

Long-term effectiveness of an online self-help intervention for people with HIV and depressive symptoms

No registrations found.

| | |
|------------------------------|---------------------|
| Ethical review | Not applicable |
| Status | Recruitment stopped |
| Health condition type | - |
| Study type | Interventional |

Summary

ID

NL-OMON25925

Source

NTR

Brief title

Long-term effectiveness of an online self-help intervention for people with HIV and depressive symptoms

Health condition

HIV, aids, depression

Sponsors and support

Primary sponsor: Leiden University

Source(s) of monetary or material Support: Gilead

Intervention

Outcome measures

Primary outcome

Depressive symptoms: Patient Health Questionnaire 9 (PHQ-9).

Secondary outcome

Anxiety symptoms: Generalized Anxiety Disorder-2 Scale (GAD-2).
For the second aim, questions regarding current needs will be included.

Study description

Background summary

Many people with HIV suffer from depressive symptoms. We developed an online self-help intervention for people with HIV and depressive symptoms, based on cognitive behavioral therapy. In an RCT (registered as Trial NL5298 (NTR5407)) it was found that the intervention was effective in decreasing depressive and anxiety symptoms, compared to a control group that received attention only. The positive effects of the intervention were confirmed up to six months later. It is not known whether the effects of the intervention remain after this period. In the current study we will investigate the long-term effectiveness of the intervention, three to four years after completion of the study. It is important to know to what extent the effect of the intervention is maintained. Primary aim is to investigate changes in depression scores between post intervention and long-term follow-up. Secondary aim will be to explore current needs of participants. These findings may provide suggestions for the development and implementation of relapse prevention activities after completion of the intervention.

Study objective

We expect that the intervention is also effective on the long term. However, we expect that the depression scores may have increased somewhat, compared to post-treatment.

Study design

Time points of the previous RCT that will be included in the analyses of the current study:

Pretest = T0

After the intervention = T1

3 month follow-up = T2

New time-point in current study: 4 year follow-up: T4.

Intervention

Intervention: "Living positive with HIV": Online self-help program to decrease depressive symptoms. The intervention included telephone coaching once a week. The program lasted 6-10 weeks, 1-2 hours a week. Participants worked on the intervention in 2015/2016.

The online intervention consists of cognitive behavioral therapy. The content of the program reflects four main components: activation, relaxation, changing maladaptive cognitions, and

goal attainment.

Contacts

Public

Leiden University
Sanne van Luenen

071-5277957

Scientific

Leiden University
Sanne van Luenen

071-5277957

Eligibility criteria

Inclusion criteria

- People that participated about four years ago in the previous RCT about the effectiveness of an online self-help intervention for people with HIV and depressive symptoms.
- Participants that were allocated to the intervention group in the previous RCT and participants in the control group that followed the intervention after the three month follow-up.

Exclusion criteria

- Participants that dropped-out of the RCT.

Study design

Design

| | |
|---------------------|----------------------|
| Study type: | Interventional |
| Intervention model: | Other |
| Allocation: | Non controlled trial |

| | |
|----------|-------------------------|
| Masking: | Open (masking not used) |
| Control: | N/A , unknown |

Recruitment

| | |
|---------------------------|---------------------|
| NL | |
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 01-01-2020 |
| Enrollment: | 113 |
| Type: | Actual |

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

| | |
|-------------------|----------------|
| Not applicable | |
| Application type: | Not applicable |

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

NTR-new NL8448

Other Ethics Committee Psychology, Leiden University : CEP19-0305/164.

Study results

Summary results

Van Luenen, S., Garnefski, N., Spinhoven, P. & Kraaij, V. (2018). Guided Internet-based intervention for people with HIV and depressive symptoms: A randomised controlled trial in the Netherlands. *The Lancet HIV*, 5, e488-e497. Doi: 10.1016/S2352-3018(18)30133-4.

Van Luenen, S., Kraaij, V., Spinhoven, P. & Garnefski, N. (2016). An Internet-based self-help intervention for people with HIV and depressive symptoms: study protocol for a randomized controlled trial. *Trials*, 17, 1-12. Doi: 10.1186/s13063-016-1292-6.