Implementation of Internet-based preventive interventions for depression and anxiety: the role of support?
A study of the effectiveness of internet interventions with different roles of support on symptoms of depression and anxiety

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Ethical review	Approved WMO
Status	Pending
Health condition type	Psychiatric disorders
Study type	Interventional

Summary

ID

NL-OMON31924

Source
ToetsingOnline

Brief title
Internetinterventions for depression and anxiety: the role of support

Condition

- Psychiatric disorders

Synonym
depression; mellowness

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit
Source(s) of monetary or material Support: ZonMw

Intervention

Keyword: anxiety, depression, guided self-help, Internet-interventions

Outcome measures

Primary outcome

Primary outcome measures are symptoms of depression and anxiety.

Secondary outcome

Secondary outcome measures are diagnosis, drop-out from the intervention,

quality of life, and economic costs. Other secondary outcome measures that may

predict outcome are also studied, e.g. working alliance, client satisfaction

and problem-solving skills.

Study description

Background summary

There is no doubt that internet-based self-help interventions for common mental disorders are effective. Several well-designed randomized controlled trials, both national and international, have examined internet-based self-help interventions for mild depression and anxiety showed that these interventions are effective in reducing these symptoms (Spek et al., 2007, van Straten et al., 2006). Advantages of these kinds of treatments are, for example, the reduced time of the therapist (Marks et al., 2003), reduced costs and the ability to reach populations with mood and anxiety disorders who are not reached with more traditional forms of treatment (Cuijpers & Riper, 2007). And,

while the use of the Internet increases among the broad public (Mendelson, 2007), it can be expected, therefore, that the use of (guided) self-help through the Internet will be increasingly used in the prevention of common mental disorders. Internet guided self help are offered in many forms. For example, the support given by a coach can vary from more input (Andersson, Cuijpers. Carlbring, Lindefors, 2007) to minimal contact with a coach (Christensen, Griffiths, Jorm, 2004). Although the efficacy of internet-based self-help has been demonstrated sufficiently, it is not clear how these interventions should be offered tot the population who can benefit from it. A major issue is whether it is better to offer the intervention with or without a coach. Advantages of a system without a coach are, for example, the easy and cheap implementation of it, it does not require a complex and costly structure of professionals and there is virtually no limit as to how many clients can enter program, since additional clients will not imply additional therapist time (Palmqvist, Carlbring & Andersson, 2007). However, there is evidence that in interventions without a coach the drop-out rate is considerably higher than in interventions with a coach. (Spek et al., 2007). On the other hand, a system organization, in which participants have to be assigned to coaches, will account for high costs and is more difficult to organize, as the coaches have to be trained, have to have sufficient time and have to be paid. Moreover, there will be limits on the amount of participants entering the program.
The scope of the population to be reached with Internet interventions without a coach is much broader than with a coach. However, Spek et al. (2007) found in their meta-analysis of international studies indications that interventions without support are effective, but with smaller effect sizes than interventions in which the user had regular contact with a coach. How large the differences in effectiveness are between interventions with and those without a coach have been studied only once and this study had several shortcomings. Moreover, it has not been examined whether there are differences in drop-out rate and costs between interventions without and with support, and in particular different levels of support. These are, however, very fundamental research questions for the dissemination of these interventions.

Study objective

in this study we want to examine whether an Internet-based self-help intervention with a coach is more effective than the same intervention without a coach in terms of clinical outcomes, drop-out and economic costs. Moreover, we want to examine which level of support by a coach is more effective compared to other levels of support.

Study design

This study is a randomized controlled trial with four active treatments with different levels of support and an information only control condition. The control condition is added to control for the non specific effects of coaching.

The four active treatment conditions are:

1. Brief internet-based problem-solving on the Internet (*self-examination* treatment, see below) without coaching (but with automated emails at regular times).
2. The same as in 1, but with the possibility for the subject to approach a coach on his or her own initiative (by email).
3. The same as in 1, but with a coach who will actively approach the subject at regular times (once per week, by email)
4. No Internet intervention, but a coach will approach the subject weekly (by telephone) to discuss problems and give general support (non-specific intervention).
5. Only information on depression and anxiety (on the Internet).

Intervention

1. Brief internet-based problem-solving on the Internet (*self-examination* treatment, see below) without coaching (but with automated emails at regular times).
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Study burden and risks

In our opinion there is a minimal burden and risk associated with participation.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1) being 18 years or older; 2) having symptoms of depression and/or anxiety (as defined by scoring above the cut-off of 16 on the CES-D and 8 on the HADS); 3) which are not too severe (1 standard deviation above the population mean on the CES-D, cut-off 39 and/or HADS< cut-off 14; Bauma et al., 1995, Olsson et al., 2005); 4) having access to a computer with a fast internet connection; 5) being prepared to participate in the study.

Exclusion criteria

Excluded are subject with severe symptoms of depression (CES-D, cut-off 39 or higher) suicidal intentions and/or currently under treatment by a mental health specialist.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial

Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-03-2008
Enrollment:	500
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Amsterdam UMC

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
CCMO	NL21483.029.08