Cross-Cultural Adaptation of The Spanish MINICHAL Instrument Into English For Use In The United Kingdom

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Research

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Abstract

**Background:** Hypertension is a highly prevalent condition, with optimal treatment to BP targets conferring significant gains in terms of cardiovascular outcomes. Understanding why some patients do not achieve BP targets would be enhanced through greater understanding of their health-related quality of life (HRQoL). However, the only English language disease-specific instruments for measurement of HRQoL in hypertension have not been validated in accordance with accepted standards. It is proposed that the Spanish MINICHAL instrument for the assessment of HRQoL in hypertension could be translated, adapted and validated for use in the United Kingdom. The aim of the study was therefore to complete this process, using a cohort of patients enrolled in an 18-week programme for the treatment of grade II-III hypertension.

**Methods:** The MINICHAL authors were contacted and the original instrument obtained. This was then translated into English by two independent English-speakers, with these versions then reconciled, before back-translation and subsequent production of a 2nd reconciled version. Thereafter, a final version was produced after cognitive debriefing, for administration and psychometric analysis in the target population.

**Results:** The final version of the instrument was administered to 30 individuals with grade II/III hypertension before and after 18 weeks’ intensive treatment. Psychometric analysis demonstrated a floor effect, though no ceiling effect. Internal consistency for both state of mind (StM) and somatic manifestations (SM) dimensions of the instrument were acceptable (Cronbach's alpha = 0.81 and 0.75), as was test-retest reliability (ICC=0.717 and 0.961) and construct validity, which was measured through co-administration with the EQ5d5L and Bulpitt-Fletcher instruments. No significant associations were found between scores and patient characteristics known to affect HRQoL. The EQ5D5L instrument found an improvement in HRQoL following treatment, with the StM and SM dimensions of the English language MINICHAL trending to support this (d=0.32 and 0.02 respectively).

**Conclusions:** The present study details the successful English translation and validation of the MINICHAL instrument for use in individuals with hypertension. The data reported also supports an improvement in HRQoL with rapid treatment of grade II/III hypertension, a strategy which has been recommended by contemporaneous European guidelines.

**Trial registration:** ISRCTN registry number: 57475376 (assigned 25/06/2015).

Background

Hypertension affects over 1 billion people worldwide, a number which is expected to rise to 1.5 billion by 2025(1). The benefits of blood pressure (BP) control are well-established, with a halving of cardiovascular risk for each incremental reduction of 20/10mmHg down to 115/80mmHg(2). Despite these clear benefits of effective antihypertensive therapy, BP control is achieved in only 63% of patients with treated hypertension in England(3).
Non-adherence to medical therapy is an important contributor to apparent treatment-resistant hypertension, as shown by the incorporation of drug level assays and directly-observed therapy into specialist hypertension clinics (4–6). Poor adherence to medication regimens is particularly understandable for a condition in which the majority of patients are asymptomatic before treatment, considering that diagnosis and treatment have the potential to negatively impact health-related quality of life (HRQoL). It is therefore clear that addressing the HRQoL of patients with hypertension should form part of the holistic approach to care for these individuals, particularly given the association between impaired subjective wellbeing and cardiovascular events (7–9).

Previous studies have shown HRQoL to be reduced in those with a diagnosis of hypertension compared with control subjects (10, 11). A cross-sectional study has demonstrated that this may, at least in part, be owing to patients’ awareness of their diagnosis (12), with higher perception of well-being found in those who were incidentally hypertensive but not treated, as compared to those with a known diagnosis of hypertension. Additionally, comorbid disease, medication side effects or under-reported symptoms attributable to hypertension (such as mood change, headache or dizziness) may adversely affect HRQoL. Treatment of hypertension, for example with 1 month of angiotensin receptor blockade (13), improves HRQoL in longitudinal studies. BP reduction and achievement of target BP following combination therapy have also been shown to be positive influencers on perceived well-being (14). Monitoring of HRQoL during treatment may therefore provide a useful tool in determining those participants at higher risk of adverse events or non-adherence.

To date, studies exploring HRQoL in hypertensive subjects have employed generic instruments alone (such as the EuroQol-5D or SF-36) or in combination with disease-specific instruments (10–13). Disease-specific instruments are valued as they are felt to be more responsive to change; it is unlikely that generic instruments are able to adequately capture HRQoL in all populations suffering from all types of conditions (15). Although disease-specific instruments for hypertension have been validated in Spanish (16, 17), Brazilian Portuguese (18) and Italian (19), those in English, such as the Bulpitt-Fletcher questionnaire (20), have not undergone appropriate validation according to current standards (21, 22).

Considering the Bulpitt-Fletcher instrument in detail, a degree of redundancy can be demonstrated, with 11 of 46 questions not contributing to the overall score as per the scoring methods proposed by the authors (20). The Bulpitt-Fletcher instrument has a not trivial administrative burden, with an estimated administration time of 20–40 minutes (20), which is incongruent with the notion that questionnaires should be kept short and simple to minimize measurement error (23) and further limiting its widespread adoption. In addition, not all questions within the Bulpitt-Fletcher instrument can be applied to all participants, with question 35 applying to men only and question 37 to only those in paid employment. This will inevitably lead to missing data when the instrument is administered, impacting on its performance. Further, the Bulpitt-Fletcher instrument includes several items (11, 14, 32, 37) that place it overall among clinimetric measures rather than psychometric measures and hence better placed to estimate disease severity than measuring HRQoL (24, 25). Finally, given that both treatment and general patient perceptions and expectations have changed markedly since the inception of the Bulpitt-Fletcher
instrument, it may no longer capture the somatic manifestations of side effects from first-line medications or up-to-date cultural values affecting HRQoL. For example, questions 21, 25 and 35 aim to establish common side effects of beta-blockers, which are no longer considered a mainstay of treatment for hypertension(26) and questions related to sexual activity (questions 31–35) may raise more doubts regarding the safe storage of sensitive personal data in the digital age.

Adapting and validating the readily available Spanish MINICHAL hypertension disease-specific instrument in English offers therefore obvious advantages and may be an efficient alternative to the development of a new instrument. The MINICHAL instrument, originally conceived and validated in Spanish(17) (Fig. 1), has an average administration time of just over 7 minutes,. Although 17 questions are described, the final question pertains to the subject’s overall perception of their own health; it is not included in the scoring (or the validation) of the original instrument. Within the remaining 16 questions, 2 domains have been determined: State of Mind (StM) and Somatic Manifestations (SM). Scores range from 0 to 30 for StM and from 0 to 18 for SM; lower scores reflect higher HRQoL (17). Psychometric evaluation (16, 17) has shown that it meets current standards for internal consistency, test-retest reliability and responsiveness to change. Validation of the MINICHAL instrument has been confirmed through co-administration with 2 generic instruments and responsiveness to change evaluated following 6 months of antihypertensive treatment intensification, finding a positive correlation between degree of BP (and heart rate) reduction and improvement in the MINICHAL score, especially the StM domain(16).

The aim of this study was therefore to translate, adapt and evaluate the psychometric performance of the existing MINICHAL for its use in the United Kingdom. Within this, we aimed to test responsiveness to change of the instrument through administration before and after an 18-week intensive treatment programme for subjects with newly diagnosed grade II-III hypertension(27).

**Methodology**

1. Translation and cross-cultural adaptation

Adaptation of the MINICHAL instrument into English followed the guidelines set out by the International Society for Quality of Life Research (ISOQOL)(28), International Society for Pharmacoeconomics and Outcomes Research (ISPOR)(22) and the Evaluating the Measurement of Patient-Reported Outcomes (EMPRO) tool(21).

The MINICHAL instrument was obtained from its original publication in Spanish(16) (Fig. 1); and permission for adaptation secured through contact with authors of the original publication.

Forward translation was provided by 2 independent native English-speakers. This version was discussed by a panel of researchers with experience of cross-cultural adaptation, including 1 of the aforementioned translators, producing a consensus for each of the 16 questions in turn. This process produced the first reconciled version of the English instrument.
The first reconciled version was then back-translated by a third independent native Spanish-speaking professional translator. To ensure that language equivalence between questionnaires had been achieved, this version was compared with the original Spanish MINICHAL to highlight discrepancies, allowing the panel to produce a second reconciled version of the questionnaire.

Following this, the second reconciled version underwent cognitive debriefing (pilot testing using the techniques “thinking aloud”, probing and debriefing) with 8 participants from the typical demographics of the target population with hypertension, all of whom were native English-speakers and included an appropriate range of educational backgrounds. Harmonization with previous Brazilian Portuguese translation of the instrument was also completed at this stage (18). The results informed the production of the final version of the adapted instrument.

2. Evaluation of psychometric properties

Accepted standards for psychometric evaluation of the instrument were followed as per ISOQOL(28), ISPOR(22) and EMPRO(21). The metric qualities were determined through administration at weeks 0, 8, 10 and 18 of an 18-week treatment programme for patients with newly-diagnosed grade II and grade III hypertension. This treatment programme aimed to enroll 50 participants and it was envisaged that the new instrument be applied to all participants enrolled subsequent to completion of the necessary translation and cross-cultural steps.

As in the original validation and subsequent cross-cultural adaptation, the StM and SM domains were reported and the final question of the instrument reflecting the subjects overall assessment of their HRQoL was not used in the analysis(16–18). Internal consistency was determined by calculating pairwise correlations between items and Cronbach’s alpha. Test-retest reliability was evaluated through administration of the instrument twice, 2 weeks apart, after no change in medication at weeks 8 and 10 after enrollment (intraclass correlation coefficient). Given the reliability of 0.80 in the original MINICHAL instrument evaluation(17), a 2-tailed intraclass correlation coefficient was expected to be > 0.70 ($\alpha = 0.05$).

Construct validity was assessed through co-administration with a generic questionnaire (EQ-5D-5L) and the hypertension-specific Bulpitt-Fletcher instrument (Spearman correlation), predicting a moderate to low correlation with the EQ-5D-5L instrument and moderate to high correlation with the Bulpitt-Fletcher instrument. Construct validity was further evaluated through association with variables known to affect quality of life measures in hypertensive patients, including heart rate, body mass index (BMI), number of antihypertensive agent, BP and female gender(13, 29) (Mann-Whitney test and Pearson’s correlation coefficient). As reported in the original evaluation of the MINICHAL instrument, it was predicted that female gender would be associated with an increased score in the StM domain, increased age and increased BMI would be associated with an increased score in the SM domain and raised BP and number of co-morbidities would correlate with an increased score in both domains(17).
Responsiveness to change was evaluated through comparison of the MINICHAL scores before and after 18 weeks’ intensive antihypertensive treatment (paired t test, following test of normality, and effect size). It is anticipated that this intervention will affect HRQoL as a previous meta-analysis has found a small but significant improvement in general well-being following active treatment of hypertension (d = 0.139) (30), including whilst using the same pharmacological groups employed in the treatment protocol, with the potential for accelerated treatment in our protocol to accentuate HRQoL gains.

In the original evaluation of the Spanish MINICHAL instrument, re-testing 6 months after treatment intensification was found to improve HRQoL, with an effect size of 0.55 and 0.46 for the StM and SM domains respectively. Moreover, there was a significant correlation between improvement in HRQoL and BP reduction (17). In the present study, univariate linear regression models were used to determine the relationship between BP response during the study and instrument scores as outcome variables, with the hypothesis that change in HRQoL would be related to degree of BP reduction, particularly the StM domain of the MINICHAL instrument, as previously reported.

Results

Translation

Differences between the forward translations were noted, in particular the grading of responses to each question being translated as “not at all, yes occasionally, yes quite often and yes often” compared with “no not at all, yes a little, yes a fair amount and yes a lot”. Reconciliation was achieved through a meeting between the investigators and one of the forward translators, with phraseology chosen to provide a more distinct gradient of response in the final reconciled version: “no not at all, yes a little, yes a moderate amount and yes a lot”. In addition, the two forward translations for question 3 were markedly different, focusing on “being understood by people” versus “getting on with other people”, requiring reconciliation to “Have you had difficulties communicating with other people?”, in order to combine both interpretations of the question. Question 8 produced differing translations: “everyday activities” versus “normal routine”, with “usual activities” chosen for the reconciled instrument as this reflected the sense of both translations. For question 11, “shortness of breath” was felt to be easier to understand than the alternative translation of “feeling of suffocation”. In question 15, “exertion” was selected over “straining”, as it was concluded that the authors of the instrument were seeking to elicit a symptom of ischaemic heart disease rather than muscular chest wall pain on straining.

The reconciled version of the instrument was then back-translated by a native Spanish speaker. This highlighted a difference in question 15 compared with the original Spanish version, with “without having exerted yourself” rephrased to “without physical exertion” as a consequence. The overall grading of response also differed in the Brazilian Portuguese translation when compared with the English back translation, though it was felt that the Portuguese translation lacked sufficient gradient of response between “yes a lot” and “yes very much” and therefore the second reconciled version was preferred.
Cognitive debriefing took place with 8 individuals: the median age was 60 years, 50% were educated to undergraduate degree level or higher and 50% were female. All participants in the cognitive debriefing process reported no difficulties in understanding the questions as drafted in the second reconciled version. No consistent changes to the instrument were suggested and, in light of these findings, a final version of the instrument was approved for evaluation (Fig. 2).

**Instrument evaluation**

The final version of the instrument was administered to 30 native English speakers before and after antihypertensive treatment. Of these, 53% were male, median age was 58.5 years and mean pre-treatment office BP measured 171/101mmHg, falling to 130/80mmHg after 18 weeks of treatment. The characteristics of these participants are given in Table 1.

| Variable                                | Before intervention | After intervention | P value |
|-----------------------------------------|---------------------|--------------------|---------|
| Office systolic BP (mmHg)               | 171 ± 15.8          | 130 ± 10.6         | <0.0001 |
| Office diastolic BP (mmHg)              | 101 ± 11.5          | 80 ± 8.7           | <0.0001 |
| Daytime average systolic BP (mmHg)     | 164 ± 12.2          | 134 ± 10.8         | <0.0001 |
| Daytime average diastolic BP (mmHg)    | 93 ± 10.1           | 78 ± 6.8           | <0.0001 |
| Heart rate (bpm)                        | 69 ± 10.9           | 66 ± 9.6           | 0.024   |
| BMI (kg/m²)                             | 30.0 ± 5.9          | 29.9 ± 5.5         | 0.79    |
| Current smoker (n)                      | 2 (7%)              | 2 (7%)             | 1.00^   |
| Alcohol (units/week)                    | 7 (1–15)            | 2 (1–10)           | 0.36§   |
| Angiotensin receptor blocker (n)        | 0                   | 25 (83%)           | n/a     |
| Calcium channel blocker (n)             | 0                   | 29 (97%)           | n/a     |
| Thiazide diuretic (n)                   | 0                   | 15 (50%)           | n/a     |
| Aldosterone antagonist (n)              | 0                   | 4 (13%)            | n/a     |
| α-blocker (n)                           | 0                   | 1 (3%)             | n/a     |
| β-blocker (n)                           | 0                   | 1 (3%)             | n/a     |
| Number of anti-hypertensives (n)        | 0                   | 2.5 (2–3)          | n/a     |
| Number of other medications (n)         | 0 (0–1)             | 0 (0–1)            | 0.32§   |
| Number of co-morbidities (n)            | 1.0 ± 0.9           | 1.0 ± 0.9          | 1.00    |
Expressed as mean ± standard deviation or median and interquartile range

§Wilcoxon's signed ranks test

^one-sample test of proportions

Floor and ceiling effects

For each item, the minimum score was returned in 67–97% responses, with the greatest floor effect seen in item 3: “Have you had difficulties communicating with other people?”. The maximum score for an item was returned in 0–3% responses, indicating no ceiling effect, as previously reported for the Spanish version of the instrument(17).

Reliability

Reliability (internal consistency) was acceptable for both the StM and SM domains: Cronbach's alpha 0.81 and 0.75 respectively. As 1 participant did not return completed questionnaires for the evaluation of test-retest reliability, the intraclass correlation coefficient (ICC) between the scores derived for the remaining 29 participants who underwent test-retest data acquisition between weeks 8 and 10 of treatment was calculated, with no change in medication undertaken between these two appointments. This determined acceptable test-retest reliability for both domains: StM ICC = 0.717 (95% CI: 0.378–0.913); SM ICC = 0.961 (95% CI: 0.876–0.988).

Validity

Both StM and SM domains significantly correlated with the EQ-5D-5L summary index, EQ-5D-5L linear scale and the Bulpitt-Fletcher instrument (Table 2).

| Instrument/dimension             | StM  | SM  |
|----------------------------------|------|-----|
|                                 | \( r_s \) | \( P \) | \( r_s \) | \( P \) |
| EQ5D5L linear scale              | -0.394 | 0.0019 | -0.362 | 0.0045 |
| EQ5D5L summary index (UK)        | -0.500 | <0.0001 | -0.491 | 0.0001 |
| Bulpitt-Fletcher                 | -0.472 | 0.0001 | -0.291 | 0.0243 |

StM: State of Mind, SM: Somatic Manifestations

Spearman's correlation coefficient (\( r_s \))

All correlations were moderate, with the strongest correlation found between the StM domain and the EQ5D5L summary index (UK values) (Fig. 3). The StM domain showed a higher correlation with the Bulpitt-Fletcher questionnaire than the SM domain. Within the same instruments, correlations were
determined between the StM and SM dimensions of the English MINICHAL ($r_s=0.5257; p < 0.0001$) and between the EQ-5D-5L summary index and EQ-5D-5L linear scale ($r_s=0.3725; p = 0.0034$).

No significant difference was found between genders for either the StM domain (female: 2 (1–5); male: 2 (1-4.5); $p = 0.164$) or SM domain (female: 1 (0–2); male: 1 (0–3); $p = 0.901$). Pearson's correlation was used to explore relationships between scores and patient characteristics. Although most of the associations were in the direction predicted by our hypotheses, none of them were found to be statistically significant (Table 3).

Table 3
Correlations between MINICHAL scores and subject demographic and clinical characteristics

| Variable                  | StM |         | SM |         |
|---------------------------|-----|---------|----|---------|
|                           | r   | P       | r  | P       |
| Age                       | -0.068 | 0.608 | 0.128 | 0.331 |
| BMI (kg/m²)               | 0.024 | 0.858  | 0.105 | 0.426  |
| Office sBP                | -0.044 | 0.737 | -0.004 | 0.975 |
| Office dBP                | -0.034 | 0.796 | -0.181 | 0.166  |
| Daytime average sBP       | 0.079 | 0.551  | 0.034 | 0.798  |
| Daytime average dBP       | -0.001 | 0.993 | -0.187 | 0.152  |
| Heart rate                | -0.117 | 0.372 | -0.194 | 0.138  |
| No. of antihypertensive medications | -0.198 | 0.129 | -0.025 | 0.851  |

StM: State of Mind, SM: Somatic Manifestations, sBP: systolic blood pressure, dBP: diastolic blood pressure

Pearson’s correlation coefficient ($r$)

**Responsiveness**

Results from the application of the patient-reported quality of life instruments before and after 18 weeks of intensive antihypertensive treatment are summarized in Table 4.
Table 4  
Change in patient-reported quality of life after 18 weeks’ intensive antihypertensive treatment  

|                                | Pre-treatment score | Week 18 score | P  | Effect size (d) |
|--------------------------------|---------------------|---------------|----|-----------------|
| EQ5D5L linear scale            | 79.6 ± 13.54        | 88.8 ± 8.11   | 0.0001 | 0.82            |
| EQ5D5L summary index (UK)      | 0.84 ± 0.18         | 0.87 ± 0.17   | 0.05 | 0.17            |
| Bulpitt-Fletcher               | 0.88 ± 0.017        | 0.91 ± 0.017  | 0.049 | 1.76            |
| MINICHAL StM                   | 3.23 ± 3.52         | 2.17 ± 3.03   | 0.076 | 0.32            |
| MINICHAL SM                    | 1.33 ± 1.86         | 1.30 ± 2.11   | 0.932 | 0.02            |

Expressed as mean ± standard deviation  
StM: State of Mind, SM: Somatic Manifestations  

§Paired t-test  
d: Cohen’s  

Following 18 weeks of intensive hypertension treatment there was a significant improvement in quality of life as measured by the EQ-5D-5L, in particular the linear scale (d = 0.82). Application of the MINICHAL instrument produced results in agreement with this, with a greater responsiveness of the StM domain (d = 0.32) when compared with the SM domain (d = 0.02), though these did not reach statistical significance. On the contrary, the Bulpitt-Fletcher instrument found a significant reduction in HRQoL following treatment.

Office systolic BP response to treatment was not associated with a change in any of the measures of HRQoL (StM domain (p = 0.342), SM domain (p = 0.406), EQ-5D-5L linear scale (p = 0.532), EQ-5D-5L summary index (p = 0.740) or Bulpitt-Fletcher scores (p = 0.553)). Neither was the case for daytime average systolic BP measured with ambulatory BP monitoring (data not shown).

Discussion

We report the first validation of a disease-specific English-language patient-reported outcome instrument for use in hypertension. The successful translation and validation of the instrument was completed in accordance with accepted standards(21, 22, 28).

Evaluation of the instrument demonstrated an important floor effect though no ceiling effect. This is inkeeping with the initial evaluation of the Spanish MINICHAL instrument(17) and reflects a relatively low symptom burden for the majority of subjects with hypertension. Internal consistency for the English MINICHAL instrument comfortably met current standards for use at group level, with dimension analysis for StM and SM finding similar values to those reported for the Spanish iteration of the instrument (0.81 and 0.75 versus 0.87 and 0.75 respectively)(17). A similar situation was observed for test-rest reliability.
and, in this case, the English version of the instrument also compared favorably with the Spanish instrument.

Construct validity was confirmed through the instrument’s correlation with generic instruments (EQ-5D-5L summary index and EQ-5D-5L linear scale) and the disease-specific Bulpitt-Fletcher instrument. In terms of strength of association, this was greatest with the EQ-5D-5L summary index and weakest with the Bulpitt-Fletcher instrument. This is not completely surprising considering that the Bulpitt-Fletcher instrument, though developed specifically for hypertension, is not an ideal instrument for measuring quality of life because of its mixed clinimetric-psychometric approach. A higher correlation between two instruments whose main focus is HRQoL can be therefore expected(31).

Responsiveness was tested through administration of the instrument before and after 18 weeks’ intensive treatment of hypertension, using medications and medication combinations recommended in current international guidelines, though over an accelerated timeframe(27), an intervention that seemed to have a measurable significant impact on genetic quality of life as measured through the visual analogue scale of the EQ-5D-5L (large effect size), but not on the EQ-5D-5L index (small effect size). The effect size for the StM scale was larger than for the EQ-5D-5L index, but not statistically significant due to a high dispersion of scores, and was negligible for the SM scale. It must be noted that scores were already very low for the latter scale, suggesting that the floor effect observed in this group of patients may have limited our ability to detect improvement.

A meta-analysis of cross-sectional studies has found that HRQoL is impaired across all eight domains of the SF-36 and SF-12 instruments in those with hypertension, when compared with normotensive individuals(32). Subsequent investigation has found reduced HRQoL in patients treated for hypertension, when compared with untreated hypertensive subjects(33), which may be related in large part to the subjects’ awareness of their diagnosis(34). However, these conclusions are limited by the inherent bias imparted by the cross-sectional nature of their design. In terms of longitudinal studies, which enable subjects to act as their own control group thereby minimizing confounding factors, improvement in HRQoL following treatment of hypertension has been demonstrated in a meta-analysis(30). This observation can be found with a variety of antihypertensive agents(35). Our report of improved HRQoL following treatment is therefore in-keeping with previous longitudinal data. Moreover, given that visits were predominantly delivered by allied healthcare professionals within the clinical study, our finding mirrors that of a recent Cochrane review, which concluded that HRQoL, in particular the physical functioning domain, improves with treatment of hypertension delivered by allied healthcare professionals(36). This would be also in line with the lack of responsiveness observed in this study for the SM scale.

In addition, our intervention was delivered in an accelerated timeframe, a manner of treatment delivery which is known to improve HRQoL in other fields of medicine, such as hip arthroplasty(37) and radiotherapy in the treatment of breast cancer(38). It would therefore be reasonable to propose that the
improvement in HRQoL conferred through treatment of hypertension will have been accentuated by the rapid treatment protocol employed in this study.

Conversely, administration of the Bulpitt-Fletcher instrument within the protocol found a significant reduction in HRQoL following hypertension treatment. Notably, psychometric evaluation with measurement of internal consistency, floor effect, ceiling effect and construct validity for the instrument has not been reported. Additionally, test-retest reliability has only been examined for selected concepts within the questionnaire, rather than the instrument itself(39). However, responsiveness to change of the Bulpitt-Fletcher questionnaire has previously been reported through administration of the instrument within clinical studies, such as a trial comparing hypertension treatment with verapamil versus propranolol(40) and a further study comparing captopril with atenolol(41). Although generic instruments were co-administered with the Bulpitt-Fletcher instrument within these studies, no direct statistical comparison was conducted and therefore construct validity was not evaluated.

Dimensions analysis of the MINICHAL instrument results revealed a nominally greater responsiveness within the StM dimension compared to the SM dimension. Different weighting between the EQ-5D-5L and the Bulpitt-Fletcher instruments in terms of somatic symptoms versus psychological well-being may also therefore explain the discrepant results between these two instruments when applied to subjects within the study.

Study limitations

The conclusions drawn from the study are limited by the relatively low number of subjects enrolled, a drawback which could be addressed through further deployment of the translated English language MINICHAL instrument in future studies of hypertension treatment. Furthermore, as this was a before-and-after study, the effects of time, rather than treatment, on HRQoL cannot be discounted from the analysis, though this is limited by the relatively short 18-week treatment phase.

In addition, it is acknowledged that our study cohort was geographically limited to south-west England. Nevertheless, region-specific language is not used within the translated instrument and no difficulties with comprehension or cultural applicability are envisaged should the instrument be used across the United Kingdom.

The evaluation of the MINICHAL instrument alongside the EQ-5D-5L linear scale has demonstrated the latter, generic instrument to be more responsive to change than our disease-specific instrument, the converse to the expected. The reason for this is unclear, though may relate to the greater range of responses afforded by the EQ-5D-5L analogue scale in comparison with the MINICHAL’s 4 response options. Furthermore, given the brevity of the MINICHAL instrument and specific nature of the questions, some subtle features of wellbeing may not be captured with this instrument, compared to a generic assessment of HRQoL. This is particularly pertinent given the broad range of medication side effects which can result from pharmacological antihypertensive treatment, which would be difficult to capture entirely with a specific questionnaire short enough to be an acceptable burden to patients. Analysis of the
components of the EQ-5D-5L summary index which changed most during treatment determined that the pain/discomfort and anxiety/depression items returned differing scores most frequently. Although anxiety/depression is covered well by the MINICHAL questions, only one question pertains to pain ("Have you experienced any pain in your chest without physical exertion?"). Therefore, a relative deficiency of the MINICHAL instrument in exploring this aspect of symptoms, together with the limited sample size in the present study, may in part explain this discrepancy in responsiveness to change.

In light of these findings, we recommend that future studies of hypertension should consider using both the MINICHAL instrument and EQ-5D-5L in tandem for the assessment of HRQoL.

**Future implications**

The availability of an English language, short, validated, disease-specific instrument for the evaluation or HRQoL in hypertension is of value, particularly given the high prevalence of this condition and therefore its wide applicability to patients. Non-adherence to treatment is a crucial element of apparent treatment-resistance in hypertension (42) and therefore the ability to monitor the impact of hypertension and its treatment for patients could help address this important limiter to successful treatment. Furthermore, it is anticipated that the newly-adapted and validated English language instrument will be used in future research practice to ensure that new treatment strategies for hypertension positively impact HRQoL.

**Conclusions**

The study describes the first validation of an English-language disease-specific instrument for use in the assessment of HRQoL in subjects with hypertension. Furthermore, evidence of acceptability for patients in the rapid treatment of moderate and severe hypertension is reported, a treatment strategy which is recommended in the most recent European guidelines(26), though previously without evidence of acceptability for patients.

**Abbreviations**

BMI: body mass index  
BP: blood pressure  
dBP: diastolic blood pressure  
EMPRO: evaluating the measurement of patient-reported outcomes  
HRQoL: health-related quality of life  
ISOQOL: International Society of Quality of Life Research  
ISPOR: International Society for Pharmacoeconomics and Outcomes Research
Declarations

Ethics approval and consent to participate

Ethical approval for this study was agreed prospectively (NRES Committee South West ref. 15/SW0077). All participants gave voluntary informed consent in accordance with the Declaration of Helsinki.

Consent for publication

Not applicable.

Availability of data and materials

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Competing interests

The authors declare that they have no competing interests.

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The design of the study and collection, analysis and interpretation of the data was free from influence from the funding organizations.

Authors’ contributions

Study concept and design: ANJ, JV, CEC, ACS, ASPS, NGB. Acquisition of the data: ANJ, CA, LW, CB, NP, DM. Analysis and interpretation of the data: ANJ, JV. Initial draft of the manuscript: ANJ. Study supervision: JV, ACS, ASPS, NGB. All authors read and approved the final manuscript.

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### Cuestionario de Calidad de Vida de la Hipertensión Arterial (MINICHAL)

| ¿En los últimos 7 días... | No, en absoluto | Sí, algo | Sí, bastante | Sí, mucho |
|--------------------------|-----------------|----------|--------------|----------|
| 1. ha tenido dificultades para conciliar el sueño? |                  |          |              |          |
| 2. ha tenido dificultades para continuar con sus relaciones sociales habituales? |                  |          |              |          |
| 3. le ha resultado difícil entenderse con la gente? |                  |          |              |          |
| 4. siente que no está jugando un papel útil en la vida? |                  |          |              |          |
| 5. se siente incapaz de tomar decisiones y empezar nuevas cosas? |                  |          |              |          |
| 6. se ha notado constantemente agobiado y en tensión? |                  |          |              |          |
| 7. tiene la sensación de que la vida es una lucha continua? |                  |          |              |          |
| 8. se siente incapaz de disfrutar sus actividades habituales de cada día? |                  |          |              |          |
| 9. se ha sentido agobiado y sin fuerzas? |                  |          |              |          |
| 10. ha tenido la sensación de que estaba enfermo? |                  |          |              |          |
| 11. ha notado dificultades al respirar o sensación de falta de aire sin causa aparente? |                  |          |              |          |
| 12. se le han hinchado los tobillos? |                  |          |              |          |
| 13. ha notado que orina más a menudo? |                  |          |              |          |
| 14. ha notado sequedad de boca? |                  |          |              |          |
| 15. ha notado dolor en el pecho sin hacer ningún esfuerzo? |                  |          |              |          |
| 16. ha notado una sensación de entumecimiento u hormigueo en alguna parte del cuerpo? |                  |          |              |          |

¿Diría usted que su hipertensión y el tratamiento de la misma afecta su calidad de vida?

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### Figure 1

**Original MINICHAL instrument**

**High Blood Pressure Quality of Life Questionnaire (HBP-QLQ)**

[UK version of the Arterial Hypertension Quality of Life Questionnaire (MINICHAL)]

| In the last 7 days... | No, not at all | Yes, a little | Yes, a moderate amount | Yes, a lot |
|-----------------------|----------------|---------------|------------------------|-----------|
| 1. Have you had difficulties falling asleep? |                  |               |                        |           |
| 2. Have you had difficulties in your social relationships? |                  |               |                        |           |
| 3. Have you had difficulties communicating with other people? |                  |               |                        |           |
| 4. Have you felt that you’re not playing a useful role in life? |                  |               |                        |           |
| 5. Have you felt unable to make decisions and start new things? |                  |               |                        |           |
| 6. Have you felt constantly overwhelmed or stressed? |                  |               |                        |           |
| 7. Have you felt that your life is a constant struggle? |                  |               |                        |           |
| 8. Have you felt unable to enjoy your usual activities? |                  |               |                        |           |
| 9. Have you felt exhausted or weak? |                  |               |                        |           |
| 10. Have you felt ill? |                  |               |                        |           |
| 11. Have you experienced any breathing difficulties or shortness of breath for no reason? |                  |               |                        |           |
| 12. Have your ankles become swollen? |                  |               |                        |           |
| 13. Have you passed water more often? |                  |               |                        |           |
| 14. Have you had a dry mouth? |                  |               |                        |           |
| 15. Have you experienced any pain in your chest without physical exertion? |                  |               |                        |           |
| 16. Have you experienced pins & needles or any numbness in any part of your body? |                  |               |                        |           |
Figure 2

English-language MINICHAL instrument

Figure 3

Correlation between the MINICHAL StM domain and EQ-5D-5L summary index Rs = -0.500, p<0.0001