

Protocol for a multi-centre epidemiological (intervention) study to determine relationships between whole-body vibration (WBV) and health effects

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1. OBJECTIVE OF A MULTICENTRE EPIDEMIOLOGICAL STUDY

The objective of a multicentre epidemiological study is to quantify the relationship between exposure to whole-body vibration and the most important adverse health effects (taking into account various contributing and confounding factors) and to identify whether intervention measures (e.g. changes in exposure or health surveillance) affect the occurrence of adverse health effects.

The multicentre approach will facilitate the inclusion of different occupational groups exposed to similar spectra of vibration but with different vibration magnitudes and duration of exposure, and it will increase the power of the study.

2. STUDY DESIGN

With respect to the required level of evidence but also determined by feasibility in a multicentre setting, the preferred study design to observe the relationship between exposure to whole-body vibration, intervention and adverse health effects is the controlled (prospective) cohort study. The duration of the prospective study will be 4 years.

3. STUDY POPULATIONS

The principal research will involve multi-centre epidemiological studies among different vibration-exposed populations. Emphasis will be on high-risk occupations: drivers of various types of industrial lift trucks, operators of earth moving equipment and other off-road machines, lorry and bus drivers. Control populations will include occupations with a prolonged seated posture and occupations with a low magnitude whole-body vibration exposure, such as taxi- and police car drivers.

4. VIBRATION INJURY NETWORK QUESTIONNAIRE

By an iterative process of group consultation, adaptation and field testing, consensus was reached in the Vibration Injury Network on a questionnaire. The questionnaire was developed based on validated questionnaires and experience in the group. Different versions were designed for health surveillance purposes and for a multicentre epidemiological study. Adapted versions of the information of exposure data (VINET Questionnaire Section 2) were designed for different groups of study and control groups. A translation protocol was used to maintain quality and validity of the questionnaire with use in different languages and an electronic database for collecting epidemiological data was established

5. COLLECTION OF DATA

5.1 Measurement and assessment of whole-body vibration exposure

The *determinants* of WBV exposure will be assessed by:

- information on kind of vehicles or machines driven, driving environment and ground surface, type of driver seat, and behavioural factors like style and speed of driving, adjustment and use of the seat (VINET Questionnaire Section 2 Work environment information)
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The *magnitude* of the exposure to WBV will be determined according to the following procedure:

- measurement and evaluation of WBV exposure under actual operating conditions according to the recommendations of the International Standard ISO 2631-1 (1997)
- estimation of past exposure by the use of exposure data available in (a.o.) the VINET database
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The *duration* of the exposure will be determined by:

- estimation of daily exposure to WBV and total exposure duration from the VINET Questionnaire (Section 2 Work environment information)
- (if available) company records on individual exposure to WBV

The *cumulative measure of exposure severity* will be determined by calculation of various dose measures:

- an equivalent vibration magnitude = $[\Sigma(a_{vi}^2 t_i)/t_i]^{\frac{1}{2}}$ (m/s² rms) where a_{vi} is the frequencyweighted acceleration of vehicle i driven for time t_i in years
- a lifetime cumulative vibration exposure = $\sum a_{vi}^{2} t_{i}$ (year m²/s⁴)
- a personal estimated vibration dose value eVDV = [(1.4 x a_{rms})⁴ x t]^{1/2} according to the British Standard BS 6841

5.2 Assessment of adverse health effects

The emphasis of the study is on the occurrence of low back pain and back disorders. The occurrence of health effects will be determined by:

- self-reported data on complaints and symptoms (VINET Questionnaire Section 3 Personal medical history):
 - low back pain or disorders (LBP) including disc herniation or protrusion
 - duration of LBP
 - treatment of LBP
 - sick leave due to LBP
 - back traumas or accidents having required medical advice or treatment
- assessment of severity of pain intensity and disability of LBP by a Visual Analogue Scale (VINET Questionnaire Section 3.6)
- assessment of disability due to LBP by the Roland and Morris Disability Scale (VINET Questionnaire Section 3.7)
- self-reported data on musculoskeletal complaints other than LBP (VINET Questionnaire Section 3.2, 3.3, and 3.4)
- self-reported data on other current and previous ill-health effects (VINET Questionnaire Section 3.5)

In selected groups of subjects or populations, additional health data will be collected by:

- available records from (occupational) health services
- physical examination: assessment of back function, straight leg raising test, neurological tests, Waddell signs (WP1W report Guidelines for whole-body vibration health surveillance)
- imaging techniques (X-ray, MRI, CT)

5.3 Assessment of confounding and contributing factors

The following potential confounding and contributing factors will be investigated:

- personal characteristics: age, height, weight, social economic status, sport and leisure activities, alcohol and tobacco use, annual amount of car driving (VINET Questionnaire Section 1 Personal and general information)
- psychological factors: assessment of the individual's belief about causation and danger of work as a cause for LBP by the Fear-Avoidance Beliefs Questionnaire (VINET Questionnaire Section 3.8)
- psychosocial aspects of work: perceived mental stress and work satisfaction (VINET Questionnaire Section 4 Work satisfaction)

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- manual handling and lifting tasks (VINET Questionnaire Section 2 Work environment information)
- postural load: assessment of frequency and duration of prolonged sitting, bending forward, twisting and lifting in awkward postures (VINET Questionnaire Section 2 Work environment information)
- previous work environment information

In selected groups of subjects or populations, additional data on postural stressors will be collected by:

observation and objective evaluation of working postures

6. DATA ANALYSIS

Collection of the data will take place at three different occasions at one year intervals. The principal independent variables are the WBV exposure characteristics and the potential confounding and contributing factors. The occurrence of low back symptoms is the major dependent variable.

In selected groups of subjects or populations, intervention (e.g. by active health surveillance) will be applied. In these cases also behavioural changes affecting WBV exposure or other independent variables will be analysed as a dependent variable.

The statistical analysis will include at the minimum:

- descriptive statistics of groups and testing for differences with *t* test, chi-square statistic or analysis of variance
- cross correlation between independent variables
- univariate logistic regression to study the effect of various predictors on the occurrence of low back symptoms
- multivariate logistic regression to assess the association between the dependent variable and the exposure characteristics while controlling for confounding factors

7. STANDARDIZATION OF THE METHODS

All persons performing measurements, tests and physical examination in this multicentre study will be trained according to the same rules. Meeting sessions will be organised prior to the start of the research and at regular intervals during the study in order to insure consistency of the procedure in time and between countries.