Verzameling van gegevens over mondgezondheid gedurende een marinemissie van vier maanden.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON21281

Source
Nationaal Trial Register

Brief title
OHMIR

Health condition

Microbiome shifts, Mucosal inflammation, Periodontal health, Gingival inflammation, Stress, Oral parafunctions

Sponsors and support

Primary sponsor: ACTA Dental Research B.V. (ADR)
Gustav Mahlerlaan 3004
1081 LA Amsterdam, NL
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Source(s) of monetary or material Support: Ministerie van Defensie

Intervention

Outcome measures

Primary outcome

The main study parameter and indicator of oral health is bleeding of the gingiva on probing (BOP; gingival inflammation).

Secondary outcome

- Number of self-reported pain complaints

- Presence or absence of dental plaque per site and dental plaque coverage percentage

- Dental pocket probing depth (in mm) and gingival recession (in mm)

- Presence or absence of aphthous lesions, mucosal ulcerations or other forms of mucositis;

- Presence or absence of peri-oral inflammation (herpetic ulcers or angular cheilitis)

- Presence or absence of old / pathogenic (red fluorescent) dental plaque and the coverage percentage of red fluorescent dental plaque (RFP)

- Number of decayed, missing or filled surfaces

- General health

- Abdominal girth

- General living and sleeping habits

- Validated Perceived Stress Scale

- Smoking habits

- Food and drinks intake

- Presence or absence of arthrogenic or myogenic temporomandibular joint problems

- Objective and subjective assessment of bruxism (grinding and/or clenching)

- Subjective assessment of bruxism

- Composition of the plaque microbiome

- Acid production of the dental plaque

- Nitrate metabolism of the dental plaque

- Protease activity of the dental plaque

Study description

Background summary

Rationale: Oral health problems are a major concern for military personnel, especially when deployed in remote regions of the world. Prior to taking part in a mission, military personnel is required to meet certain standards in oral health status, as outlined in the NATO issued dental fitness protocol. Nevertheless, military dentists frequently report mucosal inflammation (oral ulcers), fungal oral infections and gingival bleeding among personnel during a mission. In scientific literature, also reports can be found of non-military expeditions, reporting increased gingival bleeding, and oral ulcers. It has been suggested that stress, changes in diet and lifestyle along with reduced levels of personal care during mission can lead to deterioration of oral health status, but scientific data about the causes are largely lacking. In addition, it has also been reported that the composition of the oral microbial community is predictive for the development of oral disease under stress.

Objective: The primary objective of this study is to monitor changes in oral health during a 4-month naval mission and once approxemately one month thereafter. The secondary objectives are to correlate possible changes compared to the baseline measurements to lifestyle, diet and stress. Finally, to assess whether microbiome composition can predict changes in oral health or general health.

Study design: prospective observational cohort study

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: the burden exists of seven site visits of about 30 minutes. Examinations are non-invasive and do not cause physical discomfort. The subjects will complete one questionnaire per visit, with questions regarding general health, sleep, stress, physical activity, food intake and disorders of the temporomandibular joint. Participation does not benefit the subjects. The risks are negligible. The study is group-related because the research questions can only be answered in a cohort where food, circadian rhythm and stress from the mission assignment are controlled.

Study objective

The primary objective of this study is to evaluate changes in oral health during a 4-month naval mission and once one month thereafter.

Study design

Visit 1 – within the first two weeks of the mission (baseline)

Visit 2 to 4 – every 2 to 3 weeks (average 2.5 weeks) during the mission

Visit 5 – within the last two weeks of the mission (end of mission visit)

Visit 6 – within 9 weeks (± 3 weeks) after the end of the mission

Intervention

This is an observational study, without any interventions.

Contacts

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Eligibility criteria

Inclusion criteria

All Dutch service members participating are declared fit to participate in the naval mission, every service member of the mission is a potential subject. Only with written informed consent a potential subject can participate in this study.

Exclusion criteria

A potential subject that meets any of the following criteria is to be excluded from participation in this study:

- carrier of removable partial dentures

- carrier of a removable night guard

- use of antibiotics three months prior to the mission

- use of anti-inflammatory drugs on a regular basis (NSAIDs)

- adverse medical history or long-term medication

- prescribed medication (except for contraceptives)

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Single blinded (masking used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-09-2017
Enrollment:	100
Type:	Actual

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion

Date:	11-08-2017
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 44394
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL6430
NTR-old	NTR6608
CCMO	NL62301.048.17
OMON	NL-OMON44394

Study results