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Psychometric development of the individualised Retinopathy-Dependent Quality of Life Questionnaire (RetDQoL)

Leonie S Brose, MSc, Dipl.-Psych., Clare Bradley, PhD  
Royal Holloway, University of London, London, UK

Corresponding Author: Clare Bradley, Professor of Health Psychology, Department of Psychology, Royal Holloway, University of London, Egham, Surrey, TW 20 0EX, UK

Tel: +44 (0)1784 443708  
Fax: +44 (0) 1784 471168  
Email: c.bradley@rhul.ac.uk

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Keywords: Diabetic retinopathy, Patient-reported outcomes, Psychometrics, Quality of Life, Questionnaire development

Running header: Psychometric development RetDQoL

Abstract [First-level Header]

**Objectives:** Psychometric development of the RetDQoL in a cross-sectional study of 207 German patients with diabetic retinopathy. Forty patients (19%) also had clinically significant macular oedema.

**Methods:** Principal components analyses identified factor structure and Cronbach's alpha assessed internal consistencies. Construct validity was examined by testing the additional impact of macular oedema and expected relationships of RetDQoL scores with visual impairment, stage of diabetic retinopathy, subscales of the SF-12 and scores of the RetTSQ measure of treatment satisfaction. Analyses were conducted using the RetDQoL's AWI score (average weighted impact of diabetic retinopathy on 26 life domains) and its two overview items (present QoL in general and retinopathy-specific QoL). Content validity was investigated using open-ended questions to identify any additional items needed.

**Results:** A forced one-factor solution of the 26 specific weighted impact ratings showed all items except working life (applicable to 27%) to load  $>0.55$  and Cronbach's alpha was 0.96, showing very high reliability. Greater impairment, worse diabetic retinopathy and macular oedema were associated with greater negative impact on scores. AWI correlated as expected more highly with retinopathy-specific QoL ( $r=0.71$ ,  $p<0.01$ ) than with present QoL ( $r=0.28$ ,  $p<0.01$ ). RetDQoL scores correlated moderately with SF-12 subscales ( $r: 0.22 - 0.51$ ,  $p<0.01$ ) and RetTSQ scores ( $r: 0.27 - 0.51$ ,  $p<0.01$ ). For six domains,  $>60\%$  of patients reported no impact. No additional domains were needed.

**Conclusions:** The RetDQoL is valid and reliable for patients with diabetic retinopathy with or without macular oedema. It may be shortened if findings are confirmed cross-culturally.

## Introduction [First-level Header]

Diabetic retinopathy is one of the three leading causes of visual impairment and blindness in developed countries [1] and is the main reason for blindness in the working age population in Germany and other developed countries [2]. It is the most common microvascular complication of diabetes [3]; almost all patients with type 1 diabetes and over 60% of patients with type 2 diabetes develop retinopathy. The development can be classified into stages; non-proliferative or background retinopathy is characterised by retinal vascular abnormalities including microaneurysms and intraretinal haemorrhages, which at first do not have much effect on vision. Non-proliferative diabetic retinopathy can be classified as mild, moderate or severe according to the extent of these abnormalities. If retinopathy advances further, it is classified as proliferative diabetic retinopathy, which is characterised by the growth of new blood vessels on the retina or into the vitreous cavity. These vessels are weak and may bleed, causing a sudden deterioration of vision. At any stage of the condition, macular oedema can occur. Macular oedema is characterised by a thickening of the retina due to leaky blood vessels and impairs central vision [4, 5]. Currently, the main treatments are laser photocoagulation or vitrectomy with efforts to improve glycaemic control and blood pressure control. Treatment reduces the risk of progression of the condition and may increase the chance of a small improvement in visual acuity [3, 5]. Newer treatment approaches include intraocular injections to inhibit the vascular endothelial growth factor (VEGF) [5].

Evaluation of new treatments requires not only assessment of their impact on visual function but also assessment of patients' satisfaction with the treatments and the impact of the condition and its treatment on individuals' quality of life (QoL). Individual quality of life is different from health status and visual function. In asking about health rather than the eye condition, scores on health status measures such as the SF-12 [6] will be affected by comorbid conditions, while respondents may not even consider their eye condition to be an aspect of their health. Similarly, visual function measures such as the NEIVFQ [7] will be influenced by ocular comorbidities. Health status and visual function measures ask about the impact of health or vision on daily activities. They do not take account of the relevance or importance of these activities to the individual. When researching the impact of eye conditions and treatments on QoL, both

the impact of being unable to perform specific tasks and the importance of the tasks to the person need to be considered. While it is reasonable to assume that some aspects of life are universally relevant to quality of life, the weights attached to these have been shown to differ between individuals and within the same person over time following increased severity of the condition or onset of complications [8, 9]. Some aspects such as work or family life may only be relevant to some people. Individualised measures of quality of life such as the RetDQoL are designed to measure the impact of a condition on aspects of life relevant to the individual; relevant aspects are weighted by the individual's ratings of the importance of these aspects of life to their QoL.

The objectives of the current analyses are to evaluate the psychometric properties and to determine optimal scoring of the individualised Retinopathy-Dependent Quality of Life Questionnaire RetDQoL and to explore quality of life in diabetic retinopathy.

## Materials and Methods [First-level Header]

### Procedures [Second-level Header]

The data reported in this paper were collected as part of the multicentre, retrospective 'Cost of Illness Study for Diabetic Microvascular Complications - DIMICO –' in 2002 and 2003. Objectives of the main study phase were to assess the prevalence of stages of diabetic complications, to analyse the resource utilisation due to these complications and to estimate the total annual cost of diabetic microvascular complications in Germany. Health status and quality of life were assessed. Data from over 500 patients were collected after obtaining their informed consent. Participants were adults with diabetes and retinopathy, neuropathy or nephropathy. The present paper focuses exclusively on the subgroup with diabetic retinopathy (n = 207). Demographic information and medical data on diabetes and the history and course of microvascular complications were collected from medical records and an interview with the patient conducted by the physician. Patients completed questionnaires during a visit to the physician

before any treatment or examinations and physicians were asked to check questionnaires for completeness. The following questionnaire measures were used:

- Health status was measured using the SF-12 [6]. The SF-12 consists of 12 items which can be summarised into a physical health summary score (PCS) and a mental health summary score (MCS). Higher scores represent better health.
- Treatment Satisfaction: The Retinopathy Treatment Satisfaction Questionnaire (RetTSQ) consists of 13 items asking participants to rate different aspects of treatment. It can be scored as total score or as two subscales, one covering negative experiences such as side effects and pain and the other one covering positive aspects of treatment such as safety or efficacy. Higher scores represent more satisfaction [10, 11].
- Quality of Life was measured using the RetDQoL [12].

#### The RetDQoL [Second-level Header]

The RetDQoL is designed to measure individualised quality of life in people with diabetic retinopathy and is modelled on the widely used Audit of Diabetes-Dependent Quality of Life ADDQoL [9, 13, 14]. These instruments measure individualised QoL by allowing the participant to indicate where items are not applicable to them and, for applicable items, rate not only the impact of their condition (retinopathy or diabetes) on each aspect of life but also the importance of each aspect of life to their quality of life.

The RetDQoL was designed simultaneously in UK English and German for Germany. Content, wording and format were established in in-depth qualitative interviews with 44 patients in four hospitals, two in the UK and two in Germany. All patients were diagnosed with diabetic retinopathy, 31 also had macular oedema. Methods and findings from these interviews are reported elsewhere [12]. The RetDQoL is written in large font with a layout designed to facilitate reading by those with visual impairment.

#### Overview items [Third-level Header]

The measure starts with two overview items. Overview item I ('present QoL') asks participants to complete the statement 'In general, my present quality of life is:' using a seven-point scale from 'excellent', scored as 3 through 'neither good nor bad', scored as 0 to 'extremely bad', scored as -3.

Overview item II ('retinopathy-specific QoL') asks how QoL is affected by diabetic eye problems: 'If I did not have diabetic eye problems, my quality of life would be:' with the response options: 'very much better' (scored -3), 'much better' (-2), 'better' (-1), 'the same' (0), 'worse' (1).

#### Domain-specific items [Third-level Header]

The RetDQoL further includes 26 items covering different domains of life. The domain-specific items each consist of one part to measure the impact of diabetic eye problems on this domain and a second part about the importance of this domain of life to the individuals' QoL. For wording and scoring of items 1 - 26 as used in this study and the English equivalents see table 1. Some items such as 'working life' include a preliminary question to determine the applicability of the domain to the individuals' life and allow for a 'not applicable' answer. The impact and importance ratings for each applicable item are multiplied to obtain a weighted impact score (WI) with a range from -9 to 3.

#### Average weighted impact score (AWI) [Third-level Header]

A total score, the average weighted impact (AWI) of the condition on quality of life, can be obtained by summing the weighted impact scores of all applicable domain-specific items and dividing the result by the number of applicable domains. This is justified if factor analysis indicates that all domain-specific items measure one overall construct.

The RetDQoL finishes with an open-ended question that asks whether diabetic eye problems affect QoL in any way not already covered by the questionnaire. The data analysed here were obtained using the 2001 German for Germany version of the questionnaire; a few changes have been made to the

questionnaire since then (see discussion). However, structure, layout and general content have stayed the same.

## Analyses [Second-level Header]

Statistical analyses were conducted using SPSS 12.01 and 14. Principal components analyses with Varimax rotation were carried out to identify possible subscales. The 26 domain-specific items were included and 'not applicable' answers for items 6, 8, 12 and 13 were replaced with zeros to allow inclusion of all participants [8, 9]. Internal consistencies were assessed with Cronbach's alpha. Corrected item-total correlations and alpha-if-item-deleted statistics indicated the strength of each item's association with the construct.

Construct validity was assessed by examining expected relationships between questionnaire scores and clinical data, using correlation indices (Pearson's  $r$  and Spearman's  $\rho$ ),  $t$ -tests and one-way or two-way independent analyses of variance (ANOVA) with post-hoc tests. It was expected that RetDQoL scores would have significant relationships with level of visual impairment and stage of retinopathy as well as with the occurrence of macular oedema regardless of the stage of the disease, although the subgroups with macular oedema were very small. Greater visual impairment and advanced stages of disease as well as the additional impact of macular oedema were expected to lead to more negative impact on QoL. It was expected to find significant associations with clinical variables for both the overview items and the domain-specific items with stronger associations for the retinopathy-specific overview item II and average weighted impact score (AWI) than for present QoL (overview item I). When the stage of retinopathy differed between the eyes of individual participants or data were only available for one eye ( $n = 19$ , 9.2% of participants), the stage of the better eye or the available data respectively were used for subgroup categorisation. It was also expected to find significant correlations between AWI and overview items I and II, with the strongest positive relationship between AWI and overview item II (retinopathy-specific QoL). Smaller significant correlations with subscales of the SF-12 and treatment satisfaction as measured by the RetTSQ were also expected. No significant relationships with socio-demographic variables were

expected, however, these were also explored. Item distributions and total scores were non-normally distributed; therefore, non-parametric tests of relationships between variables were performed to check parametric results. When Levene's test for equality of variances indicated unequal variances for an ANOVA, an approximation to a permutation test was performed. Neither result altered the conclusion reached from parametric results, thus they are not reported. Answers to the open-ended question were assessed to see if additional items or modifications were needed.

## Results [First-level Header]

### Sample [Second-level Header]

Data for 207 participants were available. Mean age was 60.94 years with a range from 18 to 92 years. The majority (73.9%) had type 2 diabetes. Participants had been diagnosed with diabetes between 1 and 51 years ago (mean (M) = 19.89 years, Standard Deviation (SD) = 10.33). For further socio-demographic and condition-related details see tables 2a and 2b. Of the 157 participants not in employment at the time of the survey, 121 were retired; 26 of those had retired early, for 18 of them diabetes or its complications was a reason for early retirement. Visual acuity in the better eye (decimal) ranged from 0.01 to 1.25. Participants were classified in five groups from lowest visual acuity ( $\leq 0.2$ ) to good vision ( $> 0.8$ ). A high proportion of participants had little or no loss of visual acuity in their better eye; 33 had visual acuities under 0.3, classified as low vision by the World Health Organization [15]. Stage of retinopathy was categorised by one or more methods using direct fundoscopy, stereobiomicroscopic examination of the fundus or fluorescein angiography. Participants had experienced a wide range of ophthalmic treatments during the previous year.

### Descriptives [Second-level Header]

Participants on average rated present quality of life in general (overview item I) as approaching 'good' (M = 0.70; SD = 0.82), but indicated QoL would be better without diabetic eye problems (overview item II,

M = -1.43; SD = 1.07; table 3). Items were missed by very few participants; with 10 (4.8%) answers missing, the item asking for any other ways in which the condition affects their QoL (item 27) was the only one missed by more than 4% of participants. Observed scores included the minimum possible score for all domains; positive scores were infrequent (tables 4 and 5).

As shown in tables 4 and 5, on average, the least impacted domains were 'the way people in general react to me' (item 15, impact = -0.33; weighted impact = -0.71) and 'physical appearance' (item 16, impact = -0.30; weighted impact = -0.68). The most impacted domain was 'feelings about the future' (item 4, impact = -1.44; weighted impact = -3.64). For six items, over 60% of respondents indicated no weighted impact. The weighted impact for these items was zero for all but two of these participants because they reported no impact on these domains of life, not because these domains were unimportant to them. Unweighted and weighted impact scores were highly correlated ( $r = 0.9$ ). Nevertheless, weighting had considerable effects on domain scores. In total, the 207 participants responded 5010 times to domain-specific items. Of these, 1051 (21.0%) indicated little negative impact by ticking -1 in response to part a of a domain-specific item. Only a small minority of 119 (11.3% of 1051) indicated 1 – 'somewhat important' in the importance rating for the same domain, which means that weighting does not change the impact, while 666 (63.4%) indicated 2 - 'important' and 255 (24.3%) 3 - 'very important'. The remaining 11 (1%) scores were 0 – 'not at all important'. Weighting by importance also changed the ranking of 16 of 26 domains; it changed by three or more places for nine domains.

Several items correlated significantly ( $p < 0.01$ ) and highly with at least one other item, most notably item 12, 'journeys', which correlated  $> 0.75$  with 'personal affairs', 'working life', 'get out and about', 'holidays', 'leisure activities' and 'hobbies'. 'Leisure activities' also correlated highly with 'hobbies' ( $r = 0.83$ ). 'Working life' correlated  $> 0.75$  with 'get out and about' and 'finances'. 'Personal affairs' and 'household tasks' were highly correlated ( $r = 0.83$ ).

Factor structure [Second-level Header]

An unforced solution resulted in items 1 to 26 splitting onto four factors with no clear structure and several items having substantial double loadings. In a forced one-factor solution, all items loaded  $>0.55$  except 'working life' (0.22). Due to its low loading and the small number of participants to whom it was applicable ( $n = 55$ , 26.6%), 'working life' has been excluded from principal component analyses.

When the remaining 25 items were forced on one factor (table 6), this solution explained 51.7% of variance with loadings from 0.84 for 'get out and about' to 0.56 for 'close relationship'. This structure allows computing a total score, the average weighted impact (AWI) for all domain-specific items (including the working life item if applicable) with a possible range from -9 to 3. In this sample, AWI ranged from -7.33 to 0.08 with a mean of -2.05 ( $SD = 1.97$ ;  $N = 206$ ).

#### Reliability and implications for missing values [Second-level Header]

Internal consistency of weighted impact scores for all domains was excellent at  $\alpha = 0.958$  if all items were included and 'not applicable' answers substituted with 0. With 'working life' excluded, it rose marginally to  $\alpha = 0.960$ . This makes the measure suitable for application both at group and individual level [16]. Internal consistency was very robust against omissions; it stayed above 0.9 with up to the 12 strongest items omitted. Except for 'working life' (0.21), corrected item-total correlations ranged from 0.53 ('close relationship') to 0.83 ('get out and about'), thus far exceeding the recommended minimum value of 0.2 [17]. Internal consistency for the unweighted impact and the importance ratings alone was high ( $\alpha = 0.96$  and 0.84 respectively). Reliability in the form of reproducibility (test-retest) could not be assessed using the present cross-sectional data.

#### Validity [Second-level Header]

##### Overview items I and II [Third-level Header]

Participants with different levels of visual impairment showed significant differences in their rating of overview item I, present QoL ( $F(4,175) = 8.75$ ,  $p < 0.001$ ). Participants with good vision reported

significantly better present QoL than those in the three groups with visual acuities of 0.6 and worse. There were no significant differences between other groups. Level of visual impairment was also significantly associated with overview item II, retinopathy-specific QoL ( $F(4,177) = 10.20, p < 0.001$ ). Participants in the two groups with the lowest visual acuities scored significantly more negatively than participants in the other three groups. Other group differences were not significant.

Stage of diabetic retinopathy had no significant association with present QoL ( $F(3,198) = 1.322, n.s.$ ) but was related to significant differences in retinopathy-specific QoL; participants with proliferative retinopathy reported worse retinopathy-specific QoL than those with non-proliferative retinopathy ( $t = 3.33, p < 0.01$ ). Participants with mild non-proliferative retinopathy reported significantly better retinopathy-specific QoL than those with moderate or severe non-proliferative or proliferative retinopathy ( $F(3,200) = 11.22, p < 0.001$ ). Differences between other groups were not significant.

Macular oedema was associated with significantly worse present QoL ( $F(1,194) = 11.61, p < 0.01$ ) and retinopathy-specific QoL ( $F(1,196) = 6.86, p < 0.05$ ), regardless of stage of diabetic retinopathy.

AWI correlated much more strongly with retinopathy-specific QoL ( $r = 0.71, \rho = 0.75, \text{both } p < 0.001$ ) than with present QoL ( $r = 0.28, \rho = 0.27, \text{both } p < 0.001$ ).

The subscales of the SF-12 correlated significantly with the RetDQoL overview items. Present QoL correlated more strongly with the physical subscale than with the mental subscale while retinopathy-specific QoL correlated more strongly with the mental subscale. The overview items of the RetDQoL also correlated significantly with RetTSQ scores of treatment satisfaction (table 7).

Some demographic variables showed associations with present QoL. Those living with a partner or family reported better present QoL ( $t = 2.54, p < 0.05$ ) than those living alone, as did those in employment compared to people not in employment ( $t = 2.22, p < 0.05$ ). These differences lost significance when visual acuity was taken into account. Present QoL showed a tendency to decrease with age ( $r = -0.12, n.s.$ ,

$\rho = -0.18, p < 0.05$ ), which can also be explained by a significant correlation of visual acuity (ungrouped) and age ( $r = -0.29, p < 0.01$ ;  $\rho = -0.33, p < 0.01$ ). Men reported better present QoL than women ( $t = 2.74, p < 0.01$ ). As women were older, more likely not to be employed and to live alone than men in this sample, these variables were entered into a regression to explain present QoL, which showed visual acuity to be the only significant predictor of present QoL.

#### Average Weighted Impact (AWI) [Third-level Header]

Visual impairment was significantly associated with AWI. The better the vision the less negative impact participants reported ( $F(4,179) = 22.83, p < 0.001$ ); differences were significant between all groups except for the ones next to each other as shown in figure 1. Participants with proliferative diabetic retinopathy reported more negative impact on QoL than those with non-proliferative retinopathy ( $t = -3.67, p < 0.001$ ). Participants with mild non-proliferative retinopathy reported significantly less negative impact than all other groups ( $F(3,202) = 11.03, p < 0.001$ ; figure 2). Differences between other groups were not significant. Patients with macular oedema reported significantly stronger negative impact on their QoL than those without macular oedema, regardless of stage of diabetic retinopathy ( $F(1,198) = 9.08; p < 0.01$ ). AWI correlated significantly but not highly with the two subscales of the SF-12 and with RetTSQ scores (table 7).

Negative impact on QoL showed a tendency to increase with age ( $r = -0.162, p < 0.05$ ;  $\rho = -0.122, n.s.$ ). This relationship disappeared when controlling for visual acuity ( $r = -0.13, n.s.$ ). Participants not in employment reported a more negative impact than those in employment ( $t = 3.86; p < 0.01$ ) and this difference was significant regardless of level of visual impairment ( $F(1,174) = 5.01, p < 0.05$ ).

#### Additional aspects described [Third-level Header]

The open-ended question in item 27 was answered by 12 participants (5.8%). Problems in recognising acquaintances or friends on the street were mentioned twice. Some other aspects described appeared to

be covered in existing items. For example, “I am always dependent on someone, can no longer go by car, bus or train unaccompanied” underlines the relevance of item 11 ‘to get out and about’ and item 22 ‘depend on others’. “Particular difficulties when completing forms, payments into the bank etc.” emphasises difficulties handling personal affairs as described in item 2, which includes letters and bills as examples of personal affairs. Some aspects described did not appear to be directly relevant to the measure, such as “Impaired blood flow in both legs has been improved by venous catheter”. This appears to be an explanation for recent improvement unrelated to the eye condition rather than a suggestion requiring a new item.

## Discussion [First-level Header]

Psychometric properties of the measure reported here are excellent. Visual acuity of many participants in this sample was good, as seen in the skewed distribution of scores. Even though the questionnaire showed non-normally distributed data and some unequal variances across groups, non-parametric tests confirmed all results. Score distribution will be less skewed in samples with more severe visual impairment. The questionnaire showed a high completion rate, though this should be interpreted with caution as physicians were asked to check for completeness.

The overview items of the RetDQoL showed that on average, participants rated their present quality of life as being in between ‘neither good nor bad’ and ‘good’, with a modal response of ‘good’. They expected their QoL to be ‘a little better’ to ‘much better’ if they did not have their eye condition (modal response ‘a little better’). The difference between present QoL and condition-specific QoL shows the importance of using condition-specific measures and not relying on generic QoL measures alone when making statements about the impact of medical conditions on QoL.

By far the most negatively impacted domain of life was feelings about the future, showing that even a well-monitored and treated eye condition can lead to uncertainty and fear about how one’s life will be

affected by it in future. The ranking of domains is likely to be different in samples with more advanced retinopathy or visual impairment.

A highly reliable scale in terms of internal consistency resulted from principal component analysis when all items except 'working life' were forced onto a single factor. The 'working life' item was omitted because of low loadings and applicability to only few participants in the present sample, which can explain the low loading. Nonetheless, it should not be removed from the measure, as participants who completed it clearly rated it as negatively impacted and important (table 4) and it may be more applicable in samples with a lower proportion of retired participants. Internal consistency proved to be robust against missing items as it stayed above 0.9 with almost half the items omitted. This indicates clearly that excellent internal consistency reliability can be maintained if the mean scale value for the individual is substituted for up to 12 items. No more than 12 items should be substituted, as to do so would detract from content validity. The range of item-total correlations indicates that the individual items represent the underlying construct well. The measure can be used in individual patient management, for example to identify priorities for rehabilitation, and at group level, for example to compare different treatments. Reliability in the form of reproducibility or stability of QoL ratings over time needs to be assessed using longitudinal data from a sample with stable retinopathy. For the sister measure MacDQoL, Mitchell and colleagues [18] reported excellent test-retest reliability, suggesting that RetDQoL scores may be similarly stable.

Good construct validity is indicated by the measure's sensitivity to different levels of visual impairment, different stages of disease progression and macular oedema as the expected relationships were found for both the overview items and AWI. This sensitivity to group differences suggests that the measure will be responsive to changes; however, longitudinal data before and after treatment or rehabilitation are needed to confirm this. The AWI score reflects, as intended, QoL as impacted by retinopathy and not general QoL. This is suggested by a much stronger correlation of AWI with the retinopathy-specific overview item than with the present QoL item. The high correlation between AWI score and the retinopathy-specific overview item makes it possible to use overview item II alone if participant burden is of particular concern

and a very brief measure of condition-specific QoL is desirable. However, this would lead to a loss of detailed information obtainable by the specific individualised items.

The variability in importance ratings demonstrates that, without weighting by the importance of the domain, the impact of diabetic retinopathy on aspects of life would have been underestimated for many individuals. This effect is masked when correlating average scores, due to a high proportion of participants reporting no impact on life domains. Weighting also influenced the ranking of impact on life domains considerably with the rankings of 9 domains being changed by three or more places.

The RetDQoL and the SF-12 show some overlap, but with correlations of only 0.22 – 0.51 it is clear that the instruments measure very different phenomena. It is to be expected that there will be modest correlations between a health status measure and a measure of the impact of diabetic retinopathy on QoL, particularly as people who have more severe diabetic retinopathy are likely to be more at risk of other microvascular complications of diabetes including nephropathy and neuropathy, which will lead to reduced health scores. That the SF-12 subscales correlate more strongly with the overview item about present QoL than with the retinopathy-specific item or AWI confirms that the SF-12 measures a more generic construct than the condition-specific RetDQoL. Correlations between scores of the RetTSQ and the RetDQoL show that negative impact on QoL is associated with less treatment satisfaction but the modest size of the correlation indicates that the instruments measure different aspects of the experience of diabetic retinopathy.

Interestingly, at all levels of visual impairment, AWI was significantly less negatively impacted in people in employment than in those who were not in employment. Employment may have a protective effect on QoL via its benefits to well-being. The causality may also be reversed with those who feel less negatively impacted by their retinopathy being more attractive to employers and less likely to seek early retirement, or AWI and employment may be linked via a third variable.

Answers to the open-ended question mainly emphasised aspects already covered in existing items. However, similar to the answers given in the current study, when evaluating the MacDQoL, Mitchell et al. [8] also reported an additional aspect mentioned was not being able to recognise people. This is further supported by reports from focus groups on the impact of diabetic retinopathy on life [19], where difficulties recognising faces was one of the key concerns reported. This aspect was expected to be covered by 'friendships/social life' or 'people react to me', however, those adding these comments did indicate little or no impact on these domains. Other key concerns expressed in these focus groups included inability to drive or driving restrictions, decreased mobility, loss of independence, decreased social activities, impact on general day-to-day tasks, inability or difficulties in reading and difficulties in maintaining diabetes care activities, all of which are reflected in items in the RetDQoL.

Since the start of this study the number of items in the RetDQoL has been reduced. Following design and psychometric development of the MacDQoL [8, 20], 'hobbies' and 'leisure activities' have been merged; 'long journeys' has been deleted because of considerable overlap with 'holidays'. This removes most of the high correlations between items; even though some remain, the items involved cover different aspects of life separately impacted by the condition. 'Depend on others' now asks about independence instead and includes a preliminary question to establish relevance. Following linguistic validation to produce translations of the measure, 'feelings about past', 'working life', 'close relationship' and 'motivation' have been simplified and shortened. A preliminary question has been added to 'close relationship' to check applicability. 'Diet' in 'diabetes care' has been changed to 'food' to be relevant to those who do not consider themselves to be on a diet. 'Somewhat important' in the importance rating scale is now translated as 'etwas wichtig' in German because recent interviews [21] indicated that the previous wording represented a higher importance than intended. These changes are not expected to have a major influence on psychometric properties; small improvements are more likely than detrimental effects.

Removing some items with high proportions of no reported impact from the RetDQoL has been considered. This would be desirable as it would reduce the burden on the participants and it is supported by an alpha that is very robust with a shorter scale. However, before removing items, further confirmation

of these findings in different populations and cultures is necessary. This is particularly important as a large proportion of participants in this sample had no or little visual impairment and the sample had access to the comparatively good and reliable health care system in Germany where the vast majority of people are covered to a great extent by health insurance schemes.

When linguistically validated versions in other languages are used in other countries, the psychometric properties of the RetDQoL will need to be examined for each language version / country. The RetDQoL together with the MacDQoL has been used as the basis for the design of a general Eye Dependent Quality of Life Questionnaire, the EyeDQoL for use with people who have one or more of a range of eye conditions [21].

## Conclusion [First-level Header]

The individualised Retinopathy-Dependent Quality of Life Questionnaire (RetDQoL) is a valid and reliable measure of quality of life for use with people with diabetic retinopathy with or without macular oedema.

- Diabetic retinopathy has a strong negative impact on QoL as shown by the overview items and the AWI; feelings about the future are most negatively impacted. In some instances, the overview items could be used as substitutes for the complete measure.
- The RetDQoL domain-specific items form a highly reliable and robust scale. Difficulties with recognising people may need further attention.
- The high internal consistency allows for the measure to be used both at individual and group level; stability of scores over time needs to be assessed in future longitudinal studies.
- The measure is sensitive to visual acuity, stage of retinopathy and occurrence of macular oedema.
- Quality of life is correlated significantly but not strongly with health status and treatment satisfaction, but results confirm that these constructs differ.
- The RetDQoL may usefully be shortened further if present findings are confirmed cross-culturally and in other samples.

## Acknowledgements [First-level Header]

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## Access to questionnaires [First-level Header]

The copyright holder of the RetDQoL is Professor Clare Bradley, Health Psychology Research, Department of Psychology, Royal Holloway, University of London, Egham Hill, Egham, Surrey, TW20 0EX, UK; c.bradley@rhul.ac.uk. Visit [www.healthpsychologyresearch.com](http://www.healthpsychologyresearch.com) for information about language versions available and access to questionnaires.

## References [First-level Header]

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Figure 1: Average weighted impact (AWI) in groups with different levels of visual impairment (visual acuity, decimal notation).

AWI possible scores range from 3 to -9. A more negative AWI score indicates a more negative impact of visual impairment on QoL; a positive score would indicate a positive impact of visual impairment on QoL.

\*p<0.05; \*\*p<0.01; \*\*\*p<0.001

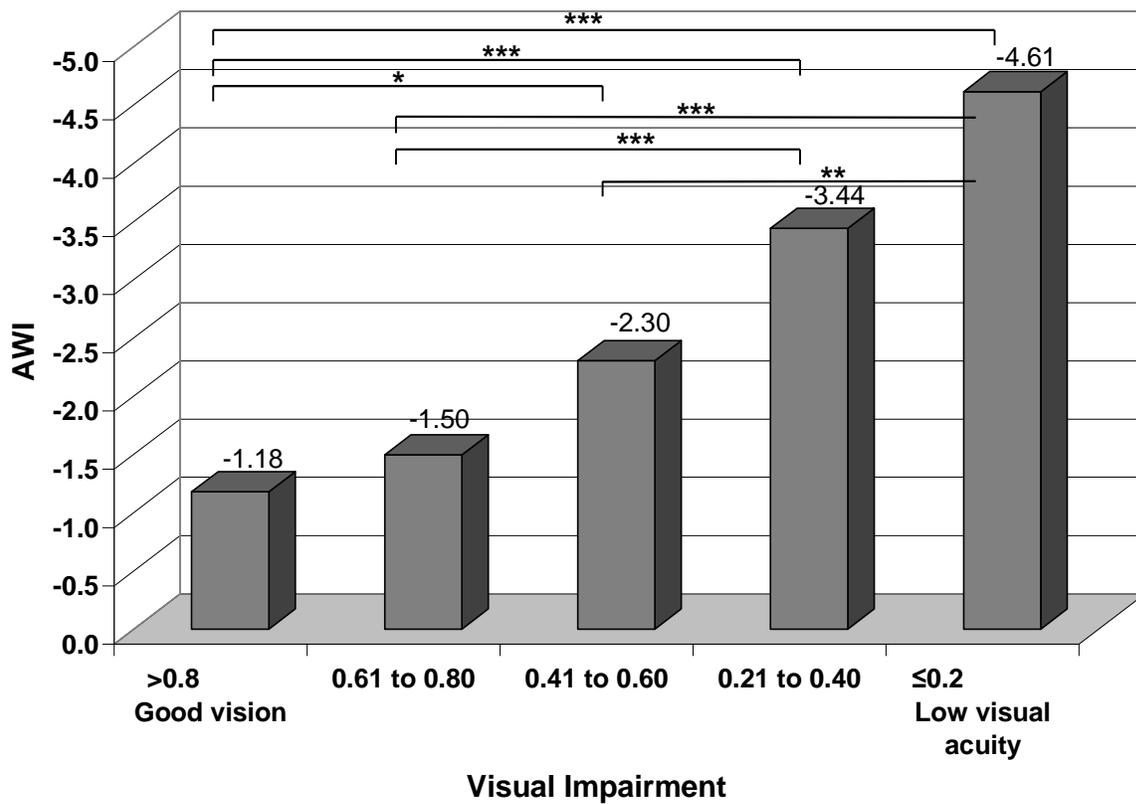
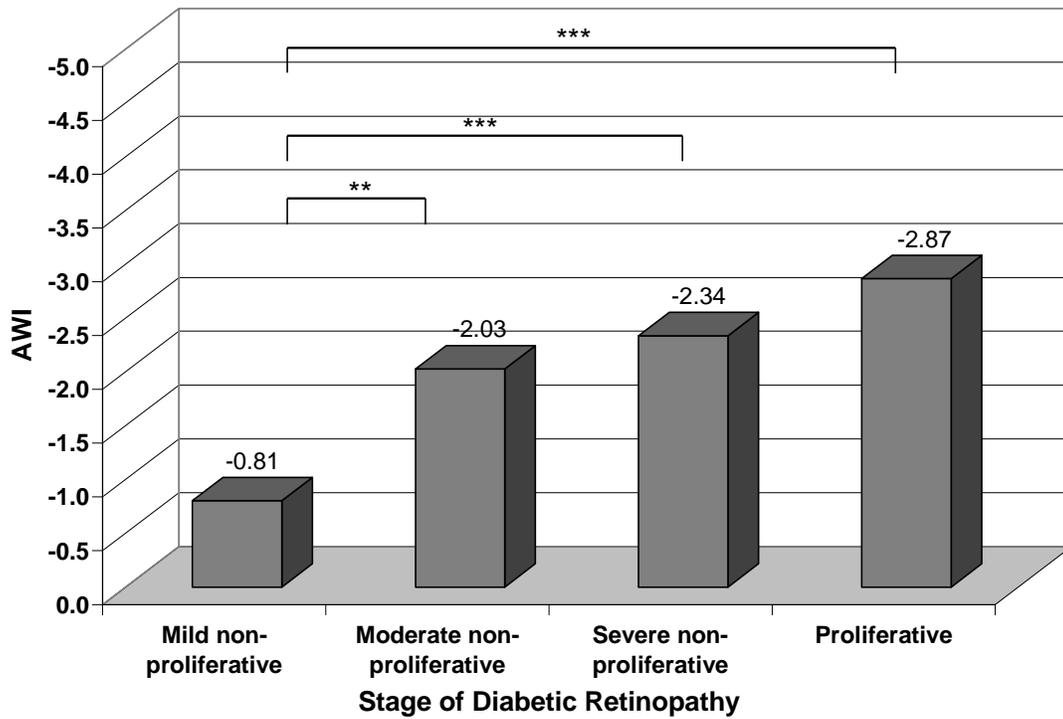


Figure 2: Average weighted impact (AWI) in different stages of diabetic retinopathy.

AWI possible scores range from 3 to -9. A more negative AWI score indicates a more negative impact of diabetic retinopathy on QoL; a positive score would indicate a positive impact of diabetic retinopathy on QoL.

\*\*p<0.01; \*\*\*p<0.001



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Table 1: Wording of RetDQoL items 1 - 26 (2001 version). RetDQoL © Prof Clare Bradley 29.11.01.

Item	Wording of part a (impact)	Response options*	Wording of part b (importance)
1	<p>UK If I did not have diabetic eye problems, I could handle my household tasks:</p> <p>DE Wenn ich keine diabetischen Augenprobleme hätte, könnte ich meine Aufgaben im Haushalt ..... erledigen:</p>	A	<p>Handling my household tasks is:</p> <p>Die Erledigung meiner Aufgaben im Haushalt ist für mich:</p>
<p>1a – 26a all begin with:</p> <p>UK: 'If I did not have diabetic eye problems,'</p> <p>DE: 'Wenn ich keine diabetischen Augenprobleme hätte,'</p>			<p>Response options for 1b – 26b:</p> <p>UK: very important (3), important (2), somewhat important (1), not at all important (0). DE: sehr wichtig (3), wichtig (2), relativ wichtig (1), gar nicht wichtig (0)</p>
2	<p>UK I could handle my personal affairs (letters, bills, etc):</p> <p>DE könnte ich meine persönlichen Angelegenheiten (Briefe, Rechnungen usw.) ..... erledigen:</p>	A	<p>Handling my personal affairs is:</p> <p>Die Erledigung meiner persönlicher Angelegenheiten ist für mich:</p>
3	<p>UK my experience of shopping would be:</p> <p>DE wären meine Erfahrungen beim Einkaufen:</p>	A	<p>My experience of shopping is:</p> <p>Meine Erfahrungen beim Einkaufen sind für mich:</p>
4	<p>UK my feelings about the future (e.g. worries, hopes) would be:</p> <p>DE wären meine Gefühle in Bezug auf die Zukunft (z.B. Sorgen, Hoffnungen):</p>	A	<p>My feelings about the future are:</p> <p>Meine Gefühle in Bezug auf die Zukunft sind für mich:</p>
5 <sup>1</sup>	<p>UK my feelings about the past (e.g. anger or regret about earlier</p>	A	<p>My feelings about the past are:</p>

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		diabetes care) would be:		
	DE	wären meine Gefühle in Bezug auf die Vergangenheit (z.B. Ärger oder Bedauern wegen der früheren Behandlung oder meiner früheren Lebensweise):	A	Meine Gefühle in Bezug auf die Vergangenheit sind für mich:
6 <sup>1,2</sup>	UK	my working life and work-related opportunities would be:	A	My working life is:
	DE	wären mein Berufsleben und meine beruflichen Möglichkeiten:	A	Mein Berufsleben ist für mich:
7 <sup>1</sup>	UK	my close personal relationship (e.g. marriage, living companion, steady relationship), now or in the future, would be:	A	For me, having a close personal relationship is:
	DE	wäre meine feste Beziehung (z. B. Ehepartner, Lebensgefährte, feste Freundschaft) jetzt oder in Zukunft:	A	Eine feste Beziehung zu haben ist für mich:
8 <sup>2</sup>	UK	my family life would be:	A	My family life is:
	DE	wäre mein Familienleben:	A	Mein Familienleben ist für mich:
9	UK	my friendships and social life would be:	A	My friendships and social life are:
	DE	wären meine Freundschaften und meine sozialen Kontakte:	A	Meine Freundschaften und sozialen Kontakte sind für mich:
10	UK	I could do things for others as I wish:	A	For me, doing things for others is:
	DE	könnte ich ..... etwas für andere tun wie ich es möchte:	A	Dinge für andere zu tun ist für mich:
11	UK	I could get out and about (e.g. on foot, or by car, bus or train):	A	For me, getting out and about is:
	DE	könnte ich ..... raus- und herumkommen (z.B. zu Fuß, mit dem Auto, dem Bus oder mit der Bahn):	A	Raus- und herumzukommen ist für mich:

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12 <sup>2,3</sup>	UK	I would find long journeys:	B	For me, long journeys are:
	DE	fände ich weite Reisen:	B	Weite Reisen sind für mich:
13 <sup>2</sup>	UK	my holidays would be:	A	For me, holidays are:
	DE	wäre mein Urlaub:	A	Urlaub ist für mich:
14	UK	my financial situation would be:	A	My financial situation is:
	DE	wäre meine finanzielle Situation:	A	Meine finanzielle Situation ist für mich:
15	UK	the way people in general react to me would be:	A	The way people in general react to me is:
	DE	wäre die Art und Weise, wie andere auf mich reagieren:	A	wie andere auf mich reagieren ist für mich:
16	UK	my physical appearance (including clothes and grooming) would be:	A	My physical appearance is:
	DE	wäre meine äußere Erscheinung (einschließlich Kleidung und Gepflegtheit):	A	Meine äußere Erscheinung ist für mich:
17	UK	physically I could do:	C	For me, how much I can do physically is:
	DE	wäre ich körperlich zu ..... in der Lage:	C	Wozu ich körperlich in der Lage bin, ist für mich:
18 <sup>1</sup>	UK	I could pursue or enjoy my leisure activities (e.g. reading, TV, radio, cinema:	A	My leisure activities are:
	DE	könnte ich meine Freizeitaktivitäten (z. B. Lesen, Fernsehen, Radio hören, Kino) ..... verfolgen oder genießen:	A	Meine Freizeitaktivitäten sind für mich:
19 <sup>3</sup>	UK	I could pursue or enjoy my hobbies and interests:	A	My hobbies and interests are:
	DE	könnte ich meine Hobbys und Interessen ..... verfolgen oder	A	Meine Hobbys und Interessen sind für mich:

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		genießen:		
20	UK	my self-confidence would be:	A	My self-confidence is:
	DE	wäre mein Selbstvertrauen:	A	Mein Selbstvertrauen ist für mich:
21 <sup>1</sup>	UK	my motivation to achieve things would be:	A	My motivation is:
	DE	wäre meine Motivation, etwas zu erreichen:	A	Meine Motivation, etwas zu erreichen, ist für mich:
22 <sup>1</sup>	UK	I would have to depend on others when I do not want to:	D	For me, not having to depend on others is:
	DE	wäre ich ..... auf andere angewiesen:	D	Nicht auf andere angewiesen zu sein ist für mich:
23	UK	I would have mishaps or would lose things:	D	For me, not having mishaps or losing things is:
	DE	würde ich ..... Missgeschicke erleben oder Dinge verlieren:	D	Keine Missgeschicke zu erleben und keine Dinge zu verlieren ist für mich:
24	UK	the time it takes me to do things would be:	D	The time it takes me to do things is:
	DE	wäre die Zeit, die ich zur Erledigung von Dingen brauche:	D	Die Zeit, die ich zur Erledigung von Dingen brauche, ist für mich:
25 <sup>1</sup>	UK	I would find taking care of my diabetes (e.g. self-testing, medication, diet, exercise):	B	Taking care of my diabetes is:
	DE	könnte ich mich ..... um meinen Diabetes kümmern (z.B. Selbstkontrollen, Medikamente einnehmen, Ernährung und körperliche Aktivität beachten):	B	Mich um meinen Diabetes zu kümmern ist für mich:
26	UK	I could enjoy nature:	C	My enjoyment of nature is:
	DE	könnte ich die Natur ..... genießen:	C	Die Natur zu genießen ist für mich:

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\* Response options for part a: A) UK: very much better (-3), much better (-2), better (-1), the same (0), worse (1). DE: sehr viel besser (-3), viel besser (-2), besser (-1), genauso (0), schlechter (1). Scoring is the same for all of the following response options for part a. B) UK: very much easier – more difficult. DE: sehr viel leichter – schwieriger. C) UK: very much more – less. DE: sehr viel mehr – weniger. D) UK: very much less – more. DE: sehr viel weniger – mehr

<sup>1)</sup> Wording of item has been changed in more recent versions of the questionnaire.

<sup>2)</sup> Preliminary yes/no question allowing 'not applicable' answer.

<sup>3)</sup> Item has been deleted in more recent versions.

Table 2a: Sample characteristics. A total &lt;100% indicates missing data.

		Frequency	Percent
Sex	Female	104	50.2
	Male	103	49.8
	Total	207	100.0
Marital status	Single	18	8.7
	Married / Partnered	148	71.5
	Divorced	16	7.7
	Widowed	23	11.1
	Total	205	99.0
Living situation	Alone	36	17.4
	With partner / family	144	69.6
	Other	1	0.5
	Total	181	87.4
Employment status	Employed	50	24.2
	Not employed	157	75.8
	Total	207	100.0
Visual acuity	≤0.2 (low acuity)	24	11.6
	0.21 to 0.40	15	7.2
	0.41 to 0.60	35	16.9
	0.61 to 0.80	45	21.7
	>0.8 (good vision)	65	31.4
	Total	184	88.8

Table 2b: Sample characteristics, stage of diabetic retinopathy (better eye if different in both eyes) and presence of clinically significant macular oedema per group.

Stage of diabetic retinopathy	Frequency (%)	Sign. macular oedema Frequency
Mild non-proliferative	46 (22.2)	1
Moderate non-proliferative	56 (27.1)	8
Severe non-proliferative	50 (24.2)	9
Proliferative	55 (26.6)	22
Total	207 (100.0)	40 (19.3%)

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Table 3: RetDQoL descriptives for overview items

Overview item	N	Missing	Minimum	Min. scored by	Maximum	Max. scored by	Mean (SD)	Skew	Kurtosis
I) present QoL	202	5	-3	0.5%	3	1%	0.70 (0.82)	-0.57	2.04
II) retinopathy-specific QoL	204	3	-3	20.1%	0	24.0%	-1.43 (1.07)	-0.08	-1.2

SD = Standard Deviation

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Table 4: Descriptives. Impact and importance of domain-specific items.

Item	N	Missing part a/b or n.a.*	Impact score			Importance score		
			Mean (SD)	Min.	Max	Mean (SD)	Min.	Max.
1) household tasks	204	3/2	-1.05 (1.09)	-3	0	2.19 (0.68)	0	3
2) personal affairs	205	2/1	-1.07 (1.13)	-3	0	2.51 (0.56)	1	3
3) shopping	204	3/2	-1.05 (1.09)	-3	0	2.12 (0.72)	0	3
4) feelings about future	203	4/3	-1.44 (1.03)	-3	0	2.37 (0.61)	0	3
5) feelings about past	201	6/3	-0.94 (1.00)	-3	1	1.75 (0.73)	0	3
6) working life *	55	5	-0.77 (0.97)	-3	0	2.27 (0.79)	0	3
7) close relationship	200	7/7	-0.43 (0.86)	-3	1	2.37 (0.83)	0	3
8) family life *	197	3	-0.60 (0.92)	-3	0	2.66 (0.49)	1	3
9) friendships/social life	204	3/2	-0.52 (0.87)	-3	1	2.34 (0.58)	1	3
10) do things for others	204	3/2	-0.82 (0.97)	-3	0	2.11 (0.59)	1	3
11) get out and about	205	2/2	-1.08 (1.17)	-3	0	2.29 (0.59)	1	3
12) journeys *	99	5	-1.03 (1.28)	-3	1	1.66 (0.84)	0	3
13) holidays *	155	5	-0.91 (1.05)	-3	1	2.07 (0.75)	0	3
14) finances	205	2/2	-0.48 (0.84)	-3	0	2.32 (0.56)	0	3
15) people react to me	204	3/3	-0.33 (0.67)	-3	0	1.80 (0.76)	0	3

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16) physical appearance	204	3/2	-0.30 (0.68)	-3	0	2.16 (0.57)	0	3
17) do physically	202	4/4	-0.98 (1.02)	-3	0	2.31 (0.55)	0	3
18) leisure activities	205	2/1	-1.14 (1.14)	-3	0	2.15 (0.62)	0	3
19) hobbies	200	7/6	-1.06 (1.10)	-3	0	2.20 (0.63)	0	3
20) self-confidence	203	4/3	-0.86 (1.04)	-3	0	2.38 (0.55)	1	3
21) motivation	205	2/2	-0.83 (1.00)	-3	1	2.10 (0.61)	0	3
22) depend on others	204	3/2	-0.82 (1.07)	-3	1	2.43 (0.61)	0	3
23) mishaps/lose things	203	4/4	-0.72 (0.95)	-3	0	2.08 (0.68)	0	3
24) time it takes	204	3/3	-0.96 (1.06)	-3	1	1.92 (0.65)	0	3
25) care of diabetes	204	3/2	-0.77 (1.04)	-3	0	2.59 (0.52)	1	3
26) enjoy nature	205	2/1	-0.97 (1.12)	-3	0	2.42 (0.61)	1	3
27) any other ways	197	10	n/a	n/a	n/a	n/a	n/a	n/a

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Table 5: Domain-specific items (sorted by rank of weighted impact) and average weighted impact (AWI)

Item (item number)	Mean WI (SD)	Min.	Max.	WI=-9 in %	WI=0 in %	WI>0 in %	Skew	Kurtosis	Rank impact
feelings about future (4)	-3.64 (2.99)	-9	0	15.3	22.7	-	-0.51	-0.82	1
personal affairs (2)	-2.80 (3.18)	-9	0	13.2	43.4	-	-0.83	-0.66	4
leisure activities (18)	-2.62 (2.91)	-9	0	8.8	42.0	-	-0.86	-0.39	2
get out and about (11)	-2.59 (3.02)	-9	0	10.2	45.9	-	-0.89	-0.42	3
hobbies (19)	-2.56 (2.98)	-9	0	11.0	43.0	-	-1.00	-0.14	5
enjoy nature (26)	-2.53 (3.14)	-9	0	11.7	50.2	-	-0.94	-0.46	10
shopping (3)	-2.50 (2.91)	-9	0	9.8	42.6	-	-1.03	-0.04	6
journeys * (12)	-2.48 (3.25)	-9	1	13.1	47.5	1.0	-1.02	-0.44	8
household tasks (1)	-2.48 (2.86)	-9	0	8.3	42.2	-	-0.99	2.04	7
do physically (17)	-2.37 (2.75)	-9	0	8.4	41.6	-	-1.14	0.42	9
self-confidence (20)	-2.15 (2.80)	-9	0	7.4	52.7	-	-1.15	0.27	13
depend on others (22)	-2.10 (2.98)	-9	3	10.3	52.9	1.0	-1.23	0.45	15
holidays * (13)	-2.10 (2.72)	-9	0	6.5	49.7	-	-1.19	0.41	17
working life * (6)	-2.09 (2.79)	-9	0	10.9	47.3	-	-1.57	1.68	19
care of diabetes (25)	-2.02 (2.90)	-9	0	8.8	57.8	-	-1.30	0.47	18
time it takes (24)	-2.01 (2.49)	-9	3	3.9	44.1	1.0	-1.08	0.55	11

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motivation (21)	-1.88 (2.53)	-9	3	5.9	48.8	1.0	-1.35	1.38	14
feelings about past (5)	-1.88 (2.42)	-9	2	4.5	45.8	0.5	-1.35	1.31	12
do things for others (10)	-1.84 (2.40)	-9	0	3.9	50.0	-	-1.35	1.19	16
mishaps/lose things (23)	-1.73 (2.50)	-9	0	4.9	55.2	-	-1.51	1.78	20
family life * (8)	-1.61 (2.55)	-9	0	4.1	64.5	-	-1.47	1.09	21
friendships/social life (9)	-1.25 (2.27)	-9	3	3.4	66.7	0.5	-1.92	3.28	22
finances (14)	-1.22 (2.26)	-9	0	3.4	70.7	-	-1.97	3.28	23
close relationship (7)	-1.06 (2.27)	-9	2	4.0	74.5	0.5	-2.29	4.51	24
people react to me (15)	-0.71 (1.62)	-9	0	1.5	76.0	-	-3.04	10.58	25
physical appearance (16)	-0.68 (1.69)	-9	0	1.5	80.4	-	-3.03	9.61	26
AWI	-2.05 (1.97)	-7.33	0.08	n/a	n/a	n/a	-0.90	-0.21	n/a

Table 6: RetDQoL Component Matrix. Extraction Method: Principal Component Analysis. Items with 'not applicable' answers scored as 0.

Item (item number)	Component 1
household tasks (1)	0.782
personal affairs (2)	0.777
shopping (3)	0.739
feelings about future (4)	0.585
feelings about past (5)	0.580
close relationship (7)	0.561
family life (8)	0.705
friendships/social life (9)	0.659
do things for others (10)	0.783
get out and about (11)	0.844
journeys (12)	0.611
holidays (13)	0.581
finances (14)	0.569
people react to me (15)	0.595
physical appearance (16)	0.574
do physically (17)	0.793
leisure activities (18)	0.841
hobbies (19)	0.833
self-confidence (20)	0.769
motivation (21)	0.802
depend on others (22)	0.770
mishaps/lose things (23)	0.793
time it takes (24)	0.772
care of diabetes (25)	0.674
enjoy nature (26)	0.816

Table 7: Correlations with SF-12 and Retinopathy Treatment Satisfaction Questionnaire (RetTSQ) scores

	RetDQoL scores					
	Present QoL		Retinopathy-specific QoL		AWI	
	r	rho	r	rho	r	rho
SF-12 physical	0.51†	0.54†	0.22†	0.22†	0.33†	0.33†
SF-12 mental	0.38†	0.37†	0.33*	0.32*	0.34†	0.34†
RetTSQ total score	0.51†	0.45†	0.43†	0.46†	0.46†	0.52†
RetTSQ subscale 1	0.46†	0.41†	0.46†	0.46†	0.48†	0.54†
RetTSQ subscale 2	0.44†	0.37†	0.28†	0.28†	0.27†	0.31†

RetTSQ subscale 1 consists of items covering negative experiences such as side effects and pain; subscale 2 covers positive aspects of the treatment such as efficacy and safety.

\*  $p < 0.05$

†  $p < 0.01$