

A psychological intervention for HIV patients in addition to medical treatment

Submission date 16/03/2012	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 28/03/2012	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 18/09/2014	Condition category Infections and Infestations	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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 Threats regarding physical survival have to a large extent been replaced by the distress associated with chronic illness.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?

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Contact information

Type(s)

Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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 group
- 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 Committee (<http://helseforskning.etikkom.no>), 15/02/2011, ref: 2010/2948-1

Study design

Two-armed randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

GP practice

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

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 measure

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.

Secondary outcome measures

No secondary outcome measures

Overall study start date

15/02/2011

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

Approximately 60 patients were needed across the two treatment arms

Key exclusion criteria

Does meet inclusion 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)

Sponsor details

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Sponsor type

Industry

Website

<http://www.abbott.com/>

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

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration