Measuring expectations of quality of life: how to improve health related quality of life assessment (CIQOL)

Health-related quality of life (HRQOL) and other self-reported outcomes are frequently used in clinical trials. Phrasing of questions is, however, often non-specific and the extent to which patients’ replies are affected by their personal frames of reference is unknown.

We investigated people’s responses to supplementary quality of life questions as part of a wider randomised controlled trial which compared different treatment regimens for Paget’s disease. Analysis of these replies showed that many participants contrasted their current health with how they had felt previously, or against some self-defined reference group. The chosen frame of reference was found to be important since it could impact on HRQOL measures to an extent considered to be clinically important.

Following on from this, we carried out a qualitative study to investigate the reference frames used by an elderly population living with a chronic metabolic bone disorder. Twenty-one participants (11 male, 10 female) with ages ranging from 59-91 years, were interviewed retrospectively about their responses to supplementary HRQOL questions, using cognitive interviewing techniques and semi-structured topic guides.

Participants discussed undergoing a process of goal setting in achieving a desired level of quality of life. Participants did this by developing reduced goals using their self in the past as a reference point from which to adjust their current expectations for their quality of life. Participants also used other unhealthy people as a reference frame from which upward comparisons were made, thus reinforcing the hypothesis that comparison with others is often used in shaping one’s own expectations.

These findings suggest the inclusion of supplementary questions in HRQOL questionnaires could be useful to identify biased or obscured results in clinical trials.

CIQOL has been funded by the Chief Scientist Office. For further information, contact Clare Robertson (E-mail: c.robertson@abdn.ac.uk; Telephone: 01224 551100)
Jonathan is keen to speak to anyone with similar research interests who
in collaboration with researchers in the UK, Germany and Canada.
The fellowship runs from August 2007 - July 2011 and will be conducted

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A new outcome measure developed for the REFLEX Trial: the Reflux questionnaire

The REFLEX Trial is a large UK multicentre randomised trial comparing a policy of relatively early laparoscopic surgery with continued best medical management for people with gastro-oesophageal reflux disease (GORD). The results of this trial will be available later this year.

The trial required a valid measurement of treatment outcome, and whilst there are a number of quality of life tools available, none were sufficiently specific to assess the spectrum of gastro-intestinal symptoms associated with the treatment of GORD. A new condition-specific outcome measure was, therefore, developed for use within this trial.

Potential items were identified via a series of interviews and focus groups with GORD patients. The final measure, which consists of 31 items covering seven categories (heartburn; acid reflux; wind; eating and swallowing; bowel movements; sleep; work, physical and social activities), has two outputs: a quality of life score and five Reflux symptom scores.

Initial findings suggest that this measure is valid, reliable, acceptable to respondents and simple to administer in both a clinical and research context. Although the principal aim was to develop an outcome measure for use in the REFLEX trial, it is hoped that the questionnaire will prove more widely applicable.

This is a UK collaborative study that has been funded by the NHS R&D HTA Programme and is co-ordinated from the Health Services Research Unit.

For further information, contact Samantha Wileman (E-mail: s.wileman@abdn.ac.uk Telephone 01224 554196)

Reference


Contamination effects in trials of educational interventions

Contamination in controlled trials occurs when people who are intended to receive an intervention inadvertently do so: for example, in a trial of a new diet, someone in the experimental group who does not wish to be randomised may inadvertently receive the experimental diet. If contamination is serious, it may be possible to randomise trial participants into a control group and an experimental group using a novel statistical technique (Comparator Average Causal Effect models).

The results show that many trials empirically demonstrate contamination and that cluster randomised trials might produce greater biases to individually randomised trials. Contamination analyses produced results that were less biased than intention to treat or per protocol analysis, when contamination was present. They showed that individually randomised trials would in most situations be more powerful than cluster randomised trials, despite contamination.

The probability, nature and process of contamination should be considered when designing and analysing controlled trials of educational interventions in health. Cluster randomisation may not be appropriate and should not be uncritically assumed always to be a solution.

For further information, contact Craig Ramsay (E-mail: c.r.ramsay@abdn.ac.uk Telephone 01224 558994)

Reference

Contamination in trials of educational interventions - measurement of degree of contamination and novel designs to overcome it. Final grant report submitted to NCIRU [document on the Internet]. Available from: URL: http://www.ncri.ernet.uk/project1570.asp

Approximately 25% of patients admitted to hospital will require urethral catheterisation at some stage during their stay, and the risk of developing bacteriuria in catheterised patients is approximately 2% per day. Catheter-associated symptomatic urinary tract infections are the leading cause of hospital acquired infections, accounting for between 23% and 40% of all cases. Such infections result in additional morbidity and mortality and represent a considerable economic burden to the health care sector, patients and their carers.

A recent Cochrane review of randomised controlled trials reported that some types of urinary catheters may reduce urinary tract infections in hospitalised patients. However, it was concluded that more research is needed to fully assess the use of antiseptic and antisepctic impregnated urethral catheters over standard urethral catheters in hospitalised adults requiring short term (≤ 14 days) catheterisation.

The CATHETER Trial is a multicentre UK trial which aims to establish the clinical benefits and cost-effectiveness of using antibiotic (nitrofurazone) or antiseptic (silver) impregnated urethral catheters over standard urethral catheters in hospitalised adults requiring short term (<14 days) catheterisation.

The trial aims to identify at risk sub-groups of patients, such as those vulnerable to severe infection; the elderly and those in intensive care, where use of more expensive catheters might be particularly beneficial.

We aim to recruit 5700 participants, from eight UK centres, who will be randomly allocated to have either a standard or treated catheter as part of their routine care. They will then be asked to fill in questionnaires in hospital and after they go home, to find out whether a urine infection occurred, and if this affected their health, treatment, or hospital stay.

The trial results will have implications for the management of patients requiring short-term urethral catheterisation in hospital and rationalisation of catheter purchasing policies for large organisations like the NHS.

This trial has been funded by the NHS R&D HTA Programme for a period of 33 months and will finish in October 2009.

For further information, contact Professor James N’Dow (E-mail: j.ndow@abdn.ac.uk Telephone: 01224 553858)

Trial website: https://www.charttrials.abdn.ac.uk/catheter/index.php

The CATHETER Trial: urethral catheters for reducing urinary tract infections

Varicose veins in the legs affect 20–30% of adults. Ultrasound-guided foam sclerotherapy is a new treatment option in which sclerosant foam is injected into affected veins, guided by ultrasound monitoring. The foam causes inflammation of the vein wall which leads to blockage and destruction of the vein. As a result of concerns about the safety of this procedure, the UK Interventional Proteges Programme of the National Institute for Health and Clinical Excellence (NICE) commissioned our group to undertake a systematic review of the evidence.

The main conclusions, derived from 69 studies involving over 9000 patients, were that:

- complete blockage of treated veins was achieved, on average, in 87.0% of cases.
- recurrence/development of new veins rate was 8.1% (at follow-up ranging from six weeks to six years after surgery).
- foam sclerotherapy was associated with a lower rate of complete blockage compared to randomised trials. However, there was substantial variation between the studies.
- serious complications, including pulmonary embolism and deep vein thrombosis, were infrequently reported (a median of less than 1.5%).
- other adverse events were more common. The main ones are listed in the table.

<table>
<thead>
<tr>
<th>Adverse events</th>
<th>Median, %</th>
<th>Range, %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pain at the site of injection</td>
<td>25.6</td>
<td>6.0 - 41.0</td>
</tr>
<tr>
<td>Matting/skin staining/ pigmentation</td>
<td>17.8</td>
<td>0 - 66.7</td>
</tr>
<tr>
<td>Thrombophlebitis</td>
<td>4.7</td>
<td>0 - 25.0</td>
</tr>
<tr>
<td>Headache</td>
<td>4.2</td>
<td>0 - 23.0</td>
</tr>
<tr>
<td>Visual disturbance</td>
<td>1.4</td>
<td>0 - 5.9</td>
</tr>
<tr>
<td>Minor vein thrombosis</td>
<td>0.7</td>
<td>0 - 17.6</td>
</tr>
<tr>
<td>Chelatedness/vasovagal symptoms</td>
<td>0.5</td>
<td>0 - 2.8</td>
</tr>
<tr>
<td>Transient confusion</td>
<td>0.5</td>
<td>0 - 1.2</td>
</tr>
<tr>
<td>Local neurological injury</td>
<td>0</td>
<td>0 - 0.7</td>
</tr>
</tbody>
</table>

In May 2007, NICE issued guidance on this procedure and concluded that ultrasound-guided foam sclerotherapy is efficacious in the short-term. However, due to the occurrence of transient side effects in a small proportion of patients, the procedure should only be used with special arrangements for consent.

For further information, contact Xueli Jia (E-mail: x.jia@abdn.ac.uk Telephone: 01224 559801)

Reference


Foam sclerotherapy for varicose veins: a systematic review of safety and efficacy

The CA THETER Trial is a multicentre UK trial which aims to establish the clinical benefits and cost-effectiveness of using antibiotic (nitrofurazone) or antiseptic (silver) impregnated urethral catheters over standard urethral catheters in hospitalised adults requiring short term (<14 days) catheterisation.