

# 100% Pure hard training

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<b>Registration date</b> 03/11/2016	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 19/10/2017	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Anabolic androgenic steroids (AAS) are drugs which mimic the male hormone testosterone, and can be used to enhance athletic performance and stimulate muscle growth. AAS are classified as illegal or controlled substances in many countries, yet their use has increased during recent years, particularly among non-competitive recreational athletes. The lifetime rate of AAS use is reported to be 3.3% globally, and use is more common among males (6.6%) than females (1.6%). Long-term use of AAS is associated with physical and mental health problems, including liver disease, cardiovascular (heart and blood vessel) complications, gynecomastia (enlargement of a man's breasts), virilization (the development of male characteristics such as bulk, body hair and a deep voice in women), and mood disorders. 100% Pure Hard Training (100% PHT) is a program which targets AAS use amount recreational sportspeople training in gyms. The aim of this study is to find out how common AAS use is and its association with alcohol, drug and nutritional supplement use, and whether 100% PHT can help reduce rates of AAS use in gyms.

### Who can participate?

Part A involves gyms involved in the Prevention of Doping in Sweden (PRODIS) network who have agreed to implement the 100% PHT programme at their facilities and gyms which have not, and any adults attending those gyms.

Part B involves key stakeholders of gyms involved in the Prevention of Doping in Sweden (PRODIS) network who have agreed to implement the 100% PHT programme (staff and owners at the intervention gyms, local police and municipal prevention coordinators, gym attendees, current and former users of AAS).

### What does the study involve?

In part A, a questionnaire is distributed to gym attendees at all gyms on a weekday afternoon /evening. All gym attendees above age 18 are invited to participate in the study, and those who agree to participate fill in the questionnaire anonymously. After this gyms involved in the Prevention of Doping in Sweden (PRODIS) network who have agreed to implement the 100% PHT programme commence the prevention programme 100% Pure Hard Training (100% PHT). The programme involves training gym staff in doping prevention, doping policy work, and enforcement and cooperation on doping prevention efforts between key stakeholders (gym staff and gym owners, police, and municipal prevention coordinators). By the end of 2016, the same questionnaire is distributed at all gyms again which is completed anonymously by members.

In part B, semi-structured interviews with key stakeholders of gyms which implemented the prevention programme are carried out after part A has finished. In these interviews, the implementation of the prevention programme is explored through semi-structured questions, and factors that have facilitated and/or impeded the implementation process are identified.

What are the possible benefits and risks of participating?

In part A, there are no direct benefits involved with participating but there is a small risk that some participants may find answering questions about AAS use to be uncomfortable as they are illegal and are seen negatively by the public.

In part B, benefits include a potential greater involvement in the implementation of the programme among stakeholders who take part in the study, as study participation could increase their interest and positive attitudes towards the 100% PHT programme. For current and former users of AAS, interviews could provide them with an opportunity to talk about a delicate subject with an impartial person, and share their opinions and experiences on a subject that they normally would not talk openly about. Interviews with the key stakeholder group are carried out face-to-face. For the majority of the stakeholders interviewed (i.e. local police, municipal prevention coordinators, gym staff, and gym attendees), questions focus on the implementation of the 100% PHT programme, and should not be perceived as sensitive. For current and former users of AAS, interview questions also include questions on AAS use. These are of a sensitive nature, and could thus be perceived as an intrusion of privacy by the informants. However, informants are informed about this at study recruitment, and all interviews are anonymous. Furthermore, informants can, at any time during the interview, decline participation.

Where is the study run from?

The study is run by STAD (Stockholm prevents alcohol and drug problems) and takes place in 54 gyms in Sweden.

When is the study starting and how long is it expected to run for?

May 2014 to December 2017

Who is funding the study?

The Public Health Agency of Sweden (Sweden)

Who is the main contact?

Dr Ann-Sofie Bakshi  
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**Study website**

<http://stad.org/en/research/evaluation-100-pure-hard-training>

## Contact information

**Type(s)**

Public

**Contact name**

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**Contact details**

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**Additional identifiers**

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

05522-2014-6.2

**Study information****Scientific Title**

A quasi-experimental control group study of the effectiveness and implementation of a community-based prevention programme targeting anabolic androgenic steroid use in gyms

**Acronym**

100% PHT

**Study objectives**

The overall aim of this study is to examine a prevention programme named 100% Pure Hard Training (100% PHT), which targets anabolic androgenic steroid (AAS) use among recreational sportspeople training in gyms.

Specifically, the project aims to:

1. Assess the prevalence of AAS, and its associations with alcohol, illicit drugs, and nutritional supplements use
2. Examine whether 100% PHT can decrease AAS use in gyms
3. Provide insights into which factors facilitate and/or impede implementation of the programme

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Regional Ethical Review Board of Karolinska Institutet, ref: 2016/142-31/3

**Study design**

Part A: Non-randomised controlled trial  
Part B: Observational cross-sectional study

### **Primary study design**

Interventional

### **Secondary study design**

Cluster randomised trial

### **Study setting(s)**

Other

### **Study type(s)**

Prevention

### **Participant information sheet**

Not available in web format, please use contact details to request a participant information sheet

### **Health condition(s) or problem(s) studied**

Anabolic androgenic steroid use

### **Interventions**

Part A:

Intervention gyms include those gyms that agree to participate in 100% PHT. These gyms are recruited through their involvement in Prevention of Doping in Sweden (PRODIS), a national network comprising governmental agencies, universities, county administrative boards, municipal prevention coordinators, representatives from the police force and gyms, the Swedish Sports Confederation, and the Anti-doping Hot-line (a national helpline one can call anonymously with questions about doping).

Control gyms are gyms not eligible for the intervention programme because they are not located in one of the approximately 100 municipalities (out of the total of 290 municipalities in Sweden) involved in PRODIS. Gyms placed in these municipalities are identified by the research group at STAD, and asked to participate in the study as control gyms.

At baseline, gyms in both groups undergo a pre-intervention assessment. This involves a questionnaire being distributed to gym attendees on a weekday afternoon/evening by research staff. During the data collection, research staff are placed inside the gym by the entrance, where they invite all arriving gym attendees aged 18 years and over to participate in the study. Gym attendees who agree to participate are asked to fill in a questionnaire. To guarantee anonymity, participants fill in the questionnaire anonymously and then place it in a sealed envelope before handing it over to the research staff.

Intervention gyms: Gyms who agree to participate in 100% Pure Hard Training (100% PHT). The intervention is ongoing, and involves:

1. Staff and owners at intervention gyms start the intervention by taking part in a day-long educational training programme with information on the symptoms and consequences of AAS use, nutritional supplements, doping laws, test methods for detecting AAS use, and techniques for conveying information about AAS to gym attendees. Local police and municipal prevention

coordinators also take part in the training. Furthermore, gyms receive AAS information material (posters and brochures) to be distributed at the gyms.

2. Each gym develops a written doping action plan and a policy document for AAS prevention, with support from the municipal prevention officer. The policy document and action plan are tailored to the needs of each gym.

3. Gyms are certified and receive a diploma. Requirements of certification include educational training of gym staff (required for all staff members that work at least 50%, i.e. 20 hours per week.), the production of a policy document and an action plan for AAS prevention, a cooperative relationship with local police and the municipal prevention coordinator, and the appointment of a gym employee responsible for AAS prevention at the gym. The gym is also required to have a folder made available for all staff members, which includes information on AAS use and prevention, contact information to the local police and the municipal prevention coordinator, the long-term action plan, and the policy document.

4. Close cooperation between stakeholders is encouraged. This includes follow-ups by the municipal prevention coordinator and regular visits to the gyms by the local police to inform about AAS use and to carry out inspections (in Sweden, AAS are listed as controlled substances, thus personal use, possession and supply are crimes punishable by up to six years in prison).

5. The municipal prevention coordinator performs an annual assessment to examine whether the gyms are continuing to meet the requirements of certification (e.g., training new staff members and updating the folder). Gyms that do not fulfil the requirements have six months to address this, or they lose their certification.

Control gyms: Gyms continue as usual for the duration of the study.

After approximately 18 months, participants attending gyms in both groups are asked to complete the initial questionnaire again.

#### Part B:

Key stakeholders (local police, municipal prevention coordinators, gym staff, gym attendees, users and former users of AAS) attend a semi-structured interview at the end of the follow-up period (i.e. after approx. 18 months). This involves the key stakeholders being asked questions about AAS use, whether the programme is perceived as an effective method for AAS intervention, factors that facilitate and/or impede the implementation process, and long-term maintenance of the intervention programme.

#### **Intervention Type**

Other

#### **Primary outcome measure**

Anabolic androgenic steroid use among gym members is measured using a questionnaire designed for the purpose of this study at approximately 18 months.

#### **Secondary outcome measures**

Factors that facilitate and/or impede implementation of the intervention programme are assessed using semi-structured interviews at approximately 18 months.

#### **Overall study start date**

01/05/2014

#### **Completion date**

01/12/2017

# Eligibility

## Key inclusion criteria

Part A:

Gym inclusion criteria:

1. Intervention gyms: Gyms that are involved in the Prevention of Doping in Sweden (PRODIS) network, and who have agreed to implement the 100% PHT programme at their facilities.
2. Control gyms: Gyms that are not located in one of the municipalities involved in PRODIS.

Participant inclusion criteria:

1. Aged 18 years or over
2. Attending a participating gym

Part B:

Key stakeholders in the intervention group (staff and owners at the intervention gyms, local police and municipal prevention coordinators, gym attendees, current and former users of AAS).

## Participant type(s)

Other

## Age group

Adult

## Lower age limit

18 Years

## Sex

Both

## Target number of participants

27 intervention gyms and 27 control gyms. Approximately 2000 gym attendees in the pre-intervention assessment, and a minimum of 1600 gym attendees in the post-intervention assessment. Approximately 30 key stakeholders in the intervention group (staff and owners at the intervention gyms, local police and municipal prevention coordinators, gym attendees, current and former users of anabolic androgenic steroids) will be interviewed on the implementation of the programme.

## Key exclusion criteria

Not meeting inclusion criteria.

## Date of first enrolment

01/05/2015

## Date of final enrolment

01/12/2016

# Locations

## Countries of recruitment

Sweden

**Study participating centre**  
**STAD (Stockholm prevents alcohol and drug problems)**  
Centrum för Psykiatrforskning  
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## **Sponsor information**

**Organisation**  
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**Sponsor type**  
Research organisation

**Website**  
<https://www.stad.org>

## **Funder(s)**

**Funder type**  
Government

**Funder Name**  
The Public Health Agency of Sweden (Folkhälsomyndigheten)

## **Results and Publications**

## Publication and dissemination plan

Planned publications in high-impact peer reviewed journals during 2017 and 2018.

## Intention to publish date

31/12/2017

## Individual participant data (IPD) sharing plan

Data will not be shared due to participant confidentiality. Data will be held at STAD, Centre for Psychiatry Research, Karolinska Institutet.

## IPD sharing plan summary

Not expected to be made available

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol article</a>	protocol	17/11/2016		Yes	No
<a href="#">Results article</a>	cross-sectional study results	29/08/2017		Yes	No