A core outcome set for aphasia treatment research: the ROMA consensus statement

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Supplementary Table 1

ROMA consensus meeting facilitators

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ROMA consensus panel

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assessment and rehabilitation, development and evaluation of novel aphasia treatments, single subject and RCT design, systematic reviews.	*assessment and rehabilitation, aphasia trial design and conduct, neuroimaging in aphasia.*	*Expertise: Post-stroke aphasia rehabilitation, therapeutic process and evaluation, quality of life evaluation in research and clinical practice, behaviour change.*	*management, Clinical Evaluation of Interventions, RCTs, Psychometric Properties of Outcome Measures.*
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Janet Patterson PhD CCC-SLP ASHA Fellow Chief, Audiology & Speech-Language Pathology Service, VA Northern California Health Care System Practicing Speech-Language Pathologist, Teaching and Research Academic. *Expertise: Post-stroke aphasia rehabilitation, systematic reviews of*	**Gill Pearl MPhil Dip Hum Commun.** Certified practicing speech and language therapist in role as Chief Executive Officer of Speakeasy - specialist aphasia centre, UK. *Expertise: Development and evaluation of novel approaches to providing long term aphasia support and therapy, facilitator of consumer involvement in research, feasibility studies, case series*	**Elizabeth Rochon PhD MSc (A) Reg CASLPO SLP(c)** Speech Pathologist, Teaching and Research Academic, Department of Speech-Language Pathology and Rehabilitation Sciences Institute, University of Toronto, Canada. *Expertise: Post-stroke aphasia assessment and rehabilitation, development of aphasia treatment*	**Miranda Rose PhD BSpPath FSPA** Speech pathologist, Teaching and Research Academic, School of Allied Health, La Trobe University, Victoria, Australia. *Expertise: Post-stroke aphasia rehabilitation, aphasia trial design and conduct, single subject designs, consumer perspective, aphasia rehabilitation guideline development.*

literature, single subject designs.	*studies, RCT design and conduct.*	*studies, feasibility studies, single subject and RCT design, systematic reviews.*	
Karen Sage PhD Dip DisHumComm BA (Hons) HCPC Registered Speech and Language Therapist, MRCSLT; Teaching and Research Academic, Department of Allied Health Professions, Sheffield Hallam University, Sheffield, UK. *Expertise: Aphasia assessment and management, stroke rehabilitation, single case, case series, mixed methods.*	**Steven L. Small PhD MD** Professor of Neurology, University of California, Irvine *Expertise: Neurobiology of Language, Cognitive Neurology.*	**Janet Webster PhD MRCSLT** Registered Speech and Language Therapist, Teaching and Research Academic, Newcastle University, UK *Expertise: Post-stroke aphasia assessment and management, single subject design.*	

Supplementary Table 2

OMIs (n=50) identified in scoping review and retained following application of the consensus-based criteria

Construct	Outcome measurement instrument
Language	• The Comprehensive Aphasia Test (CAT) (1) • The Western Aphasia Battery Revised (WAB-R) (AQ+LQ) (2) • Therapy Outcome Measures (TOM) (3-5) • The Aphasia Checklist (ACL) (6) • Aachen Aphasia Test (AAT) (7) • Aphasia Language Assessment Test (ALA) (8) • The Thai Aphasia Language Performance Scales (ALPS) (9) • Bilingual Aphasia Test (BAT) (10) • The Boston Diagnostic Aphasia Examination (BDAE) (11) • Ege Aphasia Test (12) • Kentucky Aphasia Test (KAT) (13) • Montreal-Toulouse Language Assessment Battery (MTL) (14) • The Norsk Grunntest for Afasi (NGTA) (15)
Emotional well-being	• Communication Confidence Rating Scale for Aphasia (CCRSA) (16) • Hospital Anxiety and Depression Scale (HADS) (17) • Montgomery-Asberg Depression Rating Scale (MADRS) (18) • Geriatric Depression Scale (GDS) 15 item / 30 item (19, 20) • Warwick and Edinburgh mental well-being scale (21) • Geriatric anxiety scale (22) • Stroke and Aphasia (SAD) Scale (23) • Signs of Depression Scale (SODS) (24) • Stroke Aphasic Depression Questionnaire (SADQ) (25) • Visual Analogue Self-Esteem Scale (VASES) (26) • Centre for Epidemiology Depression Scale –Revised (27) • General Health Questionnaire (GHQ) 12 item (28) • Therapy Outcome Measures (TOM) (29-31) • Patient Health Questionnaire 2 item / 9 item (32, 33) • Visual Analogue Mood Scale (VAMS) (34)

Communication	• Aphasia Communication Outcome Measure (ACOM) (35) • American Speech-Language and Hearing Association Functional Assessment of Communication Skills for Adults (ASHA-FACS) (36) • Amsterdam-Nijmegen Everyday Language Test (ANELT) (37) • The Communication Activity Log (CAL) (38) • The Communication Outcome After Stroke (COAST) (39) • The Communicative Activities Checklist (COMACT) (40) • The Social Activities Checklist (SOCACT) (40) • The Communication Disability Profile (CDP) (41) • The Communication Effectiveness Index (CETI) (42) • Community Integration Questionnaire (CIQ-R) (43) • Communication Activities of Daily Living (CADL) (44) • The Functional Outcome Questionnaire for Aphasia (FOQ-A) (45) • Measure of participation in conversation (MPC) (46) • The Scenario Test (47) • The Speech Questionnaire (48) • Therapy Outcome Measures (TOM) (29-31) • The Communication Participation Item Bank (49)
Quality of Life	• Aachen Life Quality Inventory (ALQI) (50) • Burden of Stroke Scale (BOSS) (51) • The Newcastle Stroke-Specific Quality of Life Measure (NEWSQOL) (52) • Short Form 36 Health Survey (SF-36) (53) • Stroke and Aphasia Quality of Life Scale (SAQOL-39) (54, 55)

Supplementary Table 3

Description of recommended outcome measurement instruments

Outcome instrument and abbreviation	Development / alternate versions	Aims/instrument description	Number of items	Duration	Scoring system	Training	Cost*/ availability	Language translations
Western Aphasia Battery Revised (WAB-R) (2)	Developed by Kertesz in 1979 based on the original format of the Boston Diagnostic Aphasia Examination (56). Revisions published in 1982 and 2006 (WAB-R): Supplemental tasks, revision of 15 items and testing materials (e.g. spiral-bound stimulus book replacing loose stimulus cards), as well as revised directions and scoring guidelines for clarity. The WAB-R also includes a bedside screening tool (Bedside WAB-R).	**Primary:** Assessment of linguistic skills in aphasia: 1. Spontaneous speech 2. Auditory verbal comprehension 3. Repetition 4. Naming and word finding 5. Reading 6. Writing 7. Apraxia 8. Constructional, visuospatial, and calculation tasks 9. Supplemental writing and reading tasks: reading and writing of irregular and non-words (WAB-R only) **Secondary:** Assessment of non-linguistic skills in aphasia: drawing, block design, calculation, and praxis 1. Additional aims: Classification of 8 aphasia types: Global, Broca's, Transcortical motor, Wernicke's,	>300	• Bedside WAB-R: 15 min (comprises half of the items of WAB-R Part 1) • Part 1: 30-45 min • Part 2: 45-60 min	• Aphasia Quotient (AQ): a weighted average of the WAB spoken language subtest scores. • Cortical Quotient (CQ): a weighted average of both the language and non-language subtest scores. • The Language Quotient (LQ): reflects auditory comprehension, oral expression, reading, and writing performance.	Administration: "some training" required according to developers. Scoring procedures require training.	Testing materials: +++ Available from: https://www.pearsonclinical.com	Cantonese (57) Korean (58) Bangla (59) Tagalog (60) Brazilian Portuguese (61) Japanese (62) Hungarian French Turkish (63) Hebrew Spanish (64)

		Transcortical sensory, Mixed transcortical, Conduction, and Anomic 2. Assessment of aphasia severity 3. Used to determine the location of the lesion						
Stroke and Aphasia Quality of Life Scale (SAQOL-39; SAQOL-39g) (54, 55)	The SAQOL-39 is the short form of the SAQOL (53 items), which is itself an adaptation of the SS-QOL (Stroke-specific Quality of life scale). The SAQOL-39 was originally tested in people with chronic aphasia (the measure had four domains: physical, psychosocial communication, energy.	Interview-administered self-report measure, SAQOL-39 comprises 39 questions, in four quality of life (QoL) domains: 1. Physical (17 items) 2. Communication (7 items) 3. Psychosocial (11 items) 4. Energy (4 items) SAQOL 39g comprises the same 39 questions, in three quality of life (QoL) domains: 1. Physical (16 items) 2. Communication (7 items) 3. Psychosocial (16 items) Timeframe for all questions is the past week	39	• 15-20 min (depending on severity of aphasia)	• Twenty-one of the items ask the respondents how much trouble they have had with activities (e.g., getting dressed, speaking). The response format for these questions is a 5-point scale that varies from 1='couldn't do it at all' to 5='no trouble at all'. The rest of the items (18) ask about feelings (e.g., 'did you feel irritable?') and other activities (e.g., 'did you see your friends less often than you would like?'). Their response format	Administration: Guidance is provided in administration guidelines. Administrators need to have skills in communicating with people with aphasia Scoring procedures: no training required	Free. Available from: https://blogs.city.ac.uk/cityaccess/saqol-description/	Chilean (68) Chinese (69) Chinese mandarin (70) Dutch (71) Greek (72, 73) Hindi (74) Italian (75) (76) Japanese (77) Kannada (78) Korean (79) Malayalam (80) Persian (81) Portuguese (82) Spanish (83) Turkish (84)

	Testing the SAQOL-39 in generic stroke population (n=87) resulted in the SAQOL-39g, which has the same items as the SAQOL-39 but three domains (all energy items groups with the psychosocial domain). There are alternative forms for proxy administration (65, 66) and for postal and telephone administration (67)	Multi-modal presentation, i.e., patients can both read and listen to the questions. People with expressive aphasia can point to their responses instead of verbally responding.			varies from 1='definitely yes' to 5='definitely no'. Calculation of: 1. total score: mean score of all 39 items 2. Domain scores: mean score of all items relating to the respective domain			
General Health Questionnaire (GHQ) 12	Developed in 1972. Current version published in 2011) Alternate versions: • GHQ-60: 60-item questionnaire • GHQ-30: a short form without items relating to	Primary: Screening device for identifying minor psychiatric disorders in the general population and within community or non-psychiatric clinical settings such as primary care or general medical out-patients. 12 questions relating to symptoms of various psychiatric conditions, assesses the respondent's	12	2 min administration time (in non-language impaired samples)	4-scale response options (exact wording depends on item): 1. 'better/healthier than normal' 2. 'same as usual' 3. 'worse/more than usual' 4. 'much worse/more than usual'	Administration: no training required. Scoring procedures: no training required.	Testing materials: + Available from: https://www.gl-assessment.co.uk	Italian (85) Arabic (86) Turkish (87) Persian (88) Portuguese (89) Kannada (90) Hindi (91) Spanish (92) A number of other unvalidated translations are available. The MAPI Research

	physical illness • GHQ-28: a 28 item scaled version – assesses somatic symptoms, anxiety and insomnia, social dysfunction and severe depression (7 items for each of the four scales)	current state and asks if that differs from his or her usual state, and is therefore sensitive to short-term psychiatric disorders.			4 possible methods of scoring. GHQ scoring (0-0-1-1) is advocated by the test author. GHQ-12 yields only an overall total score (range: 0 to 12 points with standard scoring procedure).			Trust distributes translated versions on behalf of GL Assessment. Contact: PROinformation@mapi-trust.org

* Free, + Up to US$100, ++ Up to US$200, +++ > US$200

Supplementary Table 4

Properties of recommended outcome measurement instruments

	Western Aphasia Battery – Revised (WAB-R)	Stroke and Aphasia Quality of Life Scale (SAQOL-39/39g)	General Health Questionnaire (GHQ-12)
Objectivity	• During assessment: Limited because no audio recordings of verbal stimulus material available • During scoring: Limited for spontaneous speech and written output subtests	• During assessment: Moderate (interaction between assessor and patient frequently required because of physical stroke symptoms (arm paresis) and lack of pictorial task instructions (written sentences only) • During scoring: High	• During assessment: High if assessor does not interact with patient • During scoring: High
Internal consistency	High: Cronbach's alpha of total score= 0.91 (93).	High: Cronbach's alpha of total score= 0.93; Cronbach's alpha of subscale scores= 0.74–0.94 (54). SAQOL-39g: High: Cronbach's alpha of total score= 0.95; Cronbach's alpha for subscale scores= 0.92-0.95 (55)	High (in general population): Cronbach's alpha of total score= 0.79-0.91 (94-96). Cronbach's alpha of subscale scores= 0.80-0.92.
Test-retest reliability*	Excellent test-retest reliability: r >0.90 Acute stage post stroke: • Korean version; (58); 5-day test–retest interval (n=20 people with aphasia; Aphasia Quotient: r=0.976; Language Quotient: r=0.977; Cortical Quotient: r=0.920; Spontaneous Speech: r=0.96; Auditory Comprehension: r=0.967; Repetition: r=0.952; Naming: r=0.934; Reading: r=0.986; Writing: r=0.988; Praxis, r=0.908; Construction: r=0.922). Chronic stage post stroke: • 1 year test–retest interval (97), n=22 patients, r=0.992 • 6 months to 6.5 test–retest interval (av.	Good to excellent test-retest reliability ICC=0.89-0.98 • English version; 2 to 14 days; n=17 people with aphasia; ICC=0.98 overall, 0.94–0.98 subscales (54). • English generic stroke version (SAQOL-39g); 7 ± 4 day test–retest interval; n=18 people with stroke/ stroke and aphasia; ICC= 0.96 overall; ICC= 0.92–0.98 subscales (55) Other translated versions: • Chilean version; ICC=0.95 (67) • Chinese ICC=0.97(69) • Chinese mandarin version; ICC=0.98 (70) • Dutch ICC=0.9 (71) • Greek ICC=0.96 (73)	Acceptable to excellent test-retest reliability • General population: ICC=0.79-0.82 (100) • Stroke (inc. aphasia) population using GHQ-28: 2 month test-retest reliability with a sample of 20 individuals (r=0.90) (101)

	12-23 months test–retest interval; (93)), n=38 patients with chronic aphasia; WAB-AQ (r=0.968), WAB-CQ (n=9, r=0.895), WAB-LQ subtests: Spontaneous Speech – Information Content (r=0.947) and Fluency (r=0.941), Comprehension (r=0.881), Repetition (r=0.970), Naming (r=0.923), Reading (n=32; r=0.927) and Writing (n=25; r=0.956) and the Construction subtest (n=14, r=974). Test-retest reliability was adequate for the Praxis subtest (n=18, r=0.581). • Danish version (98); 3.5 months test–retest interval; n=19, r=0.96. • Cantonese version (99); 12 to 16 months test–retest interval; n=16 patients, Spontaneous Speech subtest – Information, Fluency and total scores (r=0.83, 0.94, 0.96 respectively), Naming subtest (r=0.91), AQ (r=0.93).	• Hindi ICC=0.9 (74) • Italian ICC=0.916 (75) (76) • Japanese ICC=0.97 (77) • Kannada ICC=0.8 (78) • Korean ICC=0.909 (79) • Malayalam ICC=0.91 (80) • Persian ICC=0.93 (81) • Portuguese ICC=0.927 (82) • Spanish ICC=0.949 (83) • Turkish ICC=0.97 (84)	
Responsiveness	Sub-/acute phase (up to 1 month post-onset): • WAB-LQ: n=50 adults with aphasia secondary to acute stroke, who received treatment (n=42) or no treatment (n=8). Participants assessed at baseline (2-4 weeks post-onset of aphasia), 3 months, and at least 6 months post-baseline. Significant main effect for time (F=43.33, df=2.96, p<0.0001), significant differences in the mean scores for the three tests (p<0.01). (102) • Very Early Rehabilitation of Speech (VERSE) trial; n=20 participants with mild-severe aphasia receiving intervention (4-5 h/wk for 5 wks) achieved 18% greater recovery on the WAB-AQ compared to the usual care	Acute to post-acute phase (up to 6 months post-onset): • Generic stroke sample, n=87; people admitted to hospital with a first stroke were assessed two weeks, three months and six months post stroke. Moderate changes (d = 0.35—0.49; standardized response mean (SRM) = 0.29—0.53) from two weeks to six months support responsiveness. (55) Post-acute to chronic (3 months to 1 year) • Cohort study of stroke sample with and without aphasia, n=78. Effect size r=0.22. MID estimated 0.21. (107) Chronic phase (at least 6 months post-onset): • Intensive speech and language therapy	Acute to post-acute phase (up to 6 months post-onset): • Impact of stroke with and without aphasia across the first six months, n=87 people with stroke or stroke and aphasia; psychological distress significantly reduced with time on GHQ-12 [F (2,140) = 7.1, p=0.001] (109) Chronic phase (at least 6 months post-onset): • Effects of singing in a community choir on mood; n=13 people with aphasia; 2.8 point reduction in mean GHQ-12 score was seen by week 12, suggesting a possible reduction in

	group (11 min/week for 3 wks) (103). Post-acute phase (2-6 months post-onset): • See (102) above • Prospective longitudinal study with n=75 participants with aphasia post stroke, assessments at 4, 8, 12 and 24 weeks post-stroke, significant improvement in WAB-AQ across first year post-stroke (104) Chronic phase (at least 6 months post-onset): • n=10 participants with chronic aphasia. Combination of d-amphetamine, TMS, and SLT superior to control intervention of placebo with TMS and SLT; Change in AQ (from 36.13[18.23] to 38.60[19.33], P = 0.04) and LQ (from 32.41[14.93] to 35.03[15.10], P = 0.02) showed a statistically significant increase in the active experiment. Comparison of proportional changes of AQ and LQ in the active experiment with AQ and LQ in the placebo experiment showed a significant difference (AQ, P = 0.02; LQ, P = 0.008) (105) Mixed stages • n= 50 participants with aphasia (49 secondary to subacute or chronic stroke). Participants' mean scores improved significantly from pre- to post-treatment on all WAB subtests, with absolute percentages ranging from 6.5% to 13% improvement (p<0.01 to p<0.0001) (106).	compared to a waiting list control condition; n=156; Verbal communication was significantly improved from baseline to post-treatment (mean difference 2·61 points [SD 4·94]; 95% CI 1·49 to 3·72), but not from baseline to after treatment deferral (–0·03 points [4·04]; –0·94 to 0·88; between-group difference Cohen's d=0·58; p=0·0004). F-value for the main comparison is 12.97 (df1=1, df2=153), p= 0.0004 (108)	adverse mood symptoms that was sustained to week 20. (110) • Effects of solution-focused brief therapy, n=5 people with aphasia, On GHQ-12 the mean (SD) score before therapy was 4.80 (4.60) [median (IQR) = 6.00 (0–9.00)]. This was reduced after therapy to a mean (SD) score of 2.00 (2.55) [median (IQR) = 1.00 (0–4.50)]. The effect size was large: Cohen's *d* = 0.79. (111) Caregivers of people with aphasia: • Impact of a psychoeducation program on caregivers' burden and stress, n =31 caregivers of people with post stroke aphasia. Caregivers in the immediate treatment group had significant reductions in GHQ-12 measured stress (GHQ mean (SD) at baseline =6.26 (5.67), GHQ post treatment 3.21 (SD 4.20), =/0.006). (112)
Convergent validity	• Convergent validity in sample of n=15 people with aphasia (93). Comparison with corresponding subtests of the	• SAQOL-39: Good convergent validity (r=0.55 to 0.67)(54). Adequate correlation between GHQ-12 and the SAQOL-39 mean (0.53,	Convergent validity in post-stroke aphasia sample: • Good correlations with SAQOL

	Neurosensory Center Comprehensive Examination for Aphasia (NCCEA), using Pearson correlation coefficients ○ Excellent correlation between: WAB Spontaneous Speech and NCCEA Description of Use and Sentence Construction (r= 0.817); WAB Comprehension and NCCEA Identification by Name and Identification by Sentence (r= 0.915); WAB Repetition and NCCEA Sentence Repetition (r= 0.880); WAB Naming and NCCEA Visual Naming and Word Fluency (r= 0.904); WAB Reading and NCCEA Reading subtests (r=0.919); WAB Writing and NCCEA Writing subtests (r=0.905); and WAB and NCCEA total scores (r=0.973). ○ Excellent correlation between the WAB-CQ (minus the Praxis and Construction subtests) and a comparable NCCEA score (minus the Tactile Naming-Right/Left, Articulation, Digit Repetition-Forward/Backward subtests) (r=0.964). • Sample of n=45 people with aphasia. Excellent correlation between the WAB and the Czech version of the Mississippi Aphasia Screening Test (MASTcz) (r= 0.933) (113)	p<0.01). The physical, communication, and energy subscales show good convergent validity (r=0.39 to 0.67, r=0.55, r=0.32, respectively). The psychosocial subdomain shows adequate convergent (r=0.28 to 0.62) validity with only 1 correlation lower than predicted (r=0.28 with the SSS). Good correlations with Frenchay Activities Index (FAI) and ASHA Functional Assessment of Communication Skills (ASHA-FACS). • SAQOL-39g: Good/excellent convergent validity for overall scale (r=0.36–0.70); and subdomains (r=0.47–0.78) (55), evidenced by moderate to high correlations with measures of stroke severity (NIHSS), activities of daily living (Barthel Index), extended activities of daily living (Frenchay Activities Index), emotional distress (GHQ-12) and language (Frenchay Aphasia Screening Test).	39/SAQOL-39 (English, Greek, and Turkish versions). • The GHQ-12 demonstrated good convergent validity in a sample of 83 individuals with chronic stroke and aphasia, by comparison with the SAQOL-39. The study yielded an adequate correlation between the GHQ-12 and the SAQOL-39 mean (0.53, p<0.01). Correlations between the GHQ-12 and SAQOL-39 subtests were adequate (physical r=0.39, energy r=0.32, p<0.01) to excellent (psychosocial r=0.62, p<0.01). (54)
Discriminant validity	• Sample of n=140 people with aphasia. Comparison of WAB with Raven's Coloured Progressive Matrices scores Adequate correlation (r=0.547).	SAQOL-39: Discriminant validity (r = 0.02-0.27) (54) SAQOL-39g: Good/excellent discriminant validity for overall scale and subdomains, evidenced by low	Excellent discriminant validity in Swedish population (n=556 patient cases surveyed in specialized psychiatric care outpatient age and n=556 sex-matched controls). Individuals using specialized psychiatric

	• Sample of n=66 people with chronic aphasia. Discriminant validity of the WAB Aphasia Quotient (WAB-AQ) by comparison with the Scandinavian Stroke Scale (SSS), Barthel Index (BI) and Frenchay Activities Index (FAI). Excellent correlation between the WAB-AQ and the SSS (r=0.64), adequate correlations between the WAB-AQ and the BI (r=0.44) and the FAI (r=0.50).	to moderate correlations with external measures (r = 0.03-0.40). (55)	services and healthy controls (Likert index AUC=0.86, GHQ index AUC=0.83), and between individuals with current disorder from healthy controls (Likert index AUC=0.90, GHQ index AUC=0.88). (114).

*** Test-retest reliability**: 1=perfect reliability; ≥ 0.9=excellent reliability; ≥ 0.8 < 0.9=good reliability; ≥ 0.7 < 0.8=acceptable reliability; ≥ 0.6 < 0.7=questionable reliability; ≥ 0.5 < 0.6=poor reliability; < 0.5=unacceptable reliability; 0=no reliability.

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