

The effect of cognitive behavioral therapy on female sexual dysfunction: A research that compares internet-based with face-to-face therapy

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Objective of the study is to measure Cognitive Behavioral Therapy by means of internet compared to regular face-to-face therapy and waiting list at several types of sexual dysfunctions of women.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Sexual dysfunctions, disturbances and gender identity disorders
Study type	Interventional

Summary

ID

NL-OMON35192

Source

ToetsingOnline

Brief title

The effectiveness of internetbased therapy on female sexual dysfunctioning

Condition

- Sexual dysfunctions, disturbances and gender identity disorders

Synonym

dysfunction related to sexual arousal, female sexual problems

Research involving

Human

Sponsors and support

Primary sponsor: Universiteit Maastricht

Source(s) of monetary or material Support: Virenze Internettherapie;tweedelijns GGZ-instelling

Intervention

Keyword: effect, internetbased, sex, therapy

Outcome measures

Primary outcome

FSFI, FSDS

Secondary outcome

BSI, MMQ

Study description

Background summary

After two year practicing internet-based, sexual, cognitive behavioral therapy it is time to lay the theoretical foundations for an effective internettherapy. There are good results of internetbased therapy, but there is no research done on internettherapy for sexual dysfunctioning.

When we put internet sextherapy into practice we see a demand for working at problems via internet. The question is: "Do the effects of treatment last after a follow-up period of six months?"

The advances of internettherapy is that the client chooses their own safe environment and moments of doing exercises and reports. They have more control over their own process in this way in comparison with a regular face-to-face therapy.

Second is that in internettherapy the main means of communication is writing instead of talking.

The main question of this study is;

Is there a difference in effectiveness between internettherapy, regular face-to-face treatment and a control-/waiting listgroup without treatment.

Hypotheses:

- 1) The effect of cognitive behavioral therapy in internettherapy and face-to-face therapy is larger than without therapy on women with a sexual dysfunction.
- 2) The impact of Internet therapy is just as large as the impact of

treatment-as-usual (face-to-face Cognitive Behavioral Therapy).

Study objective

Objective of the study is to measure Cognitive Behavioral Therapy by means of internet compared to regular face-to-face therapy and waiting list at several types of sexual dysfunctions of women.

Study design

Randomized controlled trial with repeated measurements, between-group- and within-subjects design. The study stretches himself from over a period of 20 weeks with a follow-up period of 20 weeks. The testpersons become doubleblind randomized.

Intervention

The test persons become random ate assigned to several groups. The therapy lasts maximum 20 weeks. During the internet- and the face-to-face-treatment, the test person gets a personal coach and de upportunity to talk to this intaker or personal coach by telephone. There exists the possibility extra of calling in aid of a doctor/seksuoloog and fysiotherapist, during the treatment. Internet therapy (GROUP 1):

The ppn. to get a cognitive behaviour therapy for sexual problems in the form of onlinetreatment with personal accompaniment.

The instructions and exercises are structured in a protocol. The personal speculator or coach (psychologist/seksuoloog) becomes supervised and has a weekly intervision. A psychiatrist, relation- and psychotherapist, doctor/seksuoloog and fysiotherapeut are involved in the treatment if necessary. The coach give feedback on the exercises and accompany the pp. by means of internet one time in a week and monthly a telephone evaluation. On average the pp has two exercises in a week and one report of approximately a half hour.

The coach and the pp. to remain involved motivation mails. Both get reported, if the treatment passes through not well. At insufficiently pass through the pp become approached telephonically.

The Internet therapy offers the ppn. their own Internet portal, My Virenze, in which they have a library with information on sexuality, sexual problems and relation. They receive housework tasks, which are part of behaviour therapy, for example the cognitive behavioral reports and sensate focus tasks. After the report of the exercise by the ppn., the coach gets the possibility of giving feedback. Feedback reads the pp. in My Virenze to continue with a new exercise. The treatment has been built from modules. A module consists of three interventions and a telephone evaluation.

After three modules, respectively aimed at the conscience of the complaint, body perception and relation, the pp goes by to a more intensive form of

treatment, in which the emphasis is laid on skills.

Face-to-facetherapie (GROUP 2):

The ppn. to get standard face-to-face state-of-the-art cognitive behaviour therapy (Hengeveld & Brewaeys, 2002, Brewaeys, 2003). The treatment exists from maximum ten conversations with the same contents, as the Internet therapy.

Waiting list (GROUP 3):

The waiting list period lasts 12 weeks. After each treatment the participants themselves choose for the Internet therapy or face-to-face-therapie.

Study burden and risks

The questionnaires are already a component fixed of the treatment at the institution, like the follow-up measures. The measuring at follow-up can as extra work be considered, because one is already done with treatment and it is nevertheless still faced with the period of sexual problems. When the test person is dissatisfied with the results, then it is possible that the therapist offers a new treatmentplan in consultation with the test person.

It is possible that test persons go elsewhere in psychological treatment during the follow-up period. For this must be checked at the follow-up measuring.

There is also a check for the training and experience level of the personal mentor by means of the integrity test at end measuring.

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

Heterosexual women with sexual arousal related problems, according to the definition of Laan (Gijs e.a. 2004 blz. 370-373). Referring this definition, sexual arousal includes not only the disruption of genital change in terms of genital lubrication, like described in the DSM-IV. On the base of this definition all women with hypo sexual desire disorder, problems with sexual arousal and orgasm disorder will be include.

The women are at least three month complaining about the sexual dysfunction. It is possible that they had already help for sexual dysfunctioning. Subjects can use a contraceptive pill.

Exclusion criteria

Contra-indicators are: primary psychiatric problems on ax 1 or 2 of the DSM-IV-RT (Gijs e.a. 2004 blz. 561-577 en 609-613; van Lankveld 2009), a moderate to severe depression, BDI score > 18, the cause of the dysfunction is found in a disease, use of medication, fysical defect, pregnancy or severe relationship problems (score > 35 on the relationdyssatisfactionscale of the MMQ).

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL	
Recruitment status:	Recruiting

Start date (anticipated):	02-07-2010
Enrollment:	120
Type:	Actual

Ethics review

Approved WMO	
Date:	02-07-2010
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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
Other	1889
CCMO	NL24345.068.08