

# A SYNDEMIC BASED LINKAGE TO CARE INTERVENTION FOR HIGH RISK MEN WHO HAVE SEX WITH MEN

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Primary objective: Does a personalised behaviour intervention comprising of targeted in depth screening on mental health problems and drug use increase help seeking behaviour among MSM who are at high risk for STIs and HIV. Secondary objectives:...

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Bacterial infectious disorders
<b>Study type</b>	Observational invasive

## Summary

### ID

NL-OMON43470

### Source

ToetsingOnline

### Brief title

SYN.BAS.IN

### Condition

- Bacterial infectious disorders
- Anxiety disorders and symptoms

### Synonym

example anxiety disorder, Psychosocial problems

### Research involving

Human

### Sponsors and support

**Primary sponsor:** GGD Amsterdam

**Source(s) of monetary or material Support:** SOA-poli

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## Intervention

**Keyword:** drug use, Men who have sex with men (MSM), STI

## Outcome measures

### Primary outcome

Help seeking behaviour among MSM who are at high risk for STIs and HIV.

### Secondary outcome

change in STI prevalence and risky sex (i.e. condom use, number of partners, recreational drug use during sex).

## Study description

### Background summary

Men who have sex with men form an important risk group for sexual transmitted infections (STIs) and HIV with 18 to 30% STI prevalence in this group for HIV negative and HIV positive MSM. Besides this high positivity rate, there is a high recurrence of infections in this group. More than 10% of the men who were diagnosed with an STI had new infection within 1 year. Despite motivational interviewing and counseling, risk behavior remains high. Syndemic theory holds that psychosocial problems interact and that they mutually reinforce each other, thereby increasing high risk behaviour. If, however, co-occurring psychosocial problems were assessed and awareness raised, it might decrease high risk behavior.

### Study objective

Primary objective: Does a personalised behaviour intervention comprising of targeted in depth screening on mental health problems and drug use increase help seeking behaviour among MSM who are at high risk for STIs and HIV.  
Secondary objectives: Does a behaviour intervention comprising of targeted in depth screening on mental health problems and drug use change STI prevalence and risky sex (i.e. condom use, number of partners, recreational drug use during sex).

### Study design

An open randomized controlled trial.

## Study burden and risks

Regular screening will be offered to all participants that will help detecting STIs in an early stage. All participants with infections will be offered treatment and contact tracing according the guidelines used by the STI clinic of Amsterdam.

This study might help participants to gain better access to healthcare for mental health problems and addiction if needed. This could result in improving mental health of participants and eventually in making healthier (sexual) choices. Though we think this study poses no risk, the questionnaires might lead to decompensating which might lead participants to use more drugs and unsafe sex or leave STI healthcare.

This data can be used to improve mental health care reference for MSM.

## Contacts

### Public

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### Scientific

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

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Adults (18-64 years)  
Elderly (65 years and older)

## Inclusion criteria

MSM, 18 years or older, sufficient understanding of Dutch or English and  
-2 STIs within 1 year or a PEP treatment in the last 24 months for HIV negative MSM  
-1 STI or unprotected anal intercourse with casual partners in the last 12 months for HIV positive MSM

## Exclusion criteria

MSM will be excluded if they are deemed by clinic staff to be unsuited for participation or not able to complete follow-up.

## Study design

### Design

Study type:	Observational invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

**Primary purpose:** Health services research

### Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	24-08-2016
Enrollment:	145
Type:	Actual

## Ethics review

Approved WMO	
Date:	02-05-2016

Application type: First submission  
Review commission: METC Amsterdam UMC

## 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	NL56157.018.16