

Psychological follow-up of HIV persons participating in a cure trial

What's in a name?

CURE



- ▶ /verb/ relieve (a person or animal) of the symptoms of a disease or condition.
- ▶ /noun/ a substance or treatment that cures a disease or condition.
- ▶ A cure is when a treatment makes a health problem go away and it's not expected to come back
- ▶ Curative misconception?
 - ▶ False beliefs that participants will be “cured” from early-phase experiments

Sterilizing/complete cure

Viral eradication or eliminating all HIV in the body

Functional/treatment-free cure

Inducing a state of durable, ART-free virological suppression in which small quantities of HIV remain but do not actively increase or cause immunological damage

VIEWPOINT

Revisiting the 'sterilising cure' terminology: a call for more patient-centred perspectives on HIV cure-related research

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**Most highly desired outcomes of a cure
among PLHIV**

Alleviating uncertainty
about future health
problems

No longer being
concerned about
onward HIV
transmission

Reducing the negative
social impact of HIV
associated with stigma

Table 1. Participant expectations on completing an intensive HIV cure focused clinical trial.

Potential cure scenarios ranked most important					<i>P</i> value
Not passing HIV on to others	Not getting HIV for a second time	Being considered a person not infected with HIV	Stopping HIV medications	No longer need to see a doctor for HIV	
47%	32%	32%	25%	0%	<0.01
Desirability of sterilizing versus functional cure outcomes					
	Very desirable	Somewhat desirable	Somewhat undesirable	Very undesirable	
Sterilizing cure 'You are completely cured. So you no longer need to take HIV medications or see doctors about HIV'	90%	10%	0%	0%	
Functional cure 'The virus is still in your blood, but your body is able to keep the virus in check on its own. You no longer need to take HIV medications but you still need to visit your doctor for testing to monitor HIV'	55%	35%	0%	10%	0.02

You no longer feel bad or worry because you have HIV

You no longer have to see a doctor for regular monitoring

Your life expectancy is the same as HIV- persons

There is no risk of HIV-related health problems

You are not able to catch HIV again

You no longer have HIV in your body

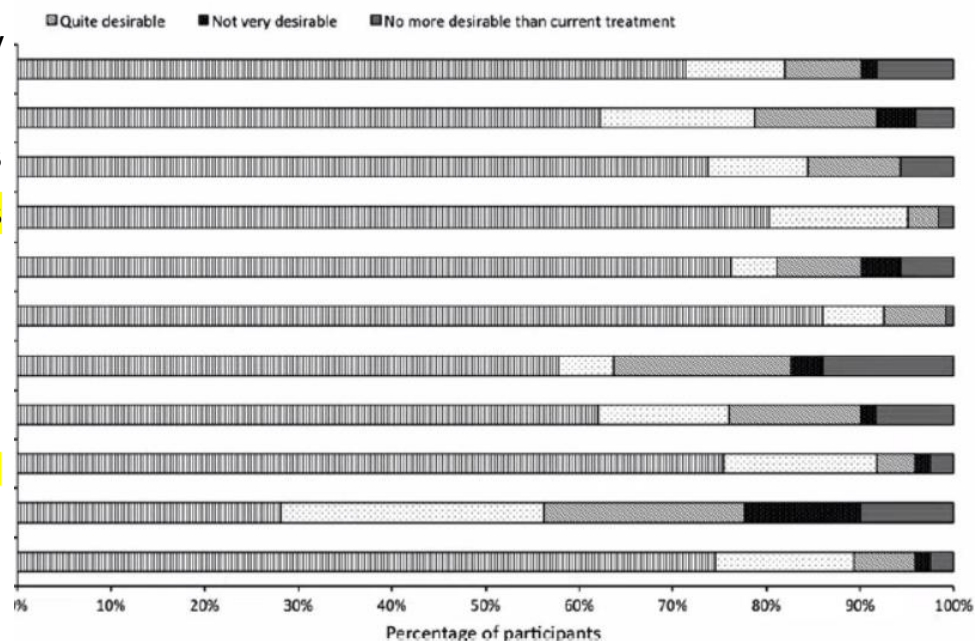
You can tell people that you don't have HIV

You would test HIV negative

There is no risk of passing HIV to sexual partners (even off treatment)

Stop ART for a number of years but you might need them in the future

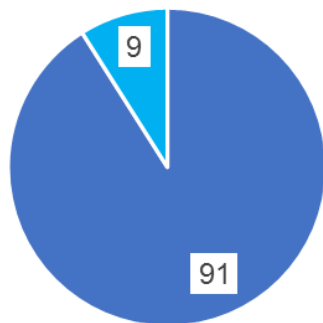
Never need to take ART



PROM UZ Ghent (N=855, N_{women}=196)

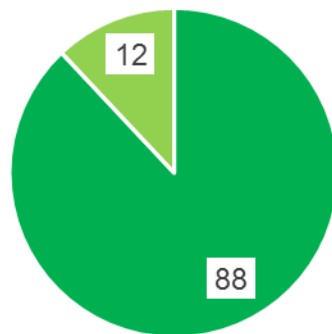
Are you **interested** in HIV cure research (%)?

all



■ yes ■ no

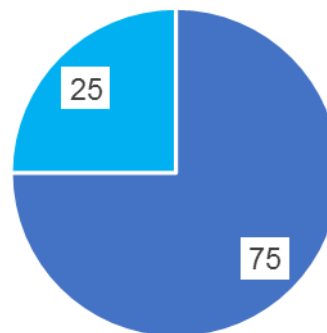
women



■ yes ■ no

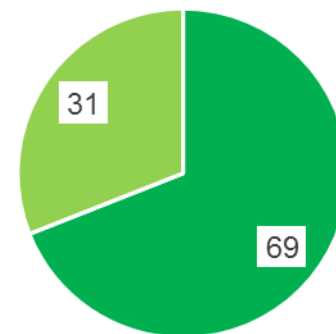
Would you willing to **participate** in HIV cure research (%)?

all

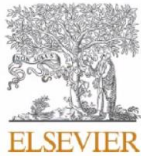


■ yes ■ no

women



■ yes ■ no



Contents lists available at [ScienceDirect](#)

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Motivations, barriers and experiences of participants in an HIV reservoir trial



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- ▶ Baseline questionnaire
 - ▶ 32 items on motives, barriers and expectations of study participation at enrollment
- ▶ Exit questionnaire
 - ▶ 23 items to assess motives and investigate the overall satisfaction and experiences of study participation
- ▶ In-depth interviews to gain more insight in issues that had emerged from the questionnaires

Questionnaire A: participation in the HIV-STAR study

1.	How would you assess your physical health	1->5
2.	Have you participated in a medical study before	Y/N
3.	If yes, please note the study subject and describe your experiences	text
4.	How big is your interest in HIV research	1->5
5.	How big is your interest in research in general	1->5
6.	Do you ever attend meetings about health-related issues	1->5
7.	My participation will provide me with extra information about my health and in particular my HIV infection	1->5
8.	There might be unexpected events preventing me from attending my study appointments	1->5
9.	Participation will have an important impact on my social life/relationship	1->5
10.	My participation will allow me to have better access to medical care in the future	1->5
11.	I hope that my participation will benefit my own health	1->5
12.	The allowance will allow me to do something extra	1->5
13.	Participating in the study makes me a better human being	1->5
14.	Participating in the study might damage my health	1->5
15.	My doctors will appreciate me more if I participate	1->5
16.	I worry about the secondary effects of treatment stop	1->5
17.	Participating in this trial will increase my chances of getting cured	1->5
18.	My family/friends will be excited about my participation	1->5
19.	Participating in this trial will give me a bigger chance not having to take my HIV medication anymore	1->5
20.	Participating in this trial will allow me to have faster access to new medication	1->5
21.	Staying in the hospital demands a lot of time	1->5
22.	This study offers the possibility to get tests I cannot pay for myself	1->5
23.	This study increases my chances of decreasing my HIV reservoir	1->5
24.	My participation will help others	1->5
25.	My participation contributes to HIV cure	1->5
26.	The number of exams makes me nervous	1->5
27.	I know the risks related to the sampling interventions	1->5
28.	The chance of resistance after stopping treatment is low	1->5
29.	Stopping treatment does not impact sexual transmission of HIV	1->5
30.	Restarting HIV medication will have physical or mental consequences	1->5
31.	The increase in viral load after stop of my HIV treatment worries me	1->5
32.	I prefer to keep my participation a secret	1->5

MOTIVES

Altruistic motives

Gaining more insight
into their own health

~~Financial incentive~~

“makes me a better
person”

contribute to the
likelihood of future
individual care

be prioritized if new
treatment options
would become
available

receiving more medical
help for HIV or other
health issues

A central dark blue rounded rectangle labeled 'BARRIERS' is surrounded by five light blue rounded rectangles, each containing a barrier. The barriers are arranged in a circular pattern around the central box. The barriers are: 'Too time-consuming' (top-left), 'Nervousness' (top-right), 'Impact on social life' (bottom-right), 'Harm of privacy' (bottom), and 'Impact on relationship' (bottom-left).

BARRIERS

Too time-consuming


Nervousness

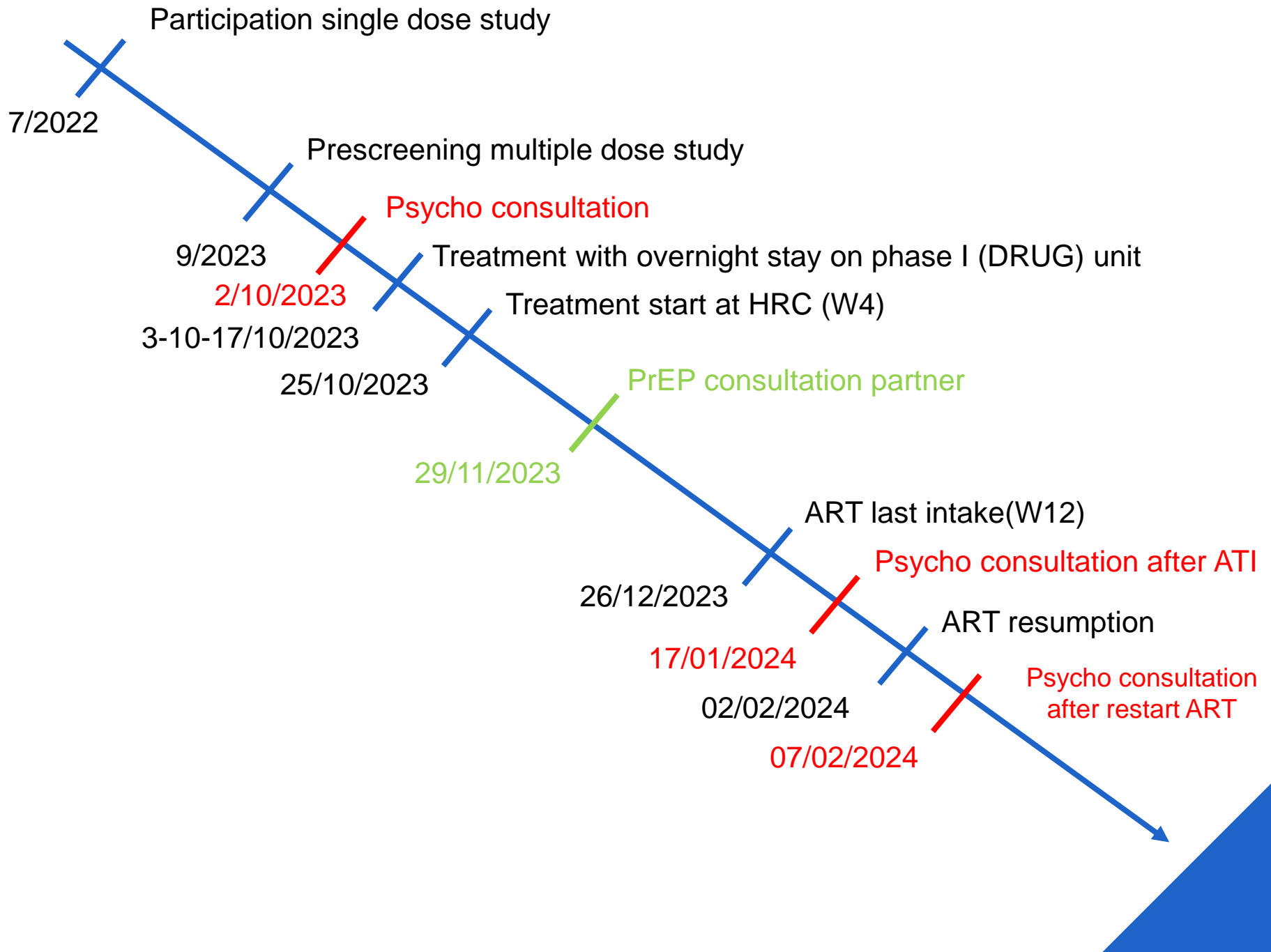
Impact on
relationship

Impact on social life

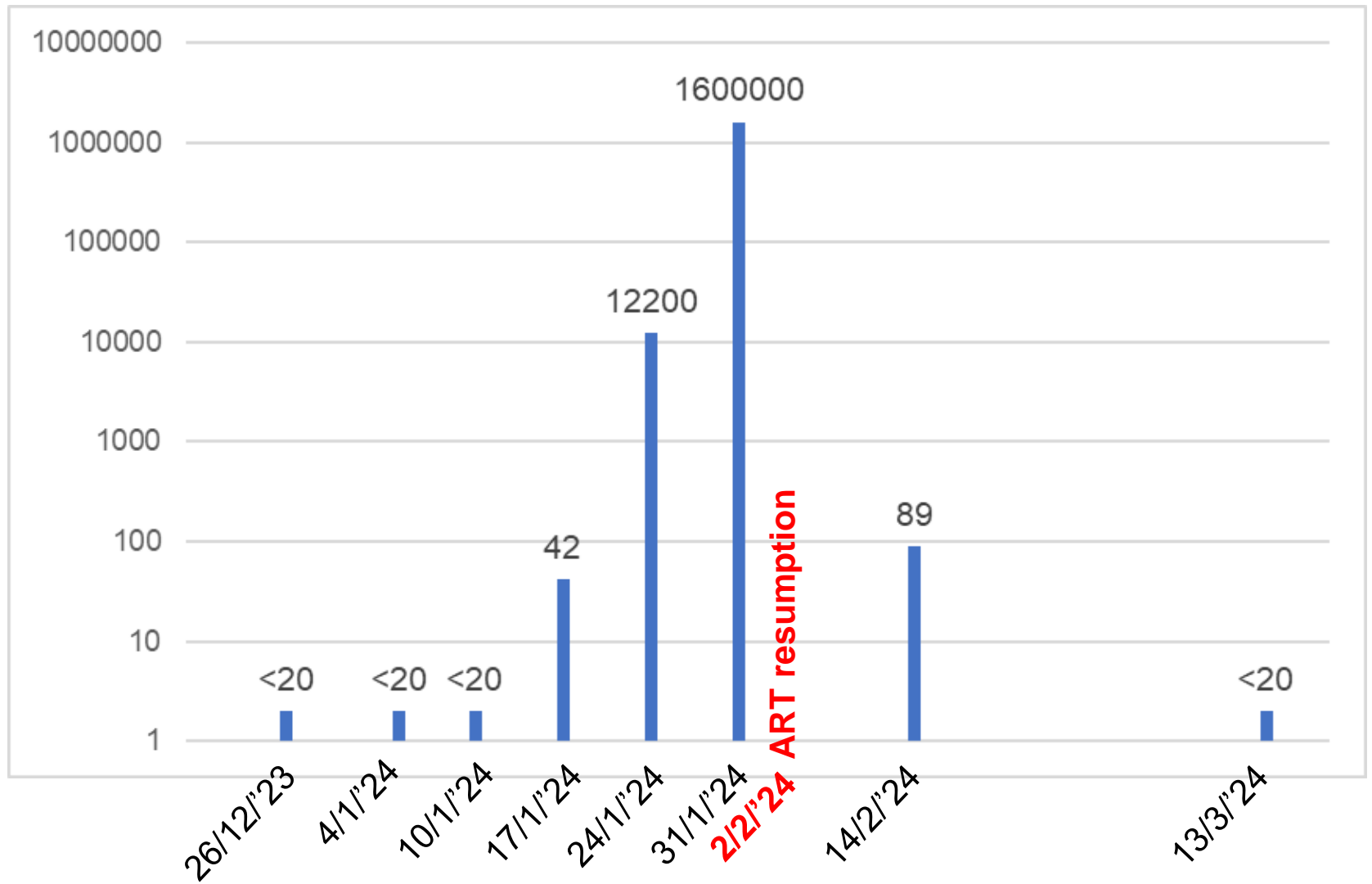
Harm of privacy

Case study G.

- ▶ 28 years
 - ▶ Born in Brazil, since 1/2020 in Belgium
 - ▶ Hiv+ since 11/2018
 - ▶ Closed relationship since 14 months, hiv- partner
 - ▶ Other medication: Trazodone
- 
- A solid blue triangle is located in the bottom right corner of the slide, pointing towards the top right.



Viral load



Psychological follow up in HIV 'cure' trial

**Prescreening
consultation**

**Follow-up
consultation
(before ATI)**

PrEP

Partner

**Follow-up
consultation (after
ATI)**

**At each medical consult: small
psycho check**

**If necessary, counseling in
between!**

Prescreening consultation

- ▶ Personality
- ▶ Work-life balance
- ▶ Relational/sexual status
- ▶ Social network
- ▶ Anxious/depressive feelings + coping mechanisms
- ▶ Motives

Psychological follow-up

Case study



- ▶ 3/10/2023: consultation before ATI
 - ▶ Motives
 - Hope for HIV cure
 - No high expectations, not too much hope
 - ▶ Only partner is informed about participation
 - ▶ Little concerns: about U=U partner
 - ▶ Partner: PrEP

Follow-up consultation (before ATI)

- ▶ How would you rate your physical health?
- ▶ How would you rate your mental health?
- ▶ Does the study meet your expectations? Why (not)?
- ▶ Did you experience any moments of hesitation?
- ▶ What are the barriers up to now?
- ▶ What is your motivation to continue?

Partner

PrEP

Psychological follow-up

Case study



- ▶ 17/1/2023: consultation one month after ATI
 - ▶ No worries (physical health 8/10, mental health 7/10)
 - ▶ Motivation ++
 - ▶ Barriers:
 - Time-consuming: impact on studies
 - Increased fatigue
 - Strange to stop taking medication
 - ▶ Partner on PrEP: more 'controlling behavior' towards PrEP intake partner

Follow-up consultation (after ATI)

- ▶ After stopping the medication, did you experience any anxious feelings or doubts?
- ▶ Did the stop of medication have an influence on your relationship/sexual life?
- ▶ Can you communicate well about the study issues with someone?

Psychological follow-up

Case study



- ▶ 7/2/2023: Consultation after restart ART
 - ▶ Anxious and difficulties with sleep
 - ▶ Experiencing sexual distance in relationship
 - Find it difficult to communicate with partner
 - Negative self-perceptions: 'anticipation of worst-case scenario'

Strange,
burdensome and
stressful

Preoccupation about
becoming detectable
again

EXPERIENCES ATI

becoming detectable
again represented a
personal confrontation
with the reality of being
HIV positive

Changes in sexual
behaviour

Impact on
relationship

Negative self-
perceptions
associated with
becoming detectable
again

Partner

How did you react on the participation of your partner in a cure trial?

Overall **very positive**. I thought it was **something very meaningful to participate in**, with a potential life-changing outcome. At the same time we felt it was important **to be careful setting too high expectations**.

Were all your questions/concerns adequately answered? If so, by whom (e.g. partner, doctor,...)?

The introduction talk with the doctor provided adequate information to answer all my initial questions; that part was very clear. Still okay but somewhat less **clear was the communication further into the trial, especially when the doctor/nurses communicated through G. rather than directly to myself**. I wasn't always confident that I got all information and I noticed G. sometimes assumed I would have been informed about something where presumably he was supposed to convey the message.

Partner

As a partner, how did you experience participation?

I had the impression G. experienced some doubts and concerns more so than myself. I mostly tried to be supportive as much as possible.

How did you experience the period when your partner was detectable again?

The specific period where the viral load was going up, and it was detectable again but hadn't reached the trigger level yet, made me a little nervous. I remember asking one or two times when the next check would be so that we would immediately know when the trigger value was reached. Once G. started taking the usual medication again I was also looking forward to the next test to have confirmation levels were dropping again.

Have you ever felt anxious during this process?

No real anxiety, but some nervousness about having to wait a week to the next check while we already knew that values were rising. It was clear though the levels were within the limits set at the beginning of the trial so it was okay.

Partner

Has this participation had an impact on your relationship?

Apart from being a topic of discussion and presenting a thing to deal with together, I don't think it affected us too much during the trial. Once everything was over I think it left us somewhat with a feeling of **improved confidence in each other** knowing that we had successfully gone through it together. During the trial, I think G. sometimes struggled a bit with convincing himself it wasn't changing my feelings for him so I tried to assure him of that on a couple of occasions.

Do you have any suggestions/comments in involving partners in participation in such cure research?

Don't rely on the patient too much to relay messages to the partner during the trial. Even if communication is open and everyone is supportive of each other, it instills confidence to receive factual information and instructions wrt medication start dates etc. via a nurse or doctor.

Take home messages?

- ▶ Importance of language use
- ▶ Privacy
- ▶ Importance of prescreening consultation
 - ▶ Explore motives
 - ▶ Explore anxiousness and coping mechanisms
- ▶ Involve partner
- ▶ PrEP for partner
- ▶ Importance of psychological counseling
 - ▶ before-during-after





References

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