Research into the efficacy and cost-effectiveness of short term, cost free and anonymous sex counselling to improve (mental) health (including development of protocol and training plan)

Published: 27-08-2009
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This project has three objectives:1. DevelopmentThe development objective is to prepare the implementation of this preventive intervention on the onehand by developing and accommodating protocols for sex counselling in the important fields of...

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

Summary

ID

NL-OMON33018

Source
ToetsingOnline

Brief title
Brief sex counselling to improve (mental) health

Condition

- Sexual dysfunctions, disturbances and gender identity disorders

Synonym
Adolescent sexual problems, dysfunction related to sexual desire/arousal/orgasm/pain

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: ZonMW

Intervention

Keyword: (cost-)efficacy, Adolescents, Brief sex counselling

Outcome measures

Primary outcome

Questionnaire for the Screening of Sexual Dysfunctions (QSSD), Female Sexual Functional Index (FSFI), International Index of Erectile Function (IIEF), Kostenvragenlijst, Credibility/Expectancy Questionnaire (CEQ), Medical Outcomes Study 36-item Short Form Health Survey (SF-36), Brief Symptom Inventory-18 (BSI-18), Center for Epidemiologic Studies Depression scale (CES-D) en Self-Esteem and Relationship Questionnaire (SEAR)

Secondary outcome

Demographic- and Biographic information

Study description

Background summary

After providing brief sex counselling sessions for two years now, it is time to confirm its effectiveness with scientific research.

It is expected that this type of treatment can prevent more serious and chronic problems in the future, as well as sexual aspects as other mental health aspects. Furthermore it is thought that a part of the current patients with sexual problems could be treated with a less expensive, low threshold treatment, like brief sex counselling. The question is if there is a difference in (cost-)effectiveness of brief sex counselling in comparison with an intensive sexological treatment and a control group/waitinglist.

Study objective

This project has three objectives:

1. Development
The development objective is to prepare the implementation of this preventive intervention on the one
hand by developing and accommodating protocols for sex counselling in the important fields of sexual
health (sexual and relational problems, STI and reproductive health) and on the other hand to develop a
plan for a training of nurses and public health workers to acquire additional expertise in sex counselling.

2. Research into the effects on (sexual) health
The aim of the research is to establish the impact on somatic, mental and sexual health of the new
preventive intervention, sex counselling.

3. Research into the cost-effectiveness
The aim of the economic evaluation is to examine if the new intervention is preferable in terms of costs,
impact and utilities from a social perspective.

Study design

The kwantitative study phase is a Randomized Controlled Trial (RCT) with repeated measures (pre- and post intervention), between-group and within-subjects design. The study stretches over a period of 20 weeks with a follow-up periode of 6 months. There is an open randomization procedure.

Intervention

Brief sex counselling: the counsellor reviews the participant*s sexual problem in maximally three 45
minute sessions and aids the participant in managing or resolving the problem, or refers to more
specialized help.
Intensive sexological treatment: a (NVVS-) certified sexologist who works in a specialized mental health
care setting has a maximum of 10 contacts with the participant within a designated time frame.
Waiting list: in this period no help is offered; upon termination of the waiting period the participant can choose between brief sex counselling or sexological treatment.

Study burden and risks

The participants have to fill in questionnaires (approximately 220 minutes).
There is a chance that the testperson will be allocated to the waitinglist period. After this period (26 weeks) they can choose between the two treatment interventions.

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 men and women with sexual problems, with or without a partner, between the age of 18 and 25.

Exclusion criteria

Contra-indicators are primary psychiatric problems on ax 1 or 2 of the DSM-IV-RT, the cause of the dysfunction is found in a disease, use of medication or physical defect.

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-10-2009
Enrollment:	450
Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO Date:	27-08-2009
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	09-11-2009

Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	14-04-2010
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	02-06-2010
Application type:	Amendment
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
CCMO	NL28205.068.09