EUROACTION PLUS:

A randomised controlled trial on preventive cardiology programme plus intensive smoking cessation with Varenicline for vascular and high CVD risk smokers and their partners

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European Guidelines on Cardiovascular Disease Prevention in Clinical Practice

- Prevention and management of smoking
  - Assess smoking status at every opportunity
  - Encourage all smokers to permanently stop smoking all forms of tobacco
  - Physician’s advice is most important factor in initiating smoking cessation process
  - Pharmacological agents are effective in aiding smoking cessation

EUROASPIRE III: Prevalence of smoking in coronary patients at interview

* Self-reported smoking or CO in breath > 10 ppm

EUROASPIRE III: Prevalence of smoking in people at high CVD risk

* Self-reported smoking or CO in breath > 10 ppm

From EUROASPIRE to EUROACTION

• RCT in 8 countries, 24 centres, with 8657 subjects
• To investigate whether a nurse-coordinated, family-based preventive cardiology programme could improve preventive care in clinical practice
• Lifestyle (smoking, diet, physical activity), blood pressure, lipids and glucose management and use of cardioprotective medication
• CHD patients and high CVD risk people assigned to intervention programme (INT) or usual care (UC) in hospitals and general practice with clinical follow-up at 16-week and 1 year

EuroAction: Coronary Patients

A higher proportion in the INT group were not smokers at 1 year compared with the UC group

+10.4% (–0.3% to +21.2%), p = 0.06

*Validated breath CO concentration <6 ppm

General Practice
The proportion of non-smoking high-risk patients did not differ between the INT and UC groups at 1 year

+0.8% (−13.1% to +14.7%), p = 0.89

*Validated breath CO concentration <6 ppm
Can we do better?
EUROACTION PLUS

Aim

The aim was to determine in high medical risk smokers if a nurse-led, family based preventive cardiology programme (EUROACTION), with an intensive smoking intervention including optional use of Varenicline, could achieve greater smoking abstinence and improved lifestyle and risk factor control in vascular patients, people at high risk of developing atherosclerotic disease, and the partners of both, in everyday clinical practice.
EUROACTION + Intensive Smoking Cessation with Varenicline

UK

Italy

Netherlands

Spain
Study Population

Vascular patients and partners

Patients (18 – 80 years) with a new or recurrent diagnosis of coronary or other atherosclerotic disease, and who are smokers

High vascular risk people and partners

Men and women (50 - 80 years) at high multifactorial risk (hypertension/dyslipidaemia/diabetes) and who are smokers
Study Design

20 General Practices

Randomisation of individuals

INTERVENTION

USUAL CARE

Initial Assessment

PATIENTS

PARTNERS

Intervention

PROGRAMME

16 weeks

16 weeks assessment

PATIENTS

PARTNERS

PATIENTS

PARTNERS
The EUROACTION PLUS preventive cardiology programme

A nurse led multidisciplinary family based programme for vascular patients, high risk individuals and their partners

- Focus on smoking cessation
- Optional Varenicline to assist quit attempts
- Comprehensive lifestyle and risk factor management
Smoking Cessation Management

Varenicline

Start: 1 week before the patient’s chosen quit date

Titration:
0.5 mg: days 1 to 3
0.5 mg twice per day: days 4 to 7
1 mg twice per day: trough week 12

Target quit date: within 4 weeks of starting Varenicline
Intention to treat analysis based on all people having a 16-week assessment
Outcome Measures

- **Primary outcome**: 7-day point prevalence of abstinence validated by breath CO (< 10 ppm) at 16 weeks

- **Secondary outcomes**: (European goals)
  - Diet (Mediterranean diet score, food habit questionnaire)
  - Physical activity (7 day recall, pedometer, Chester step test, DASI and SF36 FLP)
  - BMI ≤ 25 kg/m², waist circumference < 94 cm men, 80 cm women
  - BP < 140/90 mmHg (<130/80 mmHg diabetes and or CHD)
  - TC < 4.5 mmol/l, LDL-C < 2.5 mmol/l
  - Glucose < 6 mmol/l

- Cardio-protective drug therapies

- Health Related Quality of Life (Euroqol EQ-5D, Anxiety and Depression HADS)
Study Participants

N=696 Eligible patients
- N=559 High-Risk patients
- N=137 Vascular patients

EA+ ARM
N=350 patients
- N=276 High-Risk patients
- N=74 Vascular patients

Baseline assessment
N=328
- N=313 Participated in EA+

16-weeks assessment
- N=299 85.4%

USUAL CARE ARM
N=346 patients
- N=283 High-Risk patients
- N=63 Vascular patients

16-weeks assessment
- N=288 83.2%

N=346 Primary endpoint  N=335 Primary endpoint
## Distribution of patient characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Usual Care N=346</th>
<th>EuroAction+ N=350</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Mean age</strong></td>
<td>60.4 yrs</td>
<td>59.6 yrs</td>
</tr>
<tr>
<td><strong>Aged &lt; 60 years</strong></td>
<td>47.6%</td>
<td>51.1%</td>
</tr>
<tr>
<td><strong>Women</strong></td>
<td>39.6%</td>
<td>41.1%</td>
</tr>
<tr>
<td><strong>Vascular patient</strong></td>
<td>18.2%</td>
<td>21.1%</td>
</tr>
<tr>
<td><strong>Low education</strong></td>
<td>26.6%</td>
<td>25.3%</td>
</tr>
<tr>
<td><strong>Not employed</strong></td>
<td>43.5%</td>
<td>44.0%</td>
</tr>
<tr>
<td><strong>Centre</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Italy</td>
<td>15.3%</td>
<td>14.9%</td>
</tr>
<tr>
<td>Netherlands</td>
<td>25.4%</td>
<td>24.3%</td>
</tr>
<tr>
<td>Spain</td>
<td>32.7%</td>
<td>34.0%</td>
</tr>
<tr>
<td>UK</td>
<td>26.6%</td>
<td>26.9%</td>
</tr>
</tbody>
</table>

*primary school or less; **unemployed, house person or retired
Smoking abstinence for last 7 days confirmed by breath CO <10ppm

PRIMARY ENDPOINT

Odds Ratio (95% CI) = 4.52 (3.20 to 6.39)
Smoking abstinence for last 7 days confirmed by breath CO <10 ppm

<table>
<thead>
<tr>
<th>Group</th>
<th>EA+</th>
<th>UC</th>
</tr>
</thead>
<tbody>
<tr>
<td>All patients</td>
<td>51.2%</td>
<td>18.8%</td>
</tr>
<tr>
<td>Vascular patients</td>
<td>48.6%</td>
<td>20.0%</td>
</tr>
<tr>
<td>High Risk patients</td>
<td>51.8%</td>
<td>18.6%</td>
</tr>
<tr>
<td>Italy</td>
<td>51.9%</td>
<td>14.0%</td>
</tr>
<tr>
<td>Netherlands</td>
<td>57.8%</td>
<td>29.8%</td>
</tr>
<tr>
<td>Spain</td>
<td>53.0%</td>
<td>17.1%</td>
</tr>
<tr>
<td>UK</td>
<td>42.6%</td>
<td>13.3%</td>
</tr>
<tr>
<td>Male</td>
<td>53.2%</td>
<td>22.7%</td>
</tr>
<tr>
<td>Female</td>
<td>48.2%</td>
<td>12.9%</td>
</tr>
<tr>
<td>Aged &lt; 60 years</td>
<td>50.8%</td>
<td>16.4%</td>
</tr>
<tr>
<td>Aged ≥ 60 years</td>
<td>51.5%</td>
<td>21.0%</td>
</tr>
</tbody>
</table>

Odds Ratio (95% CI)
Smoking abstinence for last 7 days confirmed by breath CO <10 ppm

**PRIMARY ENDPOINT**

<table>
<thead>
<tr>
<th>Description</th>
<th>Usual Care arm</th>
<th>Intervention arm Not participated</th>
<th>Intervention arm Participated Not completed</th>
<th>Intervention arm Participated Completed</th>
</tr>
</thead>
<tbody>
<tr>
<td>N</td>
<td>N=335</td>
<td>N=34</td>
<td>N=24</td>
<td>N=266</td>
</tr>
<tr>
<td>Smoking abstinence</td>
<td>18.8%</td>
<td>14.7%</td>
<td>16.7%</td>
<td>62.4%</td>
</tr>
</tbody>
</table>

**N=335**

**N=34**

**N=24**

**N=266**
Smoking abstinence for last 7 days confirmed by breath CO <10 ppm
PRIMARY ENDPOINT IN PARTNERS (n=108)

Odds Ratio (95% CI) = 4.67 (1.92 to 11.48)
**Diet**

- **Mediterranean Score ≥ 9**: Usual Care 37%, EuroAction+ 52%
  - Increase: +15.0% (+6.7% to +23.2%)

- **Fish ≥ 20 g/day or oily fish ≥ 3 x/week**: Usual Care 55%, EuroAction+ 64%
  - Increase: +9.4% (+1.2% to +17.6%)

- **Fruit & Veg ≥ 400 g/day**: Usual Care 18%, EuroAction+ 22%
  - Increase: +3.7% (-2.9% to +10.4%)

- **Alcohol ≤ 30 g/day**: Usual Care 80%, EuroAction+ 87%
  - Increase: +6.3% (+0.1% to +12.7%)
On Target*

DASI score ≥ 25

Daily steps ≥ 7500

Chester Step Test

Physical Activity

Usual Care

EuroAction+

+9.0%

+5.5%

+8.4%

+10.5%

+3.7% to +14.3%

-0.3% to +11.4%

-1.1% to +17.8%

+0.5% to +20.4%

* 30 minutes of aerobic exercise at moderate intensity ≥ 5 times/week or 20 minutes of vigorous activity on ≥ 3 days/week
Blood Pressure

- SBP/DBP < 140/90 mmHg
  - Usual Care: 43%, EuroAction+: 52%
  - Change: +9.5%, +1.2% to +17.9%

- AH drug use
  - Usual Care: 53%, EuroAction+: 51%
  - Change: -1.3%, -9.5% to +6.8%

- Therapeutic control of BP
  - Usual Care: 37%, EuroAction+: 42%
  - Change: +4.9%, -6.6% to +16.4%
Serum Lipids

<table>
<thead>
<tr>
<th>Metric</th>
<th>Usual Care</th>
<th>EuroAction+</th>
</tr>
</thead>
<tbody>
<tr>
<td>TC &lt; 4.5 mmol/l</td>
<td>19%</td>
<td>14%</td>
</tr>
<tr>
<td>LDL &lt; 2.5 mmol/l</td>
<td>18%</td>
<td>17%</td>
</tr>
<tr>
<td>HDL ≥ 1 mmol/l</td>
<td>85%</td>
<td>82%</td>
</tr>
<tr>
<td>TG &lt; 1.7 mmol/l</td>
<td>61%</td>
<td>61%</td>
</tr>
</tbody>
</table>
Psychosocial Characteristics

- HADS Anxiety score < 8: 73% (Usual Care) vs 74% (EuroAction+)
  - Increase: +0.3% (range: -7.1% to +7.7%)

- HADS Depression score < 8: 81% (Usual Care) vs 81% (EuroAction+)
  - Increase: +0.8% (range: -5.8% to +7.4%)

- EQ-5D VAS score > 75: 36% (Usual Care) vs 48% (EuroAction+)
  - Increase: +12.0% (range: +3.8% to +20.2%)
Conclusions

- This nurse-led EUROACTION+ preventive cardiology programme reduced smoking by half in high risk patients.
- Smoking cessation was also significantly higher in the partners.
- Patients achieved a healthier diet, increased physical activity levels with no significant increase in weight.
- Blood pressure control was better.
- Quality of life improved.
Co-ordinating and Data Management Centre

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EUROACTION PLUS

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