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Development of a patient-centred, patient-reported outcome measure (PROM) for post-stroke cognitive rehabilitation: qualitative interviews with stroke survivors to inform design and content.

Abstract:

Background: Improving cognition is service users' top research priority for life after stroke and future research should include outcomes that they deem important. Patient perspectives on outcomes are collected using patient-reported outcome measures (PROMs). There is currently no patient-centred PROM specific for cognitive rehabilitation trials.

Objective: Inform PROM development by exploring stroke-survivor perspectives on the important, measurable impacts of persisting post-stroke cognitive problems.

Design: Qualitative semi-structured interviews in participants' homes using a framework analysis approach.

Participants: Purposive sample of 16 cognitively-impaired stroke-survivors at least six months post-stroke.

Methods: Interviews used a schedule and communication aids developed through patient consultation. Interviews were transcribed verbatim with non-verbal communication recorded using field notes. Data were analysed using a framework approach to find commonalities to shape the focus and content of an outcome measure.

Results: Participants identified important impacts of their "invisible" cognitive problems, outside of other stroke-related impairments. Cognitive problems exacerbated mood and emotional issues and vice versa. Changes in self-identity and social participation were prominent. Impact was not spoken about in terms of frequency but rather in terms of the negative affect associated with problems; terms like "bothered" and "frustration" were often used.

Conclusions: The results support the development of a PROM specifically designed to address the impact of cognitive problems. It should:

- include items addressing a comprehensive range of cognitive skills;
- ask questions about mood, self-identity and social participation;
- use accessible wording that respondents understand and endorse;
- measure impact rather than frequency.
- explore perceived impact on carers

Keywords:

Stroke; Cognition; Patient-centred; Patient-reported outcome measure (PROM); qualitative; psychometrics

Introduction

Persisting post-stroke cognitive problems are common and include issues with attention and concentration; memory; aphasia; unilateral spatial neglect; perception; dyspraxia; and executive dysfunction.[1] Cognitive problems exacerbate the long-term burden of stroke, adversely impacting confidence, self-esteem and long-term functional recovery.[2]

The National Clinical Guideline for Stroke[3] for England and Wales recommends treating cognitive problems comprehensively, but more research is required to inform best-practice interventions. Stroke survivors, caregivers, and health professionals collectively agree that improving cognition is the number one research priority for life after stroke.[4] Cochrane reviews of cognitive rehabilitation trials conclude that future research should use outcomes that are deemed important by service users.[5, 6]

Patient perspectives on outcome are often overlooked in stroke trials.[7] Trials need a 'baseline' for individual comparison of outcome and typically use a measure of impairment or function for these purposes. However, the most ecologically valid 'baseline' for assessing change would be pre-morbid performance.[8] These baseline data are rarely available and, by definition, cannot be obtained retrospectively. Given these difficulties obtaining meaningful baseline data, a potential alternative – that is arguably more relevant to service users - is to gain patient perspectives on perceived effect of an intervention. This often involves patient-reported outcome measures (PROMs).

Dawson[9] has discussed the importance of using appropriate, validated PROMs for a given specified purpose (in this case, evaluating a cognitive rehabilitation intervention) but goes on to advise that: "a patient's inability to understand a questionnaire, for reasons of impaired cognition or difficulty with the language in which it is available, should constitute an exclusion criterion." People with cognitive problems that influence understanding and expression are often routinely excluded from participation in the development and use of PROMs: so despite being patient-reported, PROMs are not necessarily appropriate, inclusive or patient-centred.[10]

The authors are not aware of a patient-centred PROM that would be suitable for use with cognitively-impaired stroke survivors to evaluate trials of post-stroke comprehensive cognitive rehabilitation. One of the most commonly used PROMs in this area is the Cognitive Failures Questionnaire.[11] The Cognitive Failures Questionnaire uses complicated language, is heavily loaded towards memory issues and, as service users were not involved in its development, it is not a 'patient-centered' measure.

A recent systematic review of stroke literature identified only three patient-centred outcome measures for stroke:[12].The first is the Subjective Index of Physical and Social Outcomes (SIPSO)[13], which measures social integration after stroke. It focuses on the impact of physical functioning and social/emotional functioning for integration, so is not appropriate for cognition. The Stroke Impact Scale (SIS)[14] is a stroke-specific self-report health status measure. However, like other stroke-specific tools (eg Stroke-Specific Quality of Life scale[15]), the SIS includes items related to cognition but does not ask about the impact of cognitive function on social participation and quality of life. The third measure is the Communication Outcome After Stroke (COAST) Scale.[16] This tool explores communication effectiveness for those with aphasia (or dysarthria) following stroke as well as the impact of these problems on life and integration. The COAST does not explore other cognitive impairments so, whilst it is useful for aphasia, it would not necessarily be suitable for trials of comprehensive cognitive rehabilitation.

Another critique of existing PROMs is that they may be too long and tiring for patients with stroke who can fatigue easily (fatigue in itself is likely to contribute to reduced scores), e.g. the European Brain Injury Questionnaire[17] and the Stroke Impact Scale,[14] with 63 and 60 items respectively.

The authors believe that there is a need for the development of a patient-centered PROM that specifically addresses the impact of a broad range of cognitive problems after stroke and is developed in collaboration with cognitively-impaired stroke survivors.

Aim

The aim was to inform the development of a comprehensive patient-centred PROM for cognition by exploring stroke-survivor perspectives on the important, measurable impacts of persisting post-stroke cognitive problems.

Methods

Ethics approval was granted by the National Research Ethics Service (reference 12/NW/0663).

Patient and Public Involvement (PPI)

To enhance patient-centeredness, prior to data collection service users were consulted as research partners to devise methods and materials used in the research. These service users were all stroke survivors or carers who had experience of cognitive problems and were approached via stroke community groups or were previously known to the researchers.

Through PPI, we agreed that semi-structured interviews (with open questions and closed prompts) would be the preferred methodology for cognitively-impaired interviewees, who may need support processing and communicating information. The decision to interview stroke survivors independently of their carers was agreed through PPI as service users felt that a more open and honest dialogue would be achieved one-to-one.

The interview schedule was refined through pilot testing with cognitively-impaired service users as part of the PPI process. This had the added benefit of providing training for researchers. Communication aids were developed through PPI to support understanding and expression. Lay pictorial representations of cognition were used to orient users to the discussion topics and cue cards used as ramps for communication, if required. Examples of the supporting aids are shown in Appendix 1.

Recruitment

Research participants were recruited between September 2012 and January 2013. The research team visited community stroke groups to inform attendees about the research and invite them to participate, if eligible. Additionally, community healthcare professionals treating stroke survivors in the North West of England gave basic information about the study to their eligible service users and invited them to self-refer to the research team for more information.

Participants were included if they were at least 6 months post-stroke with ongoing cognitive impairment. Cognitive impairment was determined predominantly by self-report; eligible and interested stroke survivors were asked about their problems informally to determine eligibility. Once recruited, the interview explored participant’s self-reported cognitive problems in more detail.

A cognitive screen was also carried out to gain *indicative* quantitative data on the nature of impairment. Cognitive screening employed the Montreal Cognitive Assessment.[18] This was supplemented by the Apraxia Screen of TULIA[19] and Star Cancellation Test[20] to better detect apraxia and neglect.

Stroke survivors were excluded if they were not pre-morbidly fluent in the English language and/or could not provide informed consent. This was due to the practical requirement to gain narratives from participants (without translation). Hospital in-patients or those living in fully supported care homes were also excluded as their experience of impact may be limited. Those who had been involved in PPI work were excluded from participation in interviews.

A purposive sampling strategy[21] - with a sample size determined by data saturation[22] - aimed to recruit participants across the following characteristics:

- Age – adults both below and above 65 years (retirement age)
- Gender – men and women
- Severity of cognitive problems – self-reported cognitive issues, observable issues and screening data described above gave an *indicator* of severity of impairment to drive purposive sampling. We sought to include survivors who achieved a range of scores on these screening instruments, including high scores or ‘passes’. We recognised the limitations of screening tools for highlighting the complex and multi-faceted nature of chronic cognitive impairment.

Procedure

The qualitative methodology explored participant's meanings and views in a structured way to inform both the conceptual underpinning of any developed PROM as well as its specific content.[23] The use of semi-structured interviews was agreed through PPI and allowed for in-depth exploration of topics that arose[22] to ensure that the derived measure captured information most relevant to patients in accessible terms.[24]

EP conducted all stroke survivor interviews one-to-one in participant's homes and independently of carers. Where carers were available and willing, they were also interviewed independently by KWN as part of a wider research programme. Carers were asked about the impact on themselves of stroke survivors cognitive impairments, amongst other things. The results of carer interviews will be reported in a separate paper.

EP had several years of research experience with communication-impaired stroke survivors; including the use of communication aids and carrying out assessments. There was no prior relationship between EP and the participants included in this research.

To facilitate interviews with cognitively-impaired participants, the researchers followed guidelines[25, 26] and utilised prior experience of members of the research team; building on previously-developed resources.[27] Interviews typically lasted between 1-2 hours with breaks factored in to overcome fatigue. Examples of the communication aids developed through PPI were used as required to support understanding and expression (see Appendix 1). Participants were asked open questions initially such as "How do your cognitive problems affect you?" with more closed prompts available (such as how they affect "what you do?" "How you live?" "How you feel?" etc.). Cognitively-impaired participants may find it difficult to talk in the abstract so these prompts were used to encourage dialogue.

Data Analysis

The goal of analysis was to find commonalities across the interviews to shape focus and content of an outcome measure for future use with a large and heterogeneous sample in a trial.

Interviews were audio-recorded and transcribed verbatim with non-verbal communication recorded using field notes. For example, if interviewees with communication disorders used communication aids to express themselves, this was noted against the recording time to support full capture of survivor story for interpretation and analysis.

A thematic analysis was conducted, using a framework approach.[22] EP repeatedly listened to recordings, alongside transcripts and field notes to achieve immersion in the data and remove any biases or ‘knee-jerk’ ideas about analysis. EP in collaboration with other members of the research team (KWN, who conducted similar interviews with informal carers of the stroke survivors included here and MH, an expert in qualitative research) then devised a first draft of codes that could be used to describe portions of the data and develop thematic codes that summarised commonalities and differences in the data across participants.

Data immersion began after the first interview was conducted with regular meetings between the research team to reach a consensus on interpretation of the data and to discuss and refine codes. NVivo software was used to attach codes to portions of the data in a way that could be instantly shared between the group to support consensus decision-making. This process also allowed the team to agree when data saturation had been achieved.

Development of thematic charts involved the gradual combination and reduction of codes into overarching themes designed to meet the aims of the research. These were presented visually for the purposes of discussion with the broader research team; to interpret the data and inform recommendations for the necessary qualities of a patient-centered outcome measure for cognitive rehabilitation. An example of the development of one theme is shown in Box 1 in the results section.

Results

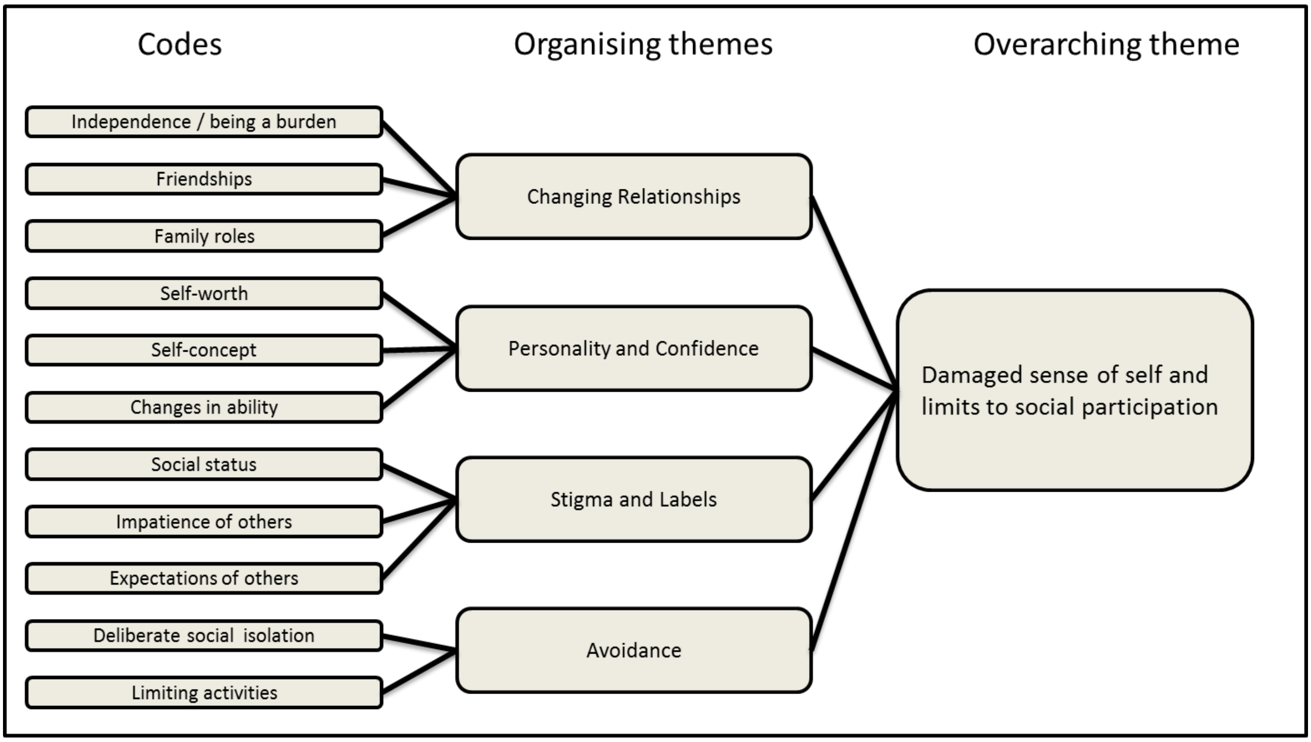
Participant characteristics (demographics and cognitive assessment data) are presented initially with a comment provided on the screening tools used for this study.

Seven themes were developed using the thematic framework approach described (see Box 1 for an example of how one theme was developed)._They are described below according to headings:

1. Hidden Problems
2. Focus on cognitive skills, not activities
3. Damaged sense of self and limits to social participation
4. Mood, emotions and fatigue
5. Impairment does not equal impact
6. Awareness of cognitive difficulties takes time
7. Perceived level of impact on carers

Information is given to describe each of the identified themes with illustrative quotes. Fieldnotes for non-verbal communication and information for quotes are inserted in square brackets.

BOX 1: example of the development of the theme 'Damaged sense of self and limits to social participation'



Participants

There were 45 eligible stroke survivors who self-referred to the research team after being invited to take part. Purposive sampling to the point of data saturation led to a total of 16 stroke survivors being interviewed

Mean age was 58 years (range: 42 to 74) which is relatively young for a stroke population.[28] Time post-stroke ranged from six months to 15 years (mean = 4.5 years). Almost all participants (N=15, 94%) lived with partners and the sample was almost exclusively White British (N=15, 94%). Summary information for each participant is given in table 1.

Participants with a broad range of cognitive impairment were included. Scores on the Montreal Cognitive Assessment ranged from eight to 29 (mean = 22). Despite all participants reporting cognitive deficits that were also observable, four out of 16 (25%) performed at a level sufficient to pass screening tests. Many were clearly employing strategies to do so; for example, mnemonic strategies or deliberate scanning in star cancellation. Others may have passed screens but had obvious impairment that interfered with their cognitively demanding lives.

The use of screening tools that employ cut-offs for ‘normal’ ranges was often seen as redundant and even offensive, as they do not take into account pre-morbid ability. After testing, one participant commented:

> *“I can’t see how you can really measure that [normal ranges]. I mean, [my] friend, he says it himself, he’s not very intelligent and he’s not very eloquent and he said that I’m now even better than he is. So, I think, when people say, the normal range, on my speech is very good, and that sort of thing, to me, it’s not very good” (P08)*

Table 1: Summary of participants

ID	Age	Years post-stroke	Sex	12 years education	Employment	MoCA*	AST**	Star***
P01	45	12.0	M	Yes	Full time	29	12	54
P02	72	7.2	F	No	Retired	13	8	43
P03	56	10.6	F	Yes	Retired±	29	11	52
P04	48	6.9	M	No	Retired±	22	10	52
P05	46	1.2	M	Yes	Retired±	23	12	54
P06	59	3.0	M	Yes	Retired	18	12	52
P07	72	15.2	F	Yes	Retired	24	12	54
P08	63	3.4	F	Yes	Retired	27	11	52
P09	55	0.6	M	No	Sick leave	25	12	53
P10	74	0.7	M	No	Retired	8	7	25
P11	55	1.2	F	Yes	Retired±	25	9	50
P12	54	1.9	M	No	Retired±	18	9	37
P13	59	1.1	M	No	Retired±	22	12	54
P14	72	1.0	F	No	Retired	16	11	54
P15	42	4.2	M	Yes	Part time	28	12	54
P16	57	1.8	M	No	Retired±	24	12	53
Mean	58.1	4.5				21.9	10.8	49.6
SD	10.3	4.6				5.9	1.7	8.0

±Retired early; employed at time of stroke

*MoCA = Montreal Cognitive Assessment (total possible score 30). A score of ≥26 is considered 'normal'

**AST = Apraxia Screen of TULIA. (total possible score of 12) A score of <9 is indicative of apraxia

*** Star cancellation test (total possible score 54). A score of <44 is indicative of neglect

Thematic Analysis

1. *Hidden problems*

One of the most striking themes was around the hidden nature of cognitive problems. When compared with physical problems, *"invisible"* cognitive problems were felt to be poorly understood by others, including immediate family:

> *"All I'd want more than anything ever is for them* [family] *to understand that I'm not stupid, I've just got problems." (P12)*

This would often lead to attempted masking of the problems and withdrawal from social situations: *"I just want to cut everybody out."(P14)*

2. Focus on cognitive skills, not activities

Participants talked about activity limitations due to cognitive difficulties. Activities of perceived importance were varied but what was common across participants was the articulation that different activities relied on the same impaired cognitive skill:

> *"I can concentrate but I'm much more easily distracted, than I was before… I was an avid reader before – and I cannot now effectively read a novel…I couldn't even watch a television programme"* (P11)

Clinically, this does not tell us anything new; but since stroke survivors themselves articulate limitations in this way, it may be valid to ask directly about impactive cognitive limitations (eg difficulties with concentration), rather than limitations in particular activities that vary widely between individuals.

3. Damaged sense of self and limits to social participation

Self-identity could be intrinsically tied to participant's cognitive abilities; being seen and praised as a *"problem-solver"* (P04), *"organised"*(P15), *"capable"* (P13), or *"intelligent"*(P08). Cognitive abilities could have a special significance in this regard and damage could lead to fundamental changes in participant's sense-of-self:

> *"I'd gone from being somebody who was the one who was always there speaking, to be someone who never said anything sat in a corner and so, of course, that's got effects on your personality." (P01)*

Participants also described negative changes in social relationships: *"ordinary people don't want to know us"* (P07). This included relationships with immediate family; losing *"dad confidence"* (P01) or now feeling like a *"burden"* (P02). Difficulties in social contacts with work and friendships were also common across participants.

4. Mood, emotions and fatigue

Cognitive and affective difficulties commonly co-occurred; many participants had low mood or were on medication for depression. Frustration, anxiety and embarrassment were also common emotions associated with cognitive limitations. Cognitive difficulties and negative emotion would often exacerbate one another.

> *"I don't feel confident passing on information... It* [getting it wrong] *starts making you lack confidence, you see and then you get* [more] *things wrong." (P03).*

Fatigue was also commonly reported. Fatigue could occur even after very little exertion, but there was a sense that the increased cognitive effort to perform everyday activities would intensify fatigue:

> *"But it's not normal in the sense of you having it* [points to EP]*…. You are tired because… You've overworked…. I try and…in my head, go asleep.* [EP: "So it's that mental effort that can make you quite tired?"]*… It must be, it must be that, because I'm not physically, you know…*[hand gestures to body and shrugs indicating he is not doing anything physically] *It must be my mind."* (P13)

5. *Impairment does not equal impact*

The perceived impact of cognitive impairment is mediated by context-specific variables, such as support networks, environmental aids and personality. This was well-captured by the following participant:

> *"How much your brain is damaged is unimportant in terms of how you live your life. So for instance I can say to you, yeah I know I've got brain damage, I know that I don't perform in certain tasks as well as I did but the outcome for me at present is not that bad because [partner] finished work to look after me so I'm really lucky."* (P11)

This lack of a simple linear relationship between impairment and impact echoes the earlier comment on the cognitive assessment scores; even participants with measurably 'normal' cognition can experience significant impacts on their daily life. Impact was typically discussed in terms of how much negative emotion it caused; how much "bother", "upset" or "frustration" it led to. Cognitive problems were sometimes considered more 'bothersome' by the very fact that they were difficult to see or measure objectively:

> *"I've accepted all my problems with my limbs, and this [points to brain] bothers me more, because people look at you and they expect you to be [alright] and really, you're not." (P15)*

6. *Awareness of cognitive difficulties takes time*

The impact of cognitive problems appeared to manifest later in the stroke recovery phase:

> *"It's not just straight away, because it took me three, four years to start thinking* [properly] *again….at first, your mind is [on], will I be able to sleep tonight."* (P02)

Cognitive problems became more apparent when participants were attempting to return to pre-stroke life including more cognitively demanding activities. The presence of pronounced physical issues may have acted as a barrier to recognising the impact of cognitive problems early on. The cognitive confusion that could be caused by cooking (e.g. ordering actions, following recipes and timing) would not become apparent if participants did not have strength or dexterity to attempt cooking.

7. *Perceived impact on carers*

Participants often felt that their cognitive problems impacted on informal carers who had to fill cognitive gaps or rectify dangerous oversights:

> *"I'll cook and I'll leave the gas on… Stupid things. The other day I made a pork chop and set fire to it. Luckily [partner] was in. I put it on but completely forgot about it." (P16)*

The impact on carers could be even more pronounced by a stroke survivor's lack of awareness or memory:

> *"She [partner] can come in here and have a row with me or whatever, because all I have to do is make a bed in the morning… So I forget about it or I have an afternoon sleep and just forget*

> *about it, and then after ten minutes of rowing I don't even know I've had a row. But she's the one dealing with all that. It's not fair for her." (P12)*

Stroke survivors were often highly concerned about being a burden due to the effect of their issues on their and loved ones; impact of problems could theoretically be reduced if perceived carer impact was reduced.

Discussion

Qualitative interviews with cognitively-impaired stroke survivors were a challenge but were possible with training, reference to guidance[25, 26] and by using the schedule and communication aids that were developed through PPI with this population in mind. Interviewees discussed the specific – and measureable - impacts of persisting cognitive problems that should be included in a PROM evaluating cognitive rehabilitation.

Participants spoke about the specific negative impact of these "invisible" cognitive problems, outside of other stroke-related impairments such as hemiplegia. Emotional issues and fatigue were commonly reported as a result of cognitive problems and appeared to mutually exacerbate one another. This co-existence of issues with mood and cognition is often observed in the literature.[29, 30] Therefore an outcome that asks about the specific impact of cognitive problems - particularly on emotion - would be worthwhile for evaluating cognitive rehabilitation trials. Generic or stroke-specific PROMs may not be sensitive enough to measure changes in the impact of cognitive problems in these areas.

Rehabilitation interventions often aim to reduce activity limitations and thus outcome measures typically include information on specific activities.[31] However, the common impacts discussed in this study tended to go beyond activity-specific dialogue. PROM items might therefore be related to cognitive skills (e.g. concentration or remembering) rather than an activity thought to be of importance (e.g. television watching or reading). Items would also usefully explore sense of self and social participation, which were highly impacted by the hidden nature of cognitive problems.

The complexities associated with assessment of cognition[8] reflect the difficulty highlighted in this study and documented in the literature that there is a lack of correlation between levels of cognitive impairment and self-reported impact.[32] The differential impact of cognitive problems (mediated by context-specific variables) means that comprehensive cognitive rehabilitation could theoretically address multiple context-specific variables (for example: support networks; thought processes; compensatory strategies) and reduce perceived impact without actually reducing the underlying problem itself. Theoretically, a problem could occur rarely but high negative impact and vice versa so we argue that it is insufficient to measure outcomes at the level of ‘frequency’ or ‘amount’ of a problem that is assumed to be of importance. Participants typically discussed impact in terms of negative emotion, such as "bother", "upset" and "frustration". “Bother” was the most frequently used emotionally-laden word in interviews and thus could usefully be what is ‘measured’ in a PROM to assess impact. For example: “how much does this problem bother you?” rather than “how often do you experience this problem?”

Participants suggested that the perceived impact of cognitive impairment manifested later in recovery post-stroke. This endorses Pollock et al's[4] priority-setting exercise highlighting the need for research to improve chronic cognitive difficulties. It also supports the use of a PROM that has been specifically developed with chronically-impaired service users to ensure it reflects that priorities and values of such individuals. Interventions for chronic conditions may require different outcomes than acute interventions, as they should aim to improve social, psychological and emotional health; issues that users are best placed to comment on.[34]

Participants also acknowledged the impact that their cognitive problems had on informal carers and the National Clinical Guideline for Stroke[3] for England and Wales recognises the important role that carers play in supporting chronic conditions. In fact, participants in this study were very concerned by carer impact; such that reduction of perceived carer impact could theoretically reduce impact for stroke survivors themselves. As such, a PROM would usefully include items that explore perceived carer impact.

Strengths and limitations of the study

Cognitively-impaired participants are often excluded from qualitative research, given their potential difficulties processing, understanding and/or expressing their experiences. However, it is important to gather views of relevant populations when developing tools for those populations. Interviewing these participants - some of whom might otherwise have been excluded - was achievable by referring to existing guides [25, 26], utilising PPI for developing materials and training researchers, and the use of supportive communication techniques with aids.

Data were collected until the research team were satisfied that data saturation had been reached. Participants had a variety of time post-stroke, education levels, current employment status and cognitive impairment. However, despite age being a driver for purposive sampling, participants in this study were relatively young. A broad age range of people was invited to participate. However, it is possible that younger stroke survivors are more bothered by their cognitive impairments - for example, if they are leading cognitively demanding lives that include work - and thus, they may have been more driven to participate in this study. This may not be a limitation as these are the very individuals who seek cognition rehabilitation.

Participants were also almost exclusively of 'White British' ethnic origin and those who were not fluent in English pre-morbidly were not included. This has implications for generalisability. Future work could include ethnicity as a target variable for purposive sampling to achieve more variability and include non-English speakers with translators or appropriate interviewers.

Carers were interviewed separately (where available) by KWN as part of a wider study. It is possible that interviewing stroke survivors and carers as dyadic pairs could have given us different results. However, the goal here was to explore stroke survivors' views for the purposes of designing a PROM specifically for stroke survivors and PPI endorsed the use of individual one-to-one interviews. The results of carer interviews will be reported in a separate paper but preliminary analysis suggests that carer views broadly corroborate patient views on impact.

For reporting of this study, we have followed consolidated criteria for reporting qualitative research (COREQ)[35]

Summary: implications for outcome measure design

These findings inform desirable qualities of a patient-centered PROM for cognitive rehabilitation trials. It should:

- Include items relating to perceived impact of a comprehensive range of cognitive skills rather than limitations in activities thought to be of importance.
- Measure impact rather than impairment: this might involve a shift away from reporting frequency of a problem and towards looking at aspects of 'botheredness' or 'frustration'.
- Address the specific impact of a broad range of cognitive problems on mood, self-identity and social participation.
- Include items that explore perceived impact on carers.
- Be accessible: including wording and items that respondents endorse and understand.

Preliminary reviews suggested that no PROM exists that meets all of the above criteria. A subsequent systematic review of existing PROMs (paper in preparation) supported this and a new PROM for cognition has been developed and is undergoing psychometric evaluation (NIHR portfolio entry: http://public.ukcrn.org.uk/Search/StudyDetail.aspx?StudyID=15113). This new tool meets the above criteria and satisfies the criteria highlighted by Lawrence and Kinn[12] for patient-centred outcome measures in that it has been informed primarily by service users and it measures outcomes that have been identified and prioritised as valued (for example, it asks specific questions about social participation and emotion as impacted by cognition). The findings of this study endorse the use of a patient-reported (as well as patient-centred) outcome measure that asks directly about perceived impact of these ‘hidden’ problems in terms of amount of associated “bother” rather than “frequency,” as this appears to be how service users articulate impact of problems.

In addition, we set out to develop a PROM for evaluation of trials to rehabilitate cognitive difficulties after stroke; we have begun to address the criteria related to using tools at “appropriate times and points” and for specific goals [12]. It is important to clearly articulate the purpose of any new measure and the context in which it has been developed. Once psychometric testing has been completed, data will be available on whether the PROM appears to be useful in terms of reliability, validity and responsiveness. If appropriate, it will then be freely disseminated with investigators’ brochure to encourage further validation; it is possible that the PROM could be useful for everyday clinical use, as well as trial evaluation.

References

1. Cumming TB, Marshall RS, Lazar RM. Stroke, cognitive deficits, and rehabilitation: still an incomplete picture. Int J Stroke. 2013 Jan;8(1):38-45.
2. Barker-Collo S, Feigin VL, Parag V, Lawes CM, Senior H. Auckland Stroke Outcomes Study. Part 2: Cognition and functional outcomes 5 years poststroke. Neurology. 2010 Nov 2;75(18):1608-16.
3. Intercollegiate Stroke Working Party. National clinical guideline for stroke. 4th ed. London: Royal College of Physicians; 2012.
4. Pollock A, St George B, Fenton M, Firkins L. Top ten research priorities relating to life after stroke. Lancet Neurol. 2012 Mar;11(3):209.
5. Bowen A, Knapp P, Gillespie D, Nicolson DJ, Vail A. Non-pharmacological interventions for perceptual disorders following stroke and other adult-acquired, non-progressive brain injury. Cochrane Database Syst Rev. 2011(Issue 4):Art. No.: CD007039. DOI: 10.1002/14651858.CD007039.pub2.
6. Bowen A, Lincoln NB. Cognitive rehabilitation for spatial neglect following stroke. Cochrane Database Syst Rev. 2007(2):CD003586.
7. Quinn TJ, Dawson J, Walters MR, Lees KR. Functional outcome measures in contemporary stroke trials. Int J Stroke. 2009 Jun;4(3):200-5.
8. Lezak MD. Neuropsychological assessment. 5th ed. Oxford: Oxford University Press; 2012.
9. Dawson J, Doll H, Fitzpatrick R, Jenkinson C, Carr AJ. The routine use of patient reported outcome measures in healthcare settings. BMJ. 2010;340:c186.
10. Kroll T, Wyke S, Jahagirdar D, Ritchie K. If patient-reported outcome measures are considered key health-care quality indicators, who is excluded from participation? Health Expectations. 2012 Apr 19.
11. Broadbent DE, Cooper PF, FitzGerald P, Parkes KR. The Cognitive Failures Questionnaire (CFQ) and its correlates. Br J Clin Psychol. 1982 Feb;21(1):1-16.

12. Lawrence M, Kinn S. Defining and measuring patient-centred care: an example from a mixed-methods systematic review of the stroke literature. Health Expectations. 2012 Sep;15(3):295-326.

13. Trigg R, Wood VA. The Subjective Index of Physical and Social Outcome (SIPSO): a new measure for use with stroke patients. Clin Rehabil. 2000 Jun;14(3):288-99.

14. Duncan PW, Wallace D, Lai SM, Johnson D, Embretson S, Laster LJ. The stroke impact scale version 2.0. Evaluation of reliability, validity, and sensitivity to change. Stroke. 1999 Oct;30(10):2131-40.

15. Williams LS, Weinberger M, Harris LE, Clark DO, Biller J. Development of a stroke-specific quality of life scale. Stroke. 1999 Jul;30(7):1362-9.

16. Long A, Hesketh A, Paszek G, Booth M, Bowen A. Development of a reliable self-report outcome measure for pragmatic trials of communication therapy following stroke: the Communication Outcome after Stroke (COAST) scale. Clin Rehabil. 2008 Dec;22(12):1083-94.

17. Teasdale TW, Christensen AL, Willmes K, Deloche G, Braga L, Stachowiak F, et al. Subjective experience in brain-injured patients and their close relatives: a European Brain Injury Questionnaire study. Brain Inj. 1997 Aug;11(8):543-63.

18. Nasreddine ZS, Phillips NA, Bedirian V, Charbonneau S, Whitehead V, Collin I, et al. The Montreal Cognitive Assessment, MoCA: a brief screening tool for mild cognitive impairment. J Am Geriatr Soc. 2005 Apr;53(4):695-9.

19. Vanbellingen T, Kersten B, Van de Winckel A, Bellion M, Baronti F, Müri R, et al. A new bedside test of gestures in stroke: the apraxia screen of TULIA (AST). J Neurol Neurosurg Psychiatry. 2011;82(4):389-92.

20. Wilson B, Cockburn J, Halligan P. Development of a behavioural test of visuo-spatial neglect Arch Phys Med Rehabil. 1987;68:98-102.

21. Patton MQ. Qualitative research and evaluation methods. 3rd ed. London: SAGE; 2002.

22. Ritchie J, Lewis J, editors. Qualitative research practice : a guide for social science students and researchers. London: Sage Publications; 2003.

23. Streiner DL, Norman GR. Health measurement scales : a practical guide to their development and use. 4th ed. Oxford: Oxford University Press; 2008.

24. Williams LA, Agarwal S, Bodurka DC, Saleeba AK, Sun CC, Cleeland CS. Capturing the patient's experience: using qualitative methods to develop a measure of patient-reported symptom burden: an example from ovarian cancer. Journal of pain and symptom management. 2013 Dec;46(6):837-45.

25. Swinburn K, Parr S, Pound C. Including people with communication disability in stroke research and consultation: a guide for researchers and service providers. London: Connect; 2007.

26. Dalemans R, Wade DT, van den Heuvel WJ, de Witte LP. Facilitating the participation of people with aphasia in research: a description of strategies. Clin Rehabil. 2009 Oct;23(10):948-59.

27. Young A, Gomersall T, Bowen A, ACT NoW Investigators. Trial participants' experiences of early enhanced speech and language therapy after stroke compared with employed visitor support: a qualitative study nested within a randomized controlled trial. Clin Rehabil. 2013 Feb;27(2):174-82.

28. Lee S, Shafe AC, Cowie MR. UK stroke incidence, mortality and cardiovascular risk management 1999-2008: time-trend analysis from the General Practice Research Database. BMJ open. 2011 Jan 1;1(2):e000269.

29. Barker-Collo S. Depression and anxiety 3 months post stroke: prevalence and correlates. Arch Clin Neuropsychol. 2007 May;22(4):519-31.

30. Kauhanen ML, Korpelainen JT, Hiltunen P, Maatta R, Mononen H, Brusin E, et al. Aphasia, depression, and non-verbal cognitive impairment in ischaemic stroke. Cerebrovasc Dis. 2000 Nov-Dec;10(6):455-61.

31. Wade DT. Outcome measures for clinical rehabilitation trials: impairment, function, quality of life, or value? Am J Phys Med Rehabil. 2003 Oct;82(10 Suppl):S26-31.

32. Horner MD, Harvey RT, Denier CA. Self-report and objective measures of cognitive deficit in patients entering substance abuse treatment. Psychiatry research. 1999 May 31;86(2):155-61.

33. McKevitt C, Fudge N, Redfern J, Sheldenkar A, Crichton S, Rudd AR, et al. Self-reported long-term needs after stroke. Stroke. 2011 May;42(5):1398-403.

34. Bowling A. Measuring health : a review of quality of life measurement scales. 3rd ed. Maidenhead: Open University Press; 2005.

35. Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. International journal for quality in health care : journal of the International Society for Quality in Health Care / ISQua. 2007 Dec;19(6):349-57.

Supplementary materials

Please contact the corresponding author to request any supplementary materials including more of the communication aids used during interviews (examples shown in appendix 1). Corresponding author would also be happy to discuss the processes involved and challenges overcome during the service-user consultation that informed the methods and materials used in the above study. We also encourage readers to peruse the references section for guides on including cognitively-impaired stroke survivors in consultation work.

Appendix 1 – examples of communication aids used in the interviews

Type of problems

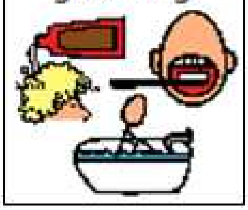
Ordering actions

Memory

PLEASE NOTE: In addition to the two aids above, we also had cue cards with images for: concentration; communication; perception – making sense of what you see and hear; problem solving; noticing things on both sides. We are unable to show them here due to copyright issues.

Impact of these problems

What you do → Activities. For example:


grooming


get around


manage money


Hobbies

How you live → Your life roles. For example:


family life

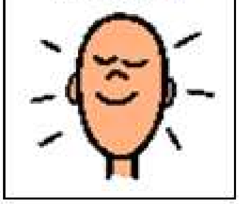

work life

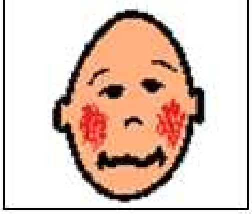

friends and social life

How you feel → About yourself? How others view you? Life? For example:

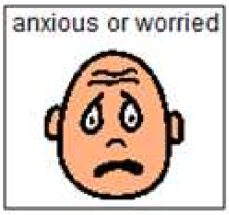

frustrated

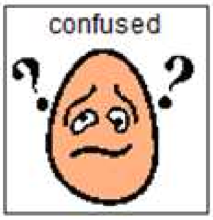

Dependent

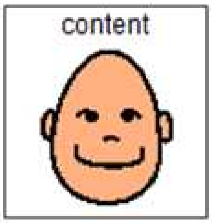

confident

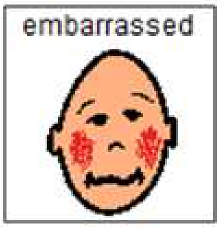

embarrassed

More of how you feel









Example of communication aids used for social roles and life participation:

More of how you live