Observation of oral health and oral microbiome during a 4-month naval mission

Published: 10-08-2017
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The primary objective of this study is to monitor changes in oral health during a 3.5-month naval mission and once one month thereafter.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Ancillary infectious topics
Study type	Observational non invasive

Summary

ID

NL-OMON44394

Source
ToetsingOnline

Brief title
OHMIR (Oral Health MIcrbiome Rotterdam)

Condition

- Ancillary infectious topics
- Lifestyle issues

Synonym
oral health, oral microbiome

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Centrum Tandheelkunde Amsterdam (ACTA)
Source(s) of monetary or material Support: Ministerie van OC&W,Ministerie van Defensie

Intervention

Keyword: fitness, marine, oral health, oral microbiome

Outcome measures

Primary outcome

Bleeding of the gingiva on probing as an indicator of oral health

Secondary outcome

- Number of self-reported pain complaints. Pain is defined as a confirmative answer to the question: Have you had any pain or discomfort from your teeth since the last visit? Pain provoked by warm, cold, sweet, sour or tenderness to touch or chewing.

- Presence or absence of dental plaque per site and dental plaque coverage percentage (mS&L) to provide a general impression of the oral hygiene (good: plaque coverage <20%, moderate: plaque coverage 20-60% and poor: plaque coverage >60%);

- Dental pocket probing depth (in mm) and gingival recession (in mm) to determine the total amount of attachment loss resulting in the presence or absence of clinical attachment loss and the Periodontal Inflamed Surface Area (PISA);

- 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) using a

dedicated single-lens-reflex-camera (Quantitative Light-induced Fluorescence; QLF-camera) and cheek retractors 35;

- Number of decayed, missing or filled surfaces (DMFS);

- Clinical Oral Dryness Score

General health

- General health questionnaire (an extensive questionnaire at visit 1 and 5 short questions during follow-up visits);

- Abdominal girth (change over time from baseline till the end of the mission);

Sleep, stress, lifestyle and diet

- Questionnaire on general living and sleeping habits: score of sleeping habits

- Validated Perceived Stress Scale, questionnaire in Dutch (PSS.nl)

- Smoking habits (smoking (yes/no) and in pack/years) etc.;

- Physical activity at home and during the mission;

- Food and drinks intake frequency questionnaire;

Oral effects of stress

- Presence or absence of arthrogenic or myogenic temporomandibular joint problems using a validated questionnaire on TMJ pain and headache. If an indicator of TMD-pain results from this questionnaire, standardized palpation, dynamic joint tests and static muscle tests will be performed on the temporomandibular joint;

- Objective and subjective assessment of bruxism (grinding and/or clenching) with once a clinical assessment of tooth wear (Tooth Wear Evaluation System,

TWES, 38 and every visit inspection of the soft tissues (tongue/cheek

impressions). -- - Subjective assessment of bruxism by asking every visit

if the subject is aware of bruxism.

Study description

Background summary

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.

Study objective

The primary objective of this study is to monitor changes in oral health during a 3.5-month naval mission and once one month thereafter.

Study design

Prospective observational cohort study

Study burden and risks

No direct benefits are expected for the subjects in joining the study. The risks and burden related to this study are judged to be limited and comparable with regular visits to the dentist. Determination of the oral clinical parameters is part of standard dental care and the collection of the microbiological samples during the research visit do not require invasive procedures. Participation does not benefit the subjects. The risks are negligible. The study is group-related because the research questions are specific for the conditions on board a ship with the ultimate goal to improve

fitness and health on board.

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

All Dutch service members are declared fit to participate in the mission Atalanta. Therefore, every service member is a potential subject.

Exclusion criteria

- carrier of removable partial denture(s)
- 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

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	03-09-2017
Enrollment:	95
Type:	Actual

Ethics review

Approved WMO

Date:	10-08-2017
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO

Date:	22-08-2017
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 21281
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL62301.048.17
OMON	NL-OMON21281

Study results

Date completed:	14-02-2018
Actual enrolment:	99