ERFURT MALE COHORT STUDY (ERFORT STUDY).
STUDY DESIGN AND DESCRIPTIVE RESULTS

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SUMMARY

Objectives: The main objective of ERFORT Study is to investigate cardiovascular risk factors, lifestyle related factors and psychosocial factors with regard to total and cause-specific mortality and morbidity. This paper describes the study design, frequency data on cardiovascular and psychosocial factors at baseline survey, and findings of three 5 year follow-up medical examinations. Life status was followed for 30 years.

Methods: The Erfurt Male Cohort Study (ERFORT Study) is a population-based prospective cohort study and has its origin in the WHO initiated feasibility study to acquire experience in multifactorial intervention programs. The baseline survey in 1973–75 examined a random population-based sample of 1,160 males aged 35–61 years (brutto response rate 74.6 %) from the city of Erfurt, East Germany.

Results: Standardized and mostly validated methods were applied for a collection of data on cardiovascular risk factors, lifestyle-related and psychosocial factors, blood tests and ECG. Three consecutive follow-up examinations yielded datasets of 907, 740 and 609 subjects' re-examination in 1978–79, 1983–85 and 1988–90. Cardiovascular diseases such as myocardial infarction, angina pectoris, and claudication intermittent approximately doubled within a 15-year follow-up. Prevalence of diabetes strongly increases from 2.8 % at baseline to 12.0 % at the 15-years follow up. High blood pressure (≥160/95 mm Hg) only slightly increased, whereas the antihypertensive treatment increased from 8.7% to 33.6%.

Conclusions: This data set of a German cohort followed for several decades is an outstanding database to answer questions about long-term associations between biological and psychosocial factors and mortality in men.

Key words: cohort, men, cardiovascular risk factors, East Germany, life status

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INTRODUCTION

At the beginning of the 1970s, the WHO initiated an interregional multicenter cardiovascular screening program under the official title ‘Behavioural and Operational Components of Health Intervention Programmes’ (1), which was commonly called the ‘Kaunas Rotterdam Intervention Study’ (KRIS), because this screening program was conducted in the cities Kaunas in Lithuania, and in Rotterdam, The Netherlands. KRIS was a feasibility study to acquire experience in multifactorial intervention and focussed mainly on general methodological problems of intervention studies (2). The objectives and methodological details were described elsewhere (2). Briefly, in each city, a population-based sample of 4,000 males between 45 and 59 years of age were invited for a screening examination in order to select a cohort consisting of men with mildly elevated risk factor levels for cardiovascular diseases. This produced as a one year randomized clinical controlled trial using double blinded methods. Although KRIS was a feasibility study which found positive feasibility results, an extension to a large-scale intervention study was not pursued. KRIS methods (2) were used in a study in the city of Erfurt in the former German Democratic Republic (GDR). Because the KRIS study protocol did not include a common follow-up study, the study conducted in Erfurt had its own follow-up. This study, labelled here as Erfurt Male Cohort Study (ERFORT Study), consists of males living in Erfurt, ideally aged 40-59 at baseline (but really 35–61 years), who were followed for 30 years. There has not yet been any publication on this study in a peer-reviewed journal until 2006, with the exception of a paper by Meisinger et al. (3) on predictivity of disturbed glucose tolerance on long-term mortality. One reason for not publishing any results of this study results from an action of the former German Democratic Republic (GDR). The data of the first two surveys were planned to be published as PhD thesis of the study’s principal investigator. However, he was in prison for one year at the beginning of the 1980s because he was accused of trying to escape from GDR. After that, he received permission to go to West Germany and therefore had no access to the data and contact with the local research team. Another issue regarding publication was the reduced pressure to publish results in international journals in GDR. It was also difficult to get political permission for publishing data in a journal specifically in an English speaking country. Finally, the Medical School of Erfurt where the ERFORT Study was conducted, was shut down shortly after German re-unification; however, a few departments, including parts of the data holding groups, were transferred and joined departments of the University of Jena. Some files of this study
were destroyed or lost, but others were archived there and could be used for data re-entry. Therefore, the study design of ERFORT Study and descriptive data on frequencies of cardiovascular risk factors and psychosocial factors of the baseline survey, the three follow-up examinations and the 30-year life status of participants is described here for the first time.

MATERIAL AND METHODS

Study Area
The city of Erfurt, an administrative and a university centre, became the capital of the state Thuringen in 1990. It was the capital of the Erfurt district before 1990. During the past 30 years about 200,000 inhabitants on average lived in the three main city districts: Erfurt-North, Erfurt-City Centre, and Erfurt-South.

Study Design
The ERFORT Study is a cohort study of men aged 40–59 years at recruitment. There were three follow-up examinations every five years and the mortality of the cohort was recorded. Figure 1 displays the flow of data collection.

Study Population
Using the residential registry and electoral rolls (ADREMA) in spring 1973 a random population sample of 1,600 men was drawn from Erfurt population who lived in the three city districts Erfurt-North, Erfurt-City and Erfurt-South and were born between 1915 and 1934. No exclusion criteria were defined. The first invitation letters were sent out within approximately two years to invite subjects for examination who were between 40 and 59 years old. Those selected subjects who were out of this age range were excluded from the study (n = 46, Fig. 1). Because the residential registry was not up to date in that time and obvious errors in date of births occurred, 43 subjects ages ranging from 35–39, and two subjects aged 60 and 61, were invited for the examination and were then also included in the study. Because data of non-eligible subjects selected for ERFORT were deleted in 1989, we could not re-construct response rates in relation to eligible subjects. This includes subjects who did not die before invitation to the examination, whose addresses were not incomplete, who had not moved before the examination, who were not permanently or temporarily out of the city, and who did not suffer from a serious chronic disease. The percentages of non-eligible persons were 8.5 % in Kaunas and 3.1 % in Rotterdam (2, p. 33). Therefore, we estimated a substantial higher netto response rate also for Erfurt, if non-eligible subjects were considered.

There were two major deviations from the study protocol of the KRIS study: compared with the original age-range of 45–59 years of the KRIS study, the age range of ERFORT population was extended to 40–44 years and the size of the study was reduced to 1,600 subjects.

Medical Examinations
Study subjects were invited to each of the medical examination between 7.00 a.m. and 9.00 a.m. and were asked not to eat or to drink for at least two hours before attending the examination.

Questionnaire Data
An interview-administered standardized questionnaire was applied with respect to family history, subject’s medical history, physical activity (2), psychosocial data were extensively collected using standardized validated instruments to assess personality traits: Freiburger Persönlichkeitsinventar FPI (5), the Jenkins Activity Survey (JAS) (6, 7, 8, 9), Minnesota Multiphasic Personality Inventory (MMPI) (10), psychic disturbances (PSR, 11), physical and mental complaints scale (BFB, 12) and a detailed psychological questionnaire (see details in 13).

Blood Pressure
The blood pressure readings were collected with a random zero Sphygmomanometer in a sitting position after 10 minutes unchanged rest. Two readings were averaged (see details in 2, p. A3). We defined hypertensive subjects as having blood pressure values exceeding 160/95 mm Hg (≥160/95 mm Hg) or taking antihypertensive drugs.

Blood Tests
Blood samples were drawn after fasting for at least two hours preceding the examination.

Total plasma cholesterol was measured according to the HUANG method (14). Plasma glucose was measured by the o-toluidine reaction of Hultman, 1959 (15) and Cooper, 1972 (16). Oral glucose tolerance was tested in all non-diabetic subjects.
The subjects were asked to drink a solution of 75 g glucose in 200 ml herbal tea. One hour later, a venous blood sample was taken without stasis from one arm of the participant while the participant was sitting upright.

Anthropometry

Height was measured by means of a fixed vertical scale with a crossbar which was placed on top of the head, while the subject stood erect, without shoes, with the heels together and the eyes directed straight ahead. Weight was measured by means of a calibrated level balance, while the subject was wearing just underwear. Skinfolds were measured with Harpenden skinfold callipers. The following skinfolds were measured: midway down the upper arm over the triceps muscle (both left and right) and just below the angle of the scapula (left and right). The sum of all four skinfolds was used as a measure of body fatness. Body mass index was calculated and categorized in underweight (< 18.5 kg/m²), normal (18.5 – 24.9 kg/m²), overweight (25.0-29.9 kg/m²), and obesity (≥ 30 kg/m²) according to WHO recommendation (17).

Electrocardiography

Resting ECGs were made using 12 standard leads. The Minnesota Code was used to code the ECGs. The observers were specially trained using the WHO standard package of ECGs.

Measurements in Urine

Glucose, protein, and blood in urine were determined by means of Hemacombistix. The urine sample was requested before the glucose load was given.

Assessment of Life Status

The life status was assessed by the residential registries. The life status could not be assessed only in four subjects who moved to West Germany before 1989 and in addition in seventeen subjects who were alive in 1989.

Statistical Methods

Standard descriptive methods were applied here by using SAS 8.2 software (Cary, NC, USA).

RESULTS

Figure 1 displays the recruitment of 1,160 males (brutto response rates of 74.6 %) the medical follow-up examinations with re-examination rates of 81 % in 1978–79, 72 % in 1983–85 and 66 % in the 1988–90 survey each calculated in relation to the living subjects. After a thirty year follow-up until September 30th, 2003 out of the baseline cohort of 1,160 men, 595 died (three additional subjects after September 30, 2003), 537 were alive and could be traced. The living subjects lived mostly in the city of Erfurt (439), a few had moved outside the city, but lived in East Germany (91), whereas 11 had moved to West Germany. Twenty-one men were lost for follow-up, but they were considered in analyses as alive.

Characteristics of the recruited study participants at the initial medical examination are shown in Table 1. Psychosocial characteristics, self-assessed health problems, and vital exhaustion are depicted in Table 2 and 3. Frequencies of

| Table 1. Characteristics of the ERFORT Study population of 1,160 men aged 35–61 years at baseline survey examined in 1973–75 |
|---------------------|---------------------|---------------------|
| Age                 | nN                  | (%)                 |
| < 50                | 690/1,160           | 59.5                |
| ≥ 50                | 470/1,160           | 40.5                |
| City district       |                     |                     |
| North               | 464/1,132           | 40.1                |
| Center              | 315/1,132           | 27.8                |
| South               | 363/1,132           | 32.1                |
| Educational levela  |                     |                     |
| ≤ 8 grades          | 604/1,156           | 52.2                |
| 10 grades           | 1071/1,156          | 9.3                 |
| 11–12 grades        | 791/1,156           | 6.8                 |
| 13–14 grades        | 2101/1,156          | 18.2                |
| University          | 1561/1,156          | 13.5                |
| Marital status      |                     |                     |
| single              | 671/1,156           | 5.8                 |
| married/partner     | 1,069/1,156         | 94.2                |
| Smoking habits      |                     |                     |
| never               | 1871/1,159          | 16.1                |
| former smoker       | 330/1,159           | 28.5                |
| current cigarette smoker | 583/1,159 | 50.2                |
| current cigar/pipe smoker | 60/1,159 | 5.2                 |
| Relative weight     |                     |                     |
| underweight (BMI < 18.5 kg/m²) | 91/1,158 | 0.8                 |
| normal (BMI 18.5 - < 25 kg/m²) | 386/1,158 | 33.3                |
| overweight (BMI 25 - < 30 kg/m²) | 625/1,158 | 54.0                |
| obese (BMI ≥ 30 kg/m²) | 138/1,158 | 11.9                |

§ Highest achieved educational level (mostly numbers of completed grades)

| Table 2. Psychosocial factor in a population-based sample of 1,160 men aged 35–61 and explored at baseline survey in 1973–75 (ERFORT Study) |
|---------------------|---------------------|---------------------|
| MMPI (n=1,043)      | AM ± SD Median 25–75 Percentile |
| Hypochondriasis (HD) | 8.5 ± 5.7 7.0 4–12 |
| Dependency (Dy)     | 19.3 ± 8.4 19.0 13–25 |
| Lie (L)             | 6.3 ± 2.8 6.0 4–8 |
| JAS (n=1,071)       | Total score 7.0 ± 3.7 7.0 4–9 |
| FPI (n=1,039)       | Nervous (FPI 1) (n = 1,029) 4.9 ± 3.2 5.0 2–7 |
| Aggressive (FPI 2)  | 2.3 ± 2.0 2.0 1–3 |
| Depressive (FPI 3)  | 3.9 ± 2.9 3.0 2–6 |
| Irritable (FPI 4)   | 4.3 ± 2.6 4.0 2–6 |
| Sociable (FPI 5)    | 7.3 ± 2.5 7.0 6–9 |
| Patient (FPI 6)     | 4.1 ±1.7 4.0 3–5 |
| Dominating (FPI 7)  | 3.9 ±2.2 4.0 2–5 |
| Inhibited (FPI 8)   | 3.7 ±2.4 4.0 2–5 |
| Open minded (FPI 9) | 8.0 ± 3.2 8.0 6–10 |
| Extraverted (FPI-E) | 5.8 ± 2.4 6.0 4–8 |
| Labile (FPI-N)      | 4.1 ± 2.4 4.0 2–6 |
| Masculine (FPI-M)   | 5.5 ± 1.9 6.0 4–7 |

§ AM arithmetic mean, SD standard deviation
selected major chronic diseases are displayed in Table 4. Details on frequencies of psychological characteristics and in relation to blood pressure, smoking and impaired glucose tolerance were presented in the unpublished thesis by the Co-PI of the ERFORT Study Michael Geyer in 1977 (13).

Temporal changes of blood pressure levels and blood test results are given in Table 5. Average systolic blood pressure levels substantially increase within the 15-year follow-up from 138.3 to 144.2 mm Hg, whereas average diastolic blood pressure remained unchanged within this time period (88.7 to 87.9 mm Hg). Furthermore, 8.7% of the study population were treated with antihypertensive drugs at baseline survey, 33.6% 15 years later. The prevalence rates of hypertension increased from 30.7% at baseline survey to 46.8% 15 years later. The mean cholesterol levels increased from 199 to 245 mg/dl within the 15-year follow-up period. The survival probability for 5, 10, 15, 20, 25, and 30 years are 97%, 91%, 81%, 70%, 57.3% and 45%.

In order to assess potential participation bias, study characteristics and cardiovascular risk factor levels at baseline survey were compared among participants, living non-participants and dead cohort members (Table 6). Subjects who died during the first five or ten years of the follow up were older, less educated, fewer never smokers, were more frequently underweight, more commonly hypertensive and showed more common 1-hour post-load hyperglycemia. The mean cholesterol levels were not substantially different between dead and living subjects. The distribution of characteristics in the non-participating but living subjects was also

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Table 3. Self-assessed health symptoms/complaints (BFB) (a) and vital exhaustion (b) in a population-based sample of 1,160 men aged 35–61 and explored at baseline survey in 1973–75 (ERFORT Study)

<table>
<thead>
<tr>
<th>a) Health Symptoms/Complaints (BFB)</th>
<th>None</th>
<th>A few (1-2)</th>
<th>Frequent complaints</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cardiovascular (BFB 1) (n = 1,112)</td>
<td>30.2</td>
<td>37.4</td>
<td>32.4</td>
</tr>
<tr>
<td>Parasympathic CV (BFB 2) (n = 1,111)</td>
<td>46.0</td>
<td>42.9</td>
<td>11.1</td>
</tr>
<tr>
<td>Stomach and gut (BFB 3) (n = 1,111)</td>
<td>66.6</td>
<td>28.3</td>
<td>5.1</td>
</tr>
<tr>
<td>Airways (BFB 4) (n = 1,112)</td>
<td>62.5</td>
<td>33.4</td>
<td>4.1</td>
</tr>
<tr>
<td>Skeletal (BFB 5) (n = 1,112)</td>
<td>58.4</td>
<td>41.5</td>
<td>0.1</td>
</tr>
<tr>
<td>Sexual-related disturbances (BFB 6) (n = 1,112)</td>
<td>82.1</td>
<td>17.5</td>
<td>0.5</td>
</tr>
<tr>
<td>Phobic symptoms (BFB 7) (n = 1,112)</td>
<td>6.7</td>
<td>17.7</td>
<td>75.6</td>
</tr>
<tr>
<td>Depressive symptoms (BFB 8) (n = 1,112)</td>
<td>53.8</td>
<td>35.7</td>
<td>10.5</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>b) Vital exhaustion</th>
<th>Very often</th>
<th>Often</th>
<th>Sometimes</th>
<th>Not at all</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tense and nervous (n = 1,062)</td>
<td>20.8</td>
<td>29.4</td>
<td>28.0</td>
<td>21.8</td>
</tr>
<tr>
<td>No worries about job (n = 1,061)</td>
<td>13.9</td>
<td>15.9</td>
<td>30.7</td>
<td>39.5</td>
</tr>
<tr>
<td>Exhausting daily work (n = 1,060)</td>
<td>29.5</td>
<td>39.5</td>
<td>22.7</td>
<td>8.3</td>
</tr>
<tr>
<td>No tension in family relations (n = 1,055)</td>
<td>52.4</td>
<td>24.6</td>
<td>12.2</td>
<td>10.8</td>
</tr>
<tr>
<td>Strong nervous strain in daily work (n = 1,060)</td>
<td>43.6</td>
<td>28.8</td>
<td>17.5</td>
<td>10.1</td>
</tr>
<tr>
<td>Frequent tensions in relationship to other persons (n = 1,061)</td>
<td>3.7</td>
<td>9.7</td>
<td>38.5</td>
<td>48.1</td>
</tr>
<tr>
<td>Total mentally and physically exhausted at the end of the day (n = 1,061)</td>
<td>9.3</td>
<td>32.6</td>
<td>37.4</td>
<td>20.7</td>
</tr>
</tbody>
</table>

Table 4. Selected chronic diseases in ERFORT Study population of 1,160 men aged 35–61 years examined in 1973–75

<table>
<thead>
<tr>
<th>Baseline 1973–75</th>
<th>5 years</th>
<th>10 years</th>
<th>15 years</th>
</tr>
</thead>
<tbody>
<tr>
<td>n/N</td>
<td>%</td>
<td>n/N</td>
<td>%</td>
</tr>
<tr>
<td><strong>Cardiovascular diseases</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Myocardial infarction$ (MI)</td>
<td>48/1,150</td>
<td>4.2</td>
<td>66/903</td>
</tr>
<tr>
<td>Silent MI$</td>
<td>9/1,146</td>
<td>0.8</td>
<td>11/905</td>
</tr>
<tr>
<td>Angina pectoris$ (AP)</td>
<td>94/1,064</td>
<td>8.8</td>
<td>112/906</td>
</tr>
<tr>
<td>Claudication intermittent (CI)$</td>
<td>24/1,157</td>
<td>2.1</td>
<td>29/906</td>
</tr>
<tr>
<td>High blood pressure$</td>
<td>323/1,160</td>
<td>27.8</td>
<td>212/906</td>
</tr>
<tr>
<td><strong>Metabolic diseases</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diabetes mellitus$</td>
<td>33/1,160</td>
<td>2.8</td>
<td>40/907</td>
</tr>
<tr>
<td>1-hour post-load hyperglycemia++</td>
<td>126/1,107</td>
<td>11.4</td>
<td></td>
</tr>
<tr>
<td>Elevated total cholesterol (≥ 216 mg/dl)</td>
<td>350/1,159</td>
<td>30.2</td>
<td>645/904</td>
</tr>
</tbody>
</table>

$ Doctor diagnosis according to medical history
$§ Minnesota codes 1.1 or 1.2 and no doctor diagnosis
$ Typical according to ROSE’s questionnaire
$ BP ≥ 160/95 mm Hg
++ Glucose > 200 mg/dl 1 hour after a 75 g glucose load
different from participants’ characteristics, but less pronounced than the differences between dead and living subcohorts. Therefore, non-participation could not be considered as random. Briefly, subjects with a higher cardiovascular risk tended to refuse study participation or to be lost due to premature death.

**DISCUSSION**

The ERFORT Study is one of the most longstanding population-based cohort studies in Germany. For several reasons this study has outstanding data quality and future analyses of this unique data set will show promising results. Although the methods used at the baseline survey were developed at the early 1970s, these standardized questionnaire-based instruments currently represent the state of the art. This holds true for the standard questionnaire on angina pectoris, potential myocardial infarction and claudication intermittens developed by one of the fathers of Cardiovascular Epidemiology, Geoffrey Rose (4). These instruments are still used in currently ongoing international studies (18, 19).

Also the recommended questionnaires on smoking, alcohol consumption and physical activity published in the standard book on Cardiovascular Survey Methods (4) were applied to the base-
line survey. These methods are considered as valid instruments in epidemiology nowadays. However, the ERFORT Study has the clear limitation of the cardiovascular focus.

The ERFORT Study shares a major limitation with several other cardiovascular risk factor studies of the 1960s and 1970s, such as for example the Goteborg Study and the Seven Countries Study (20, 21): the restriction to men.

The medical examination including blood pressure measurements and highly standardized coding of ECG changes according to the Minnesota coding also followed recommendations which are similar to the codings today (4). Already 30 years ago ERFORT Study was conducted according a written study manual (1), which was carefully translated into German and typed in 30 copies for the field workers. Today one would label these materials as standard operating procedures (SOP’s). External experts (Ed Dowd, Pekka Puska, Dusan Grafnetter) assured the quality of the field work by site visits. The baseline survey remained the same and the core questionnaires and methodology on blood pressure measurement and ECG recording were not modified within the follow-up examinations. In the ERFORT Study an increase in the measurements and ECG recording were not modified within the follow-up of several decades.

A strength which makes ERFORT Study unique is the comprehensive involvement of psychological and psychosocial inventories, again mostly validated and standardized shortly before beginning the field work. The basic papers for FPI, and JAS, and BFB were published only one to three years before launching the baseline survey. Although the initial PI could only supervise the cohort until 1980, the succeeding PI and several other members of the study teams including all study nurses were steadily involved in all of the four surveys.

A further strength of ERFORT Study is the fairly high participation rate at the baseline survey and high re-examination rate of 66 % also 15 years later. The numbers of lost due to follow-up until 1989 were extremely low. Only four subjects could not be traced until 1989. Also after German re-unification the life status of only 21 participants including the four subjects could not be gathered. With exception of those few people the life status of this 30 year follow-up cohort could be determined.

We concluded that the data of ERFORT Study revealed excellent data quality. This outstanding data base will answer questions on very long-term associations between biological and psychosocial factors and mortality in men. Thus, the ERFORT Study constitutes a valuable extension to other population-based German studies (24-27).

Acknowledgement
The professional fieldwork during two decades is deeply acknowledged. The representatives of the study physicians are PD Dr. Hartmut Holtz and PD Dr. Klaus-Dieter Dück, who examined together with the PI (G. S.) of the study a large fraction of the study populations and who were involved also in the follow-up programs. The blood tests were conducted by supervision of Prof. Dr. Peter Koehler. The program on psychosocial factors were supervised and conducted by Prof. Dr. M. Geyer, Dr. E. Kunzendorff, Edeltraud Bartel, Klaus Andrzejak, Dr. Katja Limpert, Dr. Günter Stübe, and Helma Bürger. Furthermore, we thank the study nurses Margrit Ullmann, Margot Langelotz, Anke Binding, and Siglinde Litzrodt as well as the team assistant Margret Remke and data manager Elke Siegemund, and Terinka Baldwin for their extremely cautious work. The editing work by Marie Cox and the writing of the manuscript by Gina Gillig are much appreciated. The authors acknowledge the institutional support of the directors of the department of the Erfurt Medical School, Department for Preventive Cardiology, Prof. Dr. Joachim Knappe, and of the GSF-Institute of Epidemiology, Prof. Dr. Dr. H.-Erich Wichmann.

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