Results – Impact outbreaks

- Run-in period overlapped second wave of (A) COVID-19 in winter 2021/2022 and (B) mpox outbreak in spring 2022

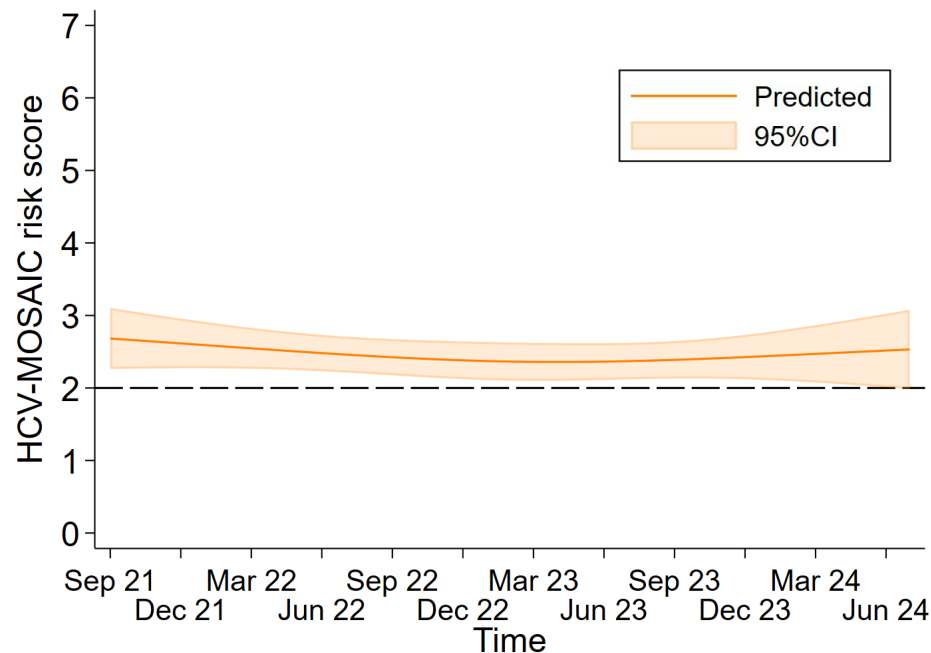


Preliminary(!)



# Results – Impact outbreaks

- 57.1% and 26.2% ever reported that COVID-19 restrictions and the mpox outbreak affected behaviours, respectively
- The majority reported it had reduced their number of sexual partners (79.2% vs. 89.5%)



Preliminary(!)



# Discussion

## Lessons learned

- Sample populations of both recruiting countries were similar at baseline and likely represent the same target population
- COVID-19 and mpox outbreaks likely had an effect on reducing sexual risk behaviours, which warrants evaluation when evaluating intervention effects

## Recommendations

- This study may help in offering information on effective behavioural prevention and easing access to HCV-RNA testing
- High behavioural risk reported during the pre-randomization phase, coupled with the overlapping outbreaks, highlights the importance of continued sexual health services and prevention efforts during such outbreaks



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