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A psychological intervention for HIV patients in addition to medical treatment

Submission date
16/03/2012

Recruitment status
No longer recruiting

Registration date
28/03/2012

Overall study status
Completed

Last Edited
18/09/2014

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] 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 Threats regarding physical survival have to a large extent been replaced by the distress associated with chronic illness.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 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

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 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)

Sponsor details
Martin Linges vei 25
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N-1330 Fornebu
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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