carers and healthcare professionals. Randomised controlled trials (RCTs) of arm rehabilitation measure numerous outcomes (e.g. Strength, pain, ability to use arm) hindering comparisons and synthesis of trial data for efficacy analyses to inform clinical practice. However, arm function is a complex concept and a variety of outcomes and measurement tools may be warranted. Therefore, we aim to develop consensus recommendations on a toolbox of key outcome measures for use in arm rehabilitation RCTs.

Objectives

Describe current outcome measures used in arm rehabilitation RCTs and their psychometric properties. Identify outcomes important to stroke survivors with arm function problems, their carers and healthcare professionals. Produce final consensus recommendations to support selection of outcome measures for use in future arm rehabilitation RCTs.

Method

Phase 1: systematically explore trial data within a Cochrane Overview of arm rehabilitation RCTs, extracting data on assessment tool use. Tools must be clearly defined and reproducible to be considered as an outcome measure in phase 2 and 3.

Phase 2: using nominal group technique (NGT) identify and agree on outcomes relevant to life after stroke with arm impairment. Eight NGTs will be undertaken with stroke survivors and carers, and eight NGTs with healthcare professionals experienced in arm function rehabilitation. This will be supplemented by eight semi-structured interviews with stroke survivors and carers. Data will be analysed using content analysis. Outcome measures identified (Phase 1) will be linked with outcomes from Phase 2 followed by systematic exploration of outcome measures psychometric properties.

Phase 3: edelphi to achieve consensus amongst stroke arm rehabilitation researchers on important and feasible outcome measures from phase 2. A final consensus meeting with stakeholders (stroke survivors, carers, researchers, trialists, and healthcare professionals) will determine which outcome measures will be recommended as part of the SMART toolbox.

Results

Phase 1: We extracted data from 254 RCTs; 208 assessment tools were identified of which 146 met the criteria of reproducible outcome measure. The Fugl-Meyer (arm function section) was used most frequently (79/254 (31%) RCTs). 120/208 (58%) outcome measures were only used in one RCT.

Phase 2: 43 stroke survivors and carers, and 58 health professionals participated in the NGT sessions. Ten stroke survivors and carers participated in eight interviews. Data analysis will be completed by January 2017.

Conclusions

Phase 1 highlighted wide variation and lack of consistency in use of arm function outcome measures in RCTs. Consensus recommendations that account for psychometric properties, and the perspective of stroke survivors, carers, and healthcare professionals, will enable valid, reliable and meaningful measurement in future RCTs of arm rehabilitation. Therefore, recommendations for priority outcome measures that measure important outcomes are warranted. By agreeing on a toolbox of key outcome measures for inclusion, subsequent RCTs' outputs will enhance comparability of RCT results and facilitate comprehensive meta-analyses of the effectiveness of interventions.

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Using proxy responses from carers to collect quality of life data on patients with brain metastases: an analysis from the UK MRC quartz trial

Matthew Nankivell[1], Paula Mulvenna[2], Rachael Barton[3], Corinne Faivre-Finn[4], Paula Wilson[5], Elaine McColl[6], Barbara Moore[7], Iona Brisbane[8], David Ardron[9], Richard Stephens[10]

[1]MRC Clinical Trials Unit at UCL AND MRC London Hub for Trials Methodology Research; [2]Northern Centre for Cancer Care; [3]Queen's Centre for Oncology and Haematology; [4]Institute of Cancer Sciences; [5]Bristol Haematology and Oncology Centre; [6]Newcastle Clinical Trials Unit and Institute of Health and Society; [7]Wales Cancer Research Network; [8]The Beatson West of Scotland Cancer Centre; [9]Patient representative; [10]MRC Clinical Trials Unit at UCL (retired)

Correspondence: Matthew Nankivell

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Background

Clinical trials requiring patient reported data involving patients with multiple symptoms and/or a poor prognosis are often considered challenging. There is concern about over-burdening trial participants, either through more regular follow-up or by using longer questionnaires. One possible solution is to obtain data about the patient indirectly by asking their carer.

The QUARTZ trial assessed the use of whole brain radiotherapy (WBRT) in patients with inoperable brain metastases from non-small cell lung cancer. This is a very poor prognosis group, and patients can experience rapid changes in condition, which necessitated frequent data collection. As the trial focused on quality of life, patients were asked to complete the EQ-5D questionnaire on a weekly basis. At the same time, their carer was asked to complete the same questionnaire from the point of view of the patient, so that the potential use of proxy scores could be assessed.

Methods

QUARTZ randomised 538 patients to receive either WBRT, or supportive care alone, with 407 carers also agreeing to participate. Here we compare the baseline responses to the EQ-5D-3 L questionnaire of the patients and carers. The trial's primary outcome measure of quality adjusted life years (QALYs) was also calculated separately from patient and carer data, and the results compared.

Results

Overall levels of agreement between patient and carer responses to the EQ-5D at baseline were 82% for mobility, 79% for self-care, 71% for usual activities, 78% for pain/discomfort, and 66% for anxiety/depression. For anxiety/depression, carers reported more problems than patients in 25% of cases, with 9% reporting fewer problems. For the other questions carers reported more problems as often as they reported fewer: mobility 9% vs 8%; self-care 11% vs 11%; usual activities 15% vs 15%; pain/discomfort 13% vs 9%.

QALYs were calculated for the 397 patients where both patient and carer data were available. The average QALY was slightly higher using patient data (45.3 days) than carer data (39.0 days). When assessing the treatment effect, the difference in average QALY (95% CI) was 3.2 days (−13.1, 7.4) when calculated from patient responses, and 5.3 days (−15.4, 3.9) from carer responses.

Conclusions

The level of agreement between patients and carers was reasonably high on most questions. The agreement was lowest for the question about anxiety and depression, with carers tending to report more problems compared to the patient's own assessment. The level of agreement seen means it may be reasonable to use the carer response in some situations where it is not appropriate to ask the patient directly. Caution is advised though as even for the question on mobility there was disagreement in 18% of cases. The difference in the analysis of the trial's primary endpoint was minor and did not change the main conclusion of the study. Therefore within the confines of a clinical trial, it could be appropriate to use these proxy assessments to assess treatment effects. QUARTZ is one of few trials in this setting, and further studies looking at the use of proxy responses in poor prognosis populations are warranted.

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Reaching a consensus on causes of pain: use of an expert independent panel to determine a reference standard

Jane Daniels[1], Konstantinos Tryposkiadis[1], Lee Middleton[1], Lee Priest[1], Khalid Khan[2], Jonathan Deeks[1]

[1]University of Birmingham; [2]Queen Mary University of London

Correspondence: Jane Daniels

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Background

In a test evaluation study, where there are a number of target conditions to be considered, not all of which have a perfect reference standard, there is a risk of partial or differential verification of the underlying causes, with the inherent bias. One approach is to use an expert independent panel (EIP) to determine the presence or absence of the target