# A psychological intervention for HIV patients in addition to medical treatment

Submission date 16/03/2012	Recruitment status  No longer recruiting	Prospectively registered
		☐ Protocol
Registration date 28/03/2012	Overall study status Completed	Statistical analysis plan
		Results
Last Edited	Edited Condition category	Individual participant data
18/09/2014	Infections and Infestations	Record updated in last year

# Plain English summary of protocol

Background and study aims

Until recent years, HIV illness was characterized by a predominately downward trajectory that ended with death after months of debilitating AIDS-defining diseases. The advent in 1996 of the new highly active antiretroviral therapies (HAART) extended survival and reduced the prevalence of AIDS opportunistic infections in many HIV-infected individuals. However, HAART has also created new challenges with important implications for mental health interventions. Threats regarding physical survival have to a large extent been replaced by the distress associated with chronic illness. Hence, as HIV-infected individuals live longer, it is increasingly important for clinicians and researchers to better understand and improve well-being and quality of life. Consequently, this study aims at testing a web-based intervention that was developed to address mental health issues among HIV-infected individuals.

#### Who can participate?

The study recruited a group of HIV-infected patients, aged 18 or older, on antiretroviral therapy at an outpatient clinic at Oslo University Hospital (Norway).

#### What does the study involve?

All participants that accepted the study invitation were randomly allocated into two groups (experiment or control group). Those participants that were assigned to the experiment group were given access to the intervention, called Avanti. Avanti is a web-based self-help program that is designed to improve and manage HIV patients' symptoms of depression and well-being. Avanti consists of 13 sessions and lasts for 4 weeks. The control group did not receive any intervention other than medical treatment as usual. Control participants were, however, given access to Avanti when the final survey data were collected. All participants were surveyed at the start of the study and 1 and 3 months later.

What are the possible benefits and risks of participating?

Participants that receive the web-based intervention can potentially experience decreases in depressive symptoms and increases in well-being. There are no expected negative side effects from treatment.

Where is the study run from?

The study is conducted at the outpatient clinic at the Department of Infectious Diseases, Ullevål, Oslo University Hospital (OUH).

When is the study starting and how long is it expected to run for? The study started in February 2011 and the final data collection ended in October 2011.

Who is funding the study?

The study was funded by Abbott Laboratories (Norway) and the intervention was funded by Medicus Plesner (Norway).

Who is the main contact? Filip Drozd fd@changetech.no

# **Contact information**

# Type(s)

Scientific

#### Contact name

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#### Contact details

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# Additional identifiers

Protocol serial number

N/A

# Study information

#### Scientific Title

A digital psychological intervention for HIV patients in adjunct to medical treatment a randomized clinical trial

# **Study objectives**

- 1. The web-based intervention decreases symptoms of depression at 3 months as compared to the treatment-as-usual group
- 2. The web-based intervention increases satisfaction with life at 3 months as compared to the treatment-as-usual group
- 3.1. The web-based intervention increases positive affect at 3 months as compared to the treatment-as-usual group

- 3.2. The web-based intervention decreases negative affect at 3 months as compared to the treatment-as-usual grou
- 3.3. The web-based intervention increases overall mood at 3 months as compared to the treatment-as-usual group
- 4. Are there any moderators (e.g., age, time since first HIV seropositive test, time since start of antiretroviral therapy) of treatment effect on depressive symptoms, life satisfaction, and positive and negative affect?

# Ethics approval required

Old ethics approval format

# Ethics approval(s)

- 1. Oslo University Hospital Ethics Committee, 27/09/2010, ref: 1557
- 2. Regional Ethics Commitee (http://helseforskning.etikkom.no), 15/02/2011, ref: 2010/2948-1

# Study design

Two-armed randomised controlled trial

# Primary study design

Interventional

# Study type(s)

Treatment

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

Patients infected with HIV for more than 12 months.

#### **Interventions**

The intervention is called Avanti.

Avanti is a web-based self-help program that is designed to improve and manage HIV patients' symptoms of depression and well-being. Avanti consists of 13 sessions and lasts for 4 weeks. Once a user is registered he or she will receive an email every Monday, Wednesday, and Friday with a unique link to each new session. Every session consists of unique content. The intervention contains psychoeducative information and applies techniques, and exercises from positive psychology and metacognitive therapy. These techniques and exercises are designed to improve well-being and manage negative emotions and thoughts. However, Avanti is not intended as a replacement but rather a supplement to existing treatments.

The control group did not receive any intervention other than medical treatment as usual. Control participants were, however, given access to Avanti when the final survey data were collected.

# Intervention Type

Other

#### Phase

Not Applicable

# Primary outcome(s)

- 1. Center for Epidemiological Studies Depression Scale (CES-D; Radloff, 1977)
- 2. Satisfaction with Life Scale (Diener et al., 1985)
- 3. Positive & Negative Affect Schedule (PANAS; Watson, Clarke & Tellegen, 1988)

All participants were measures on primary outcomes on baseline, 1, and 3 months post-intervention enrollment.

# Key secondary outcome(s))

No secondary outcome measures

# Completion date

15/10/2011

# **Eligibility**

### Key inclusion criteria

- 1. Patients registered at the outpatient clinic at Department of Infectious Diseases, Ullevål, Oslo University Hospital
- 2. 18 years or older
- 3. Norwegian speaking
- 4. White caucasian
- 5. HIV infected
- 6. Not infected by drug use
- 7. On antiretroviral therapy >12 months prior to inclusion

# Participant type(s)

**Patient** 

# Healthy volunteers allowed

No

#### Age group

Adult

#### Lower age limit

18 years

#### Sex

All

## Key exclusion criteria

Does meet inculsion criteria

#### Date of first enrolment

15/02/2011

#### Date of final enrolment

15/10/2011

# Locations

# Countries of recruitment

Norway

# Study participating centre Changetech AS

Oslo Norway 0349

# Sponsor information

# Organisation

Abbott Laboratories (Norway)

# Funder(s)

# Funder type

Industry

## **Funder Name**

Abbott Laboratories (Norway)

## Alternative Name(s)

Abbott, Abbott U.S., Abbott Alkaloidal Company

## **Funding Body Type**

Government organisation

# **Funding Body Subtype**

For-profit companies (industry)

## Location

United States of America

#### **Funder Name**

Medicus-Plesner (Norway)

# **Results and Publications**

Individual participant data (IPD) sharing plan

# IPD sharing plan summary

Not provided at time of registration

**Study outputs** 

Output type Details Date created Date added Peer reviewed? Patient-facing?

Participant information sheet
Participant information sheet
11/11/2025 No Yes