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Title	A core outcome set for aphasia treatment research: the ROMA consensus statement
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Publication date	2018-10-10
Original Citation	Wallace, S. J., Worrall, L., Rose, T., Le Dorze, G., Breitenstein, C., Hilari, K., Babbitt, E., Bose, A., Brady, M., Cherney, L. R., Copland, D., Cruice, M., Enderby, P., Hersh, D., Howe, T., Kelly, H., Kiran, S., Laska, A-C., Marshall, J., Nicholas, M., Patterson, J., Pearl, G., Rochon, E., Rose, M., Sage, K., Small S., and Webster, J. (2018) 'A core outcome set for aphasia treatment research: the ROMA consensus statement', International Journal of Stroke. doi:10.1177/1747493018806200
Type of publication	Article (peer-reviewed)
Link to publisher's version	https://doi.org/10.1177/1747493018806200 - 10.1177/1747493018806200
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Download date	2026-11-01 11:37:00
Item downloaded from	https://hdl.handle.net/10468/7246



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Abstract

Background: A core outcome set (COS; an agreed, minimum set of outcomes) was needed to address the heterogeneous measurement of outcomes in aphasia treatment research and to facilitate the production of transparent, meaningful and efficient outcome data.

Objective: The Research Outcome Measurement in Aphasia (ROMA) consensus statement provides evidence-based recommendations for the measurement of outcomes for adults with post-stroke aphasia within phase I-IV aphasia treatment studies**.**

Methods: This statement was informed by a four-year program of research which comprised investigation of stakeholder-important outcomes using consensus processes, a scoping review of aphasia outcome measurement instruments, and an international consensus meeting. This paper provides an overview of this process and presents the results and recommendations arising from the international consensus meeting.

Results: Five essential outcome constructs were identified: Language, communication, patient-reported satisfaction with treatment and impact of treatment, emotional wellbeing, and quality of life. Consensus was reached for the following measurement instruments: Language: The Western Aphasia Battery Revised (WAB-R) (74% consensus); emotional well-being: General Health Questionnaire (GHQ)-12 (83% consensus); quality of life: Stroke and Aphasia Quality of Life Scale (SAQOL-39) (96% consensus). Consensus was unable to be reached for measures of communication (where multiple measures exist) or patient-reported satisfaction with treatment or impact of treatment (where no measures exist).

Discussion: Harmonisation of the ROMA COS with other core outcome initiatives in stroke rehabilitation is discussed. Ongoing research and consensus processes are outlined.

Conclusion: The WAB-R, GHQ-12, and SAQOL-39 are recommended to be routinely included within phase I-IV aphasia treatment studies. This consensus statement has been endorsed by the Collaboration of Aphasia Trialists, the British Aphasiology Society, the

German Society for Aphasia Research and Therapy, and the Royal College of Speech Language Therapists.

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

The Research Outcome Measurement in Aphasia (ROMA) consensus statement provides recommendations for a core outcome set (COS) for use in aphasia treatment studies. A COS is a minimum set of outcomes that should be measured and reported in research trials of a specific health condition or population (1). The use of a COS does not preclude the measurement of additional outcomes, but rather represents the minimum outcomes that should be collected and reported (2). A COS for aphasia was developed in response to a trend of heterogeneous outcome measurement in research and the merits of this initiative were debated in a published forum in 2014 (3-7). The ROMA consensus statement was informed by a four-year program of research in three phases: (1) investigation of stakeholder-important outcomes using consensus processes (8-11); (2) a scoping review to identify aphasia outcome measurement instruments (OMIs) and their psychometric properties (12); and (3) an international consensus meeting (results reported herein). The ROMA COS is intended to complement other existing and ongoing initiatives to standardise the measurement of stroke recovery (13-15).

Objective

The ROMA consensus statement provides evidence-based recommendations for the measurement of outcomes for adults with post-stroke aphasia within phase I-IV aphasia treatment studies.

Target users

The primary users of this consensus statement will be researchers involved in the design and conduct of aphasia treatment studies.

Methods

The research methods are based on the recommendations of the Core Outcome Measures in Effectiveness Trials (COMET) Initiative (2, 16) and are reported in alignment with the COS-STAR (Core Outcome Set-STAndards for Reporting) statement (17). The World Health Organization International Classification of Functioning, Disability and Health (ICF) (18) has been used as a conceptual framework and classification tool. This project is registered with the COMET Initiative (http://www.comet-initiative.org/studies/details/287).

Stage 1: Identification of Core Outcome Constructs

Outcome constructs were derived from three separate stakeholder consensus studies conducted with: people with aphasia and their families (9); aphasia clinicians and managers (8); and aphasia researchers (10). Outcomes prioritised by stakeholder groups were integrated using the framework of the ICF (19). Essential constructs were identified as: Language, communication, patient-reported satisfaction with treatment and impact of treatment, emotional wellbeing, and quality of life (11).

Stage 2: Identification of Outcome Measurement Instruments

A scoping review was conducted to identify OMIs which have been validated with people with aphasia. Primary searches were run using PUBMED, EMBASE, and CINAHL databases on 10 November 2015. The search strategy incorporated filters developed for the identification of studies reporting the measurement properties of health OMIs (see 20 and supplementary file). Inclusion criteria required that studies focused on the psychometric properties of measurement instrument and included participants with aphasia or stroke patients where participants with aphasia were not specifically excluded. Studies reporting measurement instruments which primarily measure neurological function associated with, but not central to aphasia: e.g., consciousness; health; motor speech; cognition; memory; were excluded. Secondary searches were conducted for each OMI identified in the first search. In

total, 184 references for 79 measurement instruments were identified (12). No measures of patient-reported treatment impact or patient-reported satisfaction were identified through this search.

Stage 3. Formation of Consensus Panel

Researchers who participated in the first phase of this project (n=80) (10) were invited to participate in the final consensus meeting. These researchers were purposively sampled from researchers whose trials were included with the Cochrane Collaboration review of "Speech and language therapy for aphasia following stroke"(21) and the 100 most highly published aphasia treatment researchers in the Web of Science database. In total, 23 researchers participated in a consensus meeting in London, UK (December, 2016). Panel members were experienced researchers with expertise in: the design and conduct of aphasia trials; measurement instrument development and testing; and clinical guidelines development (see table 1 and supplementary table 1). Authors Wallace, Worrall, Le Dorze and T. Rose facilitated the COS development process and did not participate in COS voting.

Table 1

Characteristics of researchers who participated in the international consensus panel (n=23)

Panel Characteristics	n (%)
Country	
United Kingdom	9 (39)
United States of America	6 (26)
Australia	3 (13)
Canada	2 (9)
Germany	1 (4)
Sweden	1 (4)
Ireland	1 (4)

ICF component to which their own research relates (panel members could nominate more than one component)	
Body functions	16
Activity/Participation	21
Environmental factors	10
Personal factors	15
Quality of life*	12
Number of treatment studies published by participants	
1	2
2-5	8
6-10	4
more than 10	7
not specified	2

*****nb. Quality of life is not defined as a component of the ICF

Stage 4. International Consensus Meeting

Ethical approval for the consensus meeting was gained from the Behavioural and Social Sciences Ethical Review Committee at The University of Queensland, Australia. The following process was used:

Prior to meeting

(1) Panel members generated consensus-based criteria to enable an initial reduction of OMIs (see table 2).

(2) The consensus-based criteria were applied to the list of OMIs identified in the stage 2 scoping review (n=79) to produce a short-list (n=50) (see supplementary table 2).

(3) Panel members generated consensus-based feasibility criteria (see table 3).

(4) The short-listed OMIs (see supplementary table 2) were assigned to panel members, who reviewed OMI feasibility and measurement properties prior to the consensus meeting.

During the meeting

(1) Panel members engaged in a whole-group discussion using an iterative process to apply feasibility criteria and eliminate OMIs.

(2) Panel members divided to smaller groups to review the measurement properties for each OMI in the target population (people with aphasia). Properties considered included: acceptability/feasibility of use with people with aphasia, reliability (test-retest, inter- and intra- as applicable), construct validity, and sensitivity to change.

(3) Each small group recommended two OMIs for voting. Panel members voted YES/NO for each OMI in a closed voting process with consensus defined a priori as agreement on each OMI for each outcome construct by ≥ 70% of meeting participants, as suggested by the COMET initiative and GRADE working group (2). Potential conflicts of interest were managed through agreement that authors of OMIs under consideration could not participate in voting for that construct area.

Table 2

Criteria for initial reduction of outcome measurement instruments

Measures were excluded if:
1. The purpose of the measurement instrument was to screen for the presence of aphasia, rather than to measure outcomes.
2. The measurement instrument was published more than thirty years ago (i.e., prior to 1986) without subsequent revision and/or was not in current use.
3. The measurement instrument targeted only one severity level of aphasia.
4. For measures of language: the measurement instrument did not assess all modalities of language (e.g. reading only, writing only, comprehension only, verbal output only).

Table 3

Feasibility criteria

1. Availability in different languages or ease of translation/adaptation.
2. Cost.
3. Burden to respondents or researchers (ease of administration, length of outcome measurement instrument, completion time).
4. Ease of score calculation and provision of an aggregate score.

Results

After compilation of votes, panel members reached consensus for measures of language, emotional wellbeing, and quality of life (refer to table 4). A consensus of ≥ 70% was not reached for a measure of communication. Inability to gain consensus on a measure of communication may relate to the multi-factorial nature of this construct, as well a lack of understanding and consensus around how 'effective communication' is best operationalised in treatment research.

Table 4

Results of final voting to decide core outcome measurement instruments

Construct	Measure*	Votes for inclusion
Language	**The Western Aphasia Battery Revised (WAB-R)**	**74% (n=17)**
	The Comprehensive Aphasia Test (CAT)	22% (n=5)
	Neither	4% (n=1)
Communication	The Scenario Test	57% (n=13)
	The Communication Effectiveness Index (CETI)	39% (n=9)
	Abstained	4% (n=1)
Emotional well-being	**General Health Questionnaire (GHQ)-12**	**83% (n=19)**

	Stroke Aphasic Depression Questionnaire (SADQ)	17% (n=4)
Quality of life	**Stroke and Aphasia Quality of Life Scale (SAQOL-39)**	**96% (n=22)**
	Burden of Stroke Scale (BOSS)	0% (n=0)
	Abstained	4% (n=1)

Bolded figures indicate consensus criteria (≥70%) reached and OMI included in COS
*Refer to supplementary tables 3 & 4 for OMI characteristics, properties and references.

Recommendations

It is recommended that the WAB-R, GHQ-12 and SAQOL-39 be included as core outcome measurement instruments in phase I-IV aphasia treatment studies for adults with post-stroke aphasia. These outcome measurement instruments and their psychometric properties are described in supplementary tables 3 & 4.

Discussion

The importance of implementing standardised approaches to outcome measurement in research trials is increasing acknowledged. In the field of stroke rehabilitation, the Stroke Recovery and Rehabilitation Roundtable (SRRR) (13) have provided consensus-based core recommendations for the measurement of sensorimotor recovery after stroke. Other initiatives have addressed the measurement of stroke outcomes in clinical practice (15) and there are ongoing works to standardise measures in arm rehabilitation trials after stroke (14). The ROMA COS has sought to provide recommendations specifically for the measurement of aphasia recovery post-stroke. Accordingly, some frequently used measures of global disability and health-related quality of life (e.g., EQ-5D) which do not contain communication-specific items or which have not been validated with stroke survivors with aphasia were not considered within this process. The ROMA COS seeks to harmonise with other existing stroke rehabilitation initiatives in addressing the need for standardised

approaches to research trial outcomes measurement and its supplementary use may therefore be considered in any stroke study where people with aphasia are included.

Future Directions

The ROMA COS will be reviewed biennially. The next consensus meeting will focus on measures of communication and consider the development of measures of patient-reported satisfaction with treatment / impact of treatment. Factors relating to international COS implementation will be considered. New publications, initiatives and user feedback will also be considered in each review to: align this COS with other COSs; consider new OMIs; and to review the choice of OMIs based on user feedback.

Limitations

Participants in the international consensus meeting were predominately from English speaking countries. This may have impacted the consensus process and findings. Future meetings will seek to increase the diversity of participants with respect to cultural and linguistic background.

Funding

This work was supported by a British Aphasiology Society Initiatives in Aphasia Seed Fund grant. The Collaboration of Aphasia Trialists provided operational support for the international consensus meeting.

Conflicts of Interest

Authors Babbit, Breitenstein, Cherney, Cruice, Enderby, and Hilari authored or adapted OMIs considered in this consensus process. These authors declared their conflict of interest during the meeting and did not participate in voting which related to their authored OMIs. Authors Wallace, Worrall, Le Dorze and T. Rose did not participate in voting on OMIs.

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