EVALUATION AND VALIDATION OF THE PROACT MEASURES FOR CANCER PATIENTS AND INFORMAL CAREGIVERS

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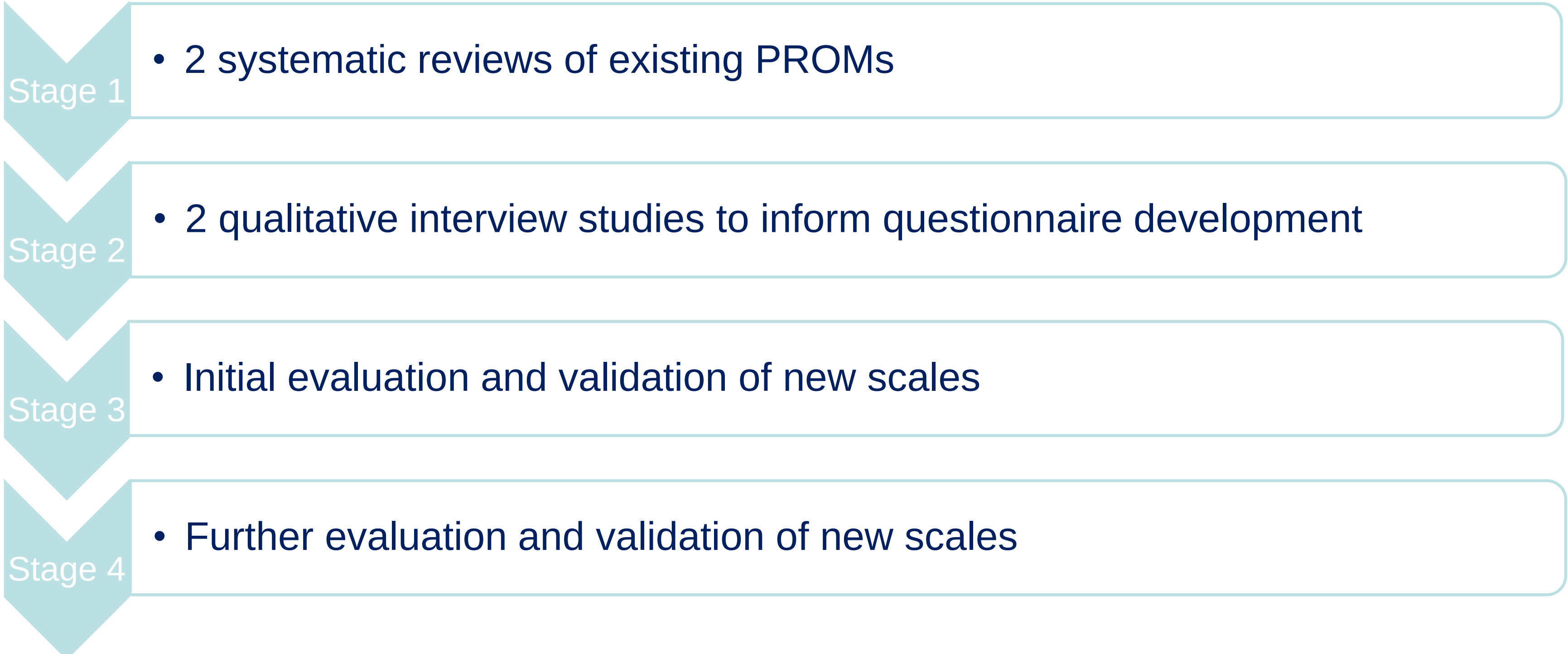
Background

Formal assessment capturing broader aspects of life that are affected by cancer and cancer treatments, e.g. the impact on roles and responsibilities, is not normal practice. However childcare, jobs and careers, finances, family relationships and future plans are all likely to be impacted by diagnosis and treatment.

Systematic reviews[1,2] revealed a need for rigorously developed, well-validated measures to assess these neglected topics. In the PROACT study we developed two scales to enable a broader evaluation of these 'real world' impacts of cancer and cancer treatment.

Aims

The primary aim of PROACT is the development and evaluation of two new scales measuring broad life impacts of cancer and cancer treatment for patients (to be administered alongside FACT-G) and informal caregivers (a standalone measure).



Stage 1
- 2 systematic reviews of existing PROMs

Stage 2
- 2 qualitative interview studies to inform questionnaire development

Stage 3
- Initial evaluation and validation of new scales

Stage 4
- Further evaluation and validation of new scales

Here we present data from Stage 3 – initial evaluation and validation of the Patient Roles and Responsibilities Scale (PRRS) and the Caregiver Roles and Responsibilities Scale (CRRS)

Methods

- Participants were recruited from 11 UK sites, stratified by age and tumour site
- PRRS or CRRS completed on paper or online (participant choice) at 3 time points: baseline, 7 days and 2 months (only baseline and test-retest data are presented here)
- PRRS/CRRS completed with other measures of Quality of Life and wellbeing at baseline and 2 months; completed alone at 7 days for test-retest

Patient Measures	Caregiver Measures
PRRS	CRRS
FACT-G	Cargiver Quality of Life Cancer (Weitzner et al)
WHOQOL-BREF	WHOQOL-BREF
Social Difficulties Inventory (SDI) (Wright et al)	

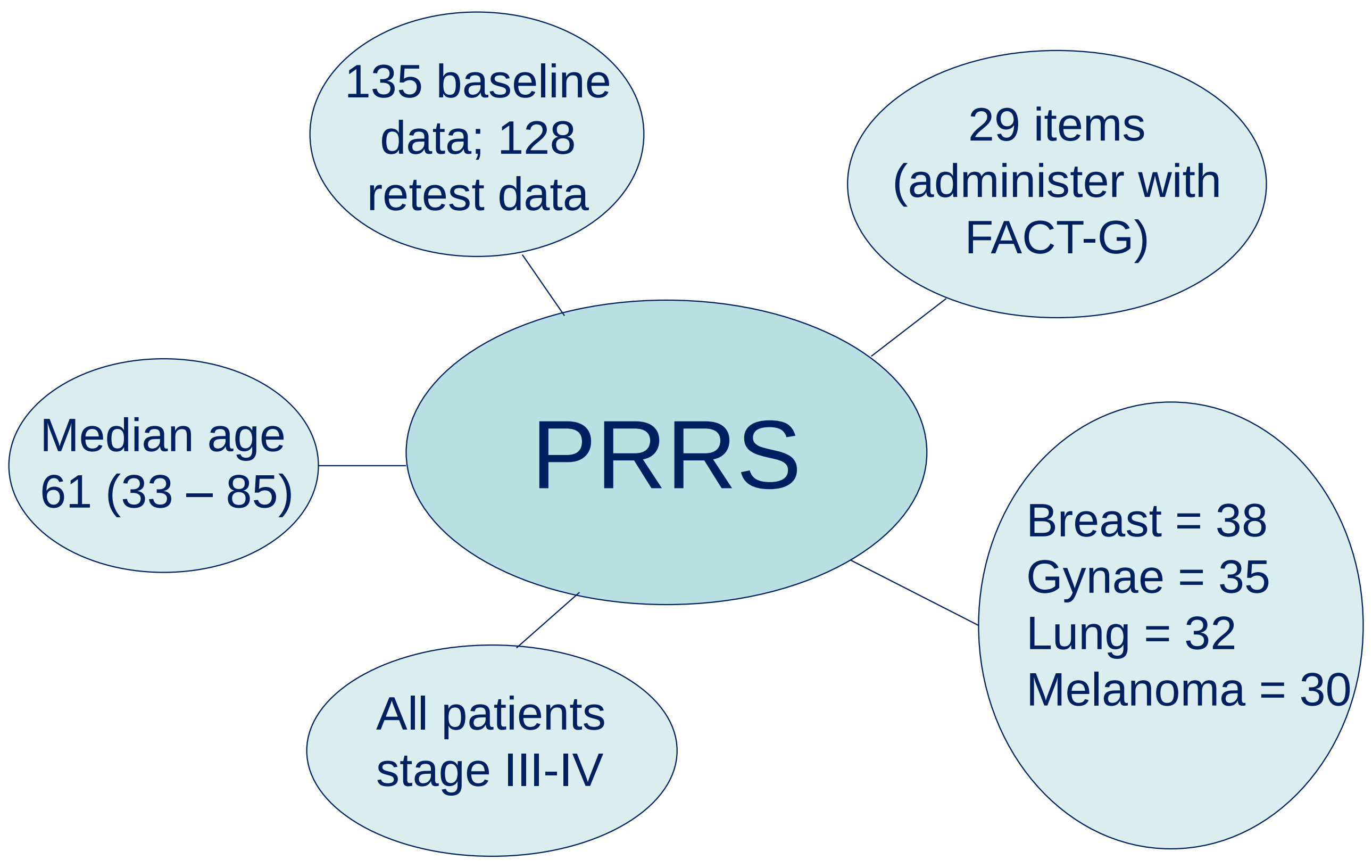
PRRS (29 items)	CRRS (60 items)
Family and home life (N=13)	Family and support (N=12)
Financial wellbeing (N=8)	Relationships and communication (N=7)
Jobs and careers (N=8)*	Lifestyle and Outlook (N=12)
	Health and wellbeing (N=14)
	Financial wellbeing (N=6)
	Jobs and careers (N=9)*

* Items relating to jobs and careers are only completed by participants currently working. These items are not included in the analysis presented here as too few participants completed to reliably evaluate the items

Example items

People with cancer:					
	Not at all	A little bit	Some-what	Quite a bit	Very much
I worry about the impact of my illness on my partner (or the person who is my main support)	0	1	2	3	4
People who offer support:					
	Not at all	A little bit	Some-what	Quite a bit	Very much
I make time to do things for myself	0	1	2	3	4
Item on both questionnaires:					
	Not at all	A little bit	Some-what	Quite a bit	Very much
I am concerned about keeping my job and income	0	1	2	3	4

Results Patients (PRRS)



PRRS

135 baseline data; 128 retest data

29 items (administer with FACT-G)

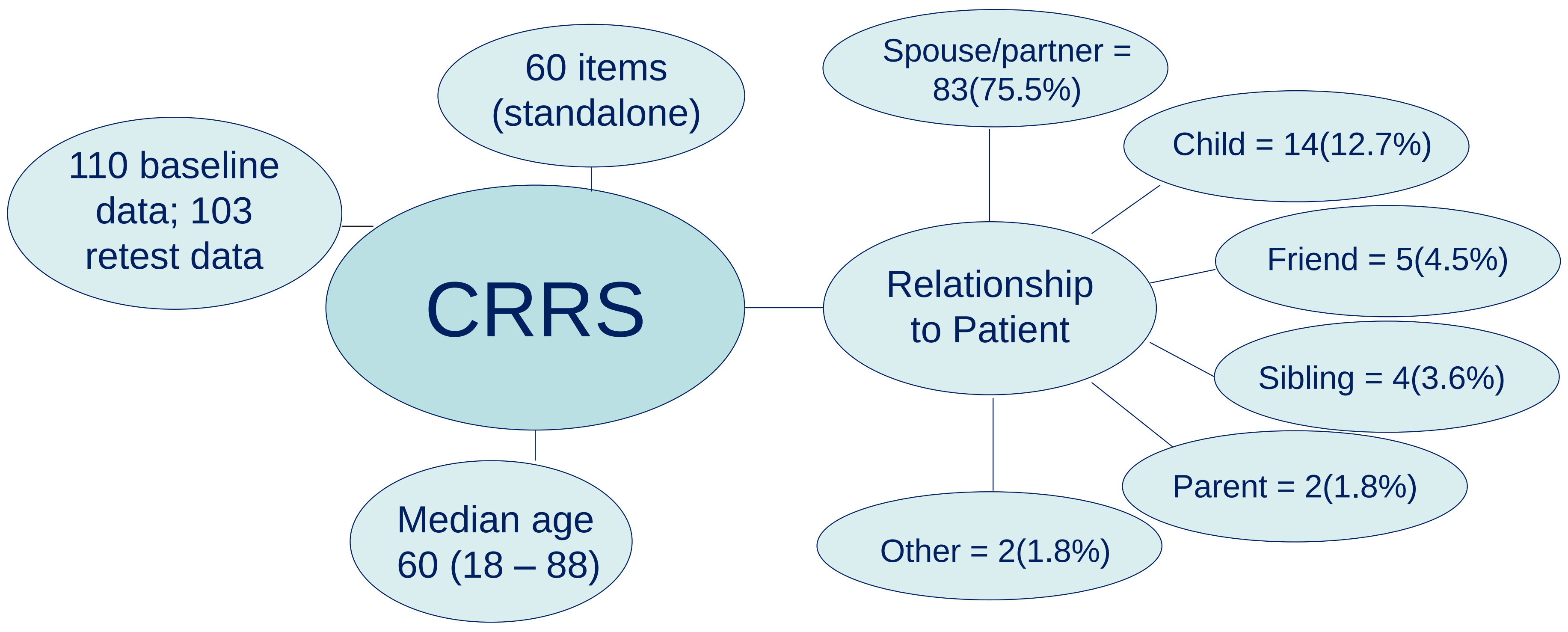
Median age 61 (33 – 85)

All patients stage III-IV

Breast = 38
Gynae = 35
Lung = 32
Melanoma = 30

- The PRRS showed good internal consistency (Chronbach's α = .87) and test-retest reliability (ICC=.859 [two-way random, absolute agreement])
- Correlations with validation measures were strong and in the predicted direction (FACT-G r=.653; SDI r= -.759; WHOQOL-BREF r=.653)
- There was no evidence of floor/ceiling effects (total score). The PRRS has a possible range of 0-84. Baseline scores ranged from 20 (N=1) to 82 (N=1) with a median of 54, mean 52.44 (s.d. 14.16)
- The measure demonstrated high levels of acceptability, as indicated by the very low missing data rate (.006% baseline; .005% retest)

Results Caregivers (CRRS)



CRRS

110 baseline data; 103 retest data

60 items (standalone)

Median age 60 (18 – 88)

Relationship to Patient

Spouse/partner = 83(75.5%)
Child = 14(12.7%)
Friend = 5(4.5%)
Sibling = 4(3.6%)
Parent = 2(1.8%)
Other = 2(1.8%)

- The CRRS also showed good internal consistency (Chronbach's α = .91) and test-retest reliability (ICC=.894 [two-way random, absolute agreement])
- Correlations with validation measures were strong and in the predicted direction (CQOLC r=.837; WHOQOL-BREF r=.710)
- There was no evidence of floor/ceiling effects (total score). The CRRS has a possible range of 0-204. Baseline scores ranged from 45 (N=1) to 172 (N=1) with a median of 131.5, mean 129.5 (s.d. 25.15)
- Like the PRRS, the CRRS demonstrated high levels of acceptability, as indicated by the very low missing data rate (.0025% baseline; .001% retest)

Modification to scales for future validation

- Several items on each scale were identified as:
  a) having poor psychometric performance with unacceptably low level of correlation with other items and low corrected item-total correlations in reliability analysis or
  b) redundant alongside other better performing similar items
- These were removed to improve the scales and reduce participant burden
- 5 items were removed from the PRRS, 10 from the CRRS
- Excluding these items, Chronbach's α for PRRS = .90 and CRRS α = .92
- In addition, we modified the wording of 2 items on the PRRS and 3 on the CRRS

Examples of items removed from the questionnaires

People with cancer	People who offer support
I know where to access financial support and advice should I need it	I take part in support groups and/or internet forums

Example of reworded items

Item as completed in PROACT study 3	Item as it will appear in PROACT study 4
I feel that support is available from the health system/ social services should I need it	I feel that support is available from the health system

Summary and Conclusions

- We developed two scales to measure broad life impacts of cancer for patients and informal caregivers
- Both scales demonstrated good internal consistency, test-retest reliability and the expected patterns of association with other measures
- Measures demonstrated high levels of acceptability; the rate of missing data was extremely low
- Measures will be further validated in a large study with a broader range of tumour sites and stages
- PROACT-IV will commence recruitment in December 2017 and will include
  - early stage (I-II) as well as advanced cancer
  - patients with head and neck, colorectal and renal cell cancers and the tumour groups represented in earlier studies
- Further validation is essential to test that the measures are sufficiently generic and appropriate for use in clinical trials and real world studies

References

1.Shilling, V. Matthews, L. Jenkins, V. Fallowfield, L.(2016) Patient-reported outcome measures for cancer caregivers: a systematic review. *Qual Life Res*, 25 (8): 1859-1876.
2. Catt, S. Starkings, R. Shilling, V. Fallowfield, L. (2017) Patient-reported outcome measures of the impact of cancer on patients' everyday lives: a systematic review. *Journal of Cancer Survivorship*, 11(2): 211-232

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