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## **Treatment Fidelity in Aphasia Randomized Controlled Trials**

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## Treatment Fidelity in Aphasia Randomised Controlled Trials

**Background:** Treatment Fidelity is at the heart of evidence based practice and treatment fidelity processes help to determine the ‘active ingredients’ of a treatment. Hinckley and Douglas in 2013 reviewed treatment fidelity processes in published aphasia trials and found 14% of aphasia treatment studies reported treatment fidelity. This led the authors to call for journals to make treatment fidelity reporting mandatory. **Aims:** To review the implementation and reporting of treatment fidelity processes in recent aphasia RCTs to update on practices since 2012. **Methods and Procedures:** Aphasia RCTs published between 2012-2017 were sourced from online databases speechBITE, MEDLINE and CINAHL provided they were: a) an investigation of an impairment based treatment for post stroke aphasia; b) not a review, protocol, feasibility or replication study c) not a surgical or pharmacological intervention and d) published in English. Articles meeting the criteria were rated using Bellg’s treatment fidelity areas with the Template for Intervention Description and Replication (TIDieR) checklist elements. **Outcomes and Results:** This search retrieved 110 articles and 42 met the above criteria. Nine (21%) articles explicitly reported on treatment fidelity processes. One article (2%) contained every element of the recommended treatment fidelity areas. Thirty-seven (88%) articles addressed the study design aspect of treatment fidelity by investigating therapy dosage. The least addressed aspect of treatment fidelity was ensuring participants used the skills gained in treatment in appropriate life settings, with two (2%) articles including this. **Conclusions:** The current review identified 21% of articles explicitly reporting treatment fidelity processes. This paper provides updated review evidence from recent RCTs and echoes recommendations for greater incorporation of treatment fidelity in research protocols and resulting publications.

Keywords: aphasia; fidelity; stroke; rehabilitation; speech language pathology

### Introduction

Aphasia, or language difficulties after stroke, affects approximately 30% of stroke survivors and has been identified as one of the top ten research priorities related to life after stroke by the Lancet (Pollock, St George, Fenton, & Firkins, 2012). The most recent systematic review by the Cochrane Collaboration acknowledged the overall benefit of aphasia therapy however established that no one treatment was more effective than another (Brady, Kelly, Godwin, Enderby, & Campbell, 2016). Within the systematic review experimental speech language pathology (SLP) treatments were

compared to ‘conventional’ SLP with insufficient detail provided in most of the studies on what therapy was implemented in this second group. This highlights the importance of investigating treatments at a sufficient level for comparison of key components. Thorough therapy fidelity reporting will assist in answering questions about why therapy works and what makes one treatment different from another. Greater clarity in the reporting of studies, beyond a surface level, may give therapists access to a sufficient level of detail to determine which treatment may be most appropriate for their client and how to replicate the research treatment within real world clinical contexts. Trials with positive treatment outcomes and demonstrated high fidelity may assist therapists translate evidence into the clinical setting.

### ***Treatment Fidelity Concept***

Treatment fidelity is the degree to which the administration of a treatment corresponds to the specified protocol for the implementation of that treatment (Kadervak & Justice, 2010).

Implementation of treatment fidelity processes enhances the reliability and validity of findings related to the impact of an intervention (Bellg et al., 2004; Walker et al., 2017). Studies with high levels of fidelity have increased external and internal validity as they may be more replicable and the details provided allow comparisons to be made between treatments (Hildebrand et al., 2012; Moncher & Prinz, 1991; Resnick et al., 2005; Schlosser, 2002). For trials with positive outcomes, treatment fidelity processes can assist in the translation of evidence into clinical practice. This is achieved through outlining the components of the prescribed (and adhered to) treatment protocol and identifying the possible active components of the intervention (Walker et al., 2017). Treatment fidelity reporting also helps explain non-significant results and assists in building a rationale for future research by identifying treatment components and processes that could be altered (Resnick et al., 2005). The cost of *not* investigating treatment fidelity is striking and could mean rejecting an effective or efficacious treatment *or* accepting an ineffective program (Borrelli et al., 2005). As per Borrelli et al. (2005, p. 858) “If a successful trial is described but adherence to protocol is not

monitored, applications of the study intervention in real world settings may be compromised or unsuccessful potentially at great cost". Additionally, some authors suggest that reporting of study treatment effects is meaningless if the treatment was not correctly implemented and/or monitored (Cordray & Pion, 2006). Sound incorporation of treatment fidelity processes can increase the researcher's confidence that the intervention outcomes are due to the effect of treatment, by ensuring that the treatment is delivered as planned. It may also increase the therapist's confidence in the research findings and the knowledge they are implementing an evidenced based treatment as it was intended.

### ***Treatment Fidelity in Research***

Treatment fidelity processes should be incorporated when designing a study, when measuring what exactly happened during the intervention and also when reporting the findings. Although including, evaluating and reporting on treatment fidelity processes should be central to an intervention study, many studies fail to adequately plan or investigate treatment fidelity or fully report their findings (Cherney, Patterson, Raymer, Frymark, & Schooling, 2008; Craig et al., 2008). If a scientific basis for clinical practice is built on studies that have not effectively incorporated treatment fidelity processes then systematic reviews, meta analyses and clinical practice guidelines can be skewed (Wheeler, Baggett, Fox, & Blevins, 2006). As treatment fidelity processes are integral at different stages of the research process, this literature review will address treatment fidelity sequentially through the planned, measured and reported components of research design.

### ***Planning Treatment Fidelity***

Treatment fidelity is at the heart of what therapists want to know about a treatment with a focus on determining what part of a treatment works. Strengthening of the research evidence component of the evidence based practice triad will allow for better integration with clinical evidence and patient preference and a clearer decision pathway for therapists (Dollaghan, 2011). This is

reflected in observations of an increased interest in understanding how interventions work (Cruice, Blom Johansson, Isaksen, & Horton, 2018). Researchers need to thoroughly plan, investigate and inform therapists about the active ingredients of their treatments and explain the ‘actual nature of the process that transforms received therapy into improved health’ (Keith & Lipsey, 1993, p. 51). This process begins at the stage of conceptualising and planning the intervention and the program of research. The conceptualisation of a theoretical framework underpinning a treatment allows the key components that underlie the intervention to be measured and reported. Adopting a treatment fidelity framework at the design stage and then developing a plan for monitoring key components of the therapy may inform the theory regarding why the intervention does or does not work as the key components are linked to the treatment outcome (Walker et al., 2017). This is important for treatment efficacy and will enhance the replication process (Turkstra, Norman, Whyte, Dijkers, & Hart, 2016).

Complex interventions are “health service interventions that are not drugs or surgical procedures but have many potential active ingredients” (Oakley, Strange, Bonell, Allen, & Stephenson, 2006) p:413). Behavioural interventions, such as those used in SLP are complex and have been described as “black boxes” referring to many potential active ingredients and interacting components (Walker et al., 2017). It is therefore important that when designing a treatment study researchers give significant consideration to the potential theoretical underpinnings of the treatment so that those components can be adequately monitored and evaluated. As such the planning and analysis of our treatments is just as complex and detailed as the treatment itself. If researchers fail to recognise potential factors of influence at the design stage, the appropriate data may not be collected and certainly not reported (Walker et al., 2017). Barriers to such planning and analysis are likely related to trial funding, time restrictions and methodological concerns. A well-researched RCT has the potential to uncover the content of the ‘black box’ of therapy, in particular accruing data on who does and does not respond to what type and what intensity of therapy (Godecke, Hird, Lalor, Rai, & Phillips, 2012). Just by virtue of a study being designed as a RCT does not mean that it will address

‘how’ and ‘why’ treatment changes communication behaviour and who will benefit from it (Dodd, 2007). There is the assumption that when a treatment is investigated and reported that treatment fidelity has been considered (Kaderavek & Justice, 2010). With the attention, effort and funding that RCTs receive, as a profession, we cannot risk them being under specified, under researched and under reported (Roulstone, 2015). The complexity of these interventions warrants a multifaceted and enriched investigation of the effects (Petticrew, 2011).

Recommendations for ways in which treatment fidelity processes can be implemented in trials have been made, including those developed by the treatment fidelity workgroup of the National Institutes of Health Behaviour Change Consortium (Bellg et al., 2004). A number of recommendations for addressing treatment fidelity in behaviour change studies are outlined across five main areas: study design, training providers, delivery of treatment, receipt of treatment and enactment of treatment skills (Bellg et al., 2004). The recommendations provide a comprehensive way to conceptualise treatment fidelity and have been used as a reference point for establishing the scope of this review. Please refer to Table 1 for an overview of these recommendations and the original article for complete descriptions (see Bellg et al., (2004)).

### *Measuring Treatment Fidelity*

Measuring treatment fidelity is not a substitute for the evaluation of treatment outcomes, rather it strengthens the meaning behind the outcomes, and aids in the interpretation of findings as it allows the researcher to show that the treatment was delivered as planned (Cordray & Pion, 2006). Analysing a study for implementation failures is complex (Brady et al., 2016). Adherence to a protocol is not binary and so it needs to be on a measurable continuum to quantify the degree to which the protocol was followed (Moncher & Prinz, 1991). As treatment fidelity is inconsistently investigated in health behaviour research (Bellg et al., 2004), there are few validated tools to use to monitor or evaluate fidelity processes in behavioural interventions (Borrelli et al., 2005). Direct observation of treatment sessions using a priori coding categories is considered the gold standard and

most thorough and objective way of measuring treatment fidelity (Kaderavek & Justice, 2010). This may come in the form of a fidelity monitor using a validated adherence and competence checklist and systematically rating the session. It serves the purpose of monitoring treatment integrity and collecting data for treatment differentiation (Hildebrand et al., 2012). Direct observation of the independent variable may be more prone to bias than dependent variable observations because the treatment variable is predefined and an observer might report what the therapist is supposed to do rather than what actually happened (Schlosser, 2002).

### *Reporting Treatment Fidelity*

Many published articles lack specific detail of treatment as it is planned and provided and therefore implementation and replication is difficult (Hoffmann et al., 2014). Guidelines such as Template for Intervention Description and Replication (TIDieR) (Hoffmann et al., 2014) have been established to encourage more complete reporting and transparency of treatments and to address the “remarkably poor” (p. 1) intervention description quality. The TIDieR statement (Hoffmann et al., 2014) includes general items related to the therapy such as task selection, therapy location and dosage. The specificity with which research is presented, in terms of the level of detail provided for the intervention and control conditions, needs to be increased to allow for a sufficient standard for replication within research and clinical contexts. A recent example of the application of the TIDieR checklist to the description of a treatment is a review of reporting standards in communication partner training (Cruice et al., 2018). Within this review it was found that 71% of studies addressed half the TIDieR checklist items. The TIDieR items that were least frequently reported in the SLP literature have been documented as the materials, tailoring and modifications (Cruice et al., 2018). Poor reporting is not unique to SLP literature. An investigation of 200 physiotherapy studies found that only 23% reported at least half of the recommended 12 TIDieR items (Yamato et al., 2016).

Concerning treatment fidelity reporting specifically, the TIDieR statement includes items 11 and 12 that reflect the planned and actual elements of treatment fidelity respectively. In the

investigation of the reporting of communication partner training these items were infrequently reported (Cruice et al., 2018). Though critical, the lack of reporting of treatment fidelity processes in journal articles may reflect a lack of knowledge or understanding of the importance of the concept. Within the broader stroke rehabilitation literature most papers have only considered one aspect of fidelity such as dose (Walker et al., 2017). Planned aspects of therapy fidelity such as developing a protocol were frequently addressed however reporting what was actually delivered in therapy was not frequently included (Cruice et al., 2018).

Research often measures rehabilitation interventions by hours of therapy but tells us little about what is done during the specified time, and therefore there is a call for treatments to be described using theory, not surface characteristics (Turkstra et al., 2016). This highlights the importance of planning treatment fidelity processes at the early research design stage to enable the theoretical underpinnings of an intervention to be monitored and then be reported on explicitly. It is also reported that there is a lack of detail surrounding the intervention given in control groups. Walker et al. (2017) reported that less than 10% of the stroke rehabilitation intervention literature fully described the control group intervention to which their intervention was being compared to (Walker et al., 2017). The authors recommended describing routine practice in sufficient detail to facilitate an indepth understanding of usual care. They questioned the professional integrity of researchers working in the field for the poor control group descriptions and highlighted the importance of treatment fidelity processes in behavioural interventions.

### *Barriers to Treatment Fidelity*

A lack of reporting of details about a treatment may not only be due to poor reporting standards as treatment fidelity may not be adequately addressed and implemented within a trial. For example the active components of aphasia treatments have not been universally established therefore, reporting the ‘therapy recipe’ accurately is a difficult task. However it is unclear whether interventions are not incorporating treatment fidelity processes into their trial design or incorporating

the processes but not reporting on them. Reasons for treatment fidelity processes being overlooked in trial design include a perceived lack of academic reward and the cost of the additional resources required to monitor treatment fidelity (Walker et al., 2017). When publishing, word limits may be prohibitive for including extra details such as treatment fidelity procedures, (Hoffmann et al., 2014) although some RCTs are publishing separate treatment fidelity specific articles to address this (Behn et al., 2018; Godecke et al., 2015; Kladouchou, Papathanasiou, Efstratiadou, Christaki, & Hilari, 2017). As with the implementation and translation of research, costs for therapy fidelity monitoring are likely difficult to capture and estimate (Damschroder et al., 2009).

### ***Treatment Fidelity in Aphasia***

A seminal paper in this area by Hinckley and Douglas (2013) outlined the findings of an investigation into the frequency of treatment fidelity reporting in the aphasia literature over a ten year span between 2002-2011. All study designs were included provided it was a self identified treatment study administered across multiple sessions. Articles that were reviews, republications of older studies and retrospective studies were excluded. The raters used binary 'yes/no' coding to indicate whether treatment fidelity was explicitly reported in the article and whether the treatment description in the study was sufficient for replication. Additional descriptive details were noted where a 'yes' was recorded. A formal framework of treatment fidelity processes and components was not used. Of the 149 studies reviewed, 14% reported on treatment fidelity. No apparent upward trend towards an increase in reporting over the ten years was identified. A noted limitation of the study being that it only reviewed articles published within three American based journals. As a result of their findings the authors called for journals to firm up guidelines of treatment fidelity as a requirement for publication.

The adequacy of SLP RCT intervention descriptions, across all SLP practice areas including aphasia, was assessed using the TIDieR statement (Hoffmann et al., 2014) and found higher rates of treatment fidelity reporting than Hinckley and Douglas (2013) at 46% (Ludemann, Power, &

Hoffmann, 2017). However, the authors concluded that this was likely not due to an increase in reporting standards but methodological difference in the studies sampling procedures (Ludemann et al., 2017). While this study also used a binary ‘yes/no’ coding, it also used a systematic rating approach by utilising the TIDieR checklist (Hoffmann et al., 2014). These processes may have increased the likelihood of capturing more subtle aspects of treatment fidelity in comparison to the Hinckley and Douglas (2013) review. A strength of the Ludemann et al. (2017) review was that authors of the RCTs included in the review were contacted to provide additional information about the intervention. This process was included to ascertain whether more information was available but not reported in the primary publication. The methodological strengths in the Ludemann et al. (2017) study provided a guide in the development of the present study.

In a similar method of review, Richardson (2016) looked at assessment fidelity within aphasia intervention studies. The raters also used a systematic approach by investigating six specific components of assessment fidelity. These were the reporting of assessment instruments, assessor qualifications, assessor training, assessor reliability and assessor blinding. There was greater reporting of assessment fidelity with 57% of the 88 studies reviewed providing information relating to assessment fidelity. Examination and reporting of assessment fidelity seems more widely done than treatment fidelity.

### *Aims*

The primary aim of this review was to provide an insight into the reporting of treatment fidelity in the aphasia RCT literature as the reporting of treatment fidelity within aphasia RCTs specifically has not yet been investigated. Specifically, the aims were to: a) document the frequency with which treatment fidelity processes were reported in aphasia RCT literature, b) describe the extent to which treatment fidelity processes were reported in aphasia RCT literature, c) explore the extent to which treatment fidelity processes were implemented within RCTs by contacting authors for further detail.

While all study designs were included in the Hinckley and Douglas (2013) review this review elected to include RCTs only. Within therapeutic trials, RCTs are considered ‘best evidence’ in an evidence based hierarchy and are guided by strict reporting standards as per statements such as TIDieR (Hoffman et al., 2014). These statements outline the inclusion of therapy fidelity processes as minimum reporting standards.

## **Method**

### *Design*

This study was a descriptive analysis of the reporting and implementation of treatment fidelity processes in aphasia RCTS from 2012-2017.

### *Procedure*

#### *Search Strategy*

Articles for the review were primarily sourced from speechBITE ([www.speechbite.com.au](http://www.speechbite.com.au)) an online database of treatment studies. The database systematically retrieves SLP relevant articles from eight databases; MEDLINE, Embase, CINAHL, PsychINFO, ERIC, AMED, LLBA, the EBM reviews and Google Scholar (Smith et al., 2010). To ensure all potential articles were captured MEDLINE and CINAHL databases were also searched separately, with duplicates excluded. The search term aphasia was used with the parameters set as a RCT published between 2012-2017. A flow chart of the search procedure and exclusions is presented in Figure 1. The following inclusion and exclusion criteria were used when screening the titles and abstracts: a) an investigation of an impairment-based treatment for aphasia that occurred post stroke, b) not a review, protocol, feasibility or replication study, c) not a surgical or pharmacological intervention and d) published in

English. Within this study an impairment-based treatment is defined as a treatment targeting a phonological, semantic or syntactic aphasia deficit and is not social or participation based.

[Insert Figure 1 near here].

### *Rating of Treatment Fidelity*

Articles that met the above criteria were reviewed and the treatment fidelity processes outlined in the article were rated using Bellg et al.'s treatment fidelity areas (2004). Bellg et al.'s (2004) areas were chosen as they provide a high level of detail into the various ways treatment fidelity can be addressed within a study. The areas were divided into items that need to be considered when planning a treatment and items that should be considered when the treatment is implemented. This matches with the planned and actual items (items 11 and 12) from the TIDieR checklist to reflect this intervention description standard (Hoffmann et al., 2014). The resulting checklist is presented in Appendix 1. Please refer to Bellg et al., (2004) for complete definitions of each treatment fidelity area and goal. A summary is provided below in Table 1. Each article was electronically searched for the words 'fidelity' and 'integrity' to determine the explicit reporting of the broad category of treatment fidelity within the article. Regardless of whether the article had explicitly used these terms it was further analysed for the reporting of treatment fidelity processes. Binary coding (yes/no) for the reporting of treatment fidelity processes was recorded in a 2013 Microsoft Excel spreadsheet as per Appendix 1. along with other article details. An article was marked as addressing the broader area of treatment fidelity if it was marked 'yes' for any of the goals within the area. Where a 'yes' was recorded the location of the information within the article and the details about the reported part of treatment fidelity were noted to allow description. If the article referred to the information in a secondary location this was investigated. Authors were contacted to identify missing information and to determine whether treatment fidelity measures were implemented but not reported. Authors were asked to provide additional information based on the coding described above. Coding was separated by identifying whether the information was provided

in the primary publication, secondary publication or from author contact. The first and last author of this paper reviewed each article independently and then discussed any differences in ratings until consensus was reached.

[Insert Table 1 near here]

### *Analysis*

Ratings were summarised for each item with a total yes/no rating. Descriptive statistics were used to analyse the data according to our aims.

### **Results**

One hundred and eighty articles were identified in the initial search across the three databases. Seventy articles were excluded as duplications. One hundred and ten titles and abstracts were screened and 68 excluded for the reasons listed in Figure 1. A total of 42 full text articles were retrieved for rating. Over the six years from 2012-2017 the average number of treatment studies that met the criteria was seven per year. A table with the complete reference list and ratings for each article is provided in Appendix 2.

Of the studies in this review nine (21.3%) explicitly used the words ‘treatment fidelity’ or ‘integrity’ in their papers. One article provided additional treatment fidelity information in a supplement. All authors were contacted and seven (16.7%) authors provided additional information that was included in these results. Using the Bellg et al.’s treatment fidelity areas (2004) with the TIDieR checklist as a framework (Hoffmann et al., 2014), the number of studies that presented each broader aspect of treatment fidelity is outlined in Table 2. Marshall et al., (2016) was the only article (2.4%) to address all five of Bellg et al.’s (2004) treatment fidelity areas after additional information was provided via author contact. The most frequently addressed aspect of treatment fidelity was study design with information included in 37 (88.1%) articles. This was commonly done in the form of information regarding dosage within and across conditions. The least addressed aspect of

treatment fidelity was enactment of treatment skills with one (2.4%) study reporting on this.

Enactment of treatment skills included ensuring the participant's use of behavioural and cognitive skills outside the research therapy setting. Figure 2. Presents the number of articles that addressed the subcategories of Bellg et al.'s (2004) treatment fidelity areas.

[Insert table 2 near here].

[Insert Figure 2 near here].

## **Discussion**

### *Explicit reporting of Treatment Fidelity*

This paper reviewed 42 aphasia RCTs and identified that 21% of articles explicitly reported treatment fidelity processes. Methodological differences between this and the Hinckley and Douglas (2013) review mean that a direct comparison is not possible and this review provides a guide to reporting in RCTs only. The majority of studies included in the current review addressed areas of treatment fidelity without using the explicit terms 'fidelity' or 'integrity'. Considering the significance of therapy fidelity to the evaluation of interventions it is important that researchers use this terminology as a minimum standard in the reporting of all aphasia treatment studies. The push for complete intervention description as per TIDieR (Hoffmann et al., 2014) and other reporting statements for clinical trials (e.g. CONSORT, SPIRIT) may contribute to an increase in therapy fidelity reporting. There is a risk that reporting of treatment fidelity may increase superficially through the use of these statements; however, addressing active ingredients and the theory behind the therapy in sufficient detail may remain an ongoing goal for aphasia research.

### *Treatment Fidelity Processes*

This review used the TIDieR statement (Hoffmann et al., 2014) and treatment fidelity areas and goals from Bellg et al., (2004) as a framework for measuring aspects of treatment fidelity and differs methodologically from Hinckley and Douglas (2013) in this way. The planned aspects of

TIDieR were more commonly reported than the aspects related to the implementation of the therapy, echoing Cruice et al. (2018) findings that reporting what was delivered was not frequently done. Even when reporting the planned aspects of therapy fidelity there was under reporting of the theoretical rationale for the therapy, or any possible active ingredients, making it difficult to determine potential factors that may influence the intervention (Walker et al., 2017). The least frequently addressed parts of treatment fidelity were protocol adherence and generalisation beyond the therapy room. These factors may be more complex and labour intensive to implement and measure within research protocols as they require additional processes to be implemented alongside the intervention elements of the research.

If aspects of therapy implementation are then not investigated or reported, readers can only assume that the intervention was implemented as planned. Current fidelity research indicates this is not always the case in complex study designs. For example, Bakheit et al., (2007) reported that only thirteen of the fifty one participants received the planned intensive aphasia intervention. In an investigation of whether patients with chronic stroke who underwent task oriented treadmill training could motor learn and improve cardiovascular fitness, Resnick (2011) reported that only 48% of the sample reached the study goal of exercising at 60-70% of their maximum heart rate. The majority of studies in this review did not report the therapy, as it was implemented, behind the closed therapy door. With complex study designs and multifaceted behavioural interventions the assumption that the intervention was delivered as planned is not yet supported in the literature. A reconceptualization of and attention to the monitoring and reporting of aphasia interventions is required. In addition to monitoring protocol adherence and the delivery of the key component(s) of the therapy, articles should specify information such as why that mode of administration was assumed to be effective (Turkstra et al., 2016). Monitoring and reporting of treatment fidelity processes will support the development of the evidence base needed to understand treatments more deeply and guide professional standards, strengthening this part of the evidence based practice triad (Dollaghan, 2011).

### *Dosage*

Treatment dosage was the most commonly reported planned element of treatment. This was most frequently reported in terms of the number of minutes of therapy received. Across many disciplines, rehabilitation interventions are frequently measured by minutes or hours of therapy provided (Turkstra et al., 2016). Measuring dosage in terms of time either assumes that each therapy minute across interventions is equal, or that time is the main ingredient in the intervention. Some studies acknowledged that dosage could be measured in terms of the number of times the active ingredient occurs in the session rather than time, as “therapy intensity is not sufficiently defined as the number of therapy hours multiplied by the total number of sessions” (Woldag, Voigt, Bley, & Hummelsheim, 2017, p. 78).

There is the question of whether it is the dosage, potential active ingredients or both within a therapy that results in a therapy effect. Frequently, and with many of the studies in this review, little detail was provided on the details of a specific intervention. Only with investigation of protocol adherence in each session can dosage be reconceptualised to be more reflective of treatment. Research is moving towards studying dosage and tailoring ingredients including schedules of practice, handling of errors and other error control to implement approaches that are effective (Turkstra et al., 2016).

### *Transcranial Magnetic Stimulation (TMS) Studies*

It should be noted that the results of this study may have been impacted by the inclusion of 15 TMS studies in this review. TMS intervention was often accompanied by traditional speech therapy and, within these studies descriptions of the behavioural intervention were particularly poor. For example some studies limited their therapy description to phrases such as ‘anomia treatment’ containing no other detail. However the dosage of the more structured TMS element of intervention was well described within these studies. This may reflect a greater ease of measurement compared to the behavioural therapy aspect and may have inflated the findings of the review. Not only does this

mean that treatment fidelity was likely not adequately investigated but replication or generalisation from the information included in the paper is unlikely. Studies that present efficacy for TMS combined with traditional speech therapy are difficult to implement in practice due to the poor therapy fidelity on the behavioural element.

### ***Limitations***

This review focused on the reporting of treatment fidelity within papers. However, supplementary papers were reviewed and authors were contacted to provide additional information to address the implementation aim of the review. As such we believe that the review represents an adequate guide to the implementation of treatment fidelity within aphasia RCTs. However, it remains likely that the reported figures are an underestimation of the treatment fidelity processes that were incorporated in each study as they may not have been reported in primary, supplementary or author contact. A limitation of this study is that it only included RCTs. Because of the implementation of reporting statements in RCTs, these studies may be more likely to report treatment fidelity and so the findings may not be generalisable to the broader aphasia literature.

### ***Future Directions***

The TIDieR (Hoffman et al., 2014) statement and recommendations from the treatment fidelity workgroup of the National Institutes of Health Behaviour Change Consortium (Bellg et al., 2004) represent the current goal standard for addressing treatment fidelity within research. Recommendations for monitoring intervention fidelity include videoed therapy sessions and subsequent analysis of these videos according to apriori criteria for the key components of the therapy. This procedure is complex and expensive, however is vital to understanding therapy theory. At the time of publishing, a portion of aphasia trials that are currently underway have published research protocols and are video recording therapy sessions. These studies include the Aphasia Action Success Knowledge (ASK) trial (Worrall et al., 2016), The Very Early Rehabilitation in

SpEech (VERSE) trial (Godecke et al., 2013), SUpporting well-being through PEeR-Befriending (SUPERB) trial (Hilari et al., 2019) and the COMPARE trial (Rose et al., 2017). Some trials are presenting their treatment fidelity processes at conferences (see Behn et al., (2018) and Godecke et al., (2015)). This is reflecting an increased focus in the area and due to these efforts, a future review into treatment fidelity reporting would likely report higher figures. As it becomes a priority to investigate treatment fidelity we encourage researchers to submit adequate budgets for inclusion in grants and funding bodies to recognise and prioritise funding for studies that include comprehensive treatment fidelity monitoring.

### ***Conclusion***

We agree with Ciccone et al. (2016) that “future aphasia studies require substantial attention to therapy adherence and differentiation to enable conclusive statements regarding therapy efficacy” (pg. 580). This review has highlighted the need for the research community to increase their therapy fidelity implementation and reporting standards to achieve a greater understanding of how and why our treatments work. The TIDieR (Hoffman et al., 2014) and Bellg et al. (2004) frameworks were particularly valuable in evaluating reporting which may guide the development and implementation of fidelity processes in future studies. The ultimate aim of our research is to build a body of evidence for therapies to add value to the service that speech therapists provide.

### **Acknowledgements**

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### **Declaration of Interest**

In accordance with Taylor & Francis policy and our ethical obligation as researchers, we report that two authors of this paper, Natalie Ciccone and Erin Godecke, have authored papers contained within

this review. Erin Godecke rated all papers for consensus with the first author, including two of her own papers. Natalie Ciccone did not rate papers however, was first author on one paper included in the review. We have fully disclosed these interests to Aphasiology.

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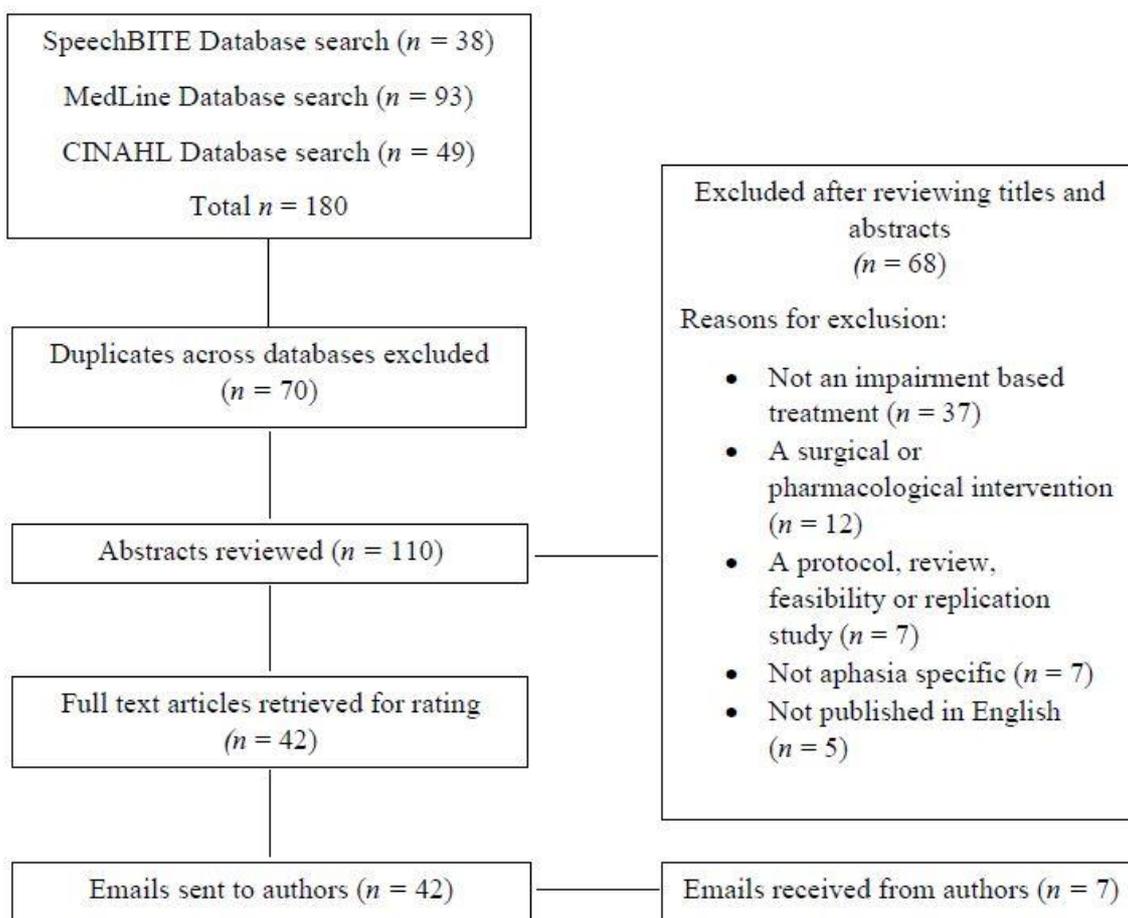
**Table 1. Bellg's (2004) Treatment Fidelity Recommendations**

| Area                          | Goal  |
|-------------------------------|---|
| Study Design                  | Ensure same treatment dose within conditions              |
|                               | Ensure equivalent dose across conditions                  |
|                               | Plan for implementation setbacks                          |
| Training providers            | Standardise training                                      |
|                               | Ensure provider skill acquisition                         |
|                               | Minimise therapist drift                                  |
|                               | Accommodate provider differences                          |
| Delivery of treatment         | Control for provider differences                          |
|                               | Reduce differences within treatment                       |
|                               | Ensure adherence to protocol                              |
|                               | Minimise contamination between conditions                 |
| Receipt of treatment          | Ensure participant comprehension                          |
|                               | Ensure participant ability to use cognitive skills        |
|                               | Ensure participants ability to perform behavioural skills |
| Enactment of treatment skills | Ensure participant use of cognitive skills                |
|                               | Ensure participant use of behavioural skills              |

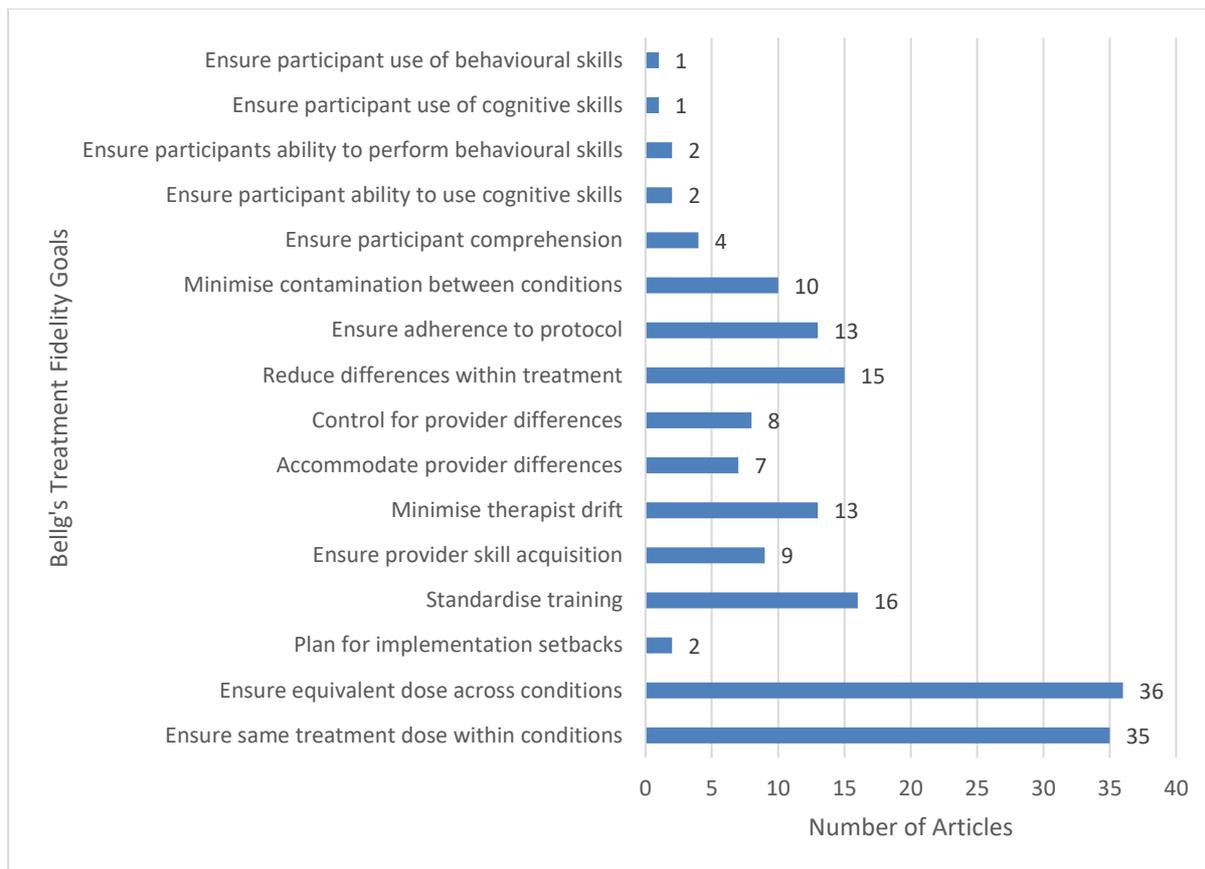
**Table 2. Articles that addressed presented aspects of Treatment Fidelity (TF)**

| TIDieR element | TF Area (Bellg et al. 2004)   | Number of articles |
|----------------|-------------------------------|--------------------|
| 11. Planned    | Study Design                  | 37 (88.1%)         |
|                | Training providers            | 20 (47.6%)         |
|                | Delivery of treatment         | 21 (50%)           |
| 12. Actual     | Receipt of treatment          | 5 (11.9%)          |
|                | Enactment of treatment skills | 1 (2.40%)          |

Note. An article was marked as addressing Bellg et al.'s (2004) broader area of treatment fidelity if it was marked 'yes' for any of the goals within the area. See Appendix 1 'Treatment Fidelity Area Checklist' for areas and corresponding goals.



**Figure 1. Flow chart indicating the selection of articles**



**Figure 2. The number of articles that addressed Bellg et al.'s (2004) Treatment Fidelity Areas**

## Appendix 1. Treatment Fidelity Area Checklist

| TIDieR Element | Area (Bellg et al. 2004)      | Goal   | Location (article, supplement, author)<br>Y/N | Description |
|----------------|-------------------------------|--|---|-------------|
| 11. Planned    | Study Design                  | 11.1 Ensure same treatment dose within conditions<br>11.2 Ensure equivalent dose across conditions<br>11.3 Plan for implementation setbacks                        |   |             |
|                | Training providers            | 11.4 Standardise training<br>11.5 Ensure provider skill acquisition<br>11.6 Minimise therapist drift<br>11.7 Accommodate provider differences                      |   |             |
|                | Delivery of treatment         | 11.8 Control for provider differences<br>11.9 Reduce differences within treatment  |   |             |
| 12. Actual     |                               | 12.1 Ensure adherence to protocol<br>12.2 Minimise contamination between conditions  |   |             |
|                | Receipt of treatment          | 12.3 Ensure participant comprehension<br>12.4 Ensure participant ability to use cognitive skills<br>12.5 Ensure participants ability to perform behavioural skills |   |             |
|                | Enactment of treatment skills | 12.6 Ensure participant use of cognitive skills<br>12.7 Ensure participant use of behavioural skills   |   |             |

## Appendix 2. Summary of Studies Reviewed

### Summary of Studies Reviewed (organised by Year)

Full Reference List below

| Article  | TF Explicitly Reported | TF Goals addressed                                     |
|--|------------------------|--|
| <b>2012</b>  |                        |  |
| (Barwood et al., 2012)*  | No                     | 11.1,11.2  |
| (Bowen, Hesketh, Patchick, Young, Davies, Vail, Long, Watkins, Wilkinson, Pearl, Lambon Ralph, et al., 2012) | No                     | 11.1,11.2,11.4,11.6,11.9,12.1,12.2                     |
| (Bowen, Hesketh, Patchick, Young, Davies, Vail, Long, Watkins, Wilkinson, Pearl, Ralph, et al., 2012)        | Yes                    | 11.1,11.2,11.4,11.5,11.6,11.8,11.9,12.1,12.2,12.3      |
| (Conklyn, Novak, Boissy, Bethoux, & Chemali, 2012)   | No                     | 12.2   |
| (Godecke et al., 2012)   | No                     | 11.1,11.2,11.4,11.5,11.9,12.1                          |
| (Kindler et al., 2012; Medina et al., 2012)*   | No                     | 11.1,11.2  |
| (Medina et al., 2012)*   | No                     | 11.1,11.2  |
| (Palmer et al., 2012)  | No                     | 11.1,11.4,11.6,11.9,12.1                               |
| (Raymer et al., 2012)  | Yes                    | 11.1,11.2,12.1   |
| (Waldowski, Seniow, Lesniak, Iwanski, & Czlonkowska, 2012)*  | No                     | Nil  |
| <b>2013</b>  |                        |  |
| (Barwood et al., 2013)*  | No                     | 11.1,11.2  |
| (Heiss et al., 2013)*  | No                     | Nil  |
| (Kendall, Hunting Pompon, Brookshire, Minkina, & Bislick, 2013)  | No                     | 11.1,11.2,11.4   |
| (Martins et al., 2013)   | No                     | 11.2,11.4,11.6   |
| (Polanowska, Lesniak, & Seniow, 2013)*   | Yes                    | 11.1,11.2,11.8,12.2                                    |
| (Seniów et al., 2013)*   | No                     | 11.1,11.2,12.2   |
| (Thiel et al., 2013)*  | No                     | 11.1,11.2  |
| <b>2014</b>  |                        |  |
| (Altmann et al., 2014)   | No                     | 11.1,11.2,11.8,12.1                                    |
| (Cherney, Kaye, & van Vuuren, 2014)  | Yes                    | 11.1,11.2,11.4,11.5,11.6,11.7,11.8,11.9,12.1,12.3,12.5 |
| (Khedr et al., 2014)*  | No                     | 11.1,11.2,11.7,11.8                                    |
| (Mattioli et al., 2014)*   | No                     | 11.1,11.2  |

|  |     |  |
|--|-----|--|
| (Nouwens et al., 2014)   | No  | 11.6   |
| (Sickert, Anders, Münte, & Sailer, 2014)   | No  | 11.1,11.2  |
| (Tsai et al., 2014)*   | No  | 11.1,11.2  |
| (van der Meulen, van de Sandt-Koenderman, Heijnenbrok-Kal, Visch-Brink, & Ribbers, 2014) | No  | 11.1,11.2,11.4,11.9  |
| (Wang et al., 2014)*   | No  | Nil  |
| <b>2015</b>  |     |  |
| (Cherney, Kaye, Lee, & van Vuuren, 2015)   | Yes | 11.1,11.2,11.4,11.5,11.6,11.7,11.8,11.9,12.1,12.4  |
| (Kendall, Oelke, Brookshire, & Nadeau, 2015)   | Yes | 11.1,11.2,11.4,11.5,11.6,11.7,11.9,12.2  |
| (Rubi-Fessen et al., 2015)*  | Yes | 11.1,11.2,11.4,11.3(a), 12.2   |
| (Szaflarski et al., 2015)  | Yes | 11.1,11.2,11.4,11.5(a),11.6(a),11.7(a),11.9  |
| (Wilssens, Vandenborre, Van Dun, Verhoeven, & Visch-Brink, 2015)                         | No  | 11.1,11.2,11.4,11.5,11.7,11.9,12.1,12.2  |
| <b>2016</b>  |     |  |
| (Cicccone et al., 2016)  | Yes | 11.1,11.2,11.3,11.4,11.6,11.8(a),11.9,12.1(a),12.2(a)                                    |
| (Kurland, Stanek Iii, Stokes, Minming, & Andrianopoulos, 2016)                           | No  | 11.1,11.2,12.2,12.3  |
| (Marshall et al., 2016)  | No  | 11.1(a),11.2(a),11.3(a),11.5(a),11.6(a),11.7,11.9(a),<br>12.4(a),12.5(a),12.6(a),12.7(a) |
| (Meinzer, Darkow, Lindenberg, & Flöel, 2016)*  | No  | 11.1,11.2,11.4(a),11.8,11.9,12.1   |
| (Raglio et al., 2016)  | No  | 11.1,11.2  |
| (Stahl, Mohr, Dreyer, Lucchese, & Pulvermüller, 2016)                                    | No  | 11.1,11.2  |
| <b>2017</b>  |     |  |
| (Breitenstein et al., 2017)  | No  | 11.1,11.2,11.4,11.5,11.6,11.9,12.1,12.2  |
| (Höeg Dembrower, von Heijne, Laska, & Laurencikas, 2017)                                 | No  | Nil  |
| (Nouwens et al., 2017)   | No  | 11.1,11.2,11.6,11.9(a),12.1  |
| (Woldag et al., 2017)  | No  | 11.1,11.2  |
| (Zumbansen et al., 2017)   | No  | 11.1,11.2  |

Note. \*denotes a Transcranial Magnetic Stimulation study. (a) = changed according to additional information provided by the author. Not reported in original article or any available supplement.

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