Grip op je dip online (Master your mood online): development and effectiveness

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The aim of the project is to further develop and study the effectiveness of the Internet groupcourse Gripop Je Dip Online for young people (16-25 years) with depressive symptoms.Development objective:The eight-session groupcourse will be adapted...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Mood disorders and disturbances NEC
Study type	Observational non invasive

Summary

ID

NL-OMON34019

Source
ToetsingOnline

Brief title
RCT Grip op je Dip online

Condition

- Mood disorders and disturbances NEC

Synonym
depression, down

Research involving
Human

Sponsors and support

Primary sponsor: Trimbos-instituut
Source(s) of monetary or material Support: ZonMw

Intervention

Keyword: Adolescents, Depression, Internet Intervention, Prevention, Randomized Trial

Outcome measures

Primary outcome

OUTCOME MEASURES AND ASSESSMENT INSTRUMENTS

Primary outcome measure: Depressive symptoms, according to the Center for

Epidemiological Studies

Depression Scale (CES-D, Dutch version. Bouma e.a., 1995).

Secondary outcome

OUTCOME MEASURES AND ASSESSMENT INSTRUMENTS

Secondary outcome measures:

- Mastery, according to the Mastery Scale (Pearlin and Schooler, 1978).

- Anxiety, according to the Hospital Anxiety and Depression Scale (HADS,

Zigmond and Snaith, 1983;

Psychometric properties: Spinhoven,e.a. 1997).

Predictors for (un)successful outcomes in terms of depression, anxiety and

mastery will be

sociodemographic variables such as age, gender, educational attainment. Course

related predictors are

webchatting experience, motivation to take part in preventive group

interventions (Nijmegen Motivation

List for Prevention, NML-P, Allart-van Dam et al., 2004), course adherence and

extent of completion of

homework assignments, as recorded by course supervisors in their log books.

Study description

Background summary

An estimated 80,000 Dutch young people aged 18 to 25 suffer from depression every year (NEMESIS study, Trimbos Institute, 2005). One out of every five young people are believed to experience depressive symptoms which have not yet culminated in full-blown depression (study by J. Kramer, Trimbos Institute, of 4443 secondary school pupils, 2001; Monck et al., 1994). In addition to the suffering that these conditions cause, early depression can be detrimental to the educational and working careers. There are also economic consequences for society. Given the nature and extent of this problem, there is much to be gained by nipping depression in the bud.

Subclinical symptoms are promising targets for intervention. Often they are omens of full-blown depression (Cuijpers, 1998). Subclinical symptoms are influenceable, and appropriate intervention can avert depression (Cuijpers et al., 2004 a/b; Clarke et al., 1995, 2001; Smit et al., 2003). Insights like these prompted us several years ago to develop the face-to-face Grip op Je Dip prevention course for young people aged 16 to 25 with depressive symptoms. It is based on the Coping with Depression Course which has been shown effective (Lewinsohn & Clarke, 1984; Clarke et al., 1995, 2001).
The face-to-face course did not sufficiently reach the target group. Young people found it too inaccessible, and that resulted in low uptake, longer waiting periods for the start of courses. At the same time, there has been a rush on youth mental health websites like www.zwaarweer.nl from the Korrelatie Foundation (Teunis, 2001). Korrelatie have indicated that many such young people need types of help that they are unable to offer. For this reason, the Trimbos Institute joined with Korrelatie and three Dutch regional mental health agencies in a new pilot project (November 2003-July 2005). The objective was to

adapt the Grip op Je Dip face-to-face course for online delivery, and then perform a pilot study to test it in practice on young people aged 16 to 25 with depressive symptoms. The course consisted of eight weekly 90-minute sessions. Small groups of up to six participants were given the course, supervised by two mental health care professionals in a secure chatroom with various functionalities.

The results of the pilot study were very promising (van der Zanden et al., 2005). Young people were easily reached, and many expressed interest (249 during two 4-week recruitment; see table 1), resulting in rapid take-up and short waits. The anonymity of the course was highly valued, and depressive symptoms according to the CES-D were reduced - from an average of 34.5 (sd=8.5) at baseline to 16.3 (sd=7.5) after the course (see table 2).

The pilot study also brought to light certain issues that now require further development and research.
The issues are as follows:
a) Course adherence. Adherence was greater in the first half of the course than in the second half. Two thirds of the participants took part in four or more sessions, but only one fifth completed all sessions (unfortunately no comparative adherence data is available on the face-to-face course). Because the specific course topics were dispersed over the eight sessions, certain essential information did not get through to all participants. Lack of exposure and drop-out to online interventions is a well-known issue (de Nooijer et al., 2005; Emmelkamp, 2005; Riper et al, in press). By adapting the course, we hope to ensure that participants will receive all the necessary information and are able to put it to use. For that purpose, we are developing a shorter variant of the course which will consist of five sessions containing the essential information (see Strategy: 'Long versus short course variant').

b) Severity of the mental health problems. Most young people who applied for the pilot course had rather high symptom levels on the CES-D; the mean score was 34.5 (sd=8.5). Many of them could have probably been diagnosed with a depressive disorder. Young people with lower levels of symptoms were in the minority, whereas they were the group we were also targeting in this prevention course. The study we are now proposing will investigate whether recruitment through channels other than Korrelatie will result in higher enrolments of people with milder

symptoms. To avoid participation by
people with more severe depression problems, we will screen them out by administering the MINI Plus
online and then refer them to appropriate mental health care providers. The MINI Plus is a structured
diagnostic interview for assessing DSM-IV mental disorders.

As this E-mental health project (a) could greatly facilitate the reaching of high-risk groups and (b) could
serve as a model for other prevention group services in the mental health sector, we feel it is more than
worthwhile to develop it further and test the effectiveness. That is the purpose of this grant application.

Study objective

The aim of the project is to further develop and study the effectiveness of the Internet groupcourse Grip
op Je Dip Online for young people (16-25 years) with depressive symptoms.

Development objective:
The eight-session groupcourse will be adapted into a shorter course of five weekly 90-minute sessions.
The shorter course is to deliver all the essential information within a more compact time frame, enabling
as many participants as possible to benefit before the dropout rate increases. The shorter course
focusses on CBT-principles and encouragement of pleasurable activities.
The recruitment procedure will also be optimised. Our goal is to reach more young people with lower
levels of depressive symptoms, by recruiting on a broader scale. We will also test the online MINI Plus
diagnostic instrument.

Research objective:
The aim of the research study that parallels the course will be to study the effectiveness of the course
and to identify groups that seem to derive the most and least benefit from the online course in terms of
depressive symptoms (which individual characteristics such as education, motivation predict the
symptom levels after the course and hence identify the most appropriate target groups).
Another aim is to ascertain whether young people with milder levels of symptoms can be sufficiently
recruited and, if so, through which channels.

Study design

DESIGN
After adaptation of the course a randomized controlled trial with two parallel groups is conducted: the
experimental course *Grip op je dip* vs. a control waiting list.

ASSESSMENTS
Assessments will be made at:
- T0 before randomization
- T1 3 months after T0 (for the experimental group this will be short after the last session)
- T2 6 months after T0.
Participants receive a bonus of 12,50 euro for completing questionnaires at T1 and T2.

NUMBER OF STUDY PARTICIPANTS / POWER
Ten Dutch mental health care agencies have committed themselves to conducting the online course four
different times for six participants. This means that a maximum of 10x4x6=240 participants can be
recruited for the study. N=120 per condition is more than sufficient to have enough power (1-bèta=0.80)
in a onesided test of alpha=0.05 (we expect a better outcome of the course compared to the waiting list
control group) to detect a reduction in depressive symptoms of d=0.33 as significant in the analysis.
(Stats syntax: sampsi 0.00 0.33, sd1(1) sd2(1) power(0.80) onesided). These numbers also give sufficient statistical possibilities for the prediction of
the most appropriate target group. Stevens (1996) argues that, in order to obtain a sufficient basis for generalising the results, 15 respondents are needed for every predictor variable in a regression equation. Tabachnick and Fidell (1996) prescribe 104 respondents plus one additional respondent for each predictor variable. As we will include a maximum of 8 predictors, we thus need a total of 120 participants according to Stevens and 112 participants according to Tabachnick and Fidell.

STATISTICAL ANALYSIS
Analyses will be conducted by using Stata (version 9.0) and SPSS (version 14.0)
To identify predictors of clinical outcomes we will perform OLS regressions. To define the outcomes in a
normative context based on clinical notions such as *improved*, *unchanged* or *worsened*, we will
express the depressive symptoms, anxiety and mastery as standardised effect sizes (Cohen*s d). The
classification of effect sizes proposed by Lipsey and Wilson (1993) will then

provide an indication of the
clinical significance of the change. Effect sizes of d=0.32 or higher indicate clinically relevant change,
d-values in the 0.32 to -0.32 range indicate no change, and values lower than 0.32 show negative
change (clinical worsening). This will enable us to differentiate groups that benefited from the
intervention from those that did not. We will then perform logistic regression analysis to identify
predictors of the success or failure of the intervention.
Analyses with regard to effectiveness. These analyses will be based on the intention-to-treat principle.
Missing values at T1 and T2 data will be imputed using either the last-observation-carried-forward
principle or a more advanced method (regression imputation or multiple imputation, both as
implemented in Stata). At T2 the conditions will both have finished the course. This means that T2 data
will not be used to answer the *effeciveness* question, but that it will be used to study effect preservation
at the longer term (for the experimental group) and to study what the outcomes are for the waiting list
condition after finishing the course.

TIME PLAN
Preparation (8 months); Execution (22 months); Data analysis and reporting and adaptation of the Grip
op Je Dip Online course manual (6 months).

Intervention

THE ONLINE INTERVENTION
The online course is based on cognitive-behavioural therapy (CBT), social skills training and
encouragement of pleasurable activities. The shortened version of the course will have five weekly
90-minute basic sessions. This shortened variant will incorporate the essential elements of the course
(CBT-principles and the encouragement of pleasurable activities). The development of this shortened
variant is part of this research proposal. The control intervention is a waiting list control group. The
waiting period is three months.

THE LONG VERSUS SHORT COURSE VARIANT: A COMPARISON
In the original course 5 of the 8 sessions are aimed at the change of behavior, thoughts and feelings and

the encouragement of pleasurable activities. Two sessions aim at enhancing one*s assertiveness and
how to manage conflicts. In the last session the accent lays at how the participant can deal with future
signals of depressed feelings. The original course has the same construction as the face to face Grip op
je dip course (Voordouw e.a., 2001; Van der Zanden e.a., 2006).
The proposed adapted course will consist 5 sessions. The content of these 5 sessions will be derived
from the first 5 and the last session of the original course. On base of experiences of the course leaders
and the feedback of course participants of past courses, the sessions will be slightly adapted.

Study burden and risks

BURDEN ASSOCIATED WITH THE ONLINE COURSE. the online course contains 5 sessions (90 minutes each). Potential participants complete the Center for Epidemiological Studies Depression Scale (CES-D) to assess the severity of their depressive symptoms. Applicants with CES-D scores between 10 and 24 will be admitted to the course; between 24 and 45 will be administered the online MINI Plus (international neuropsychiatric interview) in the chatroom to rule out the presence of severe psychiatric symptoms. We expect that the MINI Plus will be administered in 60 % of the participants. All participants are contacted by e-mail by their course instructor preceding the course.

BURDEN ASSOCIATED WITH THE STUDY. Participants complete a questionaire at three points in time: preceding the course; three months after baseline and six months after baseline. Completing each measurement will take up to 30 minutes (In total 90 minutes for the entire study).

RISKS: We expect no risks for the respondents because:
The particiapants apply voluntary to the course since they have depressive symptoms.
The intervention concerns a course and not a treatment or therapy.
a screening is taken place: adolescents with suicidality or psychosis will be carefully referred.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

INCLUSION:
(1) Age between 16 and 25 years old.
(2) Mild depressieve symptoms:
(-) CES-D score between 10 and 24 represents immediate access to the online course Grip op je Dip (master your mood).
(-) CES-D score between 24 and 45 represents access to the online course Grip op je Dip (master your mood) after suicide risk and psychosis are ruled out by the MINI plus.

Exclusion criteria

EXCLUSION:
(1) Age below 16 or above 24 years old.
(2) CES-D score below 10.
(3) CES-D score between 24 and 45 and in addition suicide risk or psychosis according to the MINI plus.

(4) CES-D score above 45.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	20-05-2008
Enrollment:	228
Type:	Actual

Ethics review

Approved WMO Date:	24-09-2007
Application type:	First submission
Review commission:	METIGG: Medisch Ethische Toetsingscommissie Instellingen Geestelijke Gezondheidszorg (Utrecht)
Approved WMO Date:	20-04-2009
Application type:	Amendment
Review commission:	METIGG: Medisch Ethische Toetsingscommissie Instellingen Geestelijke Gezondheidszorg (Utrecht)

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	NL18984.097.07