RTSQ Summary 18.9.18

#### The RTSQ

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## **Background**

The Renal Treatment Satisfaction Questionnaire (RTSQ) was designed by Clare Bradley, Professor of Health Psychology at Royal Holloway, University of London, specifically to measure satisfaction with treatment for patients with chronic kidney disease (CKD), for use in routine clinical care, clinical trials and other research. The original thirteen-item RTSQ was based on the format of the eight-item Diabetes Treatment Satisfaction Questionnaire (DTSQ; Bradley 1994; Bradley and Lewis, 1990), used extensively with people with Type 1 and Type 2 diabetes (e.g. Ashwell et al 2008; Bradley and Speight, 2002; Bradley et al. 2007; Bradley et al. 2018; Bretzel et al. 2008; DAFNE Study Group, 2002; Witthaus et al 2001). Six items from the DTSQ appeared to be useful or readily modified to be appropriate for patients on renal treatment, confirmed by interviews (Barendse et al, 2005). Additional items were designed to measure satisfaction with other aspects of treatment specific to patients with CKD. Items were designed to be answered by patients receiving any form of treatment for CKD because individual patients may experience a variety of treatments for their condition over time. Psychometric development work on an earlier 12-item RTSQ showed that 11 items could be summed to form a Treatment Satisfaction score. The item that could not be combined concerned the demands of treatment which has since been reworded and tested in the current version of the RTSQ (25.1.11) along with 11 unchanged items. Two versions of a potential new item concerning side effects were also tested:

- The Principal Component Analysis and Reliability Analysis showed that the new, re-worded item related to demands of treatment works well and can now be combined in the summation of the total treatment satisfaction score.
- One of the tested items related to side effects was selected for use in the latest 13-item version of the RTSQ (25.1.11).

Psychometric analyses conducted on data from the 5-centre UK STEPP study (Medcalf et al, 2011) demonstrated Cronbach Alpha of the current 13-item version of the RTSQ was 0.912.

Psychometric analyses conducted on data from the national ATTOM programme demonstrated Cronbach Alpha of the current 13-item version of the RTSQ was 0.905 for patients who had received a transplant, and 0.918 for those who had not received a transplant (Gibbons, Cinnirella, Bayfield, Watson, Oniscu, Draper, et al., in preparation). It was possible for up to six items from this 13-item measure to be missing and still retain a Cronbach's  $\alpha$  coefficient above 0.70 for the transplant ( $\alpha$  = 0.774) and non-transplant groups ( $\alpha$  = 0.804).

There are two versions of the RTSQ: the status version (RTSQs), and the change version (RTSQc). The instructions, format and response options of the RTSQc are modelled on the DTSQc for diabetes (Bradley et al, 2007; Howorka et al, 2000) but with item stems as for the RTSQs. The DTSQc was developed to overcome potential ceiling effects (i.e. where respondents score maximum or near-maximum satisfaction at baseline and can show little or no improvement at follow-up Bradley et al 2007; Howorka et al 2000).

The RTSQs can be used without the RTSQc. However, while the RTSQc measures the amount of relative change in treatment satisfaction in comparison with a previous treatment, the RTSQs is needed to measure absolute level of satisfaction with the current treatment. Even if a patient has scored optimally on the RTSQs at baseline indicating they are very satisfied with all aspects of treatment, they can nevertheless show they are very much more satisfied with a new treatment when they complete the RTSQc. The RTSQc is relevant for studies involving an intervention (such as a transplant or change in type of dialysis). The RTSQc will tell you how people's satisfaction has changed; it doesn't tell you whether it was high or low to start with, or where it is at endpoint. Whether or not you use the RTSQc, you should always use the RTSQs at least once during your study, preferably at the beginning. This will anchor your findings on the RTSQc, if you do go on to use the change version as well as the status version. We recommend that you use the RTSQs at baseline and endpoint (and at one or two interim points in a 12-month trial) and the RTSQc (if used) at one follow-up only. Parallel analysis, and subsequent principal axis factoring show that a one-factor solution is optimal for both the RTSQs and RTSQc for patients on the various renal replacement therapies.

## 1. Using the RTSQ

We recommend use of the RTSQs at baseline and follow-up to provide a 'difference'

score. You may wish to repeat the RTSQs between baseline and endpoint in order to have a picture of any fluctuation in satisfaction during that period. The RTSQs can usefully be given at intervals throughout a treatment period and when steady increases in RTSQs scores are seen, this provides evidence that scores are determined by experience and are not simply an initially hopeful response to a new treatment, which subsequently declines. Early on-treatment administration of the RTSQ, 4-8 weeks after start of a new treatment in a clinical trial, can be useful to ensure that there is a score available for use in Last-Observation-Carried-Forward analyses for patients who terminate the study early for whatever reason, which might otherwise threaten the credibility of the findings.

#### 1.1 Scoring the RTSQs

The latest 13-item status version produces the following measures:

- Total treatment satisfaction:
   All the items are summed to produce a treatment satisfaction score (range: 78 to 0). The higher the score, the greater the satisfaction with treatment.
- Satisfaction with each aspect of treatment can be considered using individual item scores: rated 6 (very satisfied, convenient, flexible, etc.) to 0 (very dissatisfied, inconvenient, inflexible, etc.). The higher the score, the greater the satisfaction.

### 1.2 Scoring the RTSQc

All of the items can be summed to produce a Treatment Satisfaction (change) score. Psychometric analyses including principal axis factoring and reliability analyses conducted on data from the ATTOM programme (Gibbons, Bayfield, Cinnirella, Draper, Johnson, Oniscu, et al. in preparation; Gibbons, Cinnirella, Bayfield, Watson, Oniscu, Draper, et al. in preparation) confirm that a one-factor structure is appropriate.

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## 1.3 Wording of the RTSQc instructions

The wording at the beginning of the instructions needs to relate to the particular intervention in your study. Thus it may need to be changed to be suitable for your particular study. We have produced a wording for the beginning of the introduction that is as generic as possible to minimise the need for changes, but you may need to adapt the wording to be suitable for the study duration and type of intervention. The wording has been based on the study design in which it is most commonly used (i.e. a randomised controlled trial). It may therefore need to be changed for use in an observational type of study. Please note that the last two sentences beginning "Please answer each question..." are the same for all occasions. These latter sentences should not be changed.

Please include in your protocol the details, in English, of any change to the wording of the RTSQc instructions for your particular study. If a run-in treatment period is included and involves a change of treatment for at least some people, the comparison is probably best made with treatment prior to commencement of the any aspect of the study, including the run-in. For crossover studies we would recommend that you make one comparison at the very end of the study, asking participants to compare their current treatment with the previous treatment<sup>1</sup>.

<sup>1</sup>Example for a crossover design:

For the past N\* weeks you have used either  $X^{**}$  or  $Y^{**}$ . Today we would like to know how your experience of this treatment for CKD (including medication and diet) has changed from your experience of the previous treatment, which you used in the N weeks before you changed to the treatment you are using now. Please answer...etc. Where: \*N = the number of weeks/months in each treatment period. \*\*X and Y = the two treatments being compared

# **Availability**

The RTSQ is made available to users by formal arrangement with Health Psychology Research Ltd. Requests should be made to <a href="mailto:info@healthpsychologyresearch.com">info@healthpsychologyresearch.com</a>. A user agreement is necessary to avoid breach of copyright and to ensure that the latest and most appropriate version of the questionnaire is used.

Evidence of licensing may be required by regulators, editors and/or examiners.

### **Contact Information**

For permission to use the RTSQ and to ensure that you have the most up-to-date version, please contact:

E-mail: <a href="mailto:info@healthpsychologyresearch.com">info@healthpsychologyresearch.com</a>
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#### Selected References

RTSQ and background references to the DTSQs and DTSQc

- Barendse, S., Speight, J., & Bradley, C. (2005). The Renal Treatment Satisfaction Questionnaire (RTSQ): A Measure of Satisfaction with Treatment for Chronic Kidney Failure. *American Journal of Kidney Diseases*, 45(3, 572-579.
- Ashwell, S.G., Bradley, C., Stephens, J.W., Witthaus, E., & Home, P.D. (2008). Treatment satisfaction and quality of life with insulin glargine plus insulin lispro compared with NPH insulin plus unmodified human insulin in individuals with type 1 diabetes. *Diabetes Care*, *31*(6), 1112-7. http://www.ncbi.nlm.nih.gov/pubmed/18339977
- Bradley, C. (1994). The Diabetes Treatment Satisfaction Questionnaire: DTSQ. In Bradley C (Ed) (1994). Handbook of Psychology and Diabetes: a guide to psychological measurement in diabetes research and practice. Abingdon: Routledge ISBN 9783718655625, formerly published by Harwood Academic Publishers ISBN 3-7186-5562-4: p. 111-132.
- Bradley, C., Eschwège, E., de Pablos-Velasco, P., Parhofer, K.G., Simon, D., Vandenberghe, H., & Gönder-Frederick, L, (2018). Predictors of Quality of Life and Other Patient-Reported Outcomes in the PANORAMA Multinational Study of People with Type 2 Diabetes. *Diabetes Care*, *41*(2), 267-276. doi:10.2337/dc16-2655
- Bradley, C., & Lewis, K.S. (1990). Measures of psychological well-being and treatment satisfaction developed from the responses of people with tablet-treated diabetes. *Diabetic Medicine*, 7, 445-451.
- Bradley, C., Plowright, R., Stewart, J., Valentine, J., & Witthaus, E. (2007). The Diabetes Treatment Satisfaction Questionnaire change version (DTSQc) evaluated in insulin glargine trials shows greater responsiveness to improvements than the original DTSQ. *Health and Quality of Life Outcomes*, *5*(5), 57. http://www.hglo.com/content/5/1/57
- Bretzel, R.G., Nuber, U., Landgraf, W., Owens, D.R., Bradley, C., & Linn, T. (2008). Once-daily basal insulin glargine versus thrice-daily prandial insulin lispro in people with type 2 diabetes on oral hypoglycaemic agents (APOLLO): an open randomized controlled trial. *The Lancet*, *371*, 1073-1084. <a href="http://www.thelancet.com/journals/lancet/article/PIIS0140673608604857/abstract">http://www.thelancet.com/journals/lancet/article/PIIS0140673608604857/abstract</a> http://digirep.rhul.ac.uk/items/dd2a797e-9f6c-02ed-3dfe-5d016ccf9d99/1/
- DAFNE Study Group\* (2002). Training in flexible, intensive insulin management to enable dietary freedom in people with type 1 diabetes: the dose adjustment for normal eating (DAFNE) randomised controlled trial. *British Medical Journal*, 325, 746-749 (full 6 page version: <a href="http://bmj.com/cgi/content/full/325/7367/746">http://bmj.com/cgi/content/full/325/7367/746</a>).
- Gibbons, A., Bayfield, J., Cinnirella, M., Draper, H., Johnson, R.J., Oniscu, G.C., Ravanan, R., Tomson, C.R.V., Roderick, P., Metcalfe, W., Forsythe, J., Dudley, C., Watson, C.J.E., Bradley, J.A., & Bradley, C. (in preparation). Quality of life and other patient-reported outcomes following deceased-donor or living-donor kidney transplantation.
- Gibbons, A., Cinnirella, M., Bayfield, J., Watson, C.J.E., Oniscu, G.C., Draper, H., Tomson, C.R.V., Ravanan, R., Johnson, R.J., Forsythe, J., Dudley, C., Metcalfe, W., Bradley, J.A., & Bradley, C. (in preparation). Improvements in quality of life, other patient reported outcomes and health utilities following simultaneous pancreas and kidney (SPK) transplantation in the UK: ATTOM programme.
- Howorka, K., Pumprla, J., Schlusche, C., Wagner-Nosiska, D., Schabmann, A., & Bradley, C. (2000). Dealing with ceiling baseline treatment satisfaction level in patients with diabetes under flexible, functional insulin treatment: assessment of improvements in treatment satisfaction with a new insulin analogue. *Quality of Life Research*, 9, 915-930. <a href="http://www.ncbi.nlm.nih.gov/pubmed/11284211">http://www.jstor.org/stable/4037525</a>
- Medcalf, J.F., Andrews, P.A., Bankart, J., Bradley, C., Carr, S., Feehally, J., Harden, P., Marsh, J., Newstead, C., & Thompson, J. (2011). Poorer graft survival in ethnic minorities: results from a multicentre UK study of kidney transplant outcomes. *Clinical Nephrology*, *75*(4), 294-301. http://www.ncbi.nlm.nih.gov/pubmed/21426883
- Witthau, E., Stewart, J., & Bradley, C. (2001). Treatment satisfaction and psychological well-being with insulin glargine compared with NPH in patients with Type 1 diabetes. *Diabetic Medicine*, *18*, 619-625.

See list of selected references to the DTSQ at <a href="www.healthpsychologyresearch.com">www.healthpsychologyresearch.com</a> (Guidelines tab) for further references to clinical trials using the DTSQ and to development and use of adaptations of the DTSQ for other conditions.