



City Research Online

City, University of London Institutional Repository

Citation: Brady, M. C., Ali, M., VandenBerg, K., Williams, L. J., Williams, L., Abo, M., Becker, F., Bowen, A., Brandenburg, C., Breitenstein, C., et al (2020). Communicating simply, but not too simply: Reporting of participants and speech and language interventions for aphasia after stroke. *International Journal of Speech-Language Pathology*, 22(3), pp. 302-312. doi: 10.1080/17549507.2020.1762000

This is the published version of the paper.

This version of the publication may differ from the final published version.

Permanent repository link: <https://openaccess.city.ac.uk/id/eprint/24650/>

Link to published version: <https://doi.org/10.1080/17549507.2020.1762000>

Copyright: City Research Online aims to make research outputs of City, University of London available to a wider audience. Copyright and Moral Rights remain with the author(s) and/or copyright holders. URLs from City Research Online may be freely distributed and linked to.

Reuse: Copies of full items can be used for personal research or study, educational, or not-for-profit purposes without prior permission or charge. Provided that the authors, title and full bibliographic details are credited, a hyperlink and/or URL is given for the original metadata page and the content is not changed in any way.

City Research Online: <http://openaccess.city.ac.uk/> publications@city.ac.uk

Communicating simply, but not too simply: Reporting of participants and speech and language interventions for aphasia after stroke

RELEASE COLLABORATION

Marian C. Brady, Myzoon Ali, Kathryn VandenBerg, Linda J. Williams, Louise R. Williams, Masahiro Abo, Frank Becker, Audrey Bowen, Caitlin Brandenburg, Caterina Breitenstein, Stefanie Bruehl, David A. Copland, Tamara B. Cranfill, Marie di Pietro-Bachmann, Pamela Enderby, Joanne Fillingham, Federica Lucia Galli, Mariahuisa Gandolfi, Bertrand Glize, Erin Godecke, Neil Hawkins, Katerina Hilari, Jacqueline Hinckley, Simon Horton, David Howard, Petra Jaecks, Elizabeth Jefferies, Luis Mt Jesus, Maria Kambanaros, Eun Kyoung Kang, Eman M. Khedr, Anthony Pak-Hin Kong, Tarja Kukkonen, Marina Laganaro, Matthew A. Lambon-Ralph, Ann Charlotte Laska, Béatrice Leemann, Alexander P. Leff, Roxele R. Lima, Antje Lorenz, Brian MacWhinney, Rebecca Shisler Marshall, Flavia Mattioli, İlknur Maviş, Marcus Meinzer, Reza Nilipour, Enrique Noé, Nam-Jong Paik, Rebecca Palmer, Ilias Papatthanasiou, Brigida F. Patricio, Isabel Pavão Martins, Cathy Price, Tatjana Prizl Jakovac, Elizabeth Rochon, Miranda L. Rose, Charlotte Rosso, Ilona Rubi-Fessen, Marina B. Ruiter, Claerwen Snell, Benjamin Stahl, Jerzy P. Szaflarski, Shirley A. Thomas, Mieke van de Sandt-Koenderman, Ineke van der Meulen, Evy Visch-Brink, Linda Worrall and Heather Harris Wright

Abstract

Purpose: Speech and language pathology (SLP) for aphasia is a complex intervention delivered to a heterogeneous population within diverse settings. Simplistic descriptions of participants and interventions in research hinder replication, interpretation of results, guideline and research developments through secondary data analyses. This study aimed to describe the availability of participant and intervention descriptors in existing aphasia research datasets.

Method: We systematically identified aphasia research datasets containing ≥ 10 participants with information on time since stroke and language ability. We extracted participant and SLP intervention descriptions and considered the availability of data compared to historical and current reporting standards. We developed an extension to the Template for Intervention Description and Replication checklist to support meaningful classification and synthesis of the SLP interventions to support secondary data analysis.

Result: Of 11, 314 identified records we screened 1131 full texts and received 75 dataset contributions. We extracted data from 99 additional public domain datasets. Participant age (97.1%) and sex (90.8%) were commonly available. Prior stroke (25.8%), living context (12.1%) and socio-economic status (2.3%) were rarely available. Therapy impairment target, frequency and duration were most commonly available but predominately described at group level. Home practice (46.3%) and tailoring (functional relevance 46.3%) were inconsistently available.

Conclusion: Gaps in the availability of participant and intervention details were significant, hampering clinical implementation of evidence into practice and development of our field of research. Improvements in the quality and consistency of participant and intervention data reported in aphasia research are required to maximise clinical implementation, replication in research and the generation of insights from secondary data analysis.

Systematic review registration: PROSPERO CRD42018110947

Keywords: stroke, aphasia, speech and language therapy, complex interventions

Introduction

Speech and language pathology (SLP) for aphasia is a complex, multifaceted intervention delivered to a highly heterogeneous population across a range of possible clinical settings (Medical Research Council, 2008). Stroke survivors with aphasia present with individual language, social and cognitive case histories and unique stroke and aphasia profiles which

impact on their therapy goals, rehabilitation, activities and participation in life after stroke (Brookshire, 1983; Douiri et al., 2017; Roberts, Code, & McNeil, 2003). Therapists differ in their level of experience (from those that are newly qualified to those with many years of experience) and post-qualification training (some participating in specialist conferences

Correspondence: Marian C. Brady, Nursing Midwifery and Allied Health Professions Unit, Glasgow Caledonian University, Glasgow, UK. Email: m.brady@gcu.ac.uk

ISSN 1754-9507 print/ISSN 1754-9515 online © 2020 The Author(s). Published by Informa UK Limited, trading as Taylor & Francis Group

This is an Open Access article distributed under the terms of the Creative Commons Attribution-NonCommercial-NoDerivatives License (<http://creativecommons.org/licenses/by-nc-nd/4.0/>), which permits non-commercial re-use, distribution, and reproduction in any medium, provided the original work is properly cited, and is not altered, transformed, or built upon in any way.

Published by Taylor & Francis

DOI: 10.1080/17549507.2020.1762000

or training while others may not have that opportunity). Implementation of evidence-based SLP may be adapted to the local clinical culture, context or resources (Palmer, Witts, & Chater, 2018). For example, therapy assistants, family members or other trained volunteers may also be engaged to deliver rehabilitation programmes.

Clinically, therapists tailor interventions to the individual, reflecting the patient’s goals, functional needs, remaining language skills and pattern of impairments. Availability of services in the context of increasing fiscal constraints on rehabilitation provision is also a consideration. The frequency (speech-language therapy days per week), intensity (hours per week), overall duration of input (total weeks) and dosage of therapy regimen (total hours) need to be adapted to patients’ preferences, tolerance, mental capacity and support by significant others (for example, regarding transport or home practice) (Figure 1). Strong theoretical reasons and early empirical evidence suggest that some of the factors listed above may impact on stroke rehabilitation and recovery (Brady, Kelly, Godwin, Enderby, & Campbell, 2016; Van Peppen et al., 2004) yet reporting of these features in the research context appears arbitrary.

Increasingly, aphasia healthcare professionals and researchers are working towards greater consistency

in their terminology, co-ordination of effort and research transparency (Brookshire, 1983; Roberts et al., 2003; Wallace et al., 2018; Worrall et al., 2016). Clinically, intervention descriptions need to be transparent and provide sufficient detail (rationale, processes, materials, regimen, tailoring and importance of adherence) to inform patients, family members and healthcare professionals about SLP (Brady, Clark, Dickson, Paton, & Barbour, 2011; Frost, Levati, McClurg, Brady, & Williams, 2017; Hilton, Leenhouts, Webster, & Morris, 2014; Intercollegiate Stroke Working Party, 2016; Lawton, Sage, Haddock, Conroy, & Serrant, 2018) (Figure 1). This level of understanding is essential if we are to support treatment fidelity (e.g. Lawton et al., 2018; Ball, de Riesthal, & Steele, 2018; Roulstone, 2015). The agreed aphasia research core outcome set ensures that future research will consider the effectiveness of interventions in relation to the outcomes considered important to people with aphasia, their families and healthcare professionals. Shared core outcomes also support greater co-ordination across aphasia research activities and will facilitate future secondary data analysis efforts (Brookshire, 1983; Roberts et al., 2003; Wallace et al., 2018; Worrall et al., 2016).

Interpretation of SLP research evidence, clinical implementation and secondary data analysis however is hampered by the limited transparency relating to

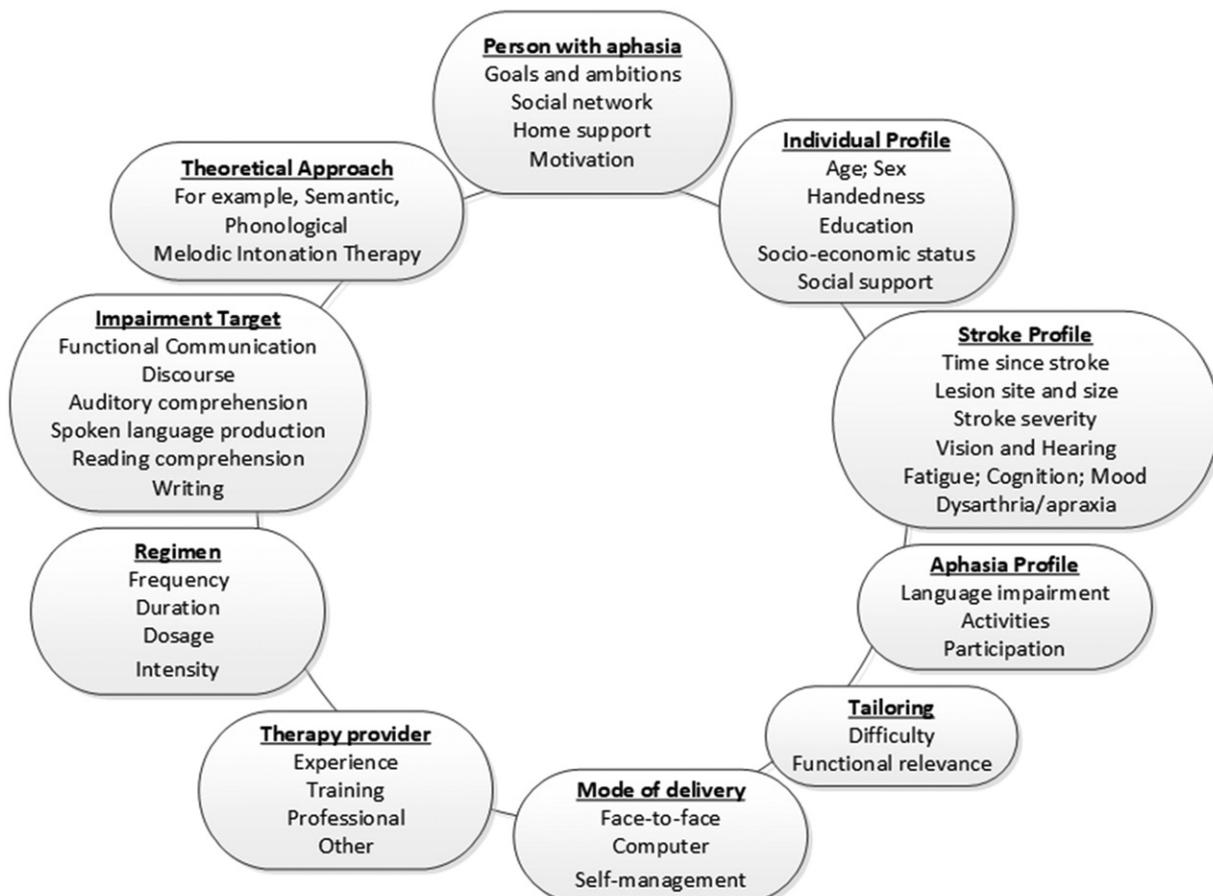


Figure 1. Complexity of speech and language interventions for aphasia after stroke.

the participant and intervention descriptions (Roulstone, 2015; Brady et al., 2016). Where descriptions are poor, replication and clinical implementation of these interventions becomes a challenge. Greater transparency facilitates replication in research, generalisation to clinical settings, and continued development of the field of science (Glasziou et al., 2014; Julious et al., 2014; Bernhardt et al., 2016; Brady et al., 2018; Downing et al., 2016; Jørgensen et al., 2000). Better reporting of participants and interventions supports timely, cost effective, secondary data analyses which can lead to new insights into the effectiveness of therapy or the identification of previously hidden biases (Lee, Alexander, Hammill, Pasquali, & Peterson, 2001; Downing et al., 2016). Guidelines have been developed to improve the quality of research design and complex intervention reporting (Stewart et al., 2015). The adoption of these guidelines in aphasia research will in turn reduce future aphasia research waste (Chalmers & Glasziou, 2009).

People with aphasia are a highly heterogeneous population, known to experience barriers to research participation (Boden-Albala et al., 2015). Thus, every effort should be made to gain new insights through the re-use of existing research data through secondary data meta-analysis. Inconsistent participant description however impedes the generalisability of findings, prevents clinicians' consideration of whether research participants reflect their own case-load and precludes secondary data analysis from combined datasets. Robust subgroup analysis on a highly heterogeneous group requires a very large sample size with sufficient information on individual participant profiles (Altman et al., 2001).

Over the last three decades, there have been calls for greater consistency in participant descriptions in aphasia research (Brady et al., 2014; Brookshire, 1983; Hallowell, 2008; Roberts et al., 2003). Since 1983 audits of published papers have highlighted participant description inconsistencies across aphasia research reports (Brookshire, 1983). A later audit of aphasia articles published from 2001 to 2002, found that only half reported 9 of 43 variables considered: age (92%), sex (91%), lesion location (83%), time since onset (83%), aphasia severity (82%), aetiology (80%), type of aphasia (78%), handedness (60%) and education (55%) (Roberts et al., 2003). A more recent review reported that two thirds of SLP for aphasia randomised controlled trials (RCTs) had inadequate between-group participant comparison data at baseline (Brady et al., 2016).

Recent methodological developments have provided SLP research with much needed infrastructural and terminology support to describe (and evaluate) SLP interventions for aphasia (Hoffmann et al., 2014, Medical Research Council, 2008). More than 23 different approaches to SLP for aphasia after stroke have been evaluated in the context of a RCTs

(Brady et al., 2016). Many more have been examined within alternative research designs. Overly simplistic or incomplete descriptions of participants and interventions in aphasia research also negatively impact on international treatment guidelines. We considered to what extent participants and interventions were described in the aphasia rehabilitation recommendations from the Australian and the UK national stroke clinical guidelines (Table I) (Rohde, Worrall, & Le Dorze, 2013, Intercollegiate Stroke Working Party, 2016). In contrast with the recommendations made relating to rehabilitation for arm function after stroke (Table I) (Rohde et al., 2013, Intercollegiate Stroke Working Party, 2016), the recommendations relating to aphasia rehabilitation lacked specific intervention details (such as intensity, timing and dosage) and target population information (such as severity and age). The paucity of intervention and target population details may be symptomatic of the inadequate description of participants and interventions in aphasia research to date.

Aim

In this article, we describe what participant and intervention descriptors were available following data extraction from aphasia datasets, systematically gathered and synthesised in the RELEASE research archive.

Method

We systematically identified pre-existing aphasia datasets with individual participant data (IPD) using a pre-specified protocol (PROSPERO CRD42018110947), reported in-depth elsewhere (Brady et al., 2020). Briefly, following a systematic review of the literature using a range of electronic databases, we identified and invited the contribution of all datasets which included IPD on at least 10 people with aphasia following stroke, detailing the aphasia severity (measured by functional language use, overall aphasia severity, expressive language, auditory comprehension, reading comprehension or writing) and time since stroke. Most study designs with suitable ethical permissions were eligible for inclusion. We did not include qualitative or aggregated group data. All identified records were screened for eligibility. Abstracts and full texts were independently reviewed by two reviewers. Disagreements were resolved by a third. Research teams that contributed their data to the RELEASE database were invited to participate in the collaboration. In addition, relevant IPD available in the public domain was extracted and included. For all included datasets, we extracted information on the participants and (where applicable) SLP interventions using relevant reporting checklists (Hoffmann et al., 2014) (Table II). We extracted information on each dataset from published and unpublished reports, further supplemented with information

Table I. Overview of therapy recommendations* for aphasia (a) and arm function (b) from two exemplar national stroke clinical guidelines (Intercollegiate Stroke Working (ISW) Party, 2016; Stroke Foundation, 2017).

Intervention	Regimen	Population	Guideline
(a) Aphasia Recommendations			
Low or high-tech aids	—	—	UK and AUS
Train person + family	—	—	UK and AUS
Goal setting for therapy	—	—	AUS
Tailored	—	—	AUS
Language and communication practice	As tolerated	Within first 4 months after stroke	UK
Assistant, family member, volunteer guided by SLP	—	—	UK
Computer practice	—	>Four months after stroke	UK
Impairment based or functional treatment	—	>Four months after stroke	UK
—	As early as tolerated	—	AUS
Direct language therapy	Intensive (at least 45 min) 5 days per week	First month after stroke	AUS
(b) Arm function recommendations			
Constraint-induced movement therapy	Intensive for a minimum of 2 h per day for 2 weeks plus restraint for at least 6 h a day (AUS)	Active wrist and finger extension	UK & AUS
Mental practice with motor training	Adjunct to therapy (UK)	Mild-moderate weakness of arm; (if cognitively able (UK)	UK & AUS
Practice functional activities, repetitive movements that are task specific	Every opportunity; high intensity	Bilateral or unilateral	UK
Repetitive, task specific training	—	Some voluntary movement of hand and arm	AUS
Mechanically assisted (e.g. robotics)	Only as adjunct to conventional therapy in a trial (UK)	(Mild-severe weakness) (AUS)	UK & AUS
Virtual reality	Minimum 15 h dosage	Mild-moderate arm impairment; Best within 6 months of stroke	AUS
Interactive games	Minimum 15 h dosage	Mild-moderate arm impairment; Best within 6 months of stroke	AUS
Electrical stimulation with motor training	—	Mild-severe; hand or arm weakness	AUS
Electrical stimulation	Only as adjunct to conventional therapy in a trial	—	UK
Mirror therapy	As adjunct to usual therapy	Mild-moderate weakness; complex regional pain syndrome or neglect	AUS

*Recommendations relating to screening for aphasia, the importance of delivering therapy to people with aphasia, assessment or reassessment, and information provision activities were excluded from this table which focuses specifically on therapy interventions.

Table II. Participant and speech and language pathology intervention data extraction items.

Participants	
Demographics	Age, sex, handedness, ethnicity, cognition, educational background, previous occupation; participant inclusion and exclusion criteria, languages spoken
Stroke	Time since stroke ^a , stroke severity (at baseline), stroke type (ischemic or haemorrhagic), hemisphere of stroke, prior stroke, mental health (depression, anxiety), cognition prior to stroke, cognition following stroke, dementia, pre-existing neurological diagnosis, visual impairment, hearing impairment, co-existing health concerns (e.g. hypertension), apraxia, dysarthria
Environmental details	Living context prior to stroke, living context following stroke, social support (marital status), socio-economic status
Speech and language pathology (based on the TIDieR checklist)	
Why	Rationale, theory, therapy goal
What was delivered	Materials, procedures, supporting activities
Who provided	Expertise, training, research specific training, SLP or not
How was therapy provided	Face-to-face, telephone, computer-based; telerehabilitation; 1-to-1, group therapy
Where	Therapy context
How much	Regimen, frequency (number of days each week); duration (total length of therapy intervention); intensity (hours of therapy per week); dosage (total number of therapy hours)
Tailoring	By difficulty; by functional relevance
Modifications	To primary study protocol
Adherence	To clinical based intervention To home practice tasks (if prescribed)

^aInclusion criteria.

gathered through direct communication with the primary researchers.

We extended the original Template for Intervention Description and Replication (TIDieR) checklist for our data extraction purposes (Hoffmann

et al., 2014). The TIDieR checklist encourages detailed narrative descriptions of interventions' rationale, theory or therapy goals (relating to the "WHY" checklist item) and the materials and procedures used (relating to the "WHAT" checklist item).

Detailed information on these items is essential to replication and clinical implementation of an intervention (Hoffmann et al., 2014). For our purposes however, the disparate narrative descriptions of SLP interventions extracted from study reports were not conducive to data synthesis, omitted specific classification of the SLP approach which in turn, hindered meaningful secondary data analysis. Where details were available, an experienced speech and language pathologist grouped similar approaches and assigned interventions to one or more category labels based on (a) the role in the study design (social support attention control, SLP, conventional therapy), (b) theoretical approach underpinning the intervention and (c) language impairment targeted. Preliminary categorisations were shared with the RELEASE collaborators ($n = 68$) (comprising contributing aphasia trialists and investigators) for review, comment and agreement via email. A videoconference supported further discussion to resolve any discrepancies in categorisation. During this discussion, two additional theoretical approaches were added; verbal therapy and multimodal therapy (Pierce, O'Halloran, Togher, & Rose, 2019). Thus, a total of nine theoretical categories and seven language impairment target categories were agreed upon. These were not mutually exclusive but reflected different ways of describing highly complex interventions (Brady et al., 2019). Where intervention descriptions were incomplete, classifications were difficult or only partially possible. Some interventions for example, were only categorised by their language impairment target but not the theoretical approach.

Result

Our systematic search of the literature generated 11 314 records of which we screened 2341 relevant abstracts and 1131 full texts. We invited contributions from 698 potentially eligible datasets and received 75 electronic dataset contributions (3940 IPD) and extracted IPD from an additional 99 public domain datasets (1988 IPD). Thus, our database included 174 datasets (91 referring to an SLP intervention; 45 RCTs) representing 5928 people with aphasia following stroke. Where details were available, data collection took place from 1973 to 2016 or was published between 1973 and 2017.

Participants

Participant inclusion and exclusion criteria were available for two-thirds of the 174 datasets (115; 66%). Selection criteria described pre-existing neurological damage (85; 48.9%); cognitive impairment (100; 57.5%); depression (62; 35.6%); significant hearing impairment (82; 47.1%); visual impairment (35; 20.1%); dysarthria (19; 10.9%) and apraxia of speech (34; 19.5%).

Our RELEASE inclusion criteria specified IPD on time since stroke and aphasia severity (or language impairment). Most datasets had details of participants' age (97.1%) and sex (90.8%) but other participant descriptors were less frequently described (for example, living context (21/174 datasets, 12.1%; 701 IPD)). Socio-economic status was available for 175 IPD (4/174 datasets, 2.3%) but additional (non-aggregatable) data were also available such as occupation or occupational status prior to or following stroke (1626 IPD) (Table III).

We lacked handedness information for a third of participants (2049 IPD, 34.6%) (Table III). Information on the index stroke and co-existing health issues were limited. Whether the index stroke was a first or subsequent stroke (45/174 datasets; 25.8%) and stroke severity at baseline (measured using National Institute of Health Stroke Scale [8/174 datasets; 4.6%], modified Rankin Scale (Bonita & Beaglehole, 1988) [6/174 datasets; 3.4%] or Barthel Index (Wade & Collin, 1988) [5/174 datasets; 2.9%]) was seldom available.

Participants' mono- or multilingualism (and the languages spoken) was rarely available (12/174; 6.9%; 526 IPD) though the language of data collection highlighted a predominance of English-language datasets (3162/5928; 53.3%). The remainder of data was collected across 22 other languages with German (420 IPD), the next most frequent data collection language. Participants' living context during the intervention period (and thus a reflection of their social support and functional practice opportunities) was only available for 701 participants (21/174 datasets; 12.1%) though the context of SLP was available for most (65/67; 97%).

Information on participants' age was slightly more available than previously reported (up from 91–92% to 97%; Table IV). Other potentially important data items highlighted in previous audits (Brookshire, 1983, Roberts et al., 2003) were also unavailable in the datasets; handedness (63.8%), multilingualism (6.9%), occupation (17%), vision (20%), hearing (52%), stroke severity (4.6%), and prior stroke (25.9%) (Table IV). Other rarely available information that we extracted was socio-economic status (2.3%) and ethnicity (13.8%).

Interventions

Approximately half of the RELEASE datasets referred to an SLP intervention (91/174, 52.3%; 2746 IPD; 46.3%). Only 67 (2330 IPD) sought to evaluate the benefit of SLP by capturing language data both prior to and following the intervention. We considered the completeness of those 67 SLP intervention descriptions (Table V). Eight SLP intervention studies (11.9%, 529 IPD, 22.7%) described therapy only in very general terms (e.g. "conventional therapy"). More detailed categorisation was not possible. Using our extended TIDieR framework, we

Table III. Participant descriptors in datasets.

Variable	IPD available (%)	IPD <i>n</i> = 5928 (%)	Datasets <i>n</i> = 174 (%)
Sex			
Female	2143 (38.6)	5550 (93.6)	158 (90.8)
Male	3407 (61.4)		
Handedness			
Right	3719 (95.9)	3879 (65.4)	111 (63.8)
Left	133 (3.4)		
Ambidextrous	27 (0.7)		
Ethnicity			
Asian	248 (16.8)	1475 (24.9)	24 (13.8)
Black	67 (4.5)		
Hispanic/Latino	9 (0.6)		
Mixed	2 (0.1)		
Other	33 (2.2)		
White	1116 (75.7)		
Living context			
Alone	146 (20.8)	701 (11.8)	21 (12.1)
Formal care environment	70 (10.0)		
Living with others	473 (67.5)		
Mixed	12 (1.7)		
Stroke			
Ischaemic	2795 (81.8)	3416 (57.6)	97 (55.7)
Intracerebral haemorrhage	547 (16.0)		
Subarachnoid haemorrhage	31 (0.9)		
Mixed	42 (1.2)		
Aneurysm	1 (0.03)		
Hemisphere			
Left	3965 (96)	4130 (69.7)	130 (74.7)
Right	81 (2.0)		
Bilateral	84 (2.0)		
Prior stroke			
Yes	110 (8.6)	1274 (21.5)	45 (25.9)
No	1164 (91.4)		
Socioeconomic status (excl. postcode, occupation, education, deprivation index)	175 (3.0)	175 (3.0)	4 (2.3)
Visual impairment			
Corrected	312 (20.9)	1494 (25.2)	35 (20.1)
No impairment ^a	1122 (75.1)		
Impairment present (unspecified) ^a	60 (4.0)		
Cognitive impairment			
No impairment ^a	3347 (84.8)	3945 (66.5)	100 (57.5)
Impairment present (unspecified) ^a	7 (0.2)		
Assessment score reported	591 (15.0)		
Dysarthria			
No dysarthria ^a	634 (67.7)	937 (15.8)	19 (10.9)
No or mild dysarthria ^a	178 (19.0)		
Dysarthria present (unspecified) ^a	125 (13.3)		
Apraxia			
No apraxia ^a	606 (59.9)	1011 (17.1)	34 (19.5)
Apraxia present (unspecified) ^a	375 (37.1)		
Assessment score available	30 (3.0)		
Depression			
Present ^a	352 (17.0)	2075 (35.0)	62 (35.6)
Absent ^a	1723 (83.0)		
	Median [IQR]	IPD <i>n</i> = 5928 (%)	Datasets <i>n</i> = 174 (%)
Age (years)	63 [53–72]	5785 (97.6)	169; 97.1
Education	12 [10, 16]	3125 (52.7)	84 (48.3)
Stroke severity			
National Institute of Health Stroke Scale (NIHSS)	11 [5–17]	716 (12.1)	8 (4.6)
Modified Rankin Scale (mRS)	4 [3–4]	489 (8.2)	6 (3.4)
Barthel Index (BI)		442 (7.5)	5 (2.9)
0–20 scale	16 [9–20]		
0–100 scale	60 [15–95]		

IPD: individual participant data; IQR: interquartile range.

^aVia categorical description.

were able to categorise 45 of the 67 interventions by their theoretical approach (67% of the datasets; 838/2330 IPD, 35.9%) and 41 by their impairment target. One intervention could target more than one aspect of language recovery and so categories were not mutually exclusive. Spoken language impairment was most commonly targeted (41 interventions, of which 30 interventions targeted naming). Few intervention

descriptions mentioned targeting reading and writing recovery (Table V).

Other therapy descriptors were also extracted (where available) including therapy provider, mode of delivery, context, therapy regimen and tailoring (Table V). Information on the therapy frequency, duration, intensity and dosage information was available for most interventions at group level (Table V).

Table IV. Descriptions of aphasia research participants; comparison of data availability.

Participant descriptor	Brookshire 1983 (<i>n</i> = 52) %	Roberts et al. (2003) (<i>n</i> = 100) %	RELEASE 2019 (<i>n</i> = 174) %
Age	91	92	97
Sex	48	91	91
Handedness	23	60	64
Education	35	55	48
SES	—	—	2
Ethnicity	—	—	14
Native Language	15 (of English)	41	—
Presence of bi/multilingualism	—	19	7
Occupation	—	36	17
IQ	3	1 (Pre-morbid)	58 (Cognitive impairment)
Social integration	—	10	12 (Living context)
Personality	—	5	—
Depression	3 (Mood/alertness)	4	36
Medical status	—	Diabetes 1 Hypertension 5	Diabetes 5 Hypertension 6
Vision	4 (Hemianopia) 2 (Acuity)	17	20
Hearing	19	30	52
Type of stroke	—	22	56
Lesion location	53 (Hemisphere) 13 (Within hemisphere)	83	75 (Hemisphere)
Stroke severity	—	—	5 ^b
Hemiplegia	10 (Hemiparesis)	—	—
Aetiology	49	80	100 ^a
Prior stroke	—	24	26
Aphasia severity	64	82	100 ^a
Time since onset	60	83	100 ^a
Type of aphasia	54	78	—
Dysarthria	—	14	11
Apraxia of speech	—	28	20
Prior treatment	—	24	—
Recruitment location	28	30	100

—: did not extract this data; SES: socio-economic status.

^aInclusion criteria therefore 100% of this dataset;

^bBased on National Institute of Health Stroke Scale.

Tailoring of SLP to the individuals' level of language difficulty was described by 42 of the datasets investigating interventions (62.7%; 1145 IPD). A third of datasets (22 datasets; 649 IPD) described tailoring SLP for functional relevance but few mentioned the prescription of home practice tasks or referred to measures of adherence, elements closely linked to the dosage of an intervention.

Methodological details

Modifications to the therapy protocol were rarely described. Methodological details such as the date of study entry (79/174; 45.4%), a full account of participant dropouts (a third of datasets described dropouts) and the use of blinded outcome assessors are important markers of research methodological quality (unreported for 92/174; 52.9%). Similarly, randomisation details including adequate sequence generation (28/45 RCTs; 62.2%) and concealment of allocation (21/45 RCTs; 46.7%) were available for some of the RCTs.

Discussion

Inadequate descriptions of participants in aphasia research has continued over an extended period of time (Brookshire, 1983; Roberts et al., 2003; Brady et al., 2014). In our more detailed approach to data retrieval, we extracted data from both published

papers, unpublished sources of information and directly from the primary researchers. We also found gaps in participant information availability. Despite access to IPD datasets, descriptions of SLP interventions were rarely available at IPD level. Most were only available at group level and often lacked information on an intervention's theoretical approach or tailoring of materials for functional relevance to the participants. Few datasets described methodological details such as study withdrawals. Study withdrawals amongst a stroke survivor population are not uncommon. Aphasia researchers should be encouraged to report whether there were study withdrawals (with reasons) because of the valuable insights this may generate into the feasibility and acceptability of an intervention. Despite the advances made across aphasia research in recent times, key participant, intervention and methodological details are lost to the research process.

We adopted a systematic approach to the identification of IPD datasets with no exclusions by date, language or publication status. Only those IPD datasets meeting our inclusion criteria, contributed by the primary research team or available in the public domain were included (Brady et al., 2019). Our RELEASE inclusion criteria which specified aphasia following stroke and IPD on time since stroke and language impairment may have excluded datasets with particularly poor participant and intervention descriptions, which failed to report these and other

Table V. Descriptions of speech and language pathology interventions for aphasia after stroke (RELEASE dataset) using an extended TIDieR framework.

Description of intervention	IPD <i>n</i> = 2330 (%)	Datasets <i>n</i> = 67 (%)
SLP by theoretical approach ^{a,b}		
Semantic	34 (1.5)	2 (1.5)
Phonological	124 (5.3)	9 (13.4)
Semantic and phonological	260 (11.2)	15 (22.4)
Functional and pragmatic	246 (10.6)	8 (11.9)
Constraint Induced aphasia therapy	113 (4.8)	7 (10.4)
Melodic intonation therapy	61 (2.6)	4 (6.0)
Conversational partner training	55 (2.4)	2
Verbal therapy	887 (38.1)	43
Multimodal therapy	308 (13.2)	13
SLP by language impairment target ^{a,b}		
Spoken language; of which naming (or word-finding) and other spoken language	734 (31.5)	41
	489 (21.0)	30
	245 (10.5)	11
Auditory comprehension	68 (2.9)	4
Auditory comprehension and spoken language	651 (27.9)	24
Reading	10 (0.4)	1
Writing	0	0
Who provided SLP ^b		
Professional	1871 (80.3)	62 (92.5)
Non-professional	274 (11.8)	7 (10.4)
How was SLP provided (mode of delivery) ^b		
Face-to-face	1957 (84.0)	60 (89.6)
Computer	315 (13.5)	15 (22.4)
Telephone	15 (0.6)	1 (1.5)
Constraint induced aphasia therapy	113 (4.8)	7 (10.4)
Self-managed	106 (4.5)	4 (6.0)
One-to-one	1613 (69.2)	47 (70.1)
Group	148 (6.4)	8 (11.9)
Mixed	207 (8.9)	9 (13.4)
Where was SLP provided ^b		
Clinic, hospital or rehabilitation setting	1866 (80.1)	48 (71.6)
Home	575 (24.7)	17 (23.4)
When and how much SLP ^b		
Frequency (days per week)	2057 (88.3)	66 (98.5)
Duration (weeks)	1960 (84.1)	64 (95.5)
Intensity (hours per week)	1882 (80.8)	60 (89.6)
Dosage (total hours)	1978 (84.9)	62 (92.5)
Home practice	1306 (56.1)	31 (46.3)
Tailoring ^b		
By difficulty	1393 (59.8)	42 (62.7)
By functional relevance	873 (37.5)	31 (46.3)

n: total; IPD: individual participant data.

^aExtended categories to TIDieR checklist;

^bCategories are not mutually exclusive. One intervention may appear more than once in this category.

data items. Other datasets also exist that were not contributed to our database; those that were still in use by the primary researchers, researchers that we failed to establish contact with, datasets that were of poorer quality and those that the primary researchers declined or were unable to share.

The increasing availability of checklists support high quality reporting of complex interventions such as SLP for aphasia, methodological factors which reduce the risk of bias and other research design features (EQUATOR Network, 2014). For our database, we extended the TIDieR checklist to categorise therapy interventions by (i) impairment target and (ii) theoretical approach to support a comprehensive, transparent description of interventions for aphasia, meaningful data synthesis, meta-analysis and ultimately implementation in clinical settings. We propose, in the context of SLP interventions for aphasia, the continued use of this extension to the TIDieR checklist (Hoffmann et al., 2014). In our study, the classification of SLP for aphasia using these categories was feasible and supported our data extraction and secondary data analysis.

Research implications

Detailed description of participants and interventions in aphasia research supports clinical implementation and secondary analysis insights. Despite previous calls to improve the quality of aphasia research reports, we found that many participants and SLP intervention details were unavailable, even when attempts were made to retrieve that information directly from the primary research teams. We acknowledge the importance of balancing the burden of data collection on participants and researchers and the need to gather a core dataset or meet reporting standards. However, in order to maximise the benefits of our research efforts and funding, to improve clinical practice and our field of science through a reduction of research waste, we need to gather and share information about our participants and SLP interventions. Steps should be taken now to reduce further loss of data.

Clinical implications

In our specialist field of research, amongst a heterogeneous population who experience barriers to research

participation and complex individually tailored interventions, it is vital that we maximise the use of any research data gathered. Reuse of existing datasets can support important secondary data analysis and novel exploration of new research questions while minimising research waste. Better participant description will inform therapists more clearly about the generalisability of the research findings to their clinical population and candidacy for new intervention approaches. Better reporting of interventions will provide therapists with sufficient information to ensure that effective interventions within the research context might be delivered as intended in the clinical setting thus achieving maximal gains for people with aphasia. Additional challenges are likely to remain in ensuring the implementation of effective therapy across “real-world” clinical settings, but these are beyond the scope of this particular manuscript.

We acknowledge that, in the context of a primary research study, some participant and intervention descriptors may be less centrally relevant to the interpretation of that study’s findings. Other descriptors are only recently being recognised as potentially relevant factors in recovery (e.g. socioeconomic status). Multidisciplinary consensus is required on a core dataset for participant and intervention reporting in aphasia research which is consistently adopted in future aphasia research activities. We plan to take this forward within the Collaboration of Aphasia Trialists (www.aphasiatrials.org). Consistent, high quality reporting will enhance the transparency of research evidence, support clinical replication and inform clinical guidelines which will in turn, benefit people with aphasia, their families and the healthcare professionals that work with them.

Conclusions

Current descriptions of participants and SLP interventions for aphasia after stroke are incomplete, restricting the reach of research findings, transparency, implementation and secondary data analysis. Our proposed extension to TIDieR categories will support more transparent description of SLP interventions in research reports.

Disclaimer

This report presents independent research commissioned by the National Institute for Health Research (NIHR). The views and opinions expressed in this publication are those of the authors and do not necessarily reflect those of the NHS, the NIHR, MRC, CCF, NETSCC, the HS&DR programme, the Department of Health, the Tavistock Trust for Aphasia, the Chief Scientist Office or the Scottish Government Health and Social Care Directorates.

Author Contributions

MB: Conceived, designed and led the grant application and study, assessed the risk of bias, drafted and finalised the final report; MA1, AB, EG, KH, JH, SH, DH, TK, ACL, BMacW, RP, CP, SAT, EVB, LW: Co-applicants and contributors to the grant application; FB, MG, LMTJ, MLR, IvdM: Named collaborator on grant application; MB, KVB, LRW: Screened records, abstracts and full titles, extracted data, checked data extraction and risk of bias; KVB, LRW: Retrieved papers; MA2, FB, AB, CB1, CB2, SB, DAC, TBC, MdiP-B, PE, JF, FLG, MG, BG, EG, KH, JH, SH, PJ, EJ, LMTJ, MK, EYK, EMK, AP-HK, TK, ML, MALP, ACL, BL, APL, RRL, AL, BMacW, RSM, FM, IM, MM, RN, EN, N-JP, RP, IP, BFP, IPM, CP, TPJ, ER, MLR, CR, IR-F, MBR, CS, BS, JPS, SAT, MvdS-K, IvdM, EV-B, LW, HHW: Contributed IPD primary data; LJW: Led and conducted the statistical analysis; MA1: Contributed to the statistical analysis, SH: Co-ordinated and facilitated patient and public involvement in the study; NH: Advised on the statistical analyses. All authors were involved in interpretation of the results, reviewing and approving of the final report.

Conflict of interest: **Marian Brady** reports grants from Chief Scientist Office (CSO), Scottish Government Health and Social Care Directorates, grants from EU Cooperation in Science and Technology (COST) funded Collaboration of Aphasia Scientists (IS1208 www.aphasiatrials.org), and grants from The Tavistock Trust for Aphasia during the conduct of the study, and is a member of the Royal College of Speech and Language Therapists.

Audrey Bowen reports that data from her research is included within the analyses in the RELEASE report. Her post at the University of Manchester is partly funded by research grants and personal awards from NIHR and Stroke Association.

Caterina Breitenstein reports grants from the German Federal Ministry of Education and Research (BMBF) during the conduct of the study.

Erin Godecke reports Western Australian State Health Research Advisory Council (SHRAC) Research Translation Project Grants RSD-02720; 2008/2009 during the conduct of the study.

Neil Hawkins reports grants from National Institute for Health Research during the conduct of the study.

Katerina Hilari reports grants from The Stroke Association, grants from European Social Fund and Greek National Strategic Reference Framework, and grants from The Tavistock Trust for Aphasia outside the submitted work.

Petra Jaecks reports a PhD grant from Weidmüller Stiftung.

Brian MacWhinney reports grants from National Institutes of Health.

Rebecca Marshall reports grants from National Institute of Deafness and Other Communication Disorders, NIH, USA during the conduct of the study.

Rebecca Palmer reports grants from NIHR senior clinical academic lectureship, grants from NIHR HTA, and grants from Tavistock Trust for Aphasia outside the submitted work.

Ilias Papathanasiou reports funding from European Social Fund and Greek National Strategic Reference Framework.

Jerzy Szaflarski reports personal fees from SK Life Sciences, personal fees from LivaNova Inc, personal fees from Lundbeck, personal fees from NeuroPace Inc, personal fees from Upsher-Smith Laboratories, Inc, grants and personal fees from SAGE Pharmaceuticals, grants and personal fees from UCB Pharma, grants from Biogen, grants from Eisai Inc, and other from GW Pharmaceuticals, outside the submitted work.

Shirley Thomas reports research grants from NIHR and The Stroke Association outside the submitted work.

Ineke van der Meulen reports grants from Stichting Rotterdams Kinderrevalidatiefonds Adriaanstichting, other from Stichting Afasie Nederland, other from Stichting Coolsingel, and other from Bohn Stafleu van Loghum during the conduct of the study.

Linda Worrall reports a grant from the National Health and Medical Research Council of Australia.

All other authors have declared no competing interests

Supplementary material

Supplemental data for this article can be accessed at <http://dx.doi.org/10.1080/17549507.2020.1762000>

Funding

This project was funded by the National Institute for Health Research (NIHR), Health Services and Delivery Research Programme (HS&DR-14/04/22) and the Tavistock Trust for Aphasia and will be published in full in the Health Services and Delivery Research Journal. Further information is available at <https://www.journalslibrary.nihr.ac.uk/programmes/hsdr/140422/#/>. MCB and the NMAHP Research Unit is funded by the Chief Scientist Office, Scottish Government Health and Social Care Directorates.

References

Altman, D.G., Schulz, K.F., Moher, D., Egger, M., Davidoff, F., Elbourne, D., ... Lang, T., & the CONSORT GROUP (2001). The revised CONSORT statement for reporting randomized trials: explanation and elaboration. *Annals of Internal Medicine*, 134, 663–694. doi:10.7326/0003-4819-134-8-200104170-00012

Ball, A.L., de Riesthal, M., & Steele, R.D. (2018). Exploring treatment fidelity in persons with aphasia autonomously practicing with computerized therapy materials. *American Journal of Speech Language Pathology*, 27, 454–463. doi:10.1044/2017_AJSLP-16-0204

Bernhardt, J., Borschmann, K., Boyd, L., Thomas Carmichael, S., Corbett, D., Cramer, S.C., ... Ward, N. (2016). Moving rehabilitation research forward: Developing consensus statements for rehabilitation and recovery research. *International Journal of Stroke*, 11, 454–458. doi:10.1177/1747493016643851

Boden-Albala, B., Carman, H., Southwick, L., Parikh, N.S., Roberts, E., Waddy, S., & Edwards, D. (2015). Examining barriers and practices to recruitment and retention in stroke clinical trials. *Stroke*, 46, 2232–2237. doi:10.1161/STROKEAHA.114.008564

Bonita, R., & Beaglehole, R. (1988). Modification of Rankin Scale: Recovery of motor function after stroke. *Stroke*, 19, 1497–1500. doi:10.1161/01.STR.19.12.1497

Brady, M.C., Ali, M., Fyndanis, C., Kambanaros, M., Grohmann, K.K., Laska, A.C., ... Varlokosta, S. (2014). Time for a step change? Improving the efficiency, relevance, reliability, validity and transparency of aphasia rehabilitation research through core outcome measures, a common data set and improved reporting criteria. *Aphasiology*, 28, 1385–1392. doi:10.1080/02687038.2014.930261

Brady, M.C., Ali, M., VandenBerg, K., Williams, L.J., Williams, L.R., Abo, M., ... Wright, H.H. (2020). RELEASE: a protocol for a systematic review based, individual participant data, meta- and network meta-analysis, of complex speech-language therapy interventions for stroke-related aphasia. *Aphasiology*, 34, 137–157. doi:10.1080/02687038.2019.1643003

Brady, M.C., Clark, A.M., Dickson, S., Paton, G., & Barbour, R.S. (2011). Dysarthria following stroke: the patient's perspective on management and rehabilitation. *Clinical Rehabilitation*, 25, 935–952. doi:10.1177/0269215511405079

Brady, M.C., Godwin, J., Kelly, H., Enderby, P., Elders, A., & Campbell, P. (2018). Attention control comparisons with SLT for people with aphasia following stroke: methodological concerns raised following a systematic review. *Clinical Rehabilitation*, 32, 1383–1395. doi:10.1177/0269215518780487

Brady, M.C., Kelly, H., Godwin, J., Enderby, P., & Campbell, P. (2016). Speech and language therapy for aphasia following stroke. *Cochrane Database of Systematic Reviews*, (6). Art. No.: CD000425. doi:10.1002/14651858.CD000425.pub4

Brookshire, R.H. (1983). Subject description and generality of results in experiments with aphasic adults. *Journal of Speech and Hearing Disorders*, 48, 342–346. doi:10.1044/jshd.4804.342

Chalmers, I., & Glasziou, P. (2009). Avoidable waste in the production and reporting of research evidence. *Obstetrics & Gynecology*, 114, 1341–1345. doi:10.1097/AOG.0b013e3181c3020d

Douiri, A., Grace, J., Sarker, S.-J., Tilling, K., McKeivitt, C., Wolfe, C.D.A., & Rudd, A.G. (2017). Patient-specific prediction of functional recovery after stroke. *International Journal of Stroke*, 12, 539–548. doi:10.1177/1747493017706241

Downing, N.S., Shah, N.D., Neiman, J.H., Aminawung, J.A., Krumholz, H.M., & Ross, J.S. (2016). Participation of the elderly, women, and minorities in pivotal trials supporting 2011–2013 U.S. Food and Drug Administration approvals. *Trials*, 17, 199. doi:10.1186/s13063-016-1322-4

EQUATOR Network. (2014). Retrieved from www.equator-network.org

Frost, R., Levati, S., McClurg, D., Brady, M., & Williams, B. (2017). What adherence measures should be used in trials of home-based rehabilitation interventions? A systematic review of the validity, reliability, and acceptability of measures. *Archives of Physical Medicine and Rehabilitation*, 98, 1241–1256. doi:10.1016/j.apmr.2016.08.482

Glasziou, P., Altman, D.G., Bossuyt, P., Boutron, I., Clarke, M., Julious, S., ... Wager, E. (2014). Reducing waste from

- incomplete or unusable reports of biomedical research. *The Lancet*, 383, 267–276. doi:10.1016/S0140-6736(13)62228-X
- Hallowell, B. (2008). Strategic design of protocols to evaluate vision in research on aphasia and related disorders. *Aphasiology*, 22, 600–617. doi:10.1080/02687030701429113
- Hilton, R., Leenhouts, S., Webster, J., & Morris, J. (2014). Information, support and training needs of relatives of people with aphasia: Evidence from the literature. *Aphasiology*, 28, 797–822. doi:10.1080/02687038.2014.906562
- Intercollegiate Stroke Working Party, (2016). National Clinical Guidelines for Stroke. Fifth Edition. Retrieved from <https://www.strokeaudit.org/Guideline/Full-Guideline.aspx>
- Jørgensen, H.S., Kammersgaard, L.P., Houth, J., Nakayama, H., Raaschou, H.O., Larsen, K., ... Olsen, T.S., et al. (2000). Who benefits from treatment and rehabilitation in a stroke Unit? A community-based study. *Stroke*, 31, 434–439. doi:10.1161/01.STR.31.2.434
- Lawton, M., Sage, K., Haddock, G., Conroy, P., & Serrant, L. (2018). Speech and language therapists' perspectives of therapeutic alliance construction and maintenance in aphasia rehabilitation post-stroke. *International Journal of Language & Communication Disorders*, 53, 550–563. doi:10.1111/1460-6984.12368
- Lee, P.Y., Alexander, K.P., Hammill, B.G., Pasquali, S.K., & Peterson, E.D. (2001). Representation of Elderly Persons and Women in Published Randomized Trials of Acute Coronary Syndromes. *JAMA*, 286, 708–713. doi:10.1001/jama.286.6.708
- Medical Research Council. (2008). Developing and evaluating complex interventions: new guidance. <https://mrc.ukri.org/documents/pdf/complex-interventions-guidance/>
- The National Institute of Neurological Disorders and Stroke rt-PA Stroke Study Group (1995). Tissue plasminogen activator for acute ischemic stroke. *The New England Journal of Medicine*, 333, 1581–1587.
- Palmer, R., Witts, H., & Chater, T. (2018). What speech and language therapy do community dwelling stroke survivors with aphasia receive in the UK?. *PLoS One*, 13, e0200096. doi:10.1371/journal.pone.0200096
- Pierce, J.E., O'Halloran, R., Togher, L., & Rose, M.L. (2019). What is meant by "Multimodal Therapy" for aphasia? *American Journal of Speech-Language Pathology*, 28, 706–716. doi:10.1044/2018_AJSLP-18-0157
- Roberts, P., Code, C., & McNeil, M. (2003). Describing participants in aphasia research: Part 1. Audit of current practice. *Aphasiology*, 17, 911–932. doi:10.1080/02687030344000328
- Rohde, A., Worrall, L., & Le Dorze, G. (2013). Systematic review of the quality of clinical guidelines for aphasia in stroke management. *Journal of Evaluation in Clinical Practice*, 19, 994–1003. doi:10.1111/jep.12023
- Roulstone, S. (2015). Exploring the relationship between client perspectives, clinical expertise and research evidence. *International Journal of Speech-Language Pathology*, 17, 211–221. doi:10.3109/17549507.2015.1016112
- Stewart, L.A., Clarke, M., Rovers, M., Riley, R.D., Simmonds, M., Stewart, G., & Tierney, J.F. (2015). Preferred reporting items for systematic review and meta-analyses of individual participant data: The PRISMA-IPD statement. *JAMA*, 313, 1657–1665. doi:10.1001/jama.2015.3656
- Stroke Foundation (2017/2019). Clinical Guidelines for Stroke Management. Melbourne Australia.
- Van Peppen, R.P., Kwakkel, G., Wood-Dauphinee, S., Hendriks, H.J., Van der Wees, P.J., & Dekker, J. (2004). The impact of physical therapy on functional outcomes after stroke: what's the evidence?. *Clinical Rehabilitation*, 18, 833–862. doi:10.1191/0269215504cr843oa
- Wade, D.T., & Collin, C. (1988). The Barthel ADL Index: a standard measure of physical disability? *International Disabilities Studies*, 10, 64–67. doi:10.3109/09638288809164105
- Wallace, S.J., Worrall, L., Rose, T., Le Dorze, G., Breitenstein, C., & Hilari, K. (2018). A core outcome set for aphasia treatment research: The ROMA consensus statement. *International Journal of Stroke*, 14, 180–185. <http://doi.org/10.1177/1747493018806200>
- Worrall, L., Simmons-Mackie, N., Wallace, S.J., Rose, T., Brady, M.C., Kong, A.P.H., ... Hallowell, B., et al. (2016). Let's call it "aphasia": Rationales for eliminating the term "dysphasia". *International Journal of Stroke*, 11, 848–851. doi:10.1177/1747493016654487