The PROACT Study
Patient Reported Outcomes in cancer, impact of Age and Carer role demands associated with Treatment

Thank you
For taking part in PROACT study 4 and helping with this research. We are sending you this information sheet because you indicated that you would be interested in what we found.

PROACT study 4 was designed to further test questionnaires that we have developed to measure the impacts that cancer and cancer treatment have on many aspects of life, for both patients and their informal caregivers.

We needed to test the questionnaires to make sure they were reliable and valid measures. This is to ensure that the questionnaires can be used with confidence.

This information sheet will tell you about what we did, what we found, and how these results will be used.

Val Shilling
Rachel Starkings

What did we do?
- We invited people with breast, colorectal, gynaecological, head and neck, lung or renal cancer or malignant melanoma to complete the patient questionnaires.
- We also asked them to nominate the person who is their main source of emotional and/or practical support to complete the informal caregiver questionnaires.
- Participants completed sets of questionnaires three times: at baseline, a week later and then 2 months after baseline.
- Participants completed the questionnaires on paper or online, whichever they preferred.
- Collecting these data meant we could test the new questionnaires in two ways:
  1) by seeing if they are reliable when completed more than once (reliability).
  2) by comparing them with other questionnaires that measure quality of life and wellbeing (validity).

Who took part?
- 170 people with cancer completed at least one set of questionnaires.
- 135 informal caregivers completed at least one set of questionnaires.
- Their relationship to the person they support was partner or spouse (109), child (8), friend (7), parent (6), sibling (4) or other (1).
- Ages ranged from 27 to 92 years for people with cancer and 21 to 87 years for informal caregivers.
- There were slightly more women in both the patient (58% women) and the caregiver (52% women) group.
- 122 people chose to complete at least the first set of questionnaires by post. 183 completed them online.
What did we find?

- In depth interview study with patients and caregivers to identify which aspects of quality of life are most important to them.
- Interview study with patients and caregivers to ‘test’ the possible questionnaire items. This was to make sure the items were easy to understand and answer and were important questions to ask.
- Validation study: 135 patients and 110 caregivers completed the new questionnaires at three time points alongside other measures for comparison. This study was conducted in exactly the same way as the one you took part in.
- This is the study you took part in. We asked you to complete the final version of our new questionnaires at three time points so that we could confirm that they are valid and reliable. 170 patients and 135 caregivers completed questionnaires.

Analysis of these interviews was used to generate possible items for the questionnaires.

After analysing these interviews we added some items and deleted others from both questionnaires and changed the wording of others. In total we made 51 changes to the patient questionnaire and 94 changes to the caregiver one!

Overall the questionnaires were found to be valid and reliable but some individual items did not perform well. We removed 5 items from the patient questionnaire and 10 from the caregiver questionnaire.

Thanks to your participation in this study, we have been able to demonstrate that the questionnaires are valid and reliable and ready to use in other research and clinical practice.

What happens next?

- The questionnaires will now be adopted into the Functional Assessment of Chronic Illness Treatment (FACIT) measurement system.
- This means they will be available for use worldwide in research such as clinical trials, and in routine clinical discussions between families and their healthcare professionals about different treatments and supportive interventions.
- You can read more about the FACIT measurement system at www.facit.org.
- We are currently talking with a group of researchers who want to translate the questionnaires into Danish. We hope for many more translation studies in the future.
- We will present the findings of this study at the annual conference of the National Cancer Research Institute in November to raise awareness of the questionnaires with clinicians and researchers.

Additional Information

- We would like to thank everyone who took part in this research, all of the members of the cancer teams and our group of patient and caregiver advisors.
- The research was conducted by SHORE-C (Sussex Health Outcomes Research and Education in Cancer), Brighton and Sussex Medical School, University of Sussex.
- SHORE-C is led by Professor Dame Lesley Fallowfield, the Deputy Director is Professor Val Jenkins.
- Read more about our research at shore-c.sussex.ac.uk
- The research was funded by the pharmaceutical company Bristol-Myers Squibb. The funder had no influence over the way the research was conducted or the findings.
- The study received ethics approval from the NRES Committee London - Central (ref: 17/LO/1773).
- If you have any questions about this research please contact Val: v.m.shilling@sussex.ac.uk or 01273 877934.