The Impact of Psychological and Medical Factors on Quality of Life in Women with Systemic Lupus Erythematosus (SLE), Systemic Scleroderma (SS) and Mixed Connective Tissue Disorder(MCTD).

Published: 17-05-2010
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to identify high risk groups in need for more specific and appropriate guidance. Also to provide adequate counselling and help.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Autoimmune disorders
Study type	Observational non invasive

Summary

ID

NL-OMON34638

Source
ToetsingOnline

Brief title
Quality of Life of women with SLE, SS and MCTD.

Condition

- Autoimmune disorders

Synonym
lupus, systemic lupus erythematosus

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit van Tilburg
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: auto-immune disease, medical factors, psychological factors, quality of life

Outcome measures

Primary outcome

Quality of life

Secondary outcome

psychological factors: stress, psychopathology and cognitive coping;

medical factors: disease and medication

demographic factors

Study description

Background summary

To identifying psychological and medical factors that influence quality of life of women with SLE, SS or MCTD.
Which factors have an influence on quality of life of these women?
* medical factors:
o disease,
o and medication;
* psychological factors:
o cognitive coping (monitoring versus blunting),
o psychopathology,
o distress;
* demographic factors: age, socioeconomic class, ethnicity, education/occupation, religion, having children, and marital status.
Already 50 women have notified that they are willing to participate in this design. They were approached through a message that was placed on both the NVLE internet site and the patients magazine. When given approval by the Medical Ethics Committee of the St. Elisabeth Hospital, they will receive an information letter together with an informed consent. After informed consent,

they will be asked to complete a set of questionnaires, which takes approximately 30 minutes. These questionnaires include a demographic questionnaire for e.g. information regarding medicine use , the *Impact of Event Scale* for (symptoms of) distress, the *Threatening Medical Situations Inventory* for cognitive coping, the *SCL-90* for psychopathology and the "WOHQOL" for measuring quality of life.

Study objective

to identify high risk groups in need for more specific and appropriate guidance. Also to provide adequate counselling and help.

Study design

explorative design with 5 questionnaires

Study burden and risks

Subjects must fill in a set of 5 questionnaires, which will take approximately 30 minutes

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

Women with SLE, SS or MCTD

Exclusion criteria

Women with other auto-immune diseases

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-06-2010
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO

Date:	17-05-2010
Application type:	First submission

Review commission: METC Brabant (Tilburg)

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	NL30488.008.10