Sarcoma UK
The bone & soft tissue cancer charity

A sequential mixed methods study to develop a sarcoma-specific patient-reported outcome measure

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on behalf of the SAM Research Team

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University College London Hospitals NHS
NHS Foundation Trust

Introduction

- ☐ Patient reported experience is central to evaluating quality of care in the NHS
- ☐ Incorporating a PROM into clinical practice improves processes, outcomes and satisfaction with care
- ☐ Current evidence inconclusive about the psychosocial impact of sarcoma (Storey et al. 2019 Sarcoma)
- ☐ Is this because current PROMs do not reflect the experiences of patients with sarcoma?

Background

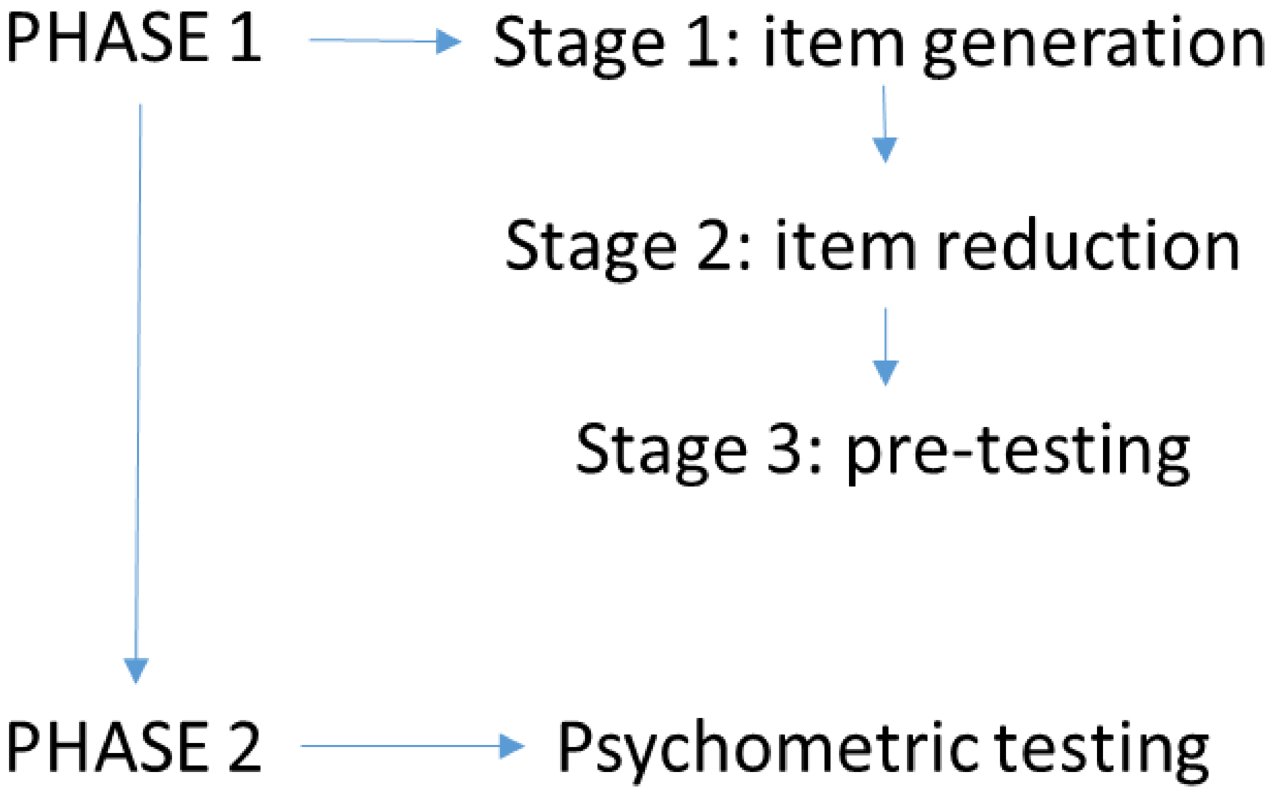
- Sarcoma: cancer of connective tissue
  - Occur in any location in the body
- Over 130 different subtypes
  - Soft tissue sarcoma, bone and gastrointestinal
- Develops from birth onwards
- Treatment can includes CTx, RTx, surgery, PBTx
- 5 year survival – 55%
- No sarcoma-specific QOL measures

Aims

- ☐ Develop and validate a measure reflecting patient experience to guide clinical practice and consultation

- ☐ Explore if/how the Sarcoma Assessment Measure (SAM) can be used as an outcome measure

Phases of development



PHASE 1 → Stage 1: item generation → Stage 2: item reduction → Stage 3: pre-testing

PHASE 1 → PHASE 2

PHASE 2 → Psychometric testing

Target population

	Cancer Type	Stage	Metastases	Recurrence	Surgery	Duration of Illness	Type of Treatment	Clinical Trial
Socio demographic variables: Age (<25; 25-40; 41-65; >65) Gender Race Income Level Education Level — — — — **Place of care** (specialist centre) **&** **Geography** (distance from follow up appointments)	**Bone**							
	Limb	1-4	Size	Yes/No	Amputation Limb preservation/ other None or RT	<2; 2-5; >5	Chemo for relapse Chemo for cure	Yes/No
	Pelvis/spine							
	Craniofacial							
	GIST							
	Surgery or adjuvant	1-4	Size	Yes/No	Yes/No	<2; 2-5; >5		Yes/No
	Advanced							
	Soft Tissue Sarcoma							
	Extremity	1-4	Size	Yes/No	Yes/No	<2; 2-5; >5	RT/ Chemo	Yes/No
	Retroperitoneal							
	Head and Neck							

Stage 1: item generation

- Aim: to understand experiences of living with and beyond a sarcoma diagnosis
- Methods: semi-structured interviews
- Participants
  - N = 121/175
  - 50% male
  - Aged 13 - 82 years
  - STS = 62%, BT = 28%, GIST = 10%

Conceptual basis of SAM

- "…subjective, multidimensional and dynamic. It is unique to each individual and includes aspects of physical, psychological and social function. It is dependent upon not only the stage of development but also the illness trajectory. This involves the achievement of goals and aspirations and the constraints imposed through ill health and treatment" (Taylor et al. 2005 JCN)
  - Physical wellbeing
  - Emotional wellbeing
  - Social wellbeing
  - Financial wellbeing
  - Sexuality

Stage 2: Item reduction

- Content analysis: 1,405 individual items reflecting experience *after* diagnosis
- Review by research team (researchers, clinicians, patient representatives)
  - Eliminate redundant items, group with similar meaning
- Item Reduction Questionnaire (n = 395 items)
  - Two scales: importance and frequency

Patient expert review

- ☐ Participants
  - n = 250
  - 51% Male
  - Aged 17 - 89 years
  - STS = 59%, BT = 36%, GIST <1%
- ☐ Calculated an impact score (importance + frequency)
- ☐ Top scoring impact items retained (≥5/≥6 for emotion)

Item reduction results

- n = 160 items
- Compared against existing PROMs
  - Removed 22 similar items
- Consensus review by research team
- n = 66 items to include in the Content Validity Questionnaire (CVQ)

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Stage 3: pre-testing (content validity)

- CVQ administered online to patients and healthcare professionals
- Patients = 33
  - 42% male
  - Aged 19 – 82 years
  - STS = 58%, BT = 39%, GIST = 3%
- Healthcare professionals = 24
  - Nurse (11), Oncologist (9), Surgeon (2), Therapist (2)

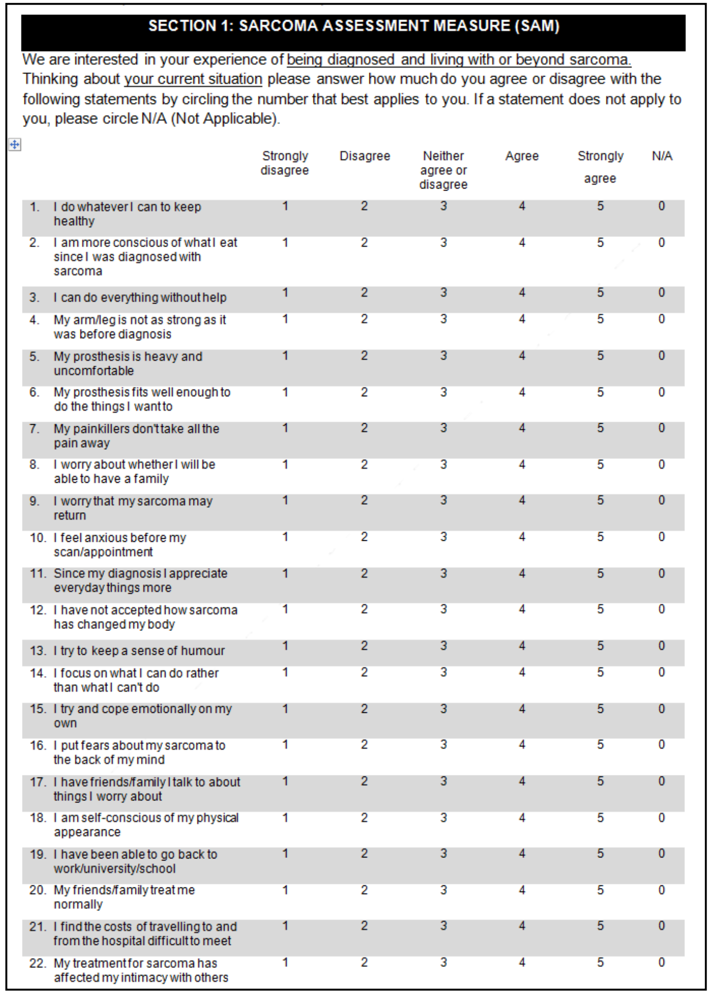
Content validity results

- ☐ Items with a CVR score <.31 were discarded
- ☐ 22 ITEMS identified
  - Physical wellbeing: 7 items
  - Emotional wellbeing: 10 items
  - Social wellbeing: 3 items
  - Financial wellbeing: 1 item
  - Sexuality: 1 item
    - The wording of final set of items was reviewed and changed to fit the proposed response variable (strongly agree – strongly disagree)

Pre-test: Establish comprehension

- Interviews with patients
  - Can patients understand the items?
  - Can patients answer the items?
  - Are questions too sensitive?
- Participants:
  - n = 10
  - 40% male
  - Aged 27 - 56 years
  - STS = 2, BT = 7, GIST = 1
- Minor changes were made to 4/22 items

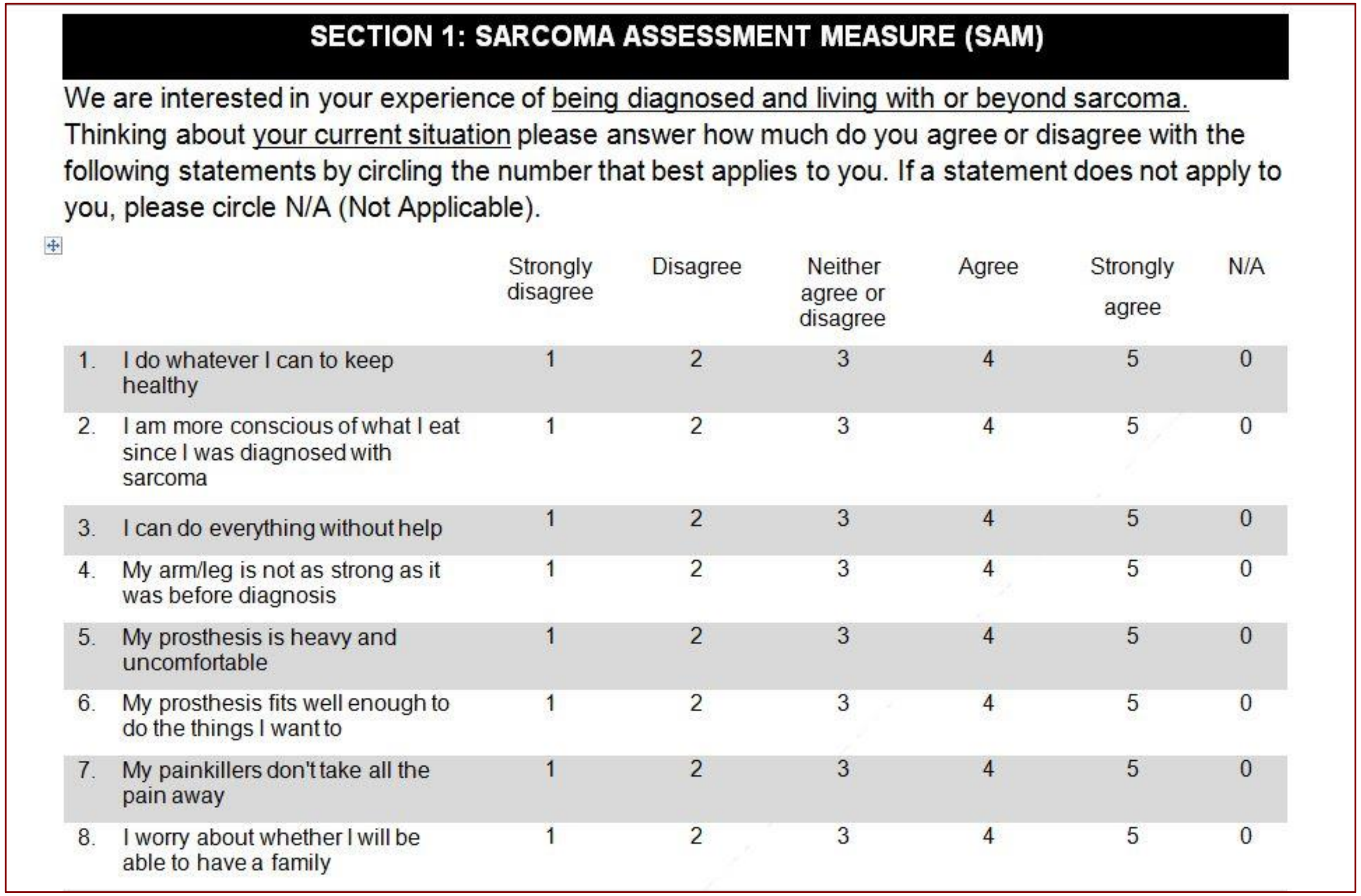
Sarcoma Assessment Measure (SAM)



SECTION 1: SARCOMA ASSESSMENT MEASURE (SAM)

We are interested in your experience of <u>being diagnosed and living with or beyond sarcoma.</u> Thinking about <u>your current situation</u> please answer how much do you agree or disagree with the following statements by circling the number that best applies to you. If a statement does not apply to you, please circle N/A (Not Applicable).

	Strongly disagree	Disagree	Neither agree or disagree	Agree	Strongly agree	N/A
1. I do whatever I can to keep healthy	1	2	3	4	5	0
2. I am more conscious of what I eat since I was diagnosed with sarcoma	1	2	3	4	5	0
3. I can do everything without help	1	2	3	4	5	0
4. My arm/leg is not as strong as it was before diagnosis	1	2	3	4	5	0
5. My prosthesis is heavy and uncomfortable	1	2	3	4	5	0
6. My prosthesis fits well enough to do the things I want to	1	2	3	4	5	0
7. My painkillers don't take all the pain away	1	2	3	4	5	0
8. I worry about whether I will be able to have a family	1	2	3	4	5	0
9. I worry that my sarcoma may return	1	2	3	4	5	0
10. I feel anxious before my scan/appointment	1	2	3	4	5	0
11. Since my diagnosis I appreciate everyday things more	1	2	3	4	5	0
12. I have not accepted how sarcoma has changed my body	1	2	3	4	5	0
13. I try to keep a sense of humour	1	2	3	4	5	0
14. I focus on what I can do rather than what I can't do	1	2	3	4	5	0
15. I try and cope emotionally on my own	1	2	3	4	5	0
16. I put fears about my sarcoma to the back of my mind	1	2	3	4	5	0
17. I have friends/family I talk to about things I worry about	1	2	3	4	5	0
18. I am self-conscious of my physical appearance	1	2	3	4	5	0
19. I have been able to go back to work/university/school	1	2	3	4	5	0
20. My friends/family treat me normally	1	2	3	4	5	0
21. I find the costs of travelling to and from the hospital difficult to meet	1	2	3	4	5	0
22. My treatment for sarcoma has affected my intimacy with others	1	2	3	4	5	0



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Phase 2: Testing SAM

- Reliability & validity
  - SAM, QLQ-C30, TESS, GRCQ
- Sample: 500 – 1,000 patients
  - Second SAM to 400 patients
- Recruitment: March – May 2019
  - 15 Trusts in the UK
  - CPES participants

SAM phase 2 participants

- N = 762
- Male/female = 349/407 (46%/54%)
- Ethnicity white: 714 (95%)
- Age: median 67 years (IQR 55,75)
- Time from diagnosis: 4 years (IQR 2,6)
- STS: 505 (66%); BT: 158 (21%); GIST: 78 (10%)
- Surgery alone: 274 (37%)
- On treatment: 169 (24%)

Is SAM valid?

What next?

- ☐ Is this a good measure of outcome?
  - Explore sub-populations
- ☐ Secondary data analysis
  - Route to diagnosis *(funded by Sarcoma UK)*
  - In-depth understanding of experience in sub-populations
- ☐ SAM-Paed *(funded by CCLG)*
  - Child self-report (8-16 years); parent report (0-16 years)
  - Rhabdomyosarcoma (FaR-RMS) study
- ☐ ICONIC (*funded by BCRT)*
  - Test ability to detect change longitudinally

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