

# Examining the effectiveness of an intervention to reduce HIV-related self-stigma in PLHIV

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This study will evaluate the RESET self-stigma reduction intervention: a face to face group workshop for PLHIV in the Netherlands that aims to reduce HIV-related self-stigma and improve wellbeing, specifically quality of life, self-esteem, resilient...

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Other condition
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON49731

### Source

ToetsingOnline

### Brief title

RESET intervention

### Condition

- Other condition

### Synonym

hiv gerelateerd stigma

### Health condition

hiv stigma en psychosociale gezondheid

### Research involving

Human

## Sponsors and support

**Primary sponsor:** Open Universiteit

**Source(s) of monetary or material Support:** Aidsfonds

## Intervention

**Keyword:** HIV, quality of life, self-stigma, stigma

## Outcome measures

### Primary outcome

Primary outcomes of the RCT are the Berger HIV Stigma Scale (HSS), the World Health Organization Quality of Life questionnaire (WHOQOL-BREF), the Rosenberg Self Esteem Scale (RSES), the Empowerment Scale Rogers (ESR), and the Brief Resilient Coping Scale (BRCS). The HSS, WHOQOL-BREF, RSES, ESR, BRCS will be administered at baseline, post intervention and at three-month (post intervention) follow up.

### Secondary outcome

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## Study description

### Background summary

HIV-related self-stigma is a significant barrier to an effective HIV response. High levels of self-stigma have been associated with reduced health outcomes, quality of life and access to HIV care and treatment for people living with HIV (PLHIV) worldwide. Programs that effectively target self-stigma among PLHIV remain scarce.

### Study objective

This study will evaluate the RESET self-stigma reduction intervention: a face to face group workshop for PLHIV in the Netherlands that aims to reduce HIV-related self-stigma and improve wellbeing, specifically quality of life,

self-esteem, resilient coping, and personal empowerment of PLHIV.

## **Study design**

A randomised clinical trial (RCT) will be performed consisting of one intervention group and one (waiting list) control group. Randomization will be done on the level of the individual.

## **Intervention**

Face to face intervention workshop of 3 weeks with a weekly session of 2 hours. PLHIV in both the intervention and waiting list control group will be able to participate in the intervention, with participants in the control group enrolling after the 3 months follow up measurement of the intervention group.

## **Study burden and risks**

To the best of our knowledge, there are no risks associated with participating in the face to face intervention workshop.

## **Contacts**

### **Public**

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### **Scientific**

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## **Trial sites**

### **Listed location countries**

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

a) having a diagnosis of HIV; b) being 18 years or older; c) being enrolled in HIV care in the Netherlands; d) able to speak Dutch or English.

### Exclusion criteria

Subjects with a serious medical, psychiatric or cognitive disease that would interfere with participation (e.g. severe clinical depression with risk of suicide or people with a serious drug or alcohol problem).

## Study design

### Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Other

### Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	29-08-2021
Enrollment:	160
Type:	Actual

## Ethics review

Approved WMO

Date: 27-11-2020

Application type: First submission

Review commission: MEC-U: Medical Research Ethics Committees United (Nieuwegein)

## Study registrations

### Followed up by the following (possibly more current) registration

No registrations found.

### Other (possibly less up-to-date) registrations in this register

No registrations found.

### In other registers

Register	ID
CCMO	NL75259.100.20