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Validation of the Chronic Venous Insufficiency Quality of Life Questionnaire in Dutch Patients Treated for Varicose Veins

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Abstract *Background:* The Chronic Venous Insufficiency Quality of Life Questionnaire (CIVIQ) is a disease-specific instrument to measure the impact of chronic venous insufficiency (CVI) on patients' lives. The objective of this study is to test the psychometric properties of the CIVIQ, and to validate the use of the questionnaire translated into the Dutch language.
Methods: A standardised questionnaire, including CIVIQ and Short Form (36) Health Survey (SF-36), was obtained before and 1 month after treatment to all new patients with varicose veins. The feasibility was tested by missing responses and response distribution. CIVIQ scores were compared to the SF-36 scores and between different levels of severity of varicose veins. The CIVIQ's reliability was assessed using Cronbach's alpha and test–retest reliability. The structure was studied using factor analysis. The scores before and after therapy were compared to assess responsiveness.
Results: There was a response rate of 93.5%. None of 20 items missed <10% of responses, but three showed ceiling effect. The CIVIQ correlated well with the physical and moderately with the mental MCS of the SF-36, suggesting a good construct validity of the CIVIQ. The median CIVIQ scores increased significantly with the severity of varicose veins. The CIVIQ showed an excellent internal consistency and an excellent test–retest reliability. The CIVIQ score decreased in 76% of patients after treatment. The results were in accordance with the Norman's rule and showed a median effect size.

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Conclusion: This study confirms the feasibility, validity, reliability and responsiveness of the CIVIQ in patients with varicose veins. The psychometric properties of the Dutch CIVIQ were comparable to the original French version.

Signs of chronic venous insufficiency (CVI) may be found in about half the adult general population and about a quarter has lower-extremity varicose veins.[1] In addition to cosmetic impairment, which may lead to psychological discomfort, common symptoms of CVI and varices are aching, tired feeling in legs, discomfort, oedema, restless legs and muscle cramps. The complications of CVI and varicose veins include eczema, lipodermatosclerosis, 'atrophy blanche', superficial thrombophlebitis and venous ulcers. Not surprisingly, patients suffering from CVI may have substantial health-related quality of life (HRQOL) impairment because of the appearance of varicose veins, the symptoms and complications of CVI.[2] Several studies confirmed that treatment of venous disease improved HRQOL.[3–8] In addition to generic HRQOL instruments, such as the Short Form (36) Health Survey (SF-36) and EQ-5D, which have been used in patients with CVI,[3–5] disease-specific instruments provide more specific information about the impact of CVI and varicose veins on patients' everyday lives. The two most commonly used disease-specific HRQOL tools for varicose veins and CVI are the Aberdeen Varicose Vein Questionnaire (AVVQ)[9,10] and the Chronic Venous Insufficiency Quality of Life Questionnaire (CIVIQ).[2] The focus of the AVVQ is on the presence of symptoms (i.e., pain and itch) and clinical signs (i.e., swelling, discolouration, eczema and ulcer). Only 4 of 13 items address the psychological impact of varicose veins, especially the functioning domain.[11,12] Therefore, the AVVQ reflects the clinical disease severity and less significantly the impact of the disease on a patient's life. In contrast to the AVVQ, the CIVIQ has focussed more on the psychosocial impact of venous disease of the lower limbs (i.e., its effect on everyday life).[2]

The CIVIQ was developed by Launois et al. in 1996.[2] This disease-specific questionnaire demonstrated to be valid, to have an excellent internal consistency, a high reproducibility and a high responsiveness. It appears to be a valuable instrument for assessing improvement in patients' HRQOL in both clinical practice and trials.[13] Although the CIVIQ has been frequently used and is available in 13 languages, it's psychometric properties are not well documented in populations other than the original study.[6,13–19]

The objective of this study is to test several psychometric properties of the CIVIQ in a heterogeneous group of Dutch patients treated for varicose veins.

Methods

Study population

Between October 2008 and March 2009, all new patients, who consulted the departments of dermatology and vascular surgery of the Catharina Hospital (Eindhoven, the Netherlands) for varicose veins, were asked to participate in this study. At their first visits, patients were asked to complete the initial standardised questionnaire (defined as CIVIQ-1). In addition, half of the participants were asked to complete the HRQOL questionnaire again on the day prior to their treatment and return them on the treatment day (i.e., CIVIQ-2). Subsequently, all patients were asked to complete a third questionnaire at their follow-up visit, which was at least 4 weeks after treatment (i.e., CIVIQ-3). Patients' varicose veins were treated by surgical and non-surgical methods or a combination (Table 2). The responsible physician was asked to record the 'C' of the CEAP (Clinical, etiologic, anatomic and pathophysiologic) classification and all performed the treatment for each study patient.

Questionnaire

Together with a standardised questionnaire, which was self-administered and included questions about demographic and disease characteristics, the SF-36 and the CIVIQ (Appendix I) were included at all visits. The 20 questions of the CIVIQ (Table 1) result in a global score and four separate domain scores: physical (items 5, 6, 7 and 9), psychological (items 12–20) and social impairment (items 8, 10 and 11) and level of pain (items 1–4). All questions have a 5-point response category, with higher scores reflecting more severe impairment. Three separate scores can be calculated: a score per item (1–5), a score of each of the four dimensions (0–100) and a global score (value 0–100). Higher scores represent lower HRQOL due to CVI or varicose veins.[2]

The translation of the CIVIQ into Dutch was based on forward–backward translation as recommended.[20] In brief, three translators, all native speakers in Dutch, independently translated the questions and the response options of the English CIVIQ into Dutch. They were instructed to pay attention to conceptual rather than literal equivalence, and to choose words and language constructions that were as simple as possible. The translators were two employees of a registered translation office and a dermatologist. The three resulting independent forward translations were compared and discussed in a group meeting of the three translators. Differences were documented and discussed until consensus was reached regarding the optimal phrasing of the Dutch CIVIQ. This common forward translation was then given to two translators, who were native speakers in English and fluent in Dutch. They each produced a backward translation that was both compared with the English CIVIQ for conceptual equivalence with the original source version. The analysis was documented and necessary adaptations to the Dutch

Table 1 English version of the CIVIQ.

1.	In the past four weeks, if you have felt pain in the ankles or legs, what was the intensity of the pain?
2.	During the past four weeks, to what extent did you feel bothered/limited in your work or your other daily activities because of your leg problem?
3.	During the past four weeks, did you sleep bad because of your legs problems, and how often?
During the past four weeks, to what extent dit your leg problems bother/limit you while doing the movements or activities listed below?	
4.	standing for a long time
5.	climbing stairs
6.	crouching, kneeling
7.	walking briskly
8.	travel by car, bus, plane
9.	housework such as working in the kitchen, carrying a child, ironing, cleaning floors or furniture, doing handy work
10.	going to discos, weddings, parties, cocktails
11.	sporting activities, making physically strenuous efforts
Leg problems can also have an effect on one's morale. To what extent do the following sentences correspond to the way you felt during the past four weeks?	
12.	I feel on edge
13.	I become tired quickly
14.	I feel I am a burden to people
15.	I must always take precautions (such as to stretch my legs, to avoid standing for a long time…)
16.	I am embarrassed to show my legs
17.	I get irritated easily
18.	I feel handicapped
19.	I have difficulty getint going in the morning
20.	I do not feel like going out

CIVIQ version were made. The resulting Dutch CIVIQ was then administrated to 20 patients with venous disease of the lower limbs to provide qualitative testing of readability and comprehension. Because this qualitative testing revealed no problem with the Dutch CIVIQ, it was subsequently administered in the study population to collect data for psychometric analysis (Appendix 1).

The SF-36 is a generic HRQOL instrument and has proven applicability in several areas of disease, including varicose veins.[3–5,7,21–23] The 36 items can be grouped in a mental and physical component scale (MCS and PCS, respectively). We included the SF-36 to test construct validity.

Analysis

Feasibility

The feasibility of the CIVIQ was evaluated by the overall response rate. Item difficulty was present, if 10% or more of the answers of individual items were missing. The score distribution of all individual items was evaluated by assessing their floor and ceiling effects (i.e., 70% or more of the respondents exhibited the worst or best possible score). If an item loaded <0.40 on the main component of a confirmative principal component analysis, it was considered complex.[8]

Patients with three or more missing scores were excluded from the analysis, except from the feasibility assessment. Missing values were replaced by the median of the completed items reported by an individual.

Structure

Before analysis, a confirmative principal axis factoring (PAF) followed by promax rotation was performed to test the structure of the CIVIQ with four dimensions.[19] This PAF analysis reflected 57.18% of the variance of the CIVIQ, but 9 of the 20 items did not load considerably (>0.40) on their original factor, suggesting that the proposed structure of four dimensions was suboptimal. Therefore, in this study, we have focussed on the global score of the CIVIQ and excluded its four subscales.

Reliability

Cronbach's alpha (reflecting the internal consistency of an instrument) was tested using the data from the first pre-therapy assessment and was considered good, if between 0.7 and 0.9. The degree of test–retest reliability was estimated by Spearman correlation coefficients (Ω) of two assessments in the pre-treatment period about 4 weeks apart and was considered excellent, if >0.80.

Validity

The construct validity of the CIVIQ (i.e., how it relates to other HRQOL measures) was tested calculating Ω between patients' CIVIQ scores and the MCS and PCS of the SF-36. To test the convergent validity of the CIVIQ, we assumed that patients with higher level of clinical severity ('C' from the CEAP classification; C1 vs. C2 vs C3-6) should have a significantly higher impact on HRQOL, which was tested using an analysis of variance (ANOVA).

Table 2 Demographic, disease and therapy characteristics of study population (159 patients).

Characteristics	No. of patients (%)
Sex	112 Women (70.4%) 35 Men (22%) 12 unknown
Age, mean (SD, range)	53 years (SD 13.13, range 17—84 year)
'C' of the CEAP classification	
C1	14.5%
C2	37.10%
C3	30.20%
C4	11.90%
C5	3.10%
C6	2.50%
unknown	0.60%
Previous therapies for varicose veins	78 (49.1%)
Sclerocompression therapy	49 (30.8%)
Phlebectomy	8 (5%)
Proximal GSV ligation (with or without stripping)	31 (19.5%)
Endovenous ablation	3 (1.9%)
Foam sclerotherapy	1 (0.6%)
Unknown	10 (6.3%)
Treated in study period	125
Not treated in study period	34
Treatments during the study period (n =)	125
Compression sclerotherapy	43 (27.0%)
Phlebectomy	47 (29.6%)
Proximal GSV ligation (with or without stripping)	20 (12.6%)
Endovenous ablation	35 (22%)
Foam sclerotherapy	22 (13.8%)
Combination	57 (46.4%)
Phlebectomy and GSV ligation	14
Phlebectomy and EVLA	10
Other	3 (2.4%)
Currently affected leg	
Left	38 (23.9%)
Right	33 (20.8%)
Both	78 (49.1%)
Missing	10 (6.3%)
Questionnaire	
1. before treatment	159
2. before treatment, after 4 weeks	73
3. after treatment	115

Responsiveness

Wilcoxon's signed ranks test was used to compare the CIVIQ scores prior to and after therapy, to estimate CIVIQ's sensitivity to changes brought about by treatment. To gauge whether the treatment-related difference in CIVIQ scores was clinically relevant, we used Norman's rule of thumb: if the change in score was more than half a standard deviation (SD) of the distribution of the CIVIQ score prior to therapy, the change was considered clinically meaningful.[24] Effect size (d) was used to measure the strength of the relationship between two variables in a statistical population. Effect sizes (d) were interpreted as follows: $d = 0.2—0.5$ is considered a small effect size, $d = 0.5—0.8$ is considered a medium effect size and $d > 0.8$ is a large effect size.[25] Because C1 varicose veins can be considered a cosmetic condition, Norman's rule of thumb and d were calculated for all patients and those with grades of C2 or more, separately.

The distribution of the global CIVIQ scores was non-parametric; therefore, it was represented by the median and its interquartile range (IQR). The other continuous variables will be presented by a mean and SD. Two sided p-values of 0.05 or less were considered statistically significant. All analyses were conducted using SPSS version 15.0. The Medical ethical committee of the Catharina Hospital (Eindhoven, The Netherlands) granted exempt status for this observational study. All participants provided written informed consent.

Results

Study population

Of the eligible 170 patients with varicose veins who were invited to participate in this study, 159 patients (response rate 93.5%) completed the initial questionnaire (CIVIQ-1). After 4 weeks, 80 participants were requested to complete a second questionnaire before treatment, to assess reproducibility, of whom 73 (response rate 91%) returned the CIVIQ-2. The CIVIQ-3 (i.e., assessment at least 4 weeks after therapy) was completed by 93.5% of the 115 treated patients.

Of the 159 participants, 70.4% were women and the mean age of the study population was 53 years (SD 13.13, range 17—84 years; Table 2). Classified according to C-component of CEAP classification, 14.5% of the participants were classified in 'C1', 37.1% in 'C2' and almost half in 'C3' levels or more. About half of the patients were considered 'treatment naïve' patients, those without previous treatment for varicose veins. The treatment of varicose veins during the study period was predominantly EVLA (and some had surgical ligation and stripping) in combination with phlebectomy and/or sclerotherapy (SCT).

Feasibility

Of the 159 patients who returned the CIVIQ-1, 10 patients (6.2%) did not respond to three or more items. None of the individual items were considered suboptimal as missing responses varied between 0% and 9.4%. However, item 10 ('going out') and 11 ('sports/heavy work') were missing in 8.8% and 9.4% of the participants, suggesting borderline feasibility of these items. Interestingly, 11 patients whose age ranged between 59 and 84 years did not respond to either of these two items, suggesting they were closely related.

Of the 20 items, three items demonstrated a substantial ceiling effect with 70% or more of the respondents indicating the lowest score (item 14 (74.8%); item 18 (79.9%)

and item 20 (84.9%)). This observation suggests that only few patients had the perception to "constitute a burden to others", to "feel disabled" or to "be anxious to meet other people" because of the complaints of their legs. This suggests a poor discriminative effect of these three items for the presence of varicose veins. None of the items showed floor effects.

Structure

PAF analysis showed that extracted of the first factor accounted for 43.7% of the variability of the CIVIQ. The loadings of the 20 CIVIQ items varied between 0.19 and 0.77. Item 16 showed item complexity with a loading of 0.19 on the factor and item 18 was borderline complex with a loading of 0.39.

Reliability

The item responses of the CIVIQ-1 during the first assessment prior to therapy showed an excellent internal consistency (Cronbach's alpha = 0.94). Among the 73 people who completed the CIVIQ twice prior to therapy (CIVIQ-1 and -2), the test–retest reliability of the CIVIQ was also excellent ($\Omega = 0.86$). The median global score of the CIVIQ-1 was 17.50 (IQR 8.13–33.75) and identical to the median score of CIVIQ-2 (17.50; IQR 7.50–33.75).

Validation

The CIVIQ-1 correlated well with the physical component scale (PCS) and moderately with the mental component scale (MCS) of the SF-36 ($\Omega = -0.64$ and $\Omega = -0.42$, respectively) suggesting a good construct validity of the CIVIQ in this population for the physical aspects but less for the mental aspects of having leg complaints. The median CIVIQ-1 scores increased significantly with higher 'C' levels (Fig. 1; $p < 0.001$). After re-grouping the patients, the median scores increased from 15 (IQR 6.25–26.25) to 23.75 (IQR 13.75–35) to 50 (IQR 24.69–65.94) for C0-1 ($n = 23$), C2-3 ($n = 107$) and C4-6 ($n = 28$).

Responsiveness

Of the 115 patients who were assessed prior to and at least 4 weeks after therapy (CIVIQ-1 and CIVIQ-3), the CIVIQ score decreased in 75.65% and increased in 16.52% of participants. The median CIVIQ score prior to therapy was 18.75 (IQR 11.25–33.75) and significantly decreased to 12.50 (IQR 5.00–22.50) after therapy. The mean global score decreased from 23.68 (SD 16.04) to 15.66 (SD 13.20). For all patients, the decrease in the mean CIVIQ score after therapy was 8.02, which was exactly half the SD of CIVIQ prior to therapy and is, therefore, in agreement with Norman's rule of thumb, clinically significant. In accordance with Norman's rule of thumb, effect size of the CIVIQ was 0.50, which is considered a medium effect size, suggesting that the treatment effect on patients HRQOL was clinically meaningful. Restricting the analyses to pre- and post-treatment outcomes in 99 patients, who were graded C2 or more, showed that both Norman's rule of thumb was satisfied (8.42 vs. 7.92) and the effect size increased to 0.53.

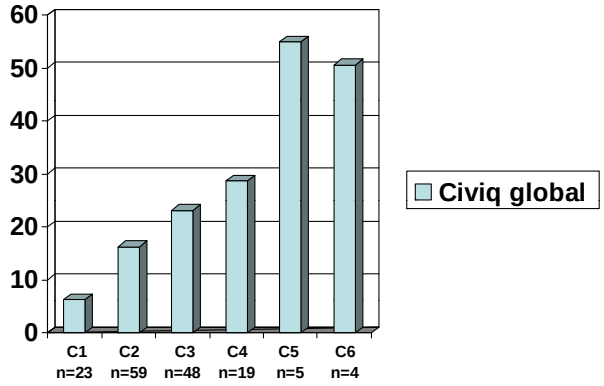

Figure 1 Correlation CIVIQ score and C-component of CEAP-classification. *Explanation*: To test the convergent validity of the CIVIQ, we assumed that patients with higher level of clinical severity ('C' from the CEAP classification; C1 vs C2 vs C3-6) should have a significantly higher impact on HRQOL, which was tested using an ANOVA. The median CIVIQ-1 scores increased significantly ($p < 0.001$) with higher 'C' levels.

Because the impact of therapy on HRQOL impairment may differ between subgroup of patients, we investigated the CIVIQ scores of several subgroups separately. Although both statistically significant and clinically relevant, the median CIVIQ score decreased in a more pronounced manner in the 10 patients who had EVLA plus phlebectomy (from 20.63 (IQR 8.1–34.06) to 11.25 (IQR 1.25–15.93)) than in the 19 patients who had EVLA only (from 25.00 (IQR 16.25–36.25) to 18.75 (IQR 12.50–28.75)). Other therapies in combination (e.g., sclerocompression therapy or cross-ectomy) with EVLA were rare ($n < 5$).

Patients whose both legs were affected by varicose veins were treated bilaterally in one session. The significant and clinically relevant decrement of the median CIVIQ scores of patients treated bilaterally and those treated unilaterally was comparable after therapy (from 16.25 (IQR 8.75–36.25) to 10.00 (IQR 5–22.50) vs. 23.75 (IQR12.50–33.75) to 15.00 (IQR 6.25–28.75)).

Discussion

In this study, we have demonstrated that the CIVIQ is a feasible, valid, reliable and responsive tool in the assessment of HRQOL in patients with varicose disease. However, because the CIVIQ's four dimensional structure could not be confirmed, we recommend using only the global score. It appears to be a reliable instrument but the extremely high internal consistency (>0.90) suggests some item redundancy, which was also observed in the initial validation study.[18]

The change in CIVIQ score after treatment for varicose veins was statistically significant and clinically meaningful, especially among patients with clinical relevant disease (C2 or more, according to the CEAP classification). The tests analysing the responsiveness of the CIVIQ confirm the importance of the concept of minimal clinical important

difference (MCID), which implies that it is insufficient only to compare the HRQOL scores before and after therapy but also estimate the size of the effect and whether it is clinically relevant to the patient.[7] Categorisation of CIVIQ scores using anchor-banding techniques would also be very useful for the interpretation of the scores because it would allow physicians to categorise patients' degree of HRQOL impairment.[8] Moreover, the responsiveness findings suggest that the CIVIQ may not be the most optimal instrument to assess the impact of varicose veins that are a cosmetic problem only. In accordance with other studies, the CIVIQ correlated better with the PCS than with the MCS of the SF-36, suggesting that the CIVIQ reflects the physical aspects better than the mental aspect of having varicose veins.[3–5] Similar findings have been reported for other varicose veins-specific HRQOL tools, such as the AVVQ and the VEINES-QOL.[12,26] This is further illustrated by the finding that the three items exhibiting poor discriminating properties (ceiling effects) were assessing the psychological impact of varicose veins, suggesting that this domain may be less relevant to the majority of patients.

In addition to anatomical success rates, patient-reported outcomes including some adverse events, such as pain, HRQOL, treatment satisfaction and preference are increasingly recognised as meaningful outcomes in comparative clinical trials.[3,5,6] It is recommended to use a generic HRQOL instrument, such as the SF-36, in conjunction with a disease-specific instrument, such as the CIVIQ or AVVQ, because the latter two may provide more specific and detailed information about the impact of varicose veins and the effect of treatment.[8] Both the CIVIQ and AVVQ have now been validated in additional patient populations and are able to assess the impact of varicose veins on patients' lives. The main difference between these tools is that the AVVQ includes multiple items on symptoms, which may affect HRQOL but may be a different construct than HRQOL, and does not fully assess the psychosocial impact of varicose veins compared with the CIVIQ.

In conclusion, this study confirms the feasibility, validity, reliability and responsiveness of the CIVIQ in a Dutch population of outpatients with varicose veins. The psychometric properties of the Dutch CIVIQ were comparable to the original French version.[2,19]

Conflict of Interest/Funding

None.

Appendix 1. Dutch CIVIQ

Nederlandstalige CIVIQ

Veel mensen hebben klachten van onaangename gevoelens in hun benen, al dan niet in samenhang met zichtbare spataderen aan de benen. Met deze vragenlijst proberen wij in kaart te brengen hoe vaak deze klachten zich voordoen en in welke mate ze invloed hebben op het dagelijkse leven van betrokkenen.

De volgende vragen hebben betrekking op deze onaangename gevoelens. Het is de bedoeling dat U elke vraag beantwoordt op de volgende wijze:

Geef aan of u datgene wat vermeld is in de vraag hebt ervaren en, indien dit zo is, in welke mate u hier last van ondervindt op een schaal van 1 tot en met 5. Omcirkel het bij u meest passende antwoord bij de desbetreffende vraag. Het is van groot belang dat alleen waarnemingen van de afgelopen 4 weken worden vermeld en niet van langer geleden.

Waardescore:

1.	Als u zich niet gehinderd voelde door of geen last had van het beschreven symptoom, ongemak of de gewaarwording.
2, 3, 4 of 5.	Als u in meer of mindere mate zich gehinderd voelt door het beschreven symptoom, ongemak of de gewaarwording (5 = meeste last).

1 Hebt U in de afgelopen 4 weken last gehad van pijn in de enkels of in de benen en wat was de ernst van deze pijn

(Omcirkel het meest passende antwoord)

geen pijn	lichte pijn	matige pijn	erge pijn	intense pijn
1	2	3	4	5

2 Voelde u zich in de afgelopen 4 weken gehinderd in Uw werk of andere activiteiten door Uw beenklachten en in welke mate?

(Omcirkel het meest passende antwoord)

geen hinder	weinig hinder	matige hinder	erge hinder	zeer erge hinder
1	2	3	4	5

3 Sliep U de afgelopen 4 weken slecht door Uw beenklachten en hoe vaak?

(Omcirkel het meest passende antwoord)

nooit	zelden	vrij vaak	zeer vaak	elke nacht
1	2	3	4	5

4 In welke mate hebben Uw beenklachten U de afgelopen 4 weken gehinderd bij de onderstaande activiteiten?

(Omcirkel achter ieder item het meest passende antwoord)

		Geen last	Beetje last	Vrij veel last	Zeer veel last	Gaat gewoon niet
4	Lang staan	1	2	3	4	5
5	Traplopen	1	2	3	4	5
6	Knielen of hurken	1	2	3	4	5
7	Snel wandelen	1	2	3	4	5
8	Reizen met tram/bus/ trein/auto/vliegtuig	1	2	3	4	5
9	Huishoudelijk werk zoals (koken, voor kind zorgen, strijken, schoonmaken)	1	2	3	4	5
10	Uitgaan naar discotheek, feesten, recepties, e.d.	1	2	3	4	5
11	Sport en/of zwaar werk	1	2	3	4	5

5 Klachten aan de benen kunnen tevens invloed hebben op de gemoedstoestand. In welke mate zijn onderstaande zinnen op u van toepassing gedurende de afgelopen vier weken?

(Omcirkel steeds het meest bij Uw situatie passende antwoord)

		Niet	Beetje	Vrij vaak	Heel vaak	Altijd
12	Ik voel mij gespannen	1	2	3	4	5
13	Ik ben snel moe	1	2	3	4	5
14	Ik heb het gevoel dat ik anderen tot last ben	1	2	3	4	5
Zie volgende pagina voor de vragen 15 tot en met 20						
15	Ik moet steeds voorzorgsmaatregelen nemen, zoals lang staan vermijden, benen op tijd strekken, benen hoog leggen, elastische kousen dragen, enz. om beenklachten te beperken	1	2	3	4	5
16	Ik schaam me om mijn benen te tonen	1	2	3	4	5
17	Ik raak snel geïrriteerd	1	2	3	4	5
18	Ik voel mij gehandicapt	1	2	3	4	5
19	Ik heb 's ochtends moeite om op gang te komen	1	2	3	4	5
20	Ik heb geen zin mij onder de mensen te begeven	1	2	3	4	5

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