BJS, 2022, 1–9
https://doi.org/10.1093/bjs/znac387
Original Article

Design of a treatment satisfaction measure for patients undergoing varicose vein treatment: Venous Treatment Satisfaction Questionnaire (VenousTSQ)

Charlie J. Gilbride[1,*], Alison Wilson[1], Anita Bradley-Gilbride[1], Janet Bayfield[1], Kathleen Gibson[2], Manjit Gohel[3] and Clare Bradley[1,4]

[1]Vascular Surgery, Health Psychology Research (HPR) Ltd, Egham, UK
[2]Vascular Surgery, Lake Washington Vascular, Bellevue, Washington, USA
[3]Vascular Surgery, Addenbrookes Hospital, Cambridge University Hospitals NHS Foundation Trust, Cambridge, UK
[4]Vascular Surgery, Royal Holloway, University of London, Egham, UK

*Correspondence to: Charlie J. Gilbride, Health Psychology Research (HPR) Ltd, 188 High Street, Egham TW20 9ED, UK (e-mail: cjg@healthpsychologyresearch.com)

Presented in part to a meeting of the International Society for Quality of Life Research, virtual, October 2020

Abstract

Background: Established condition-specific patient-reported outcome measures for varicose veins are limited to the measurement of health status and function. A treatment satisfaction measure is needed to understand patient satisfaction with different treatment options. The aim of this study was to design a Venous Treatment Satisfaction Questionnaire (VenousTSQ) that would be ready for large-scale data collection and psychometric evaluation.

Methods: Relevant items were selected from the -TSQ Item Library and new items were designed where necessary. A draft VenousTSQ was prepared using the existing AneurysmTSQ as a template. Fifteen interviews were conducted from 4 days to 16 months after the procedure. The interviews were designed to elicit important sources of satisfaction or dissatisfaction before completion of draft questionnaires. The VenousTSQ drafts were modified between sets of interviews until no further changes were required.

Results: The final VenousTSQ consists of two questionnaires: VenousTSQ early (VenousTSQe) and VenousTSQ status (VenousTSQs). Items that need be asked only once are in the VenousTSQe, whereas those that can usefully be asked more than once are in the VenousTSQs. Of the 16 unique items forming the VenousTSQ, 12 were from the -TSQ Item Library. Only 1 of these 12 required significant modification.

Conclusions: The VenousTSQ represents a condition-specific psychological outcome measure for varicose veins, enabling patient satisfaction or dissatisfaction with such treatments to be measured. Large-scale data collection is under way to establish optimal scoring, quantitative validity, and reliability of the VenousTSQ.

Introduction

Arising from impaired functioning of venous valves owing to a combination of environmental and genetic risk factors[1–4], varicose veins can cause patient distress and, if left untreated, may lead to serious complications including venous ulcers[5]. In the past, the standard treatment for varicose veins was compression therapy and/or surgical removal of affected veins. Drawbacks of surgery include the need for general anaesthesia and longer recovery times compared with those for more recently developed, less invasive treatments[6,7]. These more recent treatments, including endothermal ablation, ultrasound-guided foam sclerotherapy, and non-thermal closure with cyanoacrylate glue, might therefore be expected to be more acceptable to patients.

However, existing venous-specific patient-reported outcome measures (PROMs)[8–12] have not convincingly shown patient-reported outcome gains for various forms of ablation over surgical stripping[6,13]. There have been reports of better health status scores with a venous-specific measure during the periprocedural period (0–4 weeks after procedure) in the thermal ablation group compared with the surgical stripping group[14,15]. This statistically significant difference reappeared after 1-year follow-up and was maintained until the second year of follow-up. A likely reason why the advantages of endovenous interventions may not be reliably reflected in venous-specific PROM scores is that instruments used to date measure health status and function. Although it is useful to know whether health status and function differ after different treatments, they do not capture all aspects of the treatment experience that are important to patients.

The benefits of measuring treatment satisfaction extend beyond highlighting the merits of one treatment compared with another. Previous experience has shown that improved treatment satisfaction is a desirable outcome in its own right, and has been associated with other positive outcomes such as better well-being and blood glucose control in diabetes[16,17]. Improved treatment satisfaction has also been linked to

Received: April 27, 2022. **Revised:** August 23, 2022. **Accepted:** October 23, 2022
© The Author(s) 2022. Published by Oxford University Press on behalf of BJS Society Ltd.
This is an Open Access article distributed under the terms of the Creative Commons Attribution-NonCommercial License (https://creativecommons.org/licenses/by-nc/4.0/), which permits non-commercial re-use, distribution, and reproduction in any medium, provided the original work is properly cited. For commercial re-use, please contact journals.permissions@oup.com

improved adherence to medication in people with diabetes[18,19] and in people with human immunodeficiency virus (HIV)[20].

The aim of the present study was to develop a questionnaire to measure treatment satisfaction in patients with varicose veins, which would be ready for large-scale data collection allowing psychometric analysis.

Methods

Ethical approval

Ethical approval to interview patients in the UK was obtained via the UK Integrated Research Application System (IRAS) (reference 19/NW/0527, IRAS project ID 269525). Ethical approval for interviews in the USA was obtained from the Western Institutional Review Board (submission number 2594034-44435539).

Participant recruitment

Patients with English as a first language were sampled purposively through the clinics in the UK (Addenbrooke's, Cambridge) in the USA (Lake Washington Vascular, Bellevue, WA). Recruited patients had experience of one or more of the following varicose vein treatments: surgical stripping, endothermal ablation (including radiofrequency ablation), non-thermal foam sclerotherapy, and non-thermal, non-sclerosant, non-tumescent therapy using the VenaSeal™ Closure (Minneapolis, MN, USA) System (a type of cyanoacrylate embolization). Surgical stripping is rarely used in the UK or USA, but is still common elsewhere. To enhance the validity of the Venous Treatment Satisfaction Questionnaire (VenousTSQ) for patients experiencing surgical stripping, some patients were included who had previously undergone surgical stripping as well as a more recent endovenous treatment. Patients who might have a reason to be dissatisfied with their treatment as well as those anticipated to be satisfied were included.

-TSQ Item Library and questionnaire templates

The general layout and scoring structure of the VenousTSQ is inherited from the Diabetes Treatment Satisfaction Questionnaire (DTSQ) and other -TSQs subsequently developed for other conditions[21–26]. The -TSQ Item Library is a compilation of items from these previously developed treatment satisfaction questionnaires. These library items cover aspects of treatment satisfaction that may be relevant to different patient populations, and starting the design of a new questionnaire with the Item Library offers several benefits. These include fewer patients being needed for interviews, easier linguistic validation into other language versions, and increased confidence that the questionnaire will have good psychometric properties when tested in a larger cohort of patients.

Procedure

Generally accepted qualitative approaches of scale design were used[27,28]. Clinician co-authors received a table containing 26 items selected from the Item Library. The clinicians rated each item for relevance to patients with varicose veins on a scale of two ticks, one tick and a cross, with two ticks indicating the highest level of relevance, and the cross indicating no relevance. They suggested new items that they thought were needed to cover aspects of treatment important to patients with varicose veins.

Following clinician review, the Design Team, comprising all authors except M.G. and K.G., met four times to draft an initial version of the VenousTSQ (*Fig. 1a*) for patient interviews. Linguists in the Design Team, experienced in linguistic validation of questionnaires for other conditions, advised on the translatability of draft items.

Patients in the UK were invited to participate when they visited the clinic or by telephone call. Those who expressed interest were provided with written information about the study, together with a reply slip to provide their contact details, consent form, and postage-paid return envelope addressed to a co-author (C.B.), at the Health Psychology Research Unit at Royal Holloway, University of London. UK patients consented to participate by sending the consent form to C.B. or, if they had any questions, they were asked to return the reply slip only and consent was obtained by telephone before the interview.

Each UK patient agreeing to be contacted received an introductory telephone call from C.B., during which any questions were answered, consent to participate obtained (or confirmed) and a date was agreed for the interview. Questionnaires were then sent to participants either by post, sealed into an inner envelope, or by e-mail, as an attachment, with a covering message that confirmed the time of interview. Participants were asked not to open the inner envelope or view the questionnaires in the attachment until the time of the interview. Two members of the Design Team took part in each interview, one leading the interview and the other taking notes. Interviews were conducted in a private room by telephone on speaker and recorded using an audio recorder (Olympus WS-450S).

The interviews had two parts; the main aim of the first part was to elicit spontaneous mentions about aspects of treatment satisfaction or dissatisfaction, and the main purpose of the second part was to gain feedback on the contents of the latest draft of the VenousTSQ. The first part included introductions, confirmation of informed consent including permission to audio record the interview, and discussion of the individual's experience of varicose veins and their treatment. Participants had every opportunity to talk freely about their experiences, and interviewers were able to explore any unexpected topic introduced in the discussions. During this first part of the interview, participants were asked questions about their treatment(s): 'What was it like?', 'In what ways were you satisfied with your treatment?', and 'In what ways were you dissatisfied with your treatment?'. The responses from each participant were later assessed to determine whether they reflected existing questions in the draft VenousTSQ, or whether they may be indicators of treatment satisfaction requiring a new item in the VenousTSQ.

In the second part of the interview, participants were asked to open the envelope/attachment containing the latest draft of the VenousTSQ and complete it, reading and thinking aloud as they did so. Participants were encouraged to comment on any aspect of the content of the questionnaire, particularly if anything was ambiguous or difficult to understand. After completing the VenousTSQ, the interviewer explained that it might be necessary to shorten the questionnaire by removing less important items. Participants were therefore asked to rate how important they considered each item, using an importance rating scale with the options 'very important', 'important', 'somewhat important', and 'not at all important'. For some participants, there was insufficient time to complete the importance scales for both the VenousTSQ early (VenousTSQe) and VenousTSQ status (VenousTSQs).

Meetings between Design Team members to discuss possible revisions to the VenousTSQ were held after every two to four UK interviews. When no further revisions were proposed by recent

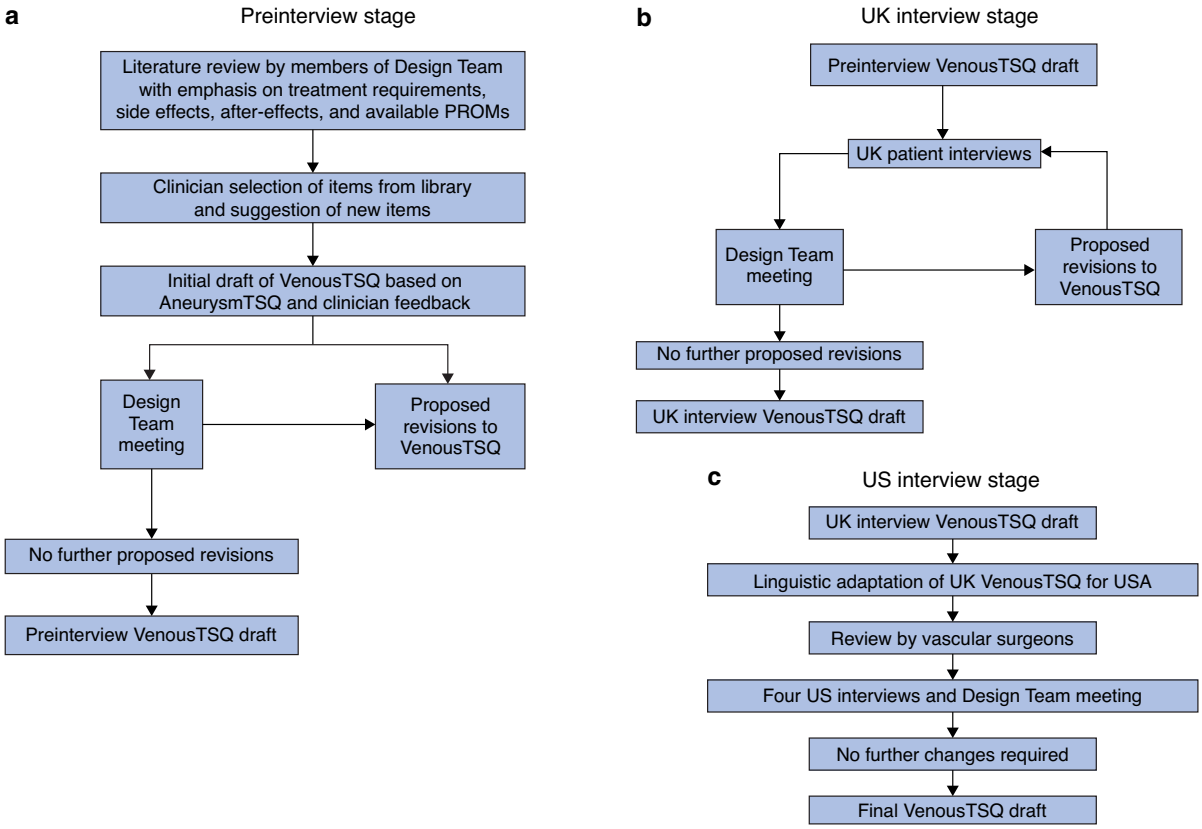

Fig. 1 Flow charts illustrating the three stages of questionnaire design to produce UK and US versions of the VenousTSQ

PROM, patient-reported outcome measure; AneurysmTSQ, Aneurysm Treatment Satisfaction Questionnaire; VenousTSQ, Venous Treatment Satisfaction Questionnaire.

participants or any Design Team member, the UK draft of the VenousTSQ was considered complete (*Fig. 1b*). Determining when no further changes were needed depended on the collective judgement of the Design Team. Once no further substantive changes were deemed necessary by the Design Team, the questionnaire was considered ready for psychometric evaluation.

Linguistic adaptation of the VenousTSQ for the USA was carried out by two native speakers of US English, one a linguist and the other an author (K.G.). US patients were invited and informed consent elicited at Lake Washington Vascular Clinic in Bellevue. Telephone and e-mail contact details for consenting patients were then sent to C.B., who telephoned them, answered any questions, and confirmed consent before agreeing a date for interview and e-mailing questionnaires. The interviews with US participants then proceeded as for the UK participants. A Design Team meeting, following four US interviews, found that no revisions were needed (*Fig. 1c*).

Results

Participants

Fourteen participants aged between 42 and 91 years were interviewed. Ten were from the UK and four from the USA. One UK participant (participant 2) was interviewed twice: once soon after the procedure and then again 4 weeks later (at which point she was referred to as participant 10). Equal numbers of men and women were recruited in each country.

Participants received their most recent treatment for varicose veins between 4 and 491 days before the interview. For their most recent treatment, four participants received the VenaSeal™ Closure System treatment alone and seven received radiofrequency ablation alone. Three participants received foam sclerotherapy in combination with radiofrequency ablation, either in the most recent procedure or a previous one. Two participants were able to talk about their previous experience of surgical stripping. Two participants had echosclerotherapy in combination with other treatments, whereas a further two had microphlebectomy in combination with other treatments (*Tables S1* and *S2*).

Designing the first VenousTSQ draft

The structure and content of the VenousTSQ changed as the design procedure was followed. Changes were made to the initial draft before UK interviews commenced and in between groups of two to four interviews. Modifications made between interviews were driven mainly by participants' spontaneous mentions of sources of satisfaction or dissatisfaction (*Fig. 2* and *Table S3*) and by participant feedback on item importance (*Fig. 3*). *Tables S3* and *S4* are comprehensive records of the changes made (with reasons) between the preinterview draft and the final draft of the VenousTSQe and VenousTSQs respectively. A summary of the final draft of the VenousTSQ is presented in *Fig. 4*.

Clinician review of Library Items

Before any Design Team meetings or interviews with participants, clinician co-authors reviewed 26 items selected from the -TSQ Item Library. Most items in the initial draft of the VenousTSQ

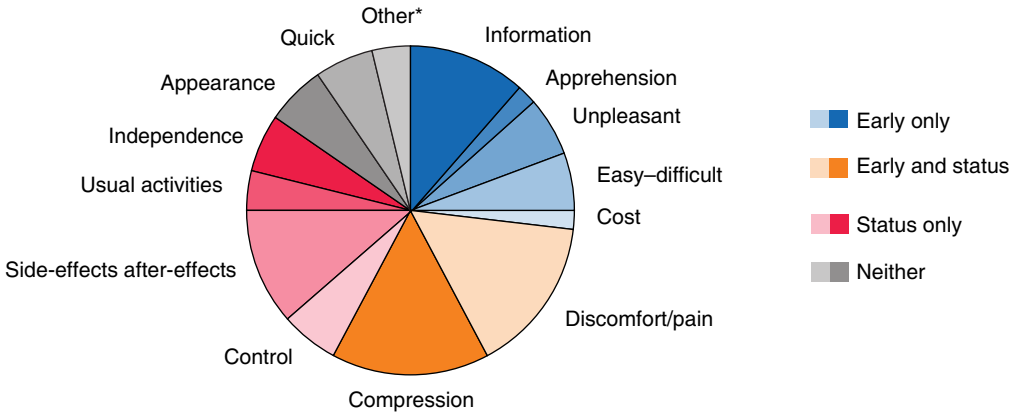

Fig. 2 Frequency of treatment satisfaction indicators mentioned spontaneously

Frequency of spontaneous mention (maximum of 1 mention per indicator per participant recorded) is proportional to segment size and segments are colour-coded according to which part of the final draft of the VenousTSQ they are in. Scale: apprehension and cost were mentioned spontaneously once. *Consists of time on waiting list and clinical care.

were ones that both authors signalled to be highly relevant, or ones that at least one clinician thought to be highly relevant and the other thought to be somewhat relevant. New items suggested during clinician review and incorporated into the final draft of the VenousTSQ were as follows (using their brief descriptive labels): compression ('How bothered were/are you by the need to wear compression stockings or bandages?'), bathing restrictions, usual activities ('How satisfied are you by the time taken to return to your usual activities?'), and independence.

Preinterview Design Team meetings

The starting point for design of the VenousTSQ was the previously developed AneurysmTSQ[25]. During preinterview Design Team meetings, items were identified for inclusion in the VenousTSQ guided by clinician co-authors' recommendations from the -TSQ Item Library and their suggestions for new items. It became clear that some of these items were concerned with preparing for and undergoing the clinical procedure, and so would only need to be asked once, whereas responses to other items may change over time and still be relevant weeks or months after the procedure. The VenousTSQ was therefore divided into two questionnaires that could be administered together or separately. The first questionnaire is the VenousTSQe, which asks about experiences before and immediately after the procedure, as well as containing items concerned with the procedure itself. The VenousTSQe is intended for administration on only one occasion, ideally within 1 month of the procedure to treat varicose veins. The second questionnaire is the VenousTSQs, which is designed for administration on one or more occasions at any time starting approximately 4 weeks after the procedure. The first trial (now under way) to include the VenousTSQ is administering the VenousTSQs for the first time immediately after the VenousTSQe at 30 days after the procedure, and giving the VenousTSQs alone at various subsequent time points to determine how satisfaction with the varicose vein treatment changes over the longer term.

VenousTSQ draft item updates during time of participant interviews

After every two to four UK patient interviews, the Design Team met and discussed potential amendments. *Tables* S4 and S5 document all changes made during the interview stage of the design process for the VenousTSQe and VenousTSQs respectively, including justifications for the changes made.

Spontaneous mentions

Aspects of treatment mentioned spontaneously by participants are more likely to be those that are most important to them. Enabling participants to talk about their treatment experience without excessive prompting from the interviewers is one means of discovering what are likely to be the most important aspects of treatment. The most common indicators of treatment satisfaction mentioned spontaneously were: information (6 participants), discomfort/pain (8 participants), side effects/after-effects (6 participants), and compression (8 participants). These, together with other spontaneously mentioned indicators, are shown in *Fig.* 2.

Several spontaneous mentions are not clearly covered by any single item in the final version of the VenousTSQ. These are shown as grey segments in *Fig.* 2. Appearance was mentioned spontaneously by three participants. No participant in the present study suggested the need for an appearance item when responding to the open question at the end of the VenousTSQs. This suggests that the present group of participants felt the questionnaire was complete without an appearance item. Nevertheless, responses to the final open question in the VenousTSQs will continue to be monitored in future studies. By giving respondents the option to offer feedback in this way, questionnaires can be assessed regularly to ensure that face and content validity are maintained. Three participants spontaneously mentioned that the procedure was quick. The treatment satisfaction-relevant parts of this issue appeared to be covered by the *Unpleasant* item. One interviewee mentioned time on waiting list, another mentioned clinical care spontaneously, and several mentioned the way they were treated by the clinical staff. These issues have more to do with the way the service is provided rather than being characteristics of a particular treatment. The Diabetes Clinic Satisfaction Questionnaire[29] and similar questionnaires (for example the MacSSQ, Macular disease Service Satisfaction Questionnaire[30]) deal with issues such as waiting times, privacy, and staff attitudes/behaviour. A similar measure could be designed for patients attending vascular clinics.

Four items in the final draft of the VenousTSQ have no clear link to the authors' compilation of spontaneously mentioned

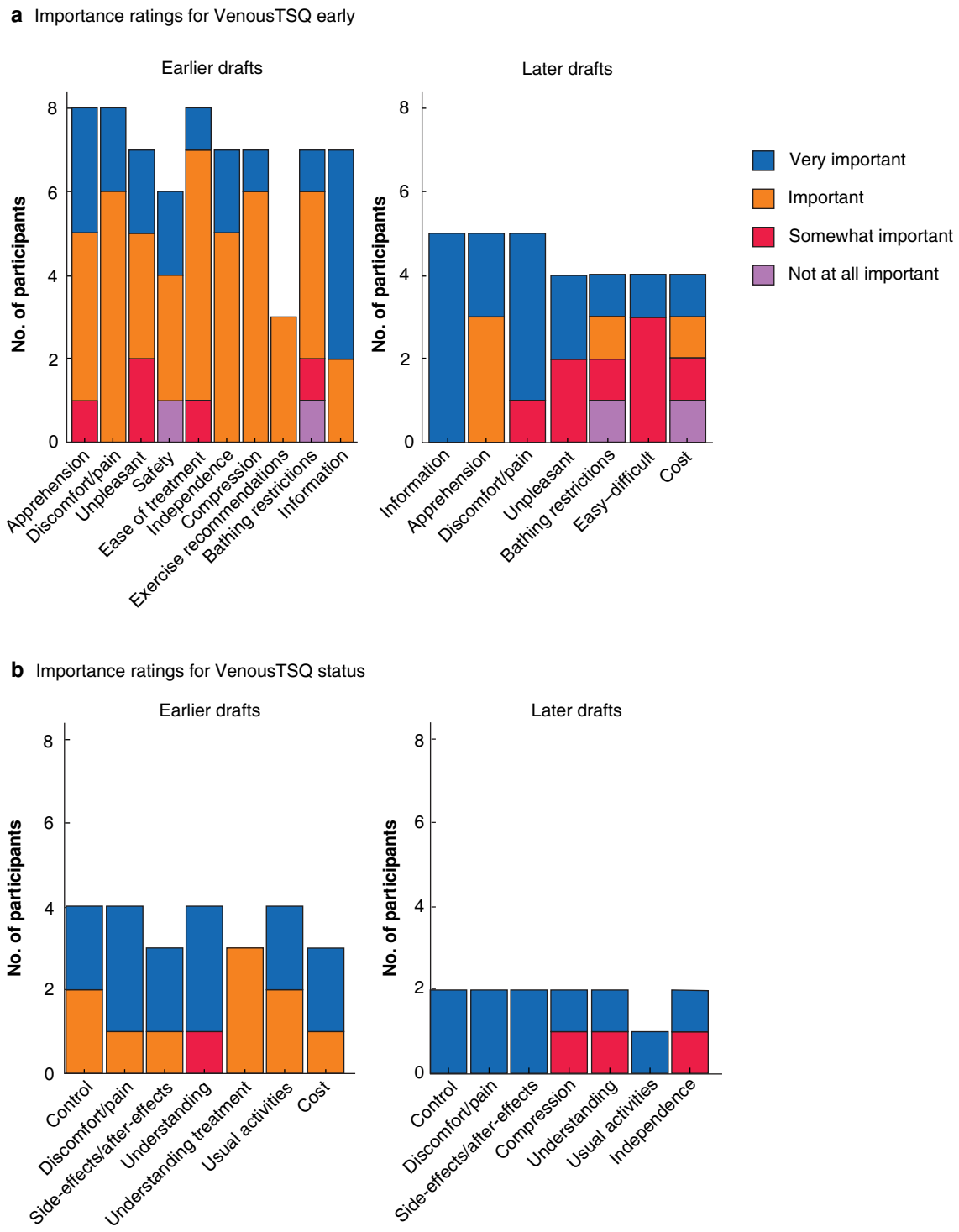

Fig. 3 Participant importance ratings for each item in VenousTSQ early and VenousTSQ status

The first eight participants rated the earlier drafts of the questionnaires, whereas five participants rated the later drafts.

indicators. These are bathing restrictions, recommend, same again?, and understanding. Bathing restrictions was suggested as a new item during clinician review and included in the preinterview questionnaire. Bathing restrictions seemed to be an indicator of dissatisfaction for several participants. Recommend and same again? ask participants whether they would recommend the treatment to someone else being offered the treatment, and how satisfied they would be to have the same treatment again, if further treatment were necessary. Recommend is a well established indicator of treatment satisfaction used in -TSQs for other conditions and received robust support during clinician review, whereas the wording of same again? was suggested during the review[16,20]. The item on understanding asks: 'How satisfied are you with your

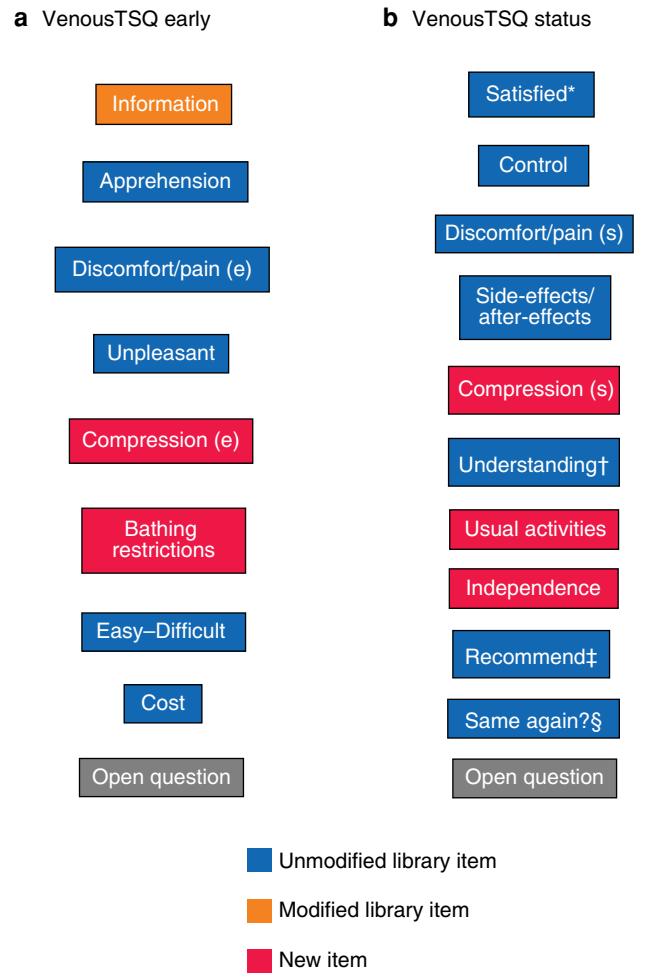

Fig. 4 Items included in the final drafts of VenousTSQ early and VenousTSQ status

Item labels (information, apprehension, etc.) are used to represent each item and are presented in the same order as they appear in the questionnaire. The discomfort/pain and compression items appear in both VenousTSQ early and VenousTSQ status, with wording adjusted to refer to the appropriate time frame. The discomfort/pain and compression items have the suffix (e) and (s) to indicate that these are different variants of the same item, with the wording adjusted to suit the early and status versions of the VenousTSQ respectively. *General satisfaction item included in all -TSQs: 'How satisfied are you with your treatment for…'? †Item asks patients about 'understanding of your vein problems'. ‡'Would you recommend your treatment…'? §'How satisfied would you be to have the same treatment'?

understanding of your vein problems?'. This item has been used previously as an indicator of treatment satisfaction[16,21,26] and was labelled 'somewhat relevant' by both clinician co-authors.

Importance ratings

As another means of increasing face and content validity in the VenousTSQ, participants were asked to rate the importance of each item. The importance rating for each item for the VenousTSQe are shown in *Fig. 3a* and those for the VenousTSQs in *Fig. 3b*. Later drafts of the VenousTSQ contained substantial updates compared with earlier drafts seen by some participants. Items were moved across from the VenousTSQs to the VenousTSQe (for example cost item), added (for example easy–difficult item) or removed entirely (for example safety item). The importance ratings are, therefore, split for both the VenousTSQe and VenousTSQs for the first eight participants who responded to the earlier drafts and the remaining five participants who received the later drafts.

Information, discomfort/pain, compression, and side effects/after-effects were mentioned spontaneously by most participants, suggesting that these are the more important indicators of treatment satisfaction for patients with varicose veins. *Figure 3* confirms that most participants considered these themes either 'very important' or 'important'. Only one participant (participant 13), who had experience of compression stockings, considered the compression item 'important or somewhat important' in the VenousTSQs.

As with the compression item, all but one of the participants rated the discomfort/pain item as either 'very important' or 'important' (13 participants completing both the VenousTSQe and VenousTSQs; combined frequencies from *Fig. 3a,b*). Participant 12, who rated the discomfort/pain item in the VenousTSQe as 'somewhat important', received radiofrequency ablation and a local anaesthetic (the importance ratings for the items in the status part of the questionnaire were not completed for participant 12 owing to time constraints). This participant stated that he felt '…very comfortable…' during the procedure and did not report any side effects or after-effects of the treatment.

Given the importance and potential relevance of the compression and discomfort/pain items in the perioperative period and in the longer term, these have been incorporated into both the VenousTSQe and VenousTSQs. The compression item did not appear in the later drafts of the VenousTSQe after it was moved to the VenousTSQs, but it was reinstated after the interviews were completed following final clinician feedback. The item is now included in both the early and status questionnaires.

Three items (all in the VenousTSQe) had at least one participant labelling them as 'not at all important' for inclusion in the questionnaire. These were the items asking about safety of the procedure, cost, and bathing restrictions. The safety item was removed because few participants expressed any safety concerns, and its inclusion risked creating anxiety about the safety of the procedure in respondents rather than measuring existing safety concerns. The cost item was judged more important in the USA than in the UK, where the National Health Service covers the cost of the procedure and paid leave entitlements are usually more generous. Although the bathing restrictions item is less likely to be important for patients who did not need to wear compression stockings or bandages for more than a few days, the item was retained for instances where patients may need compression for longer.

Spontaneous mentions by participants are expected to reveal some of the indicators of treatment satisfaction that are most important to them. However, the frequency of spontaneous mentions is not the only indicator of item importance. *Figure 3* shows that usual activities and apprehension were considered 'very important' or 'important' by almost all participants surveyed, even though they were mentioned spontaneously less often than information, discomfort/pain, compression, and side effects/after-effects, which received the most spontaneous mentions. Usual activities and apprehension were rated as more important than the number of spontaneous mentions alone would have suggested (*Figs 2* and *3*).

Summary of final VenousTSQ layout and content

Together, the VenousTSQe and VenousTSQs have 16 unique items (excluding 2 open questions at the end of each questionnaire, and counting the compression and discomfort/pain items only once). Of these 16 items, 12 are taken from the Item Library. Eleven of these 12 items required no modification other than changing the

specified condition to varicose veins (colour-coded blue in Fig. 4; discomfort/pain counted only once). The information item in the VenousTSQe was the only item needing significant modification to be suitable for varicose vein procedures (colour-coded orange in Fig. 4).

Open questions (qualitative items)

Both the VenousTSQe and VenousTSQs give the respondent the opportunity to add further information if they feel none of the existing items cover a source of satisfaction or dissatisfaction that is relevant to them. Multiple patients identifying the same source not already covered in the questionnaire would indicate that a new item needs to be designed and evaluated. If patients feel that everything has been covered, they are prompted to indicate this. All or almost all respondents indicating that the measure is comprehensive provides good evidence for the tool's content validity.

The UK participants thought the VenousTSQ to be comprehensive. In response to the open-ended question at the end of the VenousTSQs ('Are there any other aspects of the treatment for vein problems, causing either satisfaction or dissatisfaction, which have not been covered?'), the last three UK participants stated: 'No, I do not think so', 'No…not that I can think of', and 'No'.

US participants also gave positive feedback on the content of the VenousTSQ. All four patients responded 'No' to the open-ended question at the end of the VenousTSQs with participant 14 commenting in addition that 'I think you have done very well; the questionnaire covers it'. The study plan allowed for any proposed changes to the VenousTSQ emerging from the US interviews to be piloted with more UK patients. However, no changes were proposed during interviews with the 4 US patients, and the VenousTSQe and VenousTSQs could be finalized after 15 interviews.

Discussion

This qualitative work has produced two condition-specific treatment satisfaction questionnaires, the VenousTSQe and the VenousTSQs. The VenousTSQe is intended to be administered only once within 1 month of the patient having the procedure. Participants responding to the VenousTSQe will be prompted to consider their experience relating to the specific procedure, and their experiences during the time before and soon after the procedure.

When completing the VenousTSQs, participants may have undergone more than one procedure in a single leg. The wording of the VenousTSQs is intended to encourage respondents to take into account any and all additional varicose vein treatments they have received since the main procedure in the last leg to be treated. In so doing, the whole experience of treatment for that leg is taken into account. If one group of participants requires more follow-up treatment in the same leg than another group who had a different procedure, the latter group might be expected to report higher satisfaction scores (other factors being equal). If questions were asked only about satisfaction with the initial procedure without considering the experience of any repeat treatments or additional treatments, one may be misled about the patient's overall satisfaction with the varicose vein treatment.

The patient-centred approach taken in the design of the VenousTSQ will help make this instrument more sensitive than other existing venous-specific PROMs (and generic instruments) in detecting real differences between treatments both during the periprocedural period and beyond. The development of the VenousTSQ has important clinical implications. It may be useful in differentiating between endovenous modalities, but also between interventional strategies (1-stop *versus* staged procedures, different tumescent anaesthesia, different treatment settings) and different operators. It could be argued that assessment of treatment satisfaction should be a standard quality assurance measure.

Five of the participants were interviewed within 1 month of their most recent treatment, with three of these being interviewed within 1 week of treatment. One of these three participants was interviewed twice, once at 4 days and for a second time at 1 month. This participant stated explicitly that it was too early to be able to answer some of the items in the VenousTSQs when given at 4 days, but was able to answer all items at 1 month. It would be reasonable to administer the VenousTSQe between 1 week and 1 month after the procedure, whereas 1 month would seem to be the optimal time point for administering the VenousTSQs for the first time.

Analysis of participants' spontaneous mentions indicated that items asking about information, discomfort/pain, compression, and side effects/after-effects are the most important. This was largely confirmed by the importance rating survey, which found that almost all participants described these items as either 'very important' or 'important'. There were two exceptions. 'Somewhat important' was the rating given by participant 12 for the discomfort/pain item and by participant 13 for the compression item. Participant 12 reported experiencing little discomfort or pain during the procedure, and having no serious health problems or previous medical procedures. This might have contributed to his choice of rating the discomfort/pain item as having less importance compared with the other participants. Participant 13 did not find the need to wear compression stockings bothersome, although this view was unusual. Feedback from clinicians and most of the participants indicates that the need to wear compression stockings and bandages is a significant source of dissatisfaction.

It is generally appreciated[31] that provision of accessible information about treatment is important for patients' treatment satisfaction. Although the level of provision is usually viewed as an indicator of service satisfaction[31,32] rather than treatment satisfaction, the size of the discrepancies between the level of information provided *versus* the amount of information patients feel they need may well be treatment-specific. Given the importance that patients with varicose veins placed on being well informed about the treatment in advance of the procedure, this item was included in the VenousTSQe.

Condition-specific questionnaires such as the VenousTSQ enable the items to be focused while tolerating minor crossovers into other concepts (for example the information item) when appropriate. This contrasts with generic instruments, such as EuroQoL Five Dimensions (EQ-5D™; EuroQol Group, Rotterdam, the Netherlands) and Short Form 36 (SF-36®, Rand Corp, Santa Monica, CA, USA), which ask patients to rate their health status in domains and across a scale that are unlikely to capture their experience of varicose vein treatment in sufficient detail[33]. For example, in the present study, asking about bother caused by compression stockings or bandages was noted to be highly relevant for this patient group, but no generic instrument can ask such a specific question without losing its generic character and/or becoming burdensome.

The EQ-5D™[34], SF-36[35] and venous-specific measures (for example the VEnous INsufficiency Epidemiological and

Economic Study – Quality of Life/Symptom (VEINES-QOL/Sym) questionnaire[10], the Specific Quality of Life and Outcome Response - Venous (SQOR-V) questionnaire[11] and the Varicose Vein Symptom Questionnaire (VVSymQ®)[12]) are often referred to as quality-of-life measures, which is unhelpful when they measure health status and function, not quality of life. It would also be misleading to refer to the VenousTSQ as a quality-of-life measure. Treatment satisfaction is a more specific concept that may be associated positively with quality of life, but it is not the same. Mislabelling PROMs is likely to lead to misunderstanding of what these questionnaires are measuring, and misinterpretation of research findings and their clinical implications, which can have damaging consequences for patients[36]. For PROMs to be effective in improving patient outcomes, it is essential that they are labelled accurately and interpreted appropriately.

As with most other treatment satisfaction instruments developed previously (for example DTSQ[16,32], Renal Treatment Satisfaction Questionnaire[21,37], and HIV Treatment Satisfaction Questionnaire[26,38]), all or most of the items in the VenousTSQe and VenousTSQs are expected to load on to a single latent variable, which would provide measures of early procedure-related treatment satisfaction and longer-term treatment satisfaction.

Most items were derived from the Item Library compiled from previously validated -TSQ measures for other conditions (*Fig. 4*), which have been, collectively, validated linguistically in over 120 languages and dialects. In addition to accelerating the design process for new questionnaires, use of the Item Library increases confidence that the measure will be readily translatable into other languages and will have robust psychometric properties. A further practical benefit of using the Item Library is that fewer participants are needed to optimize items when the wording of these items has already been optimized with people affected by other conditions.

The large-scale data collection currently under way will allow the psychometric analyses to determine optimal scoring of the scales and any subscales. These analyses will include factor analysis and other procedures to examine how much common variance the items account for. Items that do not account for much common variance, along with the reference item 'How satisfied are you with your treatment for varicose veins?', will not be included in the scale to measure the overall treatment satisfaction score. This overall score of treatment satisfaction derived from multiple items will be a more accurate measure of treatment satisfaction than any single-item measure.

Until guidelines on the scoring of VenousTSQ scales can be provided, the individual items can be analysed and reported separately, as has been done with -TSQs developed previously[20,21,35]. The VenousTSQe and VenousTSQs can now be made available for use in clinical trials, other research, and routine clinical practice.

The VenousTSQ is the first treatment satisfaction questionnaire designed specifically for patients receiving varicose vein treatment and promises to be more sensitive to patients' perceptions of the treatment experience, particularly around the periprocedural period, than existing venous-specific PROMs, which are all measures of health status and function.

Funding

This work was funded by Medtronic (Minneapolis, MN, USA).

Acknowledgements

The authors thank A. Ali and colleagues from Medtronic for helpful feedback on the initial report, and K. Glorieux from Lake Washington Vascular for assistance in recruiting US participants. Please visit http://www.healthpsychologyresearch.com to view samples of the questionnaires (including VenousTSQ and AneurysmTSQ) online, see a list of language versions available, request review copies of the full questionnaires, or to obtain a licence to use questionnaires. Alternatively, send requests directly to info@healthpsychologyresearch.com.

Conflict of interest

C.B. is the copyright holder of all -TSQs including the VenousTSQ and the Item Library. She is also the majority shareholder and CEO of HPR Ltd, which issues licences for the VenousTSQ and other questionnaires. Licences are provided free of charge to students. Non-commercial organizations may be asked for a small contribution towards administrative costs. Commercial companies are charged licence fees and C.B. receives royalties when licence fees are paid. The authors declare no other conflict of interest.

Supplementary material

Supplementary material is available at *BJS* online.

Data availability

The data informing this study are available on request, by contacting cjg@healthpsychologyresearch.com. The data have not been uploaded to a public repository owing to privacy concerns, but the authors will be able to consider specific requests on an individual basis.

References

1. Beebe-Dimmer JL, Pfeifer JR, Engle JS, Schottenfeld D. The epidemiology of chronic venous insufficiency and varicose veins. *Ann Epidemiol* 2005;**15**:175–184
2. Fukaya E, Flores AM, Lindholm D, Gustafsson S, Zanetti D, Ingelsson E *et al.* Clinical and genetic determinants of varicose veins. *Circulation* 2018;**138**:2869–2880
3. Segiet OA, Brzozowa-Zasada M, Piecuch A, Dudek D, Reichman-Warmusz E, Wojnicz R. Biomolecular mechanisms in varicose veins development. *Ann Vasc Surg* 2015;**29**:377–384
4. Tisi PV. Varicose veins. *BMJ Clin Evid* 2011;**2011**:0212
5. Pannier F, Rabe E. Progression in venous pathology. *Phlebology* 2015;**30**:95–97
6. Belramman A, Bootun R, Lane TRA, Davies AH. Endovenous management of varicose veins. *Angiology* 2019;**70**:388–396
7. Siribumrungwong B, Wilasrusmee C, Orrapin S, Srikuea K, Benyakorn T, McKay G *et al.* Interventions for great saphenous vein reflux: network meta-analysis of randomized clinical trials. *Br J Surg* 2021;**108**:244–255
8. Launois R, Reboul-Marty J, Henry B. Construction and validation of a quality of life questionnaire in chronic lower limb venous insufficiency (CIVIQ). *Qual Life Res* 1996;**5**:539–554
9. Garratt AM, Macdonald LM, Ruta DA, Russell IT, Buckingham JK, Krukowski ZH. Towards measurement of outcome for patients with varicose veins. *Qual Health Care* 1993;**2**:5–10
10. Lamping DL, Schroter S, Kurz X, Kahn SR, Abenhaim L. Evaluation of outcomes in chronic venous disorders of the leg:

development of a scientifically rigorous, patient-reported measure of symptoms and quality of life. *J Vasc Surg* 2003;**37**:410–419
11. Guex JJ, Zimmet SE, Boussetta S, Nguyen C, Taieb C. Construction and validation of a patient-reported outcome dedicated to chronic venous disorders: SQOR-V (specific quality of life and outcome response—venous). *J Mal Vasc* 2007;**32**:135–147
12. Wright DDI, Paty J, Turner-Bowker DM, Bradbury A. Psychometric evaluation of a new patient-reported outcome (PRO) symptom diary for varicose veins: vVSymQ® instrument. *Patient* 2016;**9**:335–348
13. Nesbitt C, Bedenis R, Bhattacharya V, Stansby G. Endovenous ablation (radiofrequency and laser) and foam sclerotherapy *versus* open surgery for great saphenous vein varices. *Cochrane Database Syst Rev* 2014.
14. Lurie F, Creton D, Eklof B, Kabnick LS, Kistner RL, Pichot O *et al.* Prospective randomized study of endovenous radiofrequency obliteration (closure procedure) *versus* ligation and stripping in a selected patient population (EVOLVeS study). *J Vasc Surg* 2003;**38**:207–214
15. Lurie F, Creton D, Eklof B, Kabnick LS, Kistner RL, Pichot O *et al.* Prospective randomised study of endovenous radiofrequency obliteration (closure) *versus* ligation and vein stripping (EVOLVeS): two-year follow-up. *Euro J Vasc Endovasc Surg* 2005;**29**:67–73
16. Bradley C, Lewis KS. Measures of psychological well-being and treatment satisfaction developed from the responses of people with tablet-treated diabetes. *Diabet Med* 1990;**7**:445–451
17. Riazi A, Bradley C, Barendse S, Ishii H. Development of the well-being questionnaire short-form in Japanese: the W-BQ12. *Health Qual Life Outcomes* 2006;**4**:40
18. Bradley C, Eschwège E, de Pablos-Velasco P, Parhofer KG, Simon D, Vandenberghe H *et al.* Predictors of quality of life and other patient-reported outcomes in the PANORAMA multinational study of people with type 2 diabetes. *Diabetes Care* 2018;**41**:267–276
19. Saisho Y. Use of Diabetes Treatment Satisfaction Questionnaire in diabetes care: importance of patient-reported outcomes. *Int J Environ Res Public Health* 2018;**15**:947
20. Jordan J, Cahn P, Goebel F, Matheron S, Bradley C, Woodcock A. Abacavir compared to protease inhibitors as part of HAART regimens for treatment of HIV infection: patient satisfaction and implications for adherence. *AIDS Patient Care STDS* 2005;**19**:9–18
21. Barendse SM, Speight J, Bradley C. The Renal Treatment Satisfaction Questionnaire (RTSQ): a measure of satisfaction with treatment for chronic kidney failure. *Am J Kidney Dis* 2005;**45**:572–579
22. Brose LS, Bradley C. Psychometric development of the Retinopathy Treatment Satisfaction Questionnaire (RetTSQ). *Psychol Health Med* 2009;**14**:740–754
23. McMillan C, Bradley C, Razvi S, Weaver J. Psychometric evaluation of a new questionnaire measuring treatment satisfaction in hypothyroidism: the ThyTSQ. *Value Health* 2006;**9**:132–139
24. Mitchell J, Bradley C. Design and development of the MacTSQ measure of satisfaction with treatment for macular conditions used within the IVAN trial. *J Patient Rep Outcome* 2018;**2**:5
25. Peach G, Romaine J, Wilson A, Holt PJE, Thompson MM, Hinchliffe RJ *et al.* Design of new patient-reported outcome measures to assess quality of life, symptoms and treatment satisfaction in patients with abdominal aortic aneurysm. *Br J Surg* 2016;**103**:1003–1011
26. Romaine J, Murray M, Bradley C. Psychometric evaluation of the revised HIV Treatment Satisfaction Questionnaire (HIVTSQ). *Value Health* 2016;**19**:A420
27. Streiner DL, Norman GR. *Health Measurement Scales: a Practical Guide to Their Development and Use* (3rd edn). Oxford University Press, Oxford, UK, 2003
28. Posner T. Qualitative methods in psychosocial research. In: Bradley C (ed.), *Handbook of Psychology and Diabetes: a Guide to Psychological Measurement in Diabetes Research and Practice*. Chur: Harwood Academic Publishers, 1994, 57–62
29. Wilson AE, Home PD; Diabetes Audit Working Group of the Research Unit of the Royal College Of Physicians and the British Diabetic Association. A dataset to allow exchange of information for monitoring continuing diabetes care. The Diabetes Audit Working Group. *Diabet Med* 1993;**10**:378–390
30. Mitchell J, Bradley C. Identifying sources of patient satisfaction and dissatisfaction with eye clinics using the Macular Disease Service Satisfaction Questionnaire (MacSSQ). *Dig J Macul Dis Soc* 2009:36–39
31. Meryn S. Improving doctor–patient communication. *BMJ* 1998;**316**:1922–1930
32. Bradley C. The Diabetes Treatment Satisfaction Questionnaire: DTSQ. In: Bradley C (ed.). *Handbook of Psychology and Diabetes: a Guide to Psychological Measurement in Diabetes Research and Practice*. Harwood Academic Publishers, 1994, 111–132
33. McKenna SP. Measuring patient-reported outcomes: moving beyond misplaced common sense to hard science. *BMC Med* 2011;**9**:86
34. Oppe M, Devlin NJ, van Hout B, Krabbe PFM, de Charro F. A program of methodological research to arrive at the new international EQ-5D-5L valuation protocol. *Value Health* 2014;**17**:445–453
35. Ware JE, Sherbourne CD. The MOS 36-item short-form health survey (SF-36). I. Conceptual framework and item selection. *Med Care* 1992;**30**:473–483
36. Bradley C. Importance of differentiating health status from quality of life. *Lancet* 2001;**357**:7–8
37. Gibbons A, Bayfield J, Cinnirella M, Draper H, Johnson RJ, Oniscu GC *et al.* Changes in quality of life (QoL) and other patient-reported outcome measures (PROMs) in living-donor and deceased-donor kidney transplant recipients and those awaiting transplantation in the UK ATTOM programme: a longitudinal cohort questionnaire survey with additional qualitative interviews. *BMJ Open* 2021;**11**:e047263
38. Woodcock A, Bradley C. Validation of the revised 10-item HIV Treatment Satisfaction Questionnaire Status version and New Change version. *Value Health* 2006;**9**:320–333