The impact of community based prevention on quality of life – the necessity to control for general health trends. The Northern Sweden MONICA Study in 2014

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Abstract
Background: The Västerbotten intervention program (VIP), is a public health promotion program in northern Sweden with the aim of preventing cardiovascular disease. Positive effects on risk factors and risk of coronary heart disease have been reported although the evidence is not unequivocal. Since only historical controls have been used, effects from other sources than the program have largely been uncontrolled for and health related quality of life (QoL) has not been evaluated.
Aim: By using the neighbouring county of Norrbotten (NB) as the reference population, we compare QoL in Västerbotten (VB) and in NB.
Method: The Northern Sweden MONICA survey in 2014 examined a random sample from the two counties. QoL was measured with the EQ-5D-3L. In total, 1112 subjects participated aged 40-74 years, 516 in VB and 594 in NB.
Results: Average QoL measured by the EQ-5D-index was 0.798 in VB and 0.811 in NB, a difference of 0.013 (p=0.2, CI -0.009 to 0.036). For subjects aged 45-54 years, the QoL was lower in VB than in NB, a difference of 0.048 (p=0.041; CI 0.002 to 0.0094). In NB, QoL decreased with age, a pattern not seen in VB. Men had higher QoL than women, and university educated had higher QoL than those without university education. EQ-VAS showed similar results. Subjects from NB and from VB did not differ regarding age, gender and level of education.
Conclusion: We found similar levels of QoL in VB and in NB.

Background
Health problems due to lifestyle such as e.g. obesity, unhealthy diets, lack of physical activity and use of tobacco and alcohol are major causes of premature deaths in all high-income countries (1). In the early 1980s, the most northern counties in Sweden, Norrbotten (NB) and Västerbotten (VB), reported the highest mortality rates from cardiovascular diseases in the country. A community based primary care intervention program, the Västerbotten Intervention Program (VIP), was therefore launched in Västerbotten, with the aim of reducing morbidity and mortality from cardiovascular diseases and diabetes (2).
Studies evaluating the effects of the VIP are inconclusive; a report from 2015 draws relatively strong
conclusions regarding reduced mortality from cardiovascular diseases (3) while a report from 2019 concludes that there is no evidence that VIP has contributed to any additional reduction of morbidity and mortality from cardiovascular disease when comparing trends with the three neighbouring counties (4). Still, several studies have evaluated the effects of the Västerbotten program on intermediate outcomes and report improvement on lifestyle parameters such as reducing smoking (5), increasing physical activity (6) and that self-reported health has improved (7), in particular in those with initial poor and fair health. A study of time trends in cardiovascular risk factors in VB, using the MONICA Study, showed a faster improvement in blood pressure and smoking but no difference in the prevalence of diabetes, cholesterol levels or BMI compared to the neighbouring county of NB (8). A methodological limitation with many of these evaluations is that they lack use of reference group. It is therefore not possible to evaluate whether any effects are a result of the intervention program or stemming from other sources that are not controlled for such as secular trends in the general Swedish society, not specific for Västerbotten.

The purpose of this paper is to evaluate if there is a difference in QoL between Norrbotten NB and VB. Our hypothesis is that 20 years of the VIP should have had a health-promoting and disease-preventing effect in VB leading to higher QoL of the population of VB than in NB. By using the 2014 Northern Sweden MONICA population-based survey performed in both VB and the neighbouring county of NB, where no such program has been implemented, we were able to control for general health trends by using NB as the reference population.

Methods

Study setting
The Västerbotten Intervention Program (VIP) based in primary health care, focuses on health promotion by counselling and support for life style change with the aim of reducing morbidity and mortality from cardiovascular diseases and diabetes. The program has been described in full in previous studies (2). Since 1995, all individuals of age 40, 50 or 60, living in VB, are invited to a health examination where e.g. body mass index, blood pressure, glucose tolerance, and blood lipids are measured. The health examination also includes a comprehensive questionnaire covering
lifestyle, socioeconomic- and psychosocial conditions, general health condition, and individual advice by a nurse. Annually, about 6000-7000 health examinations, relatively evenly distributed over the age groups, are carried out in VB (9). The participation rate has varied, with an average of 63 percent participating over the period of 1990-2017(9,10). No similar program has been implemented in NB.

Data
The WHO MONICA was initiated as a multinational project with the purpose of monitoring trends and determinants in cardiovascular disease, it included repeated population-based surveys but no interventions. The Northern Sweden MONICA Study, which has been described in depth elsewhere (11), consists of the northernmost counties in Sweden, VB and NB, see figure 1.

Figure 1 Geographical map of the counties Norrbotten and Västerbotten, Sweden.

In brief, data is collected every 4-5 years by screening a subsample of the general population regarding health status, including cardiovascular disease risk factors. Socio-demographic information about the participants is also collected. In the 2014 MONICA study (12) the subjects were also asked to rate their quality of life. The invited subjects were randomly selected yet stratified for gender and 10-year age groups (25-34, 35-44, 45-54, 55-64, and 65-74). At each data-collection point, a total of 250 men and 250 women from the counties, in each 10-year age group, were invited, a total of 2500 invited subjects. Since the participants of the VIP are 40 years or older, the MONICA data used here has been restricted with 40 years as the lower cut-off.

Results from telephone interviews with the majority of non-participants in earlier surveys did not indicate any significant differences compared to participants; non-participants had somewhat lower BMI, and were more prone to smoke, but had similar levels of educational attainment, compared to participants (13). To investigate the generalizability of the MONICA sample 2014 we compared the VB and NB samples to their regional population averages with respect to age, gender, and education. Results are presented in the following sections. The regional population is defined as the inhabitants residing within the geographical region of VB and NB, year 2014.

Measurements
Quality of life
The EuroQol 5 dimension (EQ-5D) was used to measure the health related quality of life (QoL). The EuroQol 5 dimension is a standardised questionnaire developed by the EuroQol Group (14). The EQ-5D, three level version (EQ-5D-3L), consists of two parts. Part one includes five questions related to each of the five dimensions of health: mobility, self-care, usual activities, pain/discomfort and anxiety/depression. Each dimension has 3 levels: no problems=1, some problems=2, and extreme problems=3. The subject is asked to indicate health status by choosing the most appropriate level for each of the five dimensions. The digits for the five dimensions (ranging from 1-3) are combined into a 5-digit number that describes health state, ranging from 11111 to 33333. The health can be converted into a single index value (EQ5D-index), ranging between 0 and 1, where 0 represents death and 1 full health, by using the UK tariff value set (15).

Part two of the EQ-5D-3L questionnaire consists of a vertical visual analogue scale (EQ-VAS), ranging between 0 and 100, where 0 represents the worst imaginable health state and 100 represents the best imaginable health state. The participant is asked to indicate health status by drawing a line on the scale. The index value (ranging from 0 and 1) as well as the VAS-measure can be used as a quantitative measure of QoL. The EQ-5D-3L is a widely used instrument for measuring QoL and has been shown to have good reliability and validity in the Swedish context (16).

Education

In the MONICA-data, university education is defined as completing an education given at a college or university. In the National Statistics, university education is defined as post-secondary education 3 years or more, that is, a bachelor degree or higher.

Statistical methods

Differences in mean QoL between VB and NB were analysed via Student’s t-test. Potential differences between VB and NB within the five dimensions of health was analysed via the Pearson chi-square test. Determinants of QoL were analysed in a multivariable linear regression model including age, gender and academic degree as explanatory variables. To test if QoL differed between the counties, we performed two multivariable linear regression models with QoL as dependent variable including an interaction term for VB county and age, one model with the EQ-5D-index and one with the EQ-VAS.
The one-way-ANOVA-test, and the welch-test (appendix A, table A3, A4), showed that pooling the two subsamples is appropriate. Results are given with 95 % confidence intervals (CI).

Results

Sample

In the age group 40-74, 1110 of the 1750 invited participated, 516 from Västerbotten, and 594 from Norrbotten, which corresponds to a participation rate of 63 percent.

Table 1 Sample characteristics in comparison with the regional population

| County      | Participants MONICA Mean | Regional population age group:40-74 Mean |
|-------------|--------------------------|----------------------------------------|
| University education (%) | Västerbotten 35 | 19 |
|             | Norrbotten 30          | 16 |
| Proportion women (%) | Västerbotten 49 | 50 |
|             | Norrbotten 53          | 49 |
| Average age (y) | Västerbotten 57 | 57 |
|              | Norrbotten 57          | 57 |

In the MONICA sample, 35% of all subjects from VB, and 30% from NB, have a university education, which is more than in their respective regional population (Table 1)(10). In the MONICA sample, 49% were women in VB and 53% in NB, which is similar to the regional populations (Table 1). The average age was similar between the counties both in the MONICA sample and in the regional populations.

Health related quality of life – EQ-5D-index and EQ-VAS

Subjects from VB and NB report a mean EQ-5D-index and EQ-VAS of approximately 0.8, with no significant differences between the counties (Table 2).

Table 2 QoL by EQ-5D-index and EQ-VAS stratified by gender and county

| County      | EQ-5D-index Average | EQ-VAS Average |
|-------------|---------------------|----------------|
|             | Mean | Std. Deviation | p-value difference of means; CI | Mean | Std. Deviation | p-value difference of means; CI |
| Västerbotten | 0.80 | 0.19          | 0.2; -0.04 to 0.01 | 0.79 | 0.16          | 0.2; -0.03 to 0.01 |
| Norrbotten  | 0.81 | 0.19          |                      | 0.80 | 0.17          |                      |
| Västerbotten | 0.82 | 0.17          | 0.1; -0.05 to 0.06  | 0.81 | 0.15          | 0.1; -0.05 to 0.01  |
| Norrbotten  | 0.85 | 0.16          |                      | 0.83 | 0.15          |                      |
| Västerbotten | 0.77 | 0.21          | 0.6; -0.04 to 0.02  | 0.76 | 0.17          | 0.6; -0.04 to 0.05  |
| Norrbotten  | 0.78 | 0.21          |                      | 0.77 | 0.17          |                      |

The difference in EQ-5D-index between the counties was 0.01 (p=0.2; CI -0.04 to 0.01) and the difference in EQ-VAS between the counties was 0.01 (p=0.2; CI -0.03 to 0.01). There was no differences between women from VB and NB, or between men in the two counties with respect to EQ-5D nor EQ-VAS (appendix A, table A1). There was however a difference in EQ-5D and EQ-VAS between
men and women in the respective county, women in both counties rated their QoL lower than men (Appendix A, table A2).

No differences in QoL was found between the counties in any of the multivariate models (EQ-5D-index: \( p=0.13 \); CI 0.127 to -0.040. EQ-VAS: \( p=0.11 \); CI 0.109 to -0.035 (Appendix A, table A5).

Differences within the QoL dimensions

Although we do not find any statistically significant difference in QoL between the counties, measured by the global EQ-5D-index or EQ-VAS, we further investigated potential differences between the groups within any or some of the five dimensions of health (mobility, self-care, usual activities, pain/discomfort and anxiety/depression).

Figure 2 EQ-5D-questionnaire questions - distribution of responses (no problems=1, some problems=2, and extreme problems=3), by county

Figure 2 presents the distribution of the responses for the 3 levels of each dimension for each county. Both in VB and NB, the dimensions of pain/discomfort and anxiety/depression are the dimensions rated lowest. We did not find any differences between the counties in any of the dimensions, \( p \)-values ranging between 0.1 to 0.4 (Appendix B, table B1).

Differences within age groups across counties

We have also analysed whether there are any differences in self-reported QoL for different age groups between the two counties.

| Age Group | County     | N   | Mean | Std. Deviation | \( p \)-value difference of means; CI |
|-----------|------------|-----|------|----------------|--------------------------------------|
| 40-44     | Västerbotten | 70  | 0.81 | 0.19           | 0.1; -0.10 to 0.01                   |
|           | Norrbotten  | 65  | 0.85 | 0.12           |                                      |
| 45-54     | Västerbotten | 143 | 0.78 | 0.23           | 0.04; -0.09 to-0.00                  |
|           | Norrbotten  | 176 | 0.83 | 0.17           |                                      |
| 55-64     | Västerbotten | 151 | 0.80 | 0.19           | 0.7; -0.04 to 0.05                   |
|           | Norrbotten  | 189 | 0.79 | 0.22           |                                      |
| 65-74     | Västerbotten | 152 | 0.81 | 0.15           | 0.7; -0.03 to 0.05                   |
|           | Norrbotten  | 164 | 0.80 | 0.20           |                                      |

Table 3 EQ-5D-index by age group and county

Table 4 EQ-VAS by age group and county
The EQ-5D-index in the age group 45 to 54 years was lower in VB than in NB, see table 3. No such pattern was found for the EQ-VAS (Table 4 and appendix C, table C1).

The results from the two multivariable linear regression models, including also an interaction term for Västerbotten county and age, one with the EQ-5D-index and one with EQ-VAS, are given in table 5.

Table 5 Multivariable linear regression model with interaction term between Västerbotten county and age.

| Dependent variable | Independent variables | B     | Std. Error | Sig.  | t     | 95% Confidence Lower bound | 95% Confidence Upper bound |
|--------------------|-----------------------|-------|------------|-------|-------|----------------------------|-----------------------------|
| EQ-5D-index        | Intercept             | 0.915 | 0.048      | 0.000 | 18.995| 0.820                      | 1.009                       |
|                    | No univ.educ         | -0.055| 0.012      | 0.000 | -4.487| -0.079                     | -0.003                      |
|                    | Västerbotten         | 0.064 | 0.011      | 0.000 | 5.569 | 0.041                      | -0.026                      |
|                    | Men                  | -0.002| 0.001      | 0.045 | -2.010| -0.003                     | 0.000                       |
|                    | age                  | 0.003 | 0.001      | 0.035 | 2.113 | 0.000                      | 0.000                       |
|                    | Västerbotten*age     | 0.003 | 0.001      | 0.000 | 2.113 | 0.000                      | 0.000                       |
|                    | Intercept            | 0.882 | 0.041      | 0.000 | 21.382| 0.001                      | 0.002                       |
|                    | No univ.educ         | -0.114| 0.059      | 0.054 | -1.931| -0.230                     | 0.037                       |
|                    | Västerbotten         | 0.056 | 0.010      | 0.000 | 5.734 | 0.037                      | 0.003                       |
|                    | Men                  | -0.001| 0.001      | 0.056 | -1.915| -0.003                     | 0.000                       |
|                    | age                  | 0.002 | 0.001      | 0.091 | 1.689 | 0.000                      | 0.000                       |

The one-way-ANOVA-test, see appendix C, table C2, shows that the variance related to QoL and age differs between the counties. The multivariable linear regression model (table 5) shows that for the EQ-5D-index the interaction term between age and county is implying that the effect of age on QoL differs between the counties. No such effect is found for EQ-VAS.

Discussion

Results

The purpose of this paper was to evaluate if there were any difference in QoL between VB and NB, given that VB has had a community-based health-promoting program for over 20 years. The MONICA data, collected in VB and NB, gives a unique opportunity to use the subjects from NB as a reference population. Both NB and VB share similar socioeconomic and demographic characteristics, as well as a history of having the highest reported mortality rates from cardiovascular diseases in Sweden. The
counties also exhibit similar levels of living- and working conditions, leisure and social life (17). In addition, The MONICA data gives the possibility to study potential differences in QoL between the counties from a societal perspective, rather than its effect on the individuals in the intervention group. The impact of public health promotion programs on public health on a population basis, which is the purpose of the VIP, depends not only on the effectiveness of the health promoting activity, but also on the ability of the program to reach the citizens and achieve long-lasting changes in life-style. With respect to gender and age, there are no large differences between the participants from Västerbotten and Norrbotten, or in comparison with the regional averages as reported by Statistics Sweden (18). Approximately one third of the participants from both Västerbotten and Norrbotten report that they have a university degree, which is a substantially higher proportion than in the regional populations. Since education is positively related to QoL (19), there is a risk that the participants of the 2014 WHO MONICA survey report higher QoL than the general population. University education is however not defined identically in the MONICA survey and in the national statistics, while the MONICA survey defines university education as completing an education given at a college or university, the national statistics includes Bachelor’s degrees and higher. Hence, it is possible that the difference between the sample and the regional population at least to some extent stem from differences in how education is defined in the MONICA survey and national statistics. Since the difference in educational attainment in comparison to the regional average are similar for both counties, and we are interested in the difference between counties, the problems caused by selection bias is likely reduced in this context.

We found no significant differences in health-related QoL between the population of VB, with the health intervention program, and NB, without any similar program. The only previous research where VB is compared to another county, also based on the 2014 MONICA population survey and using similar methods as in this report, reported a faster decline in blood pressure and smoking in Västerbotten but similar trends for diabetes, cholesterol and obesity (8). However, the results are different from a previous evaluation of the impact of the program on self-reported health, in which a significant and positive effect was reported (7). One possible explanation for these contradicting
results is that the previous evaluation was based on the outcomes before and after the program was implemented, and did not compare the outcome with any reference population; they did not control for other factors that may have affected QoL over time, such as general societal trends affecting e.g. physical activity, education, diet, and smoking habits. It should be noted that self-reported health is not the equivalent of QoL as measured by EQ.

Results from the multivariable linear regression models also show that men and university educated report higher QoL than women and those without university education. These results are consistent with findings in the previous literature (20-22).

Even though we do not find any evidence of differences in global QoL as measured by EQ-5D, it is reasonable to expect some of the EQ-5D dimensions to be more sensitive to changes in lifestyle. Positive effects of physical exercise on anxiety and depression, as well as on pain are well documented in the literature (23,24), and since the VIP promotes physical exercise, a higher share of reported “no problems” in the VB sample could be expected within these dimensions if the program has succeeded to increase physical activity in the VB population. However, no differences within any of the EQ-5D dimensions between the two counties were found.

In addition, we tested whether there are any differences in QoL for different age groups in the two counties. It would be reasonable to expect the effect of the program on QoL to increase with age since the aim of the VIP is to prevent future illnesses and the impact of the program on QoL should presumably be more visible as age increases. Also, since all individuals aged 40-60 in VB is invited every 10 years to the health examination, those who are older has had the chance to be exposed to the program during more than one occasion which may increase the probability of improving lifestyle. We do however only find a difference for the EQ-5D-index between the counties in one of four age groups; younger participants in the NB actually have a higher QoL than the participants of similar age in VB. Thus, we do not find any evidence that global QoL is higher in VB, within any EQ-5D dimension or within any specific age group.

Still, although, the results do not support that the VIP has improved QoL, results show that although younger participants from VB have a lower QoL, QoL is not decreasing with increasing age in the VB
sample as it is in the NB sample. Based on the findings in previous studies, in Sweden and elsewhere, health status has generally been found to decrease with age (25,26). The difference found between the counties regarding the relationship between QoL and age could be an indication that the VIP has had some positive effect on QoL.

Policy implications
To break the trend with increasing lifestyle related morbidity and mortality, evidence-based population based preventative measures are needed. To make resource efficient decisions policy makers need information about the outcome as well as the costs of measures available. The main contribution of this study lies in pointing at the importance of controlling for changes in QoL stemming from other sources than the program; i.e. by comparing the population of the intervention area with a similar reference group. However, for broad population-based programs suitable reference groups are often not available (28) and as a result the effect of the program may be over- or undervalued. In such cases it is important for policy makers to be aware of the validity issues stemming from not controlling for possible changes over time in general health trends or lifestyle.

Limitations
One limitation with this study is that we only have one point of measure for the QoL. If data over QoL from multiple points over time had been available, it had been possible to account for any starting point differences between the intervention- and control group. Future MONICA surveys will collect such data and this is an important avenue for future research.

Another limitation is that we are unable to control for possible differences in the share of individuals in the MONICA data having taken part in the VIP and the share of VIP participants in the population of VB at large. The participation rate of the 2014 MONICA study was 63 percent and similar in the two counties, and although this is not significantly different from previous years, a relatively high share of non-participants constitutes a risk of selection bias. However, the subsample from the general population invited to participate in the MONICA study is randomly selected, and has been shown to adequately represent the general population with regard to sociodemographic aspects (13).
Also, although the EQ-5D-3L is found to perform well for many health conditions, there are studies who have questioned the instrument's ability to accurately capture the QoL of the general population (19,27). According to the findings of these studies, the ability of EQ-5D to capture QoL varies by dimension. The domains of self-care and usual activities did not help explaining the QoL significantly in the general population. Adding more dimensions (such as concentration, sleep, and sexual activity) did however only result in small improvements in explaining individual differences in QoL. Hence, although the EQ-5D-3L could potentially be improved, for instance by increasing the number of response levels, the overall conclusion in the literature is that the widely used EQ-5DL-3L is a valid instrument for measuring QoL in the general population.

Another limitation of the study is the potential of spill over effects of the VIP on to the population of NB (and the rest of the country). Finally, the risk of spurious result due to mass comparisons should be noted, i.e. the difference found in a single age group within eight comparisons.

Conclusions
We do not find any difference in QoL between VB and its neighbouring county NB, despite that the population in VB have been exposed to a public health promotion program for over 20 years. Even though no difference is found between the samples on average, the QoL in the VB sample did not decrease with age, which is commonly found in previous studies and in the reference population in NB. It cannot be ruled out that this is a result of the preventative focus of the program together with a repetitive exposure for older participants in VB.

Declarations
Ethics approval and consent to participate
The present study was approved by the Regional Ethical Committee at Umeå University (Umeå, Sweden) 2013, dnr 2013/97-21. Informed and signed consent was obtained from each participant. Consent for publication
Not applicable
Availability of data and material
The dataset cannot be distributed freely as it contains data traceable to individual subjects. However, this can be considered after ethical approved request to the MONICA coordination office at Umeå University, Umeå, Sweden.
Competing interests
The authors declare no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

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Authors’ contributions
ME contributed to the idea for the paper and the conception and design of the data material as present investigator of the Northern Sweden MONICA Study. ES contributed with the statistical analysis. ES and KE contributed with the interpretation of data for the work and drafted the manuscript. All authors critically revised the manuscript, gave final approval, and agree to be accountable for all aspects of work ensuring integrity and accuracy.

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Figures

Figure 1

Geographical map of the counties Norrbotten and Västerbotten, Sweden.
Figure 2

EQ-5D-questionnaire questions - distribution of responses (no problems=1, some problems=2, and extreme problems=3), by county

Supplementary Files

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Appendix A.docx