COMPARE Supplemental Information

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The COMPARE Naming Battery

We constructed a 180-item picture naming battery for the trial. The items consisted of coloured photographs of everyday objects (nouns; 100 items) and actions (verbs; 80 items). The items were presented on playing card sized (6cm by 8·5cm) semi-gloss cardboard. Preliminary name agreement was investigated in eight healthy control participants prior to the study. Only items with 100% name agreement were selected for the naming battery. A list of acceptable synonyms was compiled from the responses of the healthy controls and included as alternative responses to be coded as correct during the trial. Items were assigned to three (overlapping) sets of 80 (48nouns, 32 verbs) based on their word frequency, syllable number and syllable complexity. The hard set comprised those items with the lowest frequency, most syllables and most complex syllable structure, and the easy set those items with the highest frequency, fewest syllables and most simple syllable structure, The medium set fell between these sets in difficulty.

Test retest reliability was calculated on 24 participants with aphasia who undertook the naming battery on two separate occasions, 14-20 days apart. The ICC was 0.96.

The 180-item naming battery was used to measure the severity of word retrieval difficulties at screening, to determine which stimulus set would be used in treatment (easy set, medium set, hard set). Each participant was evaluated on the naming battery at other time points to measure impact of treatment on word finding.

Additional screening and baseline measures taken

In an initial screening and baseline assessment session the following measures were administered:

Western Aphasia Battery-R (WAB-R) Part 2 Supplemental Tests

The WAB-R[1] Part 2 contains tests of reading, writing, apraxia, construction, drawing, and non-verbal reasoning. These standardised tests provided baseline measures of cognitive functions that may have influenced response to CIAT and M-MAT

EQ-5D-3L

The EQ-5D-3L[2] is a simple questionnaire with five questions concerning mobility, self-care, usual activities, pain and discomfort, and anxiety and depression rated on a 3-point scale. In addition, there is a single value or health stats using the EQ visual analogue scale ranging from 0 to 100% which can be used to weight responses and support utility scores for economic analysis.

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Pyramids and Palm Trees Test
Pyramids and Palm Trees (three picture version)[3] is used to measure how much meaning an individual can derive from pictures and words (i.e., assesses semantic processing). It is specifically designed for people with aphasia. The participant is shown a stimulus picture and two response pictures (target and distractor) and is asked which of the two response pictures is associated with the target. The participant is not asked to name the pictures or read the words aloud. Scores range from 0 – 52 with a cut off for normal performance above 48/52

Raven's Coloured Progressive Matrices
The Raven's Coloured Progressive Matrices[4] tests non-verbal reasoning in the visual modality. Participants are presented with a choice of six patterned tiles and asked to select the tile that fits into a larger pattern missing a tile piece. There are 36 items arranged in order of increasing difficulty. The test is scored out of 36 points and if completed within five minutes an additional 1-point is awarded (/37). The test has good internal consistency, and test-retest reliability. It has been used extensively in studies of people with aphasia. Age and education-based norms are available.

Test of Everyday Attention (TEA)
The TEA[5] consists of eight subtests. We used two subtests: 1) Elevator Counting, and 2) Visual Elevator. Test 1 examines sustained attention: participants imagine they are in an elevator whose floor indicator is not working. Participants have to attend to a series of recorded tones that indicate floors. Test 2 measures attentional switching and cognitive flexibility: participants count up and down as they follow a series of visually presented "floors" in the elevator. The TEA displays excellent reliability and validity for controls and stroke participants.

The Modified Rankin Scale
The Modified Rankin Scale[6] measures the severity of individuals' disability following a stroke. Disability is measured on a scale from 0 – 5, where zero signifies no symptoms and five signifies severe disability to the extent that the individual requires constant nursing care. This test has strong evidence of reliability and validity

The Community Stroke Aphasia Depression Questionnaire-10 (SADQ-10)
The SAD-Q[7] was specifically designed to assess low mood in individuals living with post-stroke aphasia in the community. The 10-item questionnaire is completed by a caregiver on behalf of the individual with aphasia. Each of the 10 items is rated on a 4-point scale (0 – 3). A score of 14 or above indicates depressive symptoms.

The Apraxia Severity Rating Scale (ASRS)
The ASRS[8] quantifies the presence or absence, relative frequency, and severity of characteristics frequently associated with apraxia of speech (AOS). The scale includes 16-iems rated on a 5-point scale after listening to samples of speech from conversation, picture description, word and sentence repetition and rapid speech movements. Psychometric testing has shown an inter-judge ICC of 0·94 for the total ASRS score and 0·91 for the number of AOS characteristics identified as present[8]. Intra-judge ICC measures are high, ranging from 0·91 to 0·98[8]. Validity is demonstrated on the basis of strong correlations with independent clinical diagnosis, as well as strong correlations between ASRS scores and independent clinical judgments of AOS severity[8].

The Picture Span Verbal Memory Test
The Picture Span Test[9] measures auditory verbal immediate and working memory. Participants listen to strings of verbally presented single syllable words and respond by pointing to photographs of the referent of each word in either forward or reverse order of presentation. Strings (spans) begin with three words and continue to a maximum of six words. The test has acceptable test-retest reliability, internal consistency and construct validity.

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The Simplified Handedness Questionnaire
The Simplified Handedness Questionnaire[10] is a simple rating scale identifying which functions each hand (left or right) is used for. Handedness scores range from -1 to +1

References

1. Kertesz A. The Western Aphasia Battery-Revised. New York: Grune & Stratton; 2007.
2. Viney R, Norman R, Brazier J, et al. An Australian discrete choice experiment to value eq-5d health states. *Health Econ*. 2014; 23: 729–742.
3. Howard D, Patterson K. The pyramids and palm trees test. Suffolk, UK: Thames Valley Test Company; 1992.
4. Raven JC, Court J, Raven J. Coloured progressive matrices. Oxford, UK: Oxford Psychologists Press; 1995.
5. Robertson I, Ward T, Ridgeway V, Nimmo-Smith I. The Test of Everyday Attention. London, UK: Pearson Assessment; 1994.
6. Banks JL, Marotta, CA. Outcomes validity and reliability of the Modified Rankin Scale: Implications for stroke clinical trials. *Stroke.* 2007; 38: 1091–1096.
7. Sutcliffe LM, Lincoln NB. The assessment of depression in aphasic stroke patients: the development of the Stroke Aphasic Depression Questionnaire. *Clin Rehabil*. 1998; 12: 506–513.
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9. DeDe G, Ricca M, Knilans J, Trubl B. Construct validity and reliability of working memory tasks for people with aphasia. *Aphasiology.* 2014; 26: 692-712.
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TIDieR checklist of trial interventions modified to enable description of arms more specifically

1.Brief Name	Usual care	CIAT Plus	M-MAT
2.Why	To improve communication and reduce aphasia impacts p.1	To improve verbal communication through an intense dose of verbally focused aphasia therapy built on principles of experience-dependent neuroplasticity (repetition, feedback, intensity) p.1	To improve verbal communication through an intense dose of multimodal focused aphasia therapy built on principles of experience-dependent neuroplasticity (repetition, feedback, intensity) and deep encoding p.1
3.What	Whatever was available in the community: limited language and communication therapy, social group support p.1-2 and online intervention protocol	Constraint-induced Aphasia Therapy Plus-see intervention protocol for full details p.1-2	Multi-modality Aphasia Therapy- see intervention protocol for full details p.1-2
4.Procedures	Attended limited therapist delivered, social peer support groups or practiced with self-managed language therapy apps p.3	Groups of 3 participants of same aphasia severity stratum treated for 30 hours with a study trained therapist. Produced nouns and verbs in phrases and sentences in social interactive language activities. See full intervention protocol for details p.3	Groups of 3 participants of same aphasia severity stratum treated for 30 hours with a study trained therapist. Produced nouns and verbs in phrases and sentences in social interactive language activities. See full intervention protocol for details p.3
5.Who provided	Speech therapists, therapy assistants or volunteers p.3	Trial employed and trained speech therapists p.3	Trial employed and trained speech therapists p.3
6. How?	Face-to-face on a one-to-one basis, or in a group, or via self-managed therapy apps	Face-to-face in groups of three participants and one therapist; an additional daily functional communication task for home practice p.3	Face-to-face in groups of three participants and one therapist; an additional daily functional communication task for home practice p.3
7. Where	Participants' own homes or outpatient or community clinical facility p.3	Community centres and University clinics in Australia and New Zealand p.3	Community centres and University clinics in Australia and New Zealand p.3
8. When and how much?	67% of participants were not in receipt of speech therapy during the study period. The remaining 33% received a median of 10 hours (IQR 5, 20) total therapy during the 14 week study period Table 1.	3 x 1 hr sessions per day, 5 days per week, for 2 weeks (30 hours) + daily 15 minute home practice tasks Table 1	3 x 1 hr sessions per day, 5 days per week, for 2 weeks (30 hours) + daily 15 minute home practice tasks Table 1
9. Tailoring	Tailored to individual needs and preferences	Therapists selected the appropriate 80-item treatment stimulus set (easy, moderate, hard) according to patient naming severity stratum (mild, moderate, severe). Therapist chose task and the level of linguistic difficulty for each participant for each session. p.3	Therapists selected the appropriate 80-item treatment stimulus set (easy, moderate, hard) according to patient naming severity stratum (mild, moderate, severe). Therapist chose task and the level of linguistic difficulty for each participant for each session. p.3
10.Modifications	No modifications were requested by the trial team	Tasks and linguistic difficulty of targets were adapted each session according to participant success p.3	Tasks and linguistic difficulty of targets were adapted each session according to participant success p.3
11.How well (planned)	Participants recorded receipt of speech therapy in a trial diary throughout the trial and details were logged in REDCAP by trial assessors.	Therapists undertook standardised self - administered computer-based training followed by additional training with a trial staff member. Fidelity of therapy provision was assessed and feedback provided (see therapy fidelity protocol) Appendix table 1	Therapists undertook standardised self - administered computer-based training followed by additional training with a trial staff member. Fidelity of therapy provision was assessed and feedback provided (see therapy fidelity protocol) Appendix table 1
12 How well (actual)	Not measured	97 % of Day 1 sessions were compliant; 100% of Day 6 sessions were compliant Table 1	97 % of Day 1 sessions were compliant; 100% of Day 6 sessions were compliant Table 1

Legend: CIAT-Plus: Constraint Induced Aphasia Therapy; M-MAT: Multimodality Aphasia Therapy

Table I. Additional baseline characteristics and intervention data

	CIAT Plus n (%)	**M-MAT n (%)**	**UC n (%)**
Living arrangements during study			
Home alone	7 (10%)	7 (9·72%)	6 (9·38%)
Home with other	38 (54·29%)	45 (62·50%)	41 (64·06%)
Supported accommodation	3 (4·29%)	2 (2·78%)	0 (0%)
Other	3 (4·29%)	0 (0%)	2 (3·12%)
Apraxia of Speech Rating Scale			
No impairment	31 (43·66%)	34 (45·33%)	33 (47·14%)
Mild impairment	28 (39·44%)	20 (26·67%)	15 (21·43%)
Moderate impairment	8 (11·27%)	14 (18·67%)	10 (14·29%)
Moderate/severe impairment	4 (5·63%)	6 (8%)	12 (17·14%)
NA	0 (0%)	1 (1·33%)	0 (0%)
Western Aphasia Battery-Revised Reading, Writing, Drawing, Praxis Subtests			
Writing (Mean, SD) Out of 50	25·56 (17·11) n=69	23·96 (16·17) n=70	25·8 (15·3) n=64
Reading (Mean, SD) Out of 60	41·43 (15·47) n=69	39·93 (18·27) n=70	44·52 (14·72) n=64
Drawing (Mean, SD) Out of 30	20·99 (5·61) n=69	21·95 (5·58) n=70	21·4 (5·44) n=64
Praxis (Mean, SD) Out of 10	8·92 (1·15) n=69	8·71 (1·33) n=70	8·93 (1·2) n=64
Test of Everyday Attention			
Elevator Counting (Mean, SD) Out of 7	6·13 (1·24) n=64	6·13 (1·47) n=64	6·31 (1·15) n=64
Visual Elevator (Mean, SD) Out of 15	6·73 (3·55) n=52	6·41 (3·46) n=54	6·68 (3·12) n=50
Picture Span Memory Test			
Pictures forward (Mean, SD) Out of 175	40·44 (17·22) n=68	38·44 (21·60) n=68	45·88 (21·85) n=60
Pictures backwards (Mean, SD) Out of 175	37·02 (15·04) n=64	35·10 (21·66) n=63	36 (20·15) n=55
Raven's Progressive Matrices (Mean, SD) Out of 37	27·81 (6·74) n=64	27·80 (6·99) n=70	29·28 (5·57) n=64
Self-rated Fatigue (Mean, SD) Out of 10	2·51 (2·44) n=71	2·48 (2·69) n=75	1·79 (1·96) n=70
Self-rated Distress (Mean, SD) Out of 10	1·18 (1·87) n=71	1·75 (2·44) n=75	1·14 (1·45) n=69

Legend: CIAT-Plus: Constraint Induced Aphasia Therapy; M-MAT: Multimodality Aphasia Therapy; UC: Usual Care

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Table II. Additional intervention characteristics

	CIAT Plus n (%)	**M-MAT n (%)**	**UC n (%)**	**All n (%)**
Intervention Levels progressed by final session: Nouns				
- 1	0 (0%)	2 (2·67%)	NA	2 (1·43%)
0	13 (18·57%)	17 (24·29%)	NA	30 (21·43%)
1	15 (21·43%)	8 (11·43%)	NA	23 (16·43%)
2	11 (15·71%)	9 (12·86%)	NA	20 (14·29%)
3	28 (40%)	32 (45·71%)	NA	60 (42·86%)
4	3 (4·29%)	2 (2·86%)	NA	5 (3·57%)
Intervention Levels progressed by final session: Verbs				
-1	0 (0%)	3 (4·29%)	NA	3 (2·14%)
0	20 (28·57%)	21 (30%)	NA	41 (29·29%)
1	6 (8·57%)	7 (10%)	NA	13 (9·29%)
2	17 (24·29%)	8 (11·43%)	NA	25 (17·86%)
3	24 (34·29%)	28 (40%)	NA	52 (37·14%)
4	3 (4·29%)	3 (4·29%)	NA	6 (4·29%)
Therapy fidelity monitoring				
Compliant Day 1 (127 session) Protocol deviations Protocol violations	124 (97·7%) 3 (2·3%) 0 (0%)		NA	NA
Compliant Day 6 (121 sessions) Protocol deviations Protocol violations	121 (100%) 0 (0%) 0 (%)		NA	NA

Legend: CIAT-Plus: Constraint Induced Aphasia Therapy; M-MAT: Multimodality Aphasia Therapy; UC: Usual Care; NR: not reported; NA: not applicable

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Table III. Unadjusted outcomes immediately post intervention and at 12-week follow up (Mean, SD)

	CIAT Plus	M-MAT	UC
Immediately Post Intervention			
Primary outcome measure			
Western Aphasia Battery-Revised-Aphasia Quotient Out of 100	72·29 (17·61) n=70	69·36 (20·46) n=70	74·39 (17·65) n=61
Secondary outcome measures			
COMPARE Naming Battery (Mean, SD) Out of 80 (treated items)	55·83 (19·02) n=70	52·12 (22·34) n=69	50·59 (18·09) n=61
COMPARE Naming Battery (Mean, SD) Out of 100 (untreated items)	66·16 (26·91) n=70	63·23 (30·96) n=69	67·20 (29·01) n=61
Functional communication, Communicative Effectiveness Index Out of 100	59·17 (18·19) n=66	57·28 (17·70) n=66	57·21 (17·49) n=55
Multimodal communication ,Scenario Test Out of 54	45·25 (11·11) n=66	46·12 (8·52) n=66	47·95 (8·01) n=61
Stroke and Aphasia Quality of Life Scale			
Composite Score Out of 5	3·76 (0·65) n=69	3·83 (0·64) n=69	3·66 (0·61) n=61
Physical Out of 5	4·13 (0·74) n=69	4·19 (0·73) n=69	4·04 (0·78) n=61
Communication Out of 5	3·20 (0·89) n=70	3·32 (0·77) n=69	2·98 (0·74) n=61
Psychosocial Out of 5	3·65 (0·79) n=70	3·71 (0·85) n=69	3·59 (0·79) n=61
Western Aphasia Battery-Revised Aphasia Quotient Subtests			
Spontaneous Speech (Mean, SD) Out of 20	14·09 (4·22) n=70	13·57 (4·33) n=70	14·79 (3·76) n=61
Auditory Verbal Comprehension (Mean, SD) Out of 10	8·27 (1·24) n=70	7·96 (1·65) n=70	8·30 (1·68) n=61
Repetition (Mean, SD) Out of 10	6·76 (2·46) n=70	6·37 (2·68) n=70	6·65 (2·50) n=61
Naming and Wording Finding (Mean, SD) Out of 10	7·01 (2·27) n=70	6·76 (2·52) n=70	7·47 (2·20) n=61
Communication accuracy and efficiency			
No of CIUs	247·78 (203·69) n=67	201·84 (165·5) n=62	266·48 (191·7) n=54
CIUs per minute	25·54 (18·36) n=67	21·73 (17·30) n=62	32·36 (21·66) n=54
12 week follow up			
Primary outcome measure			
Western Aphasia Battery-Revised- Aphasia Quotient Out of 100	73·02 (17·30) n=66	71·21 (20·38) n=67	75·19 (17·20) n=59
Secondary outcome measures			
COMPARE Naming Battery (Mean, SD) Out of 80 (treated items)	50·98 (19·07) n=66	49·78 (22·19) n=67	50·28 (18·18) n=60
COMPARE Naming Battery (Mean, SD Out of 100 (untreated items)	66·55 (26·98) n=66	65·06 (31·48) n=67	69·23 (27·77) n=60
Communicative Effectiveness Index Out of 100	60·00 (19·31) n=61	56·17 (20·00) n=62	59·03 (17·14) n=50
Scenario Test Out of 54	46·61 (9·63) n=64	46·35 (10·35) n=66	48·17 (7·07) n=58
Stroke and Aphasia Quality of Life Scale			
Composite Score (Mean, SD) Out of 5	3·73 (0·68) n=65	3·73 (0·72) n=67	3·67 (0·64) n=58
Physical Out of 5	4·09 (0·77) n=65	4·10 (0·87) n=67	4·05 (0·78) n=58
Communication Out of 5	3·21 (0·85) n=66	3·07 (0·88) n=67	3·14 (0·70) n=58
Psychosocial Out of 5	3·59 (0·88) n=66	3·66 (0·88) n=67	3·53 (0·87) n=58
Western Aphasia Battery-Revised Aphasia Quotient Subtests			
Spontaneous Speech (Mean, SD) Out of 20	14·39 (3·95) n=66	13·75 (4·57) n=67	15·00 (3·84) n=59
Auditory Verbal Comprehension (Mean, SD) Out of 10	8·25 (1·32) n=66	8·16 (1·62) n=67	8·25 (1·59) n=59
Repetition (Mean, SD) Out of 10	6·83 (2·27) n=66	6·66 (2·51) n=67	6·84 (2·41) n=59
Naming and Wording Finding (Mean, SD) Out of 10	7·03 (2·32) n=66	7·04 (2·54) n=67	7·50 (2·12) n=59
Communication accuracy and efficiency			
No of CIUs	243·52 (196·32) n=61	199·31 (149·72) n=52	262·3 (189·69) n=46
CIUs per minute	28·23 (20·33) n=61	20·60 (15·99) n=52	31·91 (22·27) n=46

Legend: CIAT-Plus: Constraint Induced Aphasia Therapy; M-MAT: Multimodality Aphasia Therapy; UC: Usual Care; NR: not reported; NA: not applicable; CIU: correct information unit

Table IV. Connected speech effects at immediately post intervention and 12-week follow up in the intention to treat population

	CIAT Plus	**M-MAT**	**Usual Care**	**CIAT Plus vs usual care**		**M-MAT vs usual care**		**M-MAT vs CIAT Plus**	
	Unadjusted mean change score PIV-Baseline (SD)	Unadjusted mean change score PIV-Baseline (SD)	Unadjusted mean change score PIV-Baseline (SD)	Adjusted mean difference (95% CI)	p value	Adjusted mean difference (95% CI)	p value	Adjusted mean difference (95% CI)	p value
Connected speech outcomes at post-intervention									
Connected speech accuracy, number of CIUs	30·73 (80·66)	23·44 (52·77)	30·76 (62·94)	0·39 (-21·3, 22·1)	0·999	-6·80 (-29, 15·8)	0·75	-7·19 (-21·8, 13·7)	0·70
Connected speech efficiency, CIUs per min	2·72 (7·50)	1·43 (6·18)	4·40 (6·95)	-1·64 (-4·06, 0·78)	0·25	**-2·89 (-5·36, -0·42)**	**0·017***	-·1·25 (-3·57, 1·07)	0·41
Connected speech outcomes at 12 week follow up									
Connected speech accuracy, number of CIUs	20·69 (66·82)	10·67 (55·23)	25·43 (62·98)	-5·28 (-28, 17·5)	0·85	-13·30 (36·9, 10·3)	0·38	-8·02 (-30·0, 14·0)	0·66
Connected speech efficiency, CIUs per min	4·84 (8·77)	0·03 (5·67)	2·78 (7·40)	1·93 (-0·61, 4·47)	0·17	**-2·81 (-5·45, -0·18)**	**0·03***	**-4·74 (-2·03, -4·59)**	**<0·0001***

Legend: *Bold: Statistically significant difference; CIAT-Plus: Constraint Induced Aphasia Therapy; M-MAT: Multimodality Aphasia Therapy; CIU: correct information unit

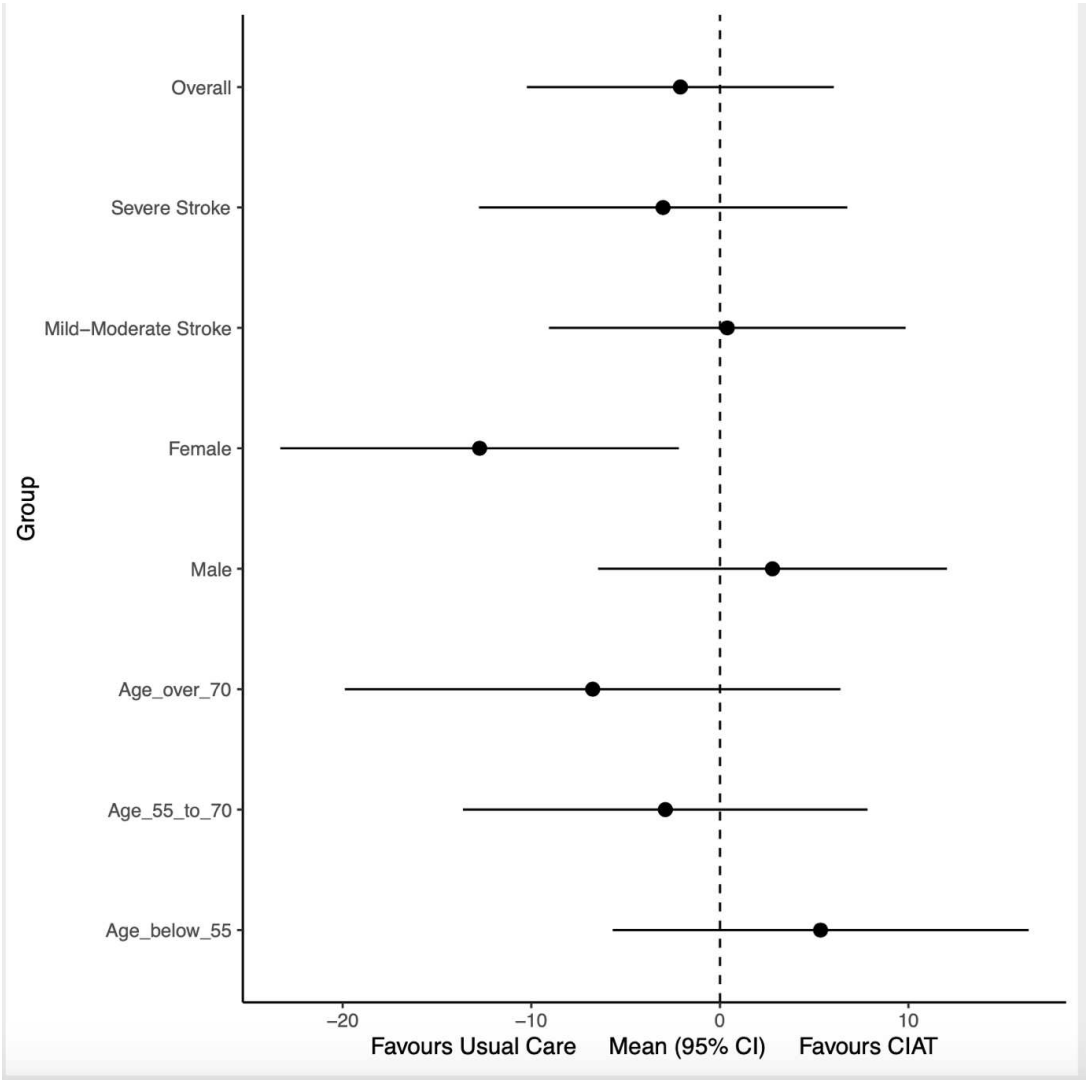

Figure I. Forest plot of participant demographic effects on primary endpoint (WAB-R-AQ) for CIAT-Plus

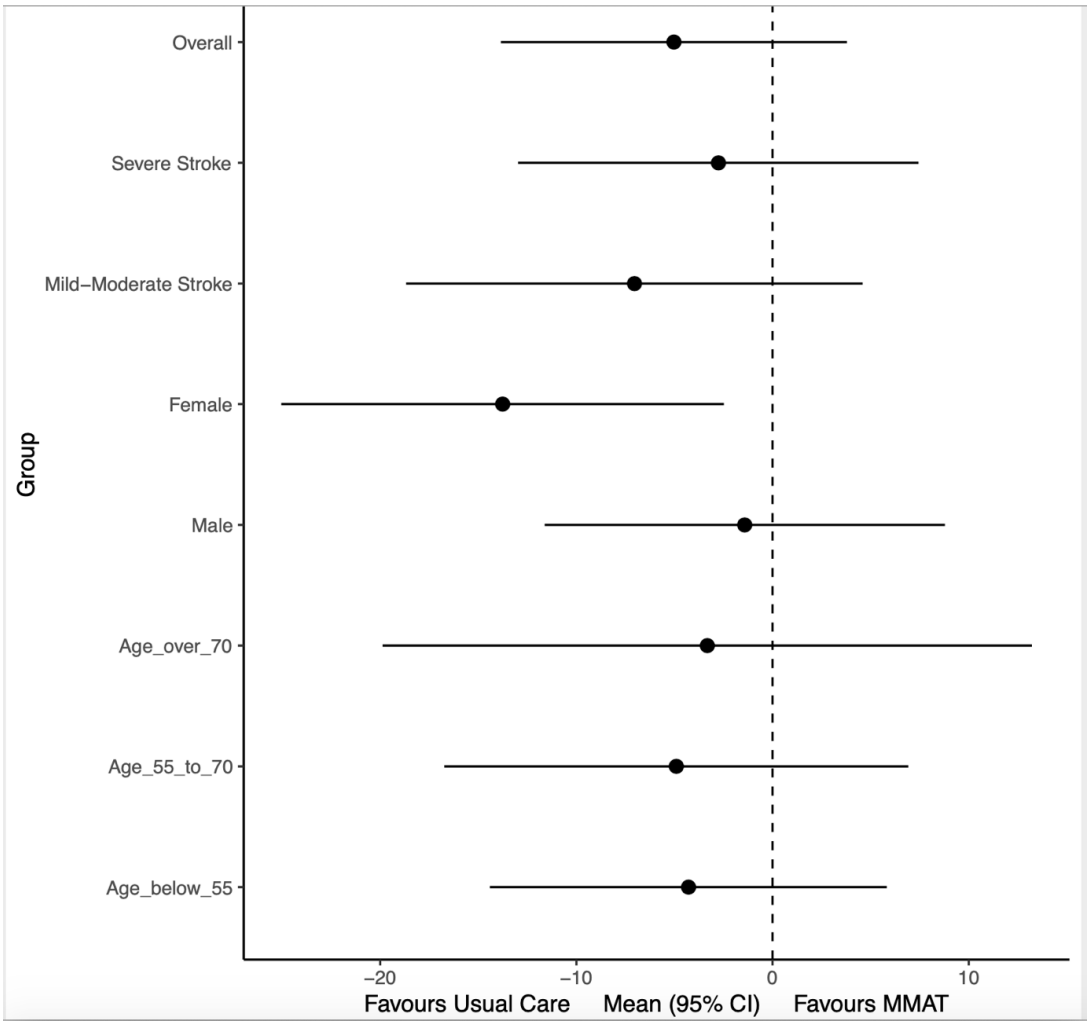

Figure II. Forest plot of participant demographic effects on primary endpoint (WAB-R-AQ) for M-MAT

CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	Title page
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	Abstract
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	1
	2b	Specific objectives or hypotheses	1
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	2
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	2
Participants	4a	Eligibility criteria for participants	2
	4b	Settings and locations where the data were collected	2
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	3 and online protocol
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	4
	6b	Any changes to trial outcomes after the trial commenced, with reasons	4
Sample size	7a	How sample size was determined	4
	7b	When applicable, explanation of any interim analyses and stopping guidelines	4
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	2
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	2
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	2
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	2
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	3

	11b	If relevant, description of the similarity of interventions	3
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	4
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	4
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	5
	13b	For each group, losses and exclusions after randomisation, together with reasons	5
Recruitment	14a	Dates defining the periods of recruitment and follow-up	5
	14b	Why the trial ended or was stopped	5
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Table 1
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	Table 1
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	Table 3 and page 6
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	NA
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	NA
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	Table 2
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	7
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	7
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	7
Other information			
Registration	23	Registration number and name of trial registry	2
Protocol	24	Where the full trial protocol can be accessed, if available	2
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	5

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

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