# **ORIGINAL ARTICLE**





# Development and psychometric validation of the gum health experience questionnaire

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#### **Abstract**

**Aim:** To develop and validate a new health-related quality of life measure to capture a wide range of gum-related impacts.

Materials and Methods: The measure was developed using a multi-stage approach and a theoretical model. Development involved semi-structured interviews, pilot testing, cross-sectional analysis among a general population (n = 152) to assess psychometric properties and test-retest reliability among a subsample (n = 27).

Results: Psychometric analysis supports the validity and reliability of the measure's impact scale. The measure has excellent internal reliability (nearly all item-total correlations above .4; Cronbach's alpha between .84 and .91 for subscales), with test-retest reliability also performing well (Intra-class correlation coefficient [ICC] of .91–.97 for subscales). Good content validity (indicated by large standard deviations for item and total scores) and construct validity (correlations of .54–.73 with global gum health rating for subscales, all p < .05) were also observed. Qualitative and quantitative data indicate that people with gum health-related symptoms experience different degrees of discomfort and impacts caused by their condition.

Conclusions: The gum health experience questionnaire holds substantial promise as a measure of gum-related quality of life in people across the gum health-disease continuum. Further face validity, refining and reducing the number of items and longitudinal studies to test evaluative properties are required before the measure can be used with confidence.

#### **KEYWORDS**

gingivitis, gum health, periodontitis, person-reported outcome measure, quality of life

# **Clinical Relevance**

Scientific rationale for study: There has been a lack of oral health-related quality of life measures focusing on the wide range of gum-related symptoms as well as the everyday impacts associated with these and quality of life.

*Principal findings*: A preliminary gum-related measure (the GHEQ) shows promise as an evaluative tool, although further longitudinal validation and revision are required.

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Practical implications: Future work should look to include symptoms from across the entire gum health-disease continuum when considering quality of life as well as a more patient-centred approach. This, along with a revised measure, could be valuable in both clinical and research settings.

## 1 | INTRODUCTION

Periodontal problems sit on a continuum ranging from healthy gums to mild gingivitis, which can involve inflamed and bleeding gums, to periodontitis, where inflammation spreads below the gums and roots and is characterised by loss of periodontal tissue support (clinical attachment loss), periodontal pocketing and gingival bleeding (European Federation of Periodontology, 2019). People's experience of gum health and disease from across this continuum is paramount to improve our understanding of the experience from a person-centred perspective as well as developing new behavioural, communication and clinical intervention strategies. Yet, to date, there has been relatively little research from a person-centred perspective exploring experiences along the gum health-disease continuum.

Historically regarded as being relatively asymptomatic, existing research demonstrates gingivitis can impact oral health-related quality of life (OHRQoL) (Barbosa et al., 2015), although most studies have involved children (Krisdapong, Prasertsom, Rattanarangsima, Sheiham, et al., 2012) or adolescents (Krisdapong, Prasertsom, Rattanarangsima, Adulyanon, et al., 2012). Additionally, periodontitis has been found to impact aspects of everyday life (Ferreira et al., 2017). However, many studies have used broad classifications of gum disease (i.e., chronic gingivitis, and mild, moderate and severe periodontitis; Al Habashneh et al., 2012), which may not accurately reflect the continuum of symptoms experienced by individuals. The importance of both a clinical perspective and needs identified by patients in finding appropriate communication and treatment plans has been previously emphasised (Ferreira et al., 2017).

Additionally, there has been a lack of gum-health-focused measures in previous studies. Most have used existing OHRQoL measures such as the short-form of the oral health impact profile (OHIP)-14 (Palma et al., 2013; Wagner et al., 2016), OHQoL-UK (Needleman et al., 2004) or EuroQol (Brennan et al., 2007). Although these measures, along with oral impact on daily performance (OIDP) (Adulyanon & Sheiham, 1997) and geriatric oral health assessment index (GOHAI) (Atchison & Dolan, 1990), contain items applicable to gum health, this is not always done so explicitly (sometimes being combined with impacts on the mouth and teeth), and there are also many of no relevance, meaning they may not reflect patients' experiences. Previous work to develop an OHRQoL measure for chronic periodontitis (Musurlieva et al., 2012; Musurlieva & Stoykova, 2015) produced a nine-item measure, although its brevity means it is unlikely to reflect all impacts felt by periodontitis patients, or those with a wider range of gum symptoms including gingivitis. This measure evaluates influences on overall outlook, self-esteem, general health, choice of food, chewing and speaking, as well as family, personal and social life.

However, previous research has shown that themes such as identity, guilt, financial concerns, worries over symptom progression, adaptations in oral hygiene routines, the range of symptoms experienced and everyday impacts are also important (Broomhead et al., 2022).

Qualitative work on gum-health and oral-health related quality of life has demonstrated the range of everyday impacts experienced by individuals with gum-related symptoms, including those with gingivitis (Broomhead et al., 2022). The aims of this research were, therefore, to use this qualitative work as the basis for developing a preliminary evaluative measure specific to gum health (the gum health experience questionnaire [GHEQ]) and to evaluate the psychometric properties of this preliminary measure.

### 2 | MATERIALS AND METHODS

The study was designed over five stages, and the following sections detail the materials and methods for each of these. Ethical approval for the qualitative work and development (application 022394) and validation (application 043367) of the GHEQ were obtained from the University of Sheffield's Ethics Committee, as administered by the School of Clinical Dentistry.

## 2.1 | Theoretical model

The Wilson and Cleary HRQoL model (Wilson & Cleary, 1995) was chosen to guide the identification of themes and questionnaire development. This model was chosen because of its focus on symptoms, functional limitations and effects on general health perceptions and life overall. This model has also previously been used to develop condition-specific OHRQoL measures for outcomes such as dentine hypersensitivity (Boiko et al., 2010).

# 2.2 | Qualitative interviews

In-depth semi-structured interviews were conducted to identify everyday impacts of gum health across the health-disease continuum. Twenty-seven participants (15 female, 12 male) were interviewed until data saturation was achieved. The sample included a range of ages (23–73) and occupations. Participants were purposively recruited from a university in two phases—one to capture the experiences of participants with symptoms associated with gingivitis (n=15), and a second phase to capture experiences of those with symptoms associated with periodontitis (n=12). Participants were recruited using a

series of questions about their periodontal health and treatment history (outlined in a previous study by Broomhead et al., 2022), as well as demographic details (age, sex, occupation) to ensure as diverse a group as possible. After gaining participant consent, interviews were arranged at a mutually suitable time and place and lasted between 20 and 90 min (47 min on average). The interview guide covered personal histories, perceptions, experiences as well as knowledge of participants' condition, impacts and limitations in everyday life, and the relationship between symptoms and identity (Broomhead et al., 2022). Interviews were transcribed verbatim and analysed using framework analysis (Ritchie & Spencer, 1994).

# 2.3 | Questionnaire development

Interview data were used to derive items in a two-stage process. First, transcribed data were searched for common themes, which were coded using NVIVO (QSR International, 2018). Second, these coded themes were mapped onto the Wilson and Cleary model (1995) (Broomhead et al., 2022). Once mapped, the coded themes were searched within the transcribed data to find quotes expressing the experiences of individuals and to identify items and wording for use in the measure that would cover as many of these themes as possible. Through this process, seven subscales emerged: 'symptoms', 'changes in daily life', 'social impacts', 'psychological impacts', 'identity', 'overall impacts and quality of life' and 'timeline of symptoms and treatment'. The items were generic to most peoples' experiences with gum health/disease, ranging from symptoms and impacts of mild gingivitis through to more severe periodontitis. A global gum health rating item was added to represent general health perceptions for the purpose of construct validation. Relevant response formats were chosen for each subscale.

# 2.4 | Pilot testing of the GHEQ

Face validation was assessed through a series of pilot interviews with 10 new participants. Participants were selected from a 'reserve list' of those with similar demographic characteristics to those who had already been interviewed (Section 2.2). Because of the low number of male volunteers on this reserve list, all pilot interviews were conducted with women (age range 29-58 years). Participants' socio-economic status (classified by the NS-SEC; Office for National Statistics, 2010) included 'higher professional traditional' (n = 3), 'higher professional new' (n = 1), 'traditional lower professional and higher technical' (n = 4) and 'intermediate clerical and administrative' (n = 2). The participants' gum health experiences ranged from very mild symptoms (bleeding when brushing) through to severe periodontitis. Participants sat with a researcher and completed the GHEQ, and were asked to comment on any issues they had with individual questions or the measure as a whole. Comments were collated at the end of this process and assessed against the original measure by the research team. Changes to the measure were made in line with these

comments. These changes typically included changes to response sets (frequency vs. severity), clarity of the meaning of some questions, positioning of items (in subscales), the wording of some items, item wording being too long and new topics arising from these discussions. Issues of clarity were a priority; however, relevance ratios were not used as part of the process.

# 2.5 | Cross-sectional validation (internal reliability, construct and criterion validity, test-retest reliability)

In line with the gold-standard approach to developing person-centred measures, the next step in the development of this new conditionspecific gum health-related quality of life measure was cross-sectional validation, to assess its psychometric properties. In the context of this study, the key elements of cross-sectional validation are defined as the evaluation of internal reliability, construct and criterion validity and test-retest reliability of the preliminary measure. To examine construct and criterion validity and internal reliability, the GHEQ was tested cross-sectionally in a sample of 152 participants recruited online through the University of Sheffield (67.1%) and a third-party recruitment company (32.9%). This number was based on previous research that validated an oral health measure using a similar sample size (Boiko et al., 2010). An additional four participants were recruited through the University of Sheffield but did not access the questionnaire, and no reason was given for this. Questionnaires were administered through SurveyMonkey (www.surveymonkey.co.uk) and the recruitment company's custom online platform.

Potential participants were asked a series of questions to assess their gum-related symptoms, and whether they had been diagnosed with periodontitis, were currently having treatment for periodontitis (a list was given; work on the root, root planing), currently had symptoms that were consistent with periodontitis (a list was given: tooth mobility, sores in mouth, bad breath, pus between gums and teeth, none of the above). Participants answering 'no' to these questions were included based on having symptoms associated with gingivitis (or no symptoms). Participants answering 'yes' to the above questions were also asked whether they currently wore dentures or had experienced tooth loss due to decay or through removal of wisdom teeth. Anyone responding 'yes' to either of these two questions was excluded, as dentures can affect gum health, and tooth loss through caries and removal of wisdom teeth are not gum related. An additional question on whether participants were currently undergoing orthodontic treatment (which can affect gum health) was also asked, and anyone responding 'yes' was also excluded.

Questionnaire items could not be skipped, and therefore there were no missing responses. Efforts were made to recruit participants with a range of ages, genders and socio-economic backgrounds, although no quotas were in place, and the sample is unlikely to be nationally representative. Of this sample, 111 were identified as having self-reported symptoms associated with gingivitis (based on the recruitment questions), with 41 having self-reported symptoms associated with periodontitis.

For assessing test–retest reliability, it was estimated that 25–30 participants would need to complete the GHEQ again, roughly 2 weeks after completing it the first time. Twenty-seven participants completed this task. Again, attempts were made to include a range of ages, genders and socio-economic backgrounds in this sub-group.

## 2.5.1 | Analytical procedures

Assessment of the GHEQ's construct and criterion validity and internal reliability was conducted in multiple stages. First, data were described using appropriate measures of central tendency and spread for each item and scale score. Item impact values for scale items were also calculated, as a product of the mean score and the percentage of participants who were impacted by an item (Boiko et al., 2010)—those responding 'occasionally', 'fairly often' or 'very often', or 'agree a little', 'agree' or 'strongly agree' depending on the item and its response format. Preliminary psychometric analysis determined internal consistency using item and subscale total correlations, Cronbach's alpha and test–retest reliability via intra-class correlation coefficients (ICCs). Construct validity was assessed by correlating impact scales and subscale scores with a global gum health rating. Data were analysed using SPSS 25 (IBM, 2017). A *p*-value of .05 was used as the level of significance in hypothesis testing.

# 3 | RESULTS

Issues identified by the pilot testing included changes to response formats (switching from agreement scales to frequency scales, and changing the wording or number of response options), removal of one unclear question (whether participant noticed space between their teeth), changing of question wording for clarity (i.e., 'reddened gums' instead of 'red gums'; 'to others' added to 'noticeability of symptoms' as a reference point), movement of items to different subscales (i.e., an item on whether participants felt they could do anything about problems with their gums was moved from the 'changes in everyday life' subscale to the 'identity' subscale), changing item order to aid the flow of the measure and adding two items due to these topics coming up in the pilot testing (whether participants had been formally diagnosed with a gum condition, and whether participants had experienced previous treatment for gum disease). Despite these issues, participants understood the scales in the measure, and did not have any major or consistent problems in using the GHEQ.

An initial 64-item measure was generated from analysis of the qualitative data and pilot testing. This consisted of seven subscales: symptoms (n = 17); changes in everyday life (n = 13); social impacts (n = 5); psychological impacts (n = 11); identity (n = 5); overall impact and quality of life (n = 7); and an additional subscale on the timeline of symptoms and treatment (n = 6) (Table 1). Items were worded in line with participants' comments from the qualitative interviews, which tended to reflect on their experiences in a negative way. Response formats were designed so that anyone who did not view their gum health (or individual items) in a negative way could answer 'never' or 'strongly disagree' to reflect this. Subscales had differing response options depending on what that subscale was measuring. For example, subscales on symptoms and changes in everyday life were concerned with how often participants experienced these issues ('very often' to 'never'), while subscales on themes such as social and psychological impacts were concerned with the extent to which a given item affected a participant ('strongly agree' to 'strongly disagree'). Again, these scales were determined by the way participants tended to talk about these issues during the qualitative interviews.

**TABLE 1** Format of the gum health experience questionnaire.

| Subscale                           | No. of items | Purpose  | Summary measure   |
|------------------------------------|--------------|--|---|
| Symptoms                           | 17           | Measure the impacts of gum-related symptoms                  | 5-point Likert scale: $5 = \text{Never to } 1 = \text{Very often}$  |
| Changes in everyday life           | 13           | Measure everyday impacts                                     | 5-point Likert scale: $5 = \text{Never to } 1 = \text{Very often}$  |
| Social impacts                     | 5            | Measure impacts on social activities                         | $\label{eq:constraints} \mbox{6-point Likert scale: } \mbox{6} = \mbox{Strongly agree to } \mbox{1} = \mbox{Strongly} \\ \mbox{disagree}$ |
| Psychological impacts              | 11           | Measure impacts on psychological<br>and emotional factors    | $\label{eq:constraints}                                    $  |
| Identity                           | 5            | Measure the way participants see themselves                  | $\label{eq:constraints}                                    $  |
| Overall impact and quality of life | 7            | Measure overall impacts and health perceptions               | 6-point Likert scale: 6 = Strongly agree to 1 = Strongly disagree   |
|                                    |              |  | 5-point Likert scale: $5 = Very \text{ bad to } 1 = Very \text{ good}$ (Global gum health rating)   |
|                                    |              |  | 5-point Likert scale: $4 = \text{Extremely to } 1 = \text{Not at all}$ (How much gums affect quality of life/bother)                      |
| Timeline of symptoms and treatment | 6            | Measure history of symptoms, dental attendance and treatment | Each item treated separately  |

Summary measures were created for the total score and the subscale total scores. The total score was calculated as the sum of the item scores for each participant, with a possible range of 55-300. The 'timeline of symptoms and treatment' (n=6) and the three global gum health questions in the 'overall impact and quality of life' subscale did not count towards the impact scale. Subscale scores were also calculated this way. The extent of impact was calculated as the number of impacts per participant, recorded by the number of items with which each participant broadly agreed. Depending on the question, item responses of 3-5 ('occasionally' to 'very often') and 4-6 ('agree a little' to 'strongly agree') were counted as 1 for the total extent score. The extent score had a possible range of 0-55.

# 3.1 Descriptive analysis

Mean scores for all summary measures were towards the lower end of the possible range. Although there was substantial spread (mean total score = 111.6; possible range for total score = 55–300), the data were skewed, reflecting the 72.4% of participants who did not believe they had gum disease. Total score and extent data were also non-normally distributed. The data are summarised in subscale scores in Table 2.

Mean scores (SD), item impacts and item-total correlations for individual items in the impact scale (Q1–55) are presented in Table 3. Item impact (mean score multiplied by the proportion with that impact) demonstrated a wide range (0.00–211.42).

# 3.2 | Reliability and validity

Nearly all item-total correlations were above .4 (Table 3), with the exceptions of the following items: I avoid certain foods; Bleeding when eating; I avoid brushing my teeth; I have had to use interdental brushes. The impact scale and subscales of the GHEQ also demonstrated high internal consistency (Table 4). Cronbach's alpha (a measure of how closely related sets of items are as a group) for the total impact score was .972, with the alpha scores for the subscales

ranging from .835 (identity subscale) to .956 (psychological subscale), indicating good to excellent internal consistency.

Test–rest reliability was calculated for the participants (n=27) who repeated the measure 2 weeks after first completing it. The ICC (two-way random, absolute agreement) was 0.964, indicating very high agreement. Test–retest reliability was lowest for the 'overall impact and quality of life' subscale (0.906), although this was still very high. Total and subscale scores for the GHEQ all correlated significantly with a global gum health rating (Table 5), indicating good construct validity, although the 'social impacts' subscales scored poorly relative to the other subscales.

### 4 | DISCUSSION

The aim of this study was to develop and conduct a preliminary validation of the GHEQ as a measure of quality of life in people across the gum health–disease continuum. This is the first study to develop a condition-specific measure related to this continuum. The GHEQ was developed through multiple stages, including use of a robust theoretical framework (Wilson & Cleary, 1995), informing the interview guide, analysis and development. Previous qualitative research was used to populate both the model and instrument with items, with face validity considered carefully in its development by deriving items from statements in qualitative interviews (Broomhead et al., 2022). The measure is person-centred in taking into the account the experiences of participants in its design, although it is also essential to acknowledge the importance of the experience and knowledge of dental professionals and what this can add in the design of such measures. Outcomes of pilot testing support the face validity of the measure.

Descriptive analysis of the GHEQ data demonstrated that, aside from symptoms and management of gums, there were relatively high mean and item impact scores for items related to feelings of guilt, concerns over gum problems leading to further expenses and treatment, concerns that gum problems cannot be reversed or will get worse and participants feeling that it would be hard to improve the state of their gums. This demonstrates the types of worries and concerns that people experiencing problems with their gums may face in everyday life, as well as the importance of a person-centred approach in developing

**TABLE 3** Mean scores, items impacts and item-total correlations for individual items in the gum health experience questionnaire.

|          |   |      |     |             | Item-total  |
|----------|---|------|-----|-------------|-------------|
| Item no. | Item  | Mean | SD  | Item impact | correlation |
| 1        | Bleeding when spitting after brushing or flossing?                                | 2.7  | 1.3 | 158.63      | .546        |
| 2        | Bleeding when eating?   | 1.3  | 0.6 | 6.74        | .487        |
| 3        | Pus when pressing your gums?  | 1.0  | 0.2 | 0.00        | .161        |
| 4        | Receding gums?  | 2.0  | 1.4 | 59.51       | .598        |
| 5        | Swollen gums?   | 1.8  | 1.1 | 43.09       | .664        |
| 6        | Reddened gums?  | 1.9  | 1.1 | 59.37       | .677        |
| 7        | Loose teeth?  | 1.2  | 0.7 | 4.74        | .240        |
| 8        | Bad breath?   | 2.1  | 1.1 | 72.87       | .571        |
| 9        | A bad taste in your mouth?  | 2.0  | 1.0 | 62.15       | .501        |
| 10       | A metallic taste?   | 1.7  | 0.9 | 37.36       | .516        |
| 11       | Sore gums?  | 1.9  | 1.0 | 56.25       | .597        |
| 12       | Painful gums?   | 1.6  | 0.8 | 26.15       | .614        |
| 13       | Irritated gums?   | 1.7  | 0.9 | 34.26       | .633        |
| 14       | Sensitive gums?   | 2.1  | 1.2 | 68.75       | .597        |
| 15       | Uncomfortable gums?   | 1.7  | 0.9 | 36.00       | .574        |
| 16       | Tender gums?  | 1.8  | 1.0 | 43.33       | .663        |
| 17       | Throbbing gums?   | 1.3  | 0.7 | 13.22       | .591        |
| 18       | I have had to change what I eat   | 1.3  | 0.7 | 13.22       | .579        |
| 19       | I have had to change where I eat in my mouth                                      | 1.7  | 0.9 | 39.61       | .625        |
| 20       | I have to eat more slowly   | 1.5  | 0.9 | 24.00       | .549        |
| 21       | Problems with my gums make it difficult for me to chew certain foods              | 1.4  | 0.8 | 16.93       | .572        |
| 22       | I avoid certain foods   | 1.6  | 1.0 | 24.47       | .577        |
| 23       | Food gets stuck in the space between my teeth                                     | 3.1  | 1.3 | 211.42      | .588        |
| 24       | I have had to change my toothbrush  | 1.8  | 1.1 | 44.00       | .611        |
| 25       | I have had to change how I brush my teeth   | 1.9  | 1.2 | 53.18       | .656        |
| 26       | I avoid brushing my teeth   | 1.1  | 0.4 | 3.72        | .283        |
| 27       | I have had to change the type of toothpaste I use                                 | 1.6  | 1.1 | 34.53       | .465        |
| 28       | I have had to use mouthwash   | 2.1  | 1.5 | 76.03       | .463        |
| 29       | I have had to floss   | 2.5  | 1.6 | 113.75      | .428        |
| 30       | I have had to use interdental brushes   | 1.8  | 1.4 | 43.34       | .294        |
| 31       | I avoid smiling or laughing   | 1.8  | 1.2 | 26.63       | .592        |
| 32       | I avoid intimacy  | 1.6  | 1.1 | 14.03       | .612        |
| 33       | I have difficulty talking   | 1.3  | 0.7 | 2.51        | .507        |
| 34       | The problems with my gums are very noticeable to others                           | 1.5  | 0.9 | 8.59        | .568        |
| 35       | I worry about what other people think of me                                       | 1.9  | 1.4 | 36.63       | .609        |
| 36       | I feel guilty that I am not doing enough to look after my gums                    | 2.9  | 1.5 | 122.11      | .603        |
| 37       | I am concerned that the problems with my gums will lead to more financial expense | 2.9  | 1.7 | 120.61      | .784        |
| 38       | I am concerned that the problems with my gums will lead to more treatment         | 3.0  | 1.7 | 129.83      | .835        |
| 39       | I am concerned that the problems with my gums cannot be reversed                  | 3.0  | 1.7 | 119.19      | .792        |
| 40       | I am concerned that the problems with my gums will get worse                      | 3.2  | 1.7 | 164.13      | .787        |
| 41       | I am frustrated because of the problems with my gums                              | 2.5  | 1.5 | 68.25       | .848        |
| 42       | It is hard to improve the state of my gums  | 2.9  | 1.6 | 114.47      | .712        |
| 43       | I get irritated because of the problems with my gums                              | 2.3  | 1.5 | 52.34       | .774        |
| 44       | The problems with my gums make me miserable                                       | 1.9  | 1.3 | 22.26       | .737        |
|          |   |      |     |             |             |

| Item no. | Item   | Mean | SD  | Item impact | Item-total correlation |
|----------|--|------|-----|-------------|------------------------|
| 45       | The problems with my gums make me feel self-conscious  | 2.2  | 1.5 | 46.32       | .788                   |
| 46       | The problems with my gums make me feel embarrassed   | 2.0  | 1.4 | 24.75       | .775                   |
| 47       | They have made me feel different   | 2.0  | 1.3 | 32.05       | .766                   |
| 48       | They make me feel old  | 2.4  | 1.6 | 64.93       | .660                   |
| 49       | They stop me doing what I want to do   | 1.7  | 1.0 | 10.92       | .623                   |
| 50       | I do not feel I can do anything about the problems with my gums  | 2.4  | 1.5 | 56.61       | .673                   |
| 51       | I have accepted that the problems with my gums are part of me  | 2.8  | 1.7 | 119.58      | .576                   |
| 52       | I am concerned that I could lose some of my teeth because of the problems with my gums                           | 3.1  | 1.7 | 141.18      | .751                   |
| 53       | The problems with my gums make me feel unhealthy   | 2.6  | 1.5 | 86.57       | .785                   |
| 54       | I am concerned the problems with my gums may be linked to other health conditions, e.g., diabetes, heart disease | 2.3  | 1.5 | 52.96       | .764                   |
| 55       | I think the problems with my gums are serious  | 2.2  | 1.4 | 40.16       | .781                   |

Reliability of the impact scale and subscales. TABLE 4

|                                    | No. of items | Cronbach's alpha $(n=152)$ | ICC (n = 27) | ICC 95%<br>CI (upper) | ICC 95%<br>CI (lower) |
|------------------------------------|--------------|----------------------------|--------------|-----------------------|-----------------------|
| Total score                        | 55           | .972                       | 0.964        | 0.983                 | 0.921                 |
| Subscales                          |              |                            |              |                       |                       |
| Symptoms                           | 17           | .910                       | 0.952        | 0.978                 | 0.895                 |
| Changes in everyday life           | 13           | .861                       | 0.957        | 0.980                 | 0.906                 |
| Social impacts                     | 5            | .864                       | 0.970        | 0.986                 | 0.934                 |
| Psychological impacts              | 11           | .956                       | 0.927        | 0.967                 | 0.837                 |
| Identity                           | 5            | .835                       | 0.950        | 0.977                 | 0.890                 |
| Overall impact and quality of life | 4            | .913                       | 0.906        | 0.957                 | 0.793                 |

Abbreviations: CI. confidence interval: ICC. intra-class correlation coefficient.

TABLE 5 Correlations between total score, subscales and global gum health status.

|                                    | Correlation |
|------------------------------------|-------------|
| Total score                        | .728        |
| Subscales                          |             |
| Symptoms                           | .606        |
| Changes in everyday life           | .541        |
| Social impacts                     | .440        |
| Psychological impacts              | .725        |
| Identity                           | .678        |
| Overall impact and quality of life | .718        |

Note: All p < .05, Pearson correlation.

measures such as the GHEQ. Additionally, these types of concerns have not often been included in previous OHRQoL measures. Previous research has demonstrated that both self-impression and self-awareness of oral health are associated with periodontal presence and stages (Deng et al., 2021a), while gingival bleeding when brushing

has been shown to perform acceptably in discriminating gingivitis from periodontal health (Deng et al., 2021b). Additionally, selfreported outcomes are considered to be central in understanding oral health conditions and what it means to live with them (Sischo & Broder, 2011).

The core part of the questionnaire comprised 55 items, divided into 6 subscales that form an impact scale. Preliminary assessment of the items and subscales supports the validity and reliability of the impact scales. Content validity is indicated by a wide range of responses (indicated by large standard deviations) in both item scores and total scores and allows scope for the items and scores to discriminate between different levels of experience of impact. The range of responses to individual items suggests that participants can distinguish precise gradations of impact and supports the use of a Likert scale with many points.

The GHEQ has excellent internal reliability as measured by itemtotal correlations and Cronbach's alpha. Internal reliability is a measure of the extent to which all the items relate to the same dimension, with 51 of the 55 impact scale items having an item-total correlation of .4 or more. Correlations of at least .3 were required in a similar study

of validity of the Child Oral Health Impact Profile (Dunlow et al., 2007). A Cronbach's alpha score of at least .7 is required for health-related quality of life measures (Nunnally, 1978) but values greater than .9 may indicate redundant items (alpha = .972 in this study), and is an area that should be considered with the measure. Item impacts demonstrated a wide range, although not as wide a range as has been shown with other oral health outcomes such as dentine hypersensitivity (Boiko et al., 2010).

Test-retest reliability of the measure was also acceptable, providing a reproducible base against which changes can be assessed when the measure is used for evaluative purposes. This validation supports the feasibility of a condition-specific measure for recording biopsychosocial impacts of different periodontal conditions, and the value of condition-specific impacts and their measurement (Boiko et al., 2010). Often, existing OHRQoL measures do not address links between a given condition and OHRQoL in enough depth. Such measures have been subject to previous critiques (Locker & Allen, 2007). The GHEQ offers a promising alternative to existing OHRQoL measures due to its direct relevance to a large range of impacts associated with gum health, related to symptoms, changes in eating and oral hygiene habits, social situations, psychological distress, adaptations and identity. This aids in the discriminative capacity of the measure.

Construct validity was indicated by significant correlations between total and subscale scores and global ratings of gum health. It should be noted that the 'social impacts' subscale scored relatively poorly in this regard and is an area that should be further investigated. This ability to distinguish between people who perceive themselves as having different levels of gum health and with varying degrees of impact on overall quality of life suggests that the measure may be useful as a discriminant index. Furthermore, when coupled with the very high test-retest reliability, this level of discriminant validity hints at good evaluative properties, as both these qualities are required in such an evaluative scale. However, longitudinal evaluation is required for the measure to be considered evaluative. Although not the purpose of this study, the GHEQ detected impacts on OHRQoL associated with gum health. Issues related to gum health also had tangible impacts on everyday life and may have detrimental effects on health.

Limitations of the research include the pilot testing of the original measure among a less than representative (relatively small) sample, which may have affected face validity. It is hard to say from the sample size used in the qualitative stage of the work whether the lack of male participants in the pilot testing was a reflection of differing attitudes towards the questionnaire, or whether this affected the face validation of the measure. This is a potential limitation though. Over two-thirds of the sample for the quantitative analysis coming from a university setting means it is unlikely to be nationally representative, and this should be borne in mind when considering the applicability of these findings in other settings. Although attempts were made to avoid the sample becoming skewed by a given group or socio-demographic characteristic through checking of participant details as the study progressed, unfortunately some groups were underrepresented. Additionally, the GHEQ may

contain redundant items (indicated by Cronbach's alpha scores over .9) that are too similar, and may therefore require removal of numerous items as part of future research before it is suitable for future use. The large number of items may also make the GHEQ less practical to administer in clinical settings, further emphasizing the need for refining and reducing the overall number of items. Despite the risk of additional burden to participants, the inclusion of existing measures such as OHIP (Slade & Spencer, 1994) or OIDP (Adulyanon & Sheiham, 1997) and clinical measures alongside a single global health rating question may also have aided with the evaluation of the measure's construct validity.

Additionally, despite the encouraging results of the study, the lack of sample power calculations is another limitation. It should be noted though that all but one confidence interval (CI) (the lower CI for the 'overall impact and quality of life' subscale) for the ICC scores were above 0.8, and these scores, in line with previous research on sample sizes for reliability studies (Borg et al., 2022), suggest the sample used in this research may be of an appropriate size. The lack of relevance ratios during the process of determining face validity and the lack of confirmatory factor analysis are further limitations, although in the case of the latter this would form part of a separate stage of the research as part of the gold-standard approach to developing person-centred measures (Guyatt et al., 1986). Finally, despite inclusion of test-retest reliability in this research (over a 2-week period), further longitudinal evaluation is required for the measure to be considered evaluative. Further testing of the face validity of the measure would also be required.

Nevertheless, these data indicate great potential. There is no gold-standard measure of OHRQoL in relation to gum health, and so no assessments of criterion validity could be made. These preliminary assessments indicate that the GHEQ holds substantial promise as a measure of gum health-related quality of life. However, before the measure can be used with confidence, further work is required, including considering the face validity of the measure, as well as refining the measure and reducing the overall number of items. A number of items with low item-total correlations were identified, which could be removed ('I avoid certain foods'; 'Bleeding when eating'; 'I avoid brushing my teeth'; 'I have had to use interdental brushes'). However, in line with the gold-standard approach for developing person-centred measures (Guyatt et al., 1986), the measure will need to be further refined using longitudinal validation (as well as confirmatory factor analysis and examination of responsiveness) in a different sample, where redundant items will then be deleted. This process is particularly important (given the low item-total correlations of the items above and the Cronbach's alpha scores over .9) in order to identify the most and least important items before further refinement of the measure.

This measure continues the shift from existing oral health instruments (used for comparison with general health measures; Allen et al., 1999) towards condition-specific oral health measures based on theory and on the impacts of specific oral conditions in both practical and linguistic terms, and allows for the conceptualisation of quality of life through specific impacts of different oral conditions backed by

theoretical frameworks and qualitative data (Boiko et al., 2010). Many items in OHRQoL measures such as OHIP (Slade & Spencer, 1994), OIDP (Adulyanon & Sheiham, 1997) and GOHAI (Atchison & Dolan, 1990) are combined with impacts on teeth and the mouth or are not explicitly related to gum health. Although subscales of the GHEQ are similar to themes covered in the aforementioned measures, items such as those covering identity, guilt, financial concerns, worries over symptom progression and adaptations made to accommodate symptoms were important themes emerging from this research, which are not accounted for in other OHRQoL measures. This is also the case for the range of gum symptoms, everyday impacts and individual feelings towards symptoms, demonstrating that current measures do not consider all aspects relevant to gum health and that a gumspecific measure may have value in research and clinical settings (Broomhead et al., 2022).

## 5 | CONCLUSION

Preliminary psychometric validation of the GHEQ found that the measure shows promise as condition-specific measure of quality of life in people from across the gum health-disease continuum. The measure has good to excellent internal and test-retest reliability, good content validity and significant construct validity. The data also indicate that people with gum health-related symptoms experience different degrees of discomfort and impacts caused by their condition (gingivitis and periodontitis).

Further work is required to revise the GHEQ based on the results of the psychometric assessments of the measure, including further work on face validity. In line with the gold-standard approach to developing person-centred measures (Guyatt et al., 1986), the next steps would need to revise and reduce the measure in length through a separate longitudinal follow-up study, use confirmatory factor analysis to see how well scale items measure underlying constructs (Boiko et al., 2010) and examine the responsiveness and evaluative properties of the measure. The results of the assessments are in line with conclusions from previous qualitative work (Broomhead et al., 2022) and shed new light on findings of research on gum health-related conditions. Gum health shows promise as an area to study the way in which people construct their knowledge about their oral health.

### **AUTHOR CONTRIBUTIONS**

S. R. Baker, T. Broomhead, B. J. Gibson, C. Parkinson and P. G. Robinson conceived and planned the idea. S. R. Baker conceived and designed the study. T. Broomhead collected the research data. S. R. Baker, T. Broomhead, B. J. Gibson, M. V. Vettore and P. G. Robinson were involved in the analysis of the qualitative data, and S. R. Baker, T. Broomhead, B. J. Gibson and P. G. Robinson were involved in the analysis of the quantitative data. All authors were involved in the interpretation of data, reviewed and critically contributed to the drafting of the manuscript and approved the final version of the manuscript.

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#### CONFLICT OF INTEREST STATEMENT

T. Broomhead and B. J. Gibson report grants from GlaxoSmithKline Consumer Healthcare (now Haleon), during the conduct of the study, and grants from Haleon, outside the submitted work. S. R. Baker, P. G. Robinson and M. V. Vettore report grants from GlaxoSmithKline Consumer Healthcare (now Haleon), during the conduct of the study. C. Parkinson is an employee of Haleon.

#### DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available on reasonable request from the corresponding author.

#### **ETHICS STATEMENT**

This research was approved by the University of Sheffield's research ethics committee (Applications 022394 and 036474).

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