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Running heading: Intervention descriptions in cerebral palsy research

Title: Do we really know what they were testing? Incomplete reporting of interventions in randomised trials of upper limb therapies in unilateral cerebral palsy

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ABSTRACT

Background: Incomplete reporting of components of interventions limits uptake of evidence into clinical practice.

Aims: To evaluate the completeness of reporting of research and control interventions in randomised trials of upper limb therapies for children with unilateral cerebral palsy.

Methods and procedures: Sixty randomized trials were included, encompassing 60 research and 68 control interventions. Using the 12-item Template for Intervention Description and Replication (TIDieR) checklist, two reviewers independently rated intervention and control descriptions.

Outcomes and results: When using 50% of studies as the benchmark, five of the 12 TIDieR items for the research intervention, eight of the 12 items for the control intervention and 11 of 12 items for “usual care” interventions were inadequately reported. Procedures used to deliver the research intervention were adequately reported for 63% of studies. Materials were used in 94% of research interventions, yet only 27% provided details to access/replicate materials. Training materials for interventionists were used in 38% of trials, 10 (17%) had procedure manuals, yet only 3 reported details to access materials. The location where the research intervention was provided was detailed in 65% of studies. Reporting of all items was poorer for the control intervention.

Conclusions: No study adequately reported all elements on the TIDieR checklist. Details crucial for replication of interventions and interpretation of results were missing. Authors, reviewers, and editors all have a responsibility to improve the quality of intervention reporting in published trials. The TIDieR guide is a potential solution, helping to structure accounts of interventions.

What this study adds:

This is the first study

- This is the first study to evaluate the completeness of reporting of intervention components in complex cerebral palsy interventions
- This is the first study to rate completeness of reporting of control interventions
- This study provides information to increase awareness of editors, reviewers and authors of the importance of complete reporting of intervention components in cerebral palsy rehabilitation.

Key Words: cerebral palsy, upper limb, rehabilitation, randomised trials; intervention description

Abbreviations:

CIMT Constraint induced movement therapy

CP Cerebral Palsy

TIDieR Template for Intervention Description and Replication

1. Introduction

In the last decade, there has been a rapid increase in evidence from clinical trials for a variety of upper limb therapies for children with unilateral cerebral palsy (Novak, McIntyre, Morgan, Campbell, Dark, Morton et al., 2013; Sakzewski, Ziviani, & Boyd, 2014). Despite there being over 45 published randomized trials, there is a lag in the uptake of this evidence into clinical practice. In particular, the uptake of contemporary motor learning based approaches such as constraint induced movement therapy, intensive bimanual therapy and hybrid models combining the two approaches has been slow (McConnell, Johnston, & Kerr, 2012; Schertz & Gordon, 2008).

Incomplete description of interventions in randomized trials is one barrier to evidence uptake, yet one that is remediable. Incomplete descriptions of interventions limit clinicians' ability to reliably use those that have proven efficacy. There are also implications for researchers who seek to replicate and extend on previous research findings, and service managers, policy makers and consumers who endeavour to ensure that current evidence is effectively incorporated into contemporary service delivery. Lack of detail for control interventions in randomized trials further impacts interpretation of the magnitude of treatment effect of the therapies being evaluated.

Inadequate reporting of interventions is considered part of the final stage of waste that can occur across the continuum from research generation to publication (Glasziou, Altman, Bossuyt, Boutron, Clarke, Julious et al., 2014). The extent of inadequate reporting of interventions has been investigated in a number of studies, with between 50 to 60 percent of papers missing essential elements in the description of the interventions (Glasziou, Meats, Heneghan, & Shepperd, 2008; Schroter, Glasziou, & Heneghan, 2012). Reporting of non-pharmacological interventions is typically worse than pharmacological interventions (Douet, Milne, Anstee, Habens, Young, & Wright, 2014; Glasziou et al., 2008). In a cross-sectional

analysis of 137 non-pharmacological interventions, only 39% were described adequately in the primary paper, protocols or related websites (Hoffmann, Eructi, & Glasziou, 2013). The completeness of description of control interventions in randomized trials has not been explored in any previous studies.

To help authors of evaluative studies provide complete descriptions of interventions, the Template for Intervention Description and Replication (TIDieR) guide and checklist was recently published (Hoffmann, Glasziou, Boutron, Milne, Perera, Moher et al., 2014b).

TIDieR is an extension of Item 5 of the Consolidated Standards of Reporting Trials (CONSORT) 2010 Statement (Moher, Hopewell, Schulz, Montori, Gotzsche, Devereaux et al., 2010) and Item 11 of a guide for reporting trial protocols (SPIRIT Standard Protocol Items: Recommendations for Intervention Trials) (Chan, Tetzlaff, Altman, Laupacis, Gotzsche, Krleza-Jeric et al., 2013).

This analysis of trials from a systematic review (Sakzewski et al., 2014) and subsequent publications of non-surgical upper limb therapies for children with unilateral cerebral palsy aimed to evaluate the completeness of reporting of both intervention and control therapies using the TIDieR checklist.

2. Method

2.1 Search strategy and trial selection

Forty-two studies reporting 13 upper limb therapy approaches identified in a recently published systematic review (Sakzewski et al., 2014) were included. This systematic review included randomised controlled trials of non-surgical upper limb interventions for children aged 0 to 18 years with unilateral cerebral palsy to improve upper limb capacity and performance, individualised outcomes and self-care skills. A subsequent search following the same method and inclusion criteria used in the systematic review (Sakzewski et al., 2014) was conducted in May 2015 to ensure that any new trials were also included in this study.

For each included study, reference lists were scrutinised and citation tracking used to identify other related publications, trial protocols, additional appendices, online supplementary materials, or relevant web-based resources. Study protocols of ongoing trials were not included unless the primary outcome paper of the study had been published.

2.2 Rating of research intervention and control descriptions

The TIDieR checklist comprises 12 items to guide reporting on the rationale underpinning the intervention, materials and procedures, intervention providers and location, individualization or tailoring, measurement and reporting of treatment adherence/fidelity, and any intervention modifications between the protocol and trial or during the trial itself (Table 1) (Hoffmann et al., 2014b). The TIDieR checklist and guide was used to rate the completeness of descriptions of interventions and control therapies of included studies.

Descriptions of interventions and control conditions were rated separately. Control interventions were either a dose matched alternative therapy to the research intervention, or were reported as “usual care”, “traditional rehabilitation”, “standard care” or similar descriptor. When the study compared two dose matched interventions, the categorisation of the intervention as being research or control reflected the specific aims and directional hypotheses articulated in the study. In studies where there was more than one control condition, each was rated separately on the TIDieR checklist. For trials where the intervention also contained a pharmacological component, such as Botulinum Toxin A, only the non-pharmacological rehabilitation/therapy component of the intervention was rated.

Each TIDieR item was rated as “yes”, indicating the item had been adequately described or “no” indicating inadequate or incomplete reporting. Many of the items in the TIDieR checklist have a number of separate components. For example: Item 3 “materials” includes both the materials used in the delivery of the intervention and any materials used to train intervention providers. Such items were reported as an overall score, however where

applicable, elements of the item were recorded so to further understand inadequacies of reporting. As a benchmark to summarise and report findings of the TIDieR ratings, items will be described based on whether they have been reported adequately in more or less than 50% of studies.

Two researchers independently rated included studies. To maximise consistency between raters, each researcher independently piloted the checklist on five studies and then met to discuss any differences in interpretation of items. The researchers then completed rating of the remaining studies and met to discuss ratings. Disagreements in ratings were discussed until consensus was reached or referred to a third rater (TH) when unable to be resolved. Ratings of trials and study protocols were reported together so that final ratings for intervention and control groups in each research study were determined from all sources of available information (trial reports, study protocols, and any supplementary information available).

2.3 Analysis

Data were entered in Excel and analysed descriptively. Ratings for research and control interventions are reported separately. The control interventions described as “usual care” were reported as a separate subgroup of the control interventions.

3. Results

Forty-two randomized trials were included in the original systematic review (Sakzewski et al., 2014) and a further 18 were identified from the subsequent search (Abd El-Kafy, Elshemy, & Alghamdi, 2014; Bleyenheuft, Arnould, Brandao, Bleyenheuft, & Gordon, 2014; Brandao, Ferre, Kuo, Rameckers, Bleyenheuft, Hung et al., 2013; Chiu, Ada, & Lee, 2014; Deppe, Thuemmler, Fleischer, Berger, Meyer, & Wiedemann, 2013; Dong & Fong, 2014; Ferrari, Maoret, Muzzini, Alboresi, Lombardi, Sgandurra et al., 2014; Gelkop, Burshtein, Lahav, Brezner, Al-Oraibi, Ferre et al., 2014; Gilliaux, Renders, Dispa, Holvoet,

Sapin, Dehez et al., 2015; James, Ziviani, Ware, & Boyd, 2015; Kaya Kara, Atasavun Uysal, Turker, Karayazgan, Gunel, & Baltaci, 2015; Klingels, Feys, Molenaers, Verbeke, Van Daele, Hoskens et al., 2013; Koman, Smith, Williams, Richardson, Naughton, Griffin et al., 2013; Lidman, Nachemson, Peny-Dahlstrand, & Himmelmann, 2015; Sakzewski, Miller, Ziviani, Abbott, Rose, Macdonell et al., 2015; Sgandurra, Ferrari, Cossu, Guzzetta, Fogassi, & Cioni, 2013; Yu, Kang, & Jung, 2012; Zoccolillo, Morelli, Cincotti, Muzzioli, Gobbetti, Paolucci et al., 2015). In total, 60 randomized trials (the outcomes of which were reported in 71 papers), three feasibility studies informing a randomized trial (Novak, Cusick, & Lowe, 2007; Wallen, Ziviani, Herbert, Evans, & Novak, 2009; Wallen, O'Flaherty S, & Waugh, 2004), and 12 supporting papers reporting the study protocols or development of the intervention (Aarts, van Hartingsveldt, Anderson, van den Tillaar, van der Burg, & Geurts, 2012; Bleyenheuft & Gordon, 2014; Boyd, Sakzewski, Ziviani, Abbott, Badawy, Gilmore et al., 2010; Boyd, Mitchell, James, Ziviani, Sakzewski, Smith et al., 2013; Boyd, Ziviani, Sakzewski, Miller, Bowden, Cunnington et al., 2013; Charles & Gordon, 2006; Eliasson, Krumlinde-Sundholm, Shaw, & Wang, 2005; Facchin, Rosa-Rizzotto, Turconi, Pagliano, Fazzi, Stortini et al., 2009; Gordon, Charles, & Wolf, 2005; Hoare, Imms, Rawicki, & Carey, 2010; Law, Darrah, Pollock, Rosenbaum, Russell, Walter et al., 2007; Sgandurra, Sicola, Di Pietro, Burzi, Filippi, Parente et al., 2011) were included, encompassing 60 research and 68 control interventions. Upper limb interventions included constraint induced movement therapy (CIMT); Hand-Arm Bimanual Intensive Therapy; Botulinum toxin A and occupational therapy; splinting; action observation training; context-focused intervention; mirror therapy; neurodevelopmental therapy; occupational therapy home programs; acupuncture and occupational therapy; kinesiotape; sensory cuing; virtual reality/robotics; and forced use therapy (Table 2).

Items three to nine on the TIDier checklist reflect core elements necessary for

replication of the intervention. No study adequately reported all of these seven core elements. The percentage of TIDieR items adequately described for the research and control interventions is depicted in Figure 1. The TIDieR items are described in greater detail and examples of good reporting from the included studies are summarized in Table 1.

3.1 Research Interventions

The first two items on the TIDieR checklist (brief name Item 1, and rationale Item 2) were the most consistently reported. All studies provided a name and brief description of the intervention being investigated. The rationale underpinning the research intervention was described in 56 (93%) of the studies.

Crucial details about the number of times the intervention was provided, over what length of time, scheduling and duration of sessions was described for 48 (80%) of research interventions (Dose Item 8). The most common missing detail was the duration of therapy sessions.

The mode of therapy delivery (Item 6 “How”, e.g. face to face, and whether individual or group-based) was adequately reported in 46 (77%) of research interventions. Delivery of individual therapy rather than group-delivered therapy was often implied, but not explicitly stated. Nine studies (15%) reported using group-delivered therapy, with eight (13%) specifying the group size and child to therapist ratio.

Individualization (tailoring) of the research intervention (Item 9) was mentioned in 46 (77%) of research interventions, most commonly reflecting the identification and targeting of individual client goals in therapy. However, decision points or guidelines for progression or adaptation of the intervention based on individual participants’ response to therapy were described by a few studies (Charles, Wolf, Schneider, & Gordon, 2006; Elvrum, Braendvik, Saether, Lamvik, Vereijken, & Roeleveld, 2012; Gordon, Schneider, Chinnan, & Charles, 2007; Gordon, Hung, Brandao, Ferre, Kuo, Friel et al., 2011). One study of resistance

training and Botulinum Toxin injections described the grading of the program: *“Once the participants were able to perform three sets of ten repetitions in an exercise, intensity was build up progressively on an individualized basis by increasing the weights by 0.25 – 0.5kg.”* (Elvrum et al., 2012). Thirty-nine (65%) of studies adequately reported the procedure (Item 4) for the research intervention, detailing the activities and/or processes used.

The location of where the intervention occurred (e.g. home, outpatient clinic, community leisure facility – Item 7) was described for 39 (65%) of research interventions. Details about how intervention fidelity (Items 11 and 12) was measured and reported or any strategies to monitor or maintain it were described in less than 50% of the studies. Provision of the intervention by more than one therapist/provider is mentioned in 60% of the trials, which highlights the need for ascertaining fidelity of intervention across interventionists. Of the trials that reported measuring intervention fidelity, methods included: therapist logs detailing the intervention provided; home practice logs describing the amount, frequency and/or type of home practice; or videoed treatment sessions that were later reviewed by the researchers.

Overall, 23 (38%) of trials reported adequate details on the provider of the research intervention (Item 5) including their profession and either described their expertise, assessed their competence or provided additional therapist training. When the components of this item are considered, 51 (85%) of studies identified the profession of the intervention provider, their expertise (9 studies – 15%) and 17 (28%) reported providing further intervention-specific training although minimal detail explained the structure, content or method of training.

Less than 20% of studies adequately reported materials used in the interventions and/or provider training (Item 3). Materials used in the interventions included but were not limited to, written home programs, home program practice logs, splints/mitts/casts or slings,

lists of home practice activities, videos and written instructions. Most 56 (93%) trials reported that materials were part of the research intervention, yet only 16 (27%) trials provided sufficient details to either access or replicate all the materials used in the intervention. For example, restraints were not described in enough detail in 13 (46%) of 28 constraint induced movement therapy and forced use studies to allow replication. An example of inadequate reporting is “*participants in the constraint-induced therapy group were required to wear an elastic bandage and restraint glove that limited their wrist and individual finger movement*” (Hsin, Chen, Lin, Kang, Chen, & Chen, 2012). In contrast, in another trial a more detailed description and supporting photograph provided sufficient detail to allow replication: “*A comfortable neoprene (wet suit material) glove was worn on the hand of the non-affected upper limb.... The neoprene glove, with palmar thermoplastic insert over the fingers and thumb to prevent grasp, allowed the child to use the hand as an effective assist in bilateral activities, but did not allow active grasp of objects (see Figure 2.)*” (Hoare et al., 2010). Home programs were provided in 31 (52%) of studies however only 7 (23%) provided adequate description to replicate the programs or details on how to obtain the program from authors. Home programs were variously described as lists of activities, manual of exercises (Klingels et al., 2013), home program with neurodevelopmental activities (Law, Cadman, Rosenbaum, Walter, Russell, & Dematteo, 1991; Law, Russell, Pollock, Rosenbaum, Walter, & King, 1997) or written lists of training tasks (Taub, Griffin, Uswatte, Gammons, Nick, & Law, 2011). Four studies provided details of the content and structure of the home program (Aarts et al., 2012; Abd El-Kafy et al., 2014; Deppe et al., 2013; Eliasson, Shaw, Berg, & Krumlinde-Sundholm, 2011), three described commercially available video or web-based games (Chiu et al., 2014; James et al., 2015; Zoccolillo et al., 2015) and the remaining studies had inadequate details to replicate either the structure or content of the home program.

Training for research intervention providers (e.g. workshops) was reported in 17 studies (28%), however, no study reported adequate details about the content or structure of training, whether there were training materials or where these could be accessed. A further 10 studies (17%) reported having procedure manuals, generic or standardized task specific therapy protocols (Charles et al., 2006; Duncan, Shen, Zou, Han, Lu, Zheng et al., 2012; Fehlings, Rang, Glazier, & Steele, 2000; Gordon et al., 2011; Kawamura, Campbell, Lam-Damji, & Fehlings, 2007; Klingels et al., 2013; Olesch, Greaves, Imms, Reid, & Graham, 2010; Rameckers, Speth, Duysens, Vles, & Smits-Engelsman, 2009; Speth, Leffers, Janssen-Potten, & Vles, 2005) to guide clinicians in the provision of therapy, however only three provided details that the protocols could be accessed on request (Duncan et al., 2012; Olesch et al., 2010; Sakzewski et al., 2015).

Only one study reported modifications to the intervention during the course of the study (Item 10); with scheduling changes to ensure the anticipated dose of CIMT was provided for children in another study (Deluca, Echols, Law, & Ramey, 2006). It is not possible to know whether other studies made modifications to aspects of the intervention throughout the duration of the study, but did not report this in the trial report.

3.2 Control Interventions Compared to Research Interventions

Compared to the research interventions, description of all items was poorer for the 68 control interventions. The largest differences (20 to 30%) between the research and control interventions were in descriptions of the intervention rationale, procedures, location of the intervention, and tailoring.

The rationale underpinning the control intervention was adequately described for 40 (60%) studies, 33% less than the research intervention (93%). The procedure for delivering control interventions was described sufficiently in only 25 (37%) of the studies. Details about whether the control intervention was delivered face to face, individually or in a group was

described adequately in only 30 (44%) of studies. The best reported item was a brief name of the control intervention (Item 1). Materials were reportedly used in 48 (70%) control interventions, but adequate details of these were only provided in 10 (20%) studies.

A subgroup of 26 (40%) of the included studies described the control group as receiving “usual care”, “standard care” or a similar descriptor. Details on the “usual care” intervention were poor for all items including the rationale or goal underpinning usual care (31%), materials (8%); procedures (19%), intervention provider (8%), how the care was delivered (31%), location (31%), frequency, duration and length (58%); tailoring (23%) and methods and reporting of fidelity (15%).

4. Discussion

This study highlights the lack of adequate details in reporting research interventions and control interventions in published upper limb rehabilitation trials for children with unilateral cerebral palsy. When using 50% of studies as the benchmark, five of the 12 TIDieR items for the research intervention, eight of the 12 items for the control intervention and 11 of 12 items for “usual care” interventions were inadequately reported.

Similar to previous findings (Abell, Glasziou, & Hoffmann, 2015; Bryant, Passey, Hall, & Sanson-Fisher, 2014; Hoffmann et al., 2013; Pino, Boutron, & Ravaud, 2012), our results highlight that details about the materials used in the delivery of interventions and in the training of intervention providers were the most poorly reported. Home programs were a key component in many upper limb studies, and one study directly investigated their efficacy (Novak, Cusick, & Lannin, 2009). Yet, little detail was provided as to what home programs consisted of, their content, how instructions were provided, parent training, the number of activities that were used and how these were developed, individualized and graded. The use of home practice logs by parents was one strategy to measure treatment adherence, yet only one study provided an example (Aarts et al., 2012). Adequate detail and availability of

intervention materials is a crucial element missing from intervention descriptions and limits reproducibility and implementation of the interventions (Hoffmann et al., 2013). Descriptions of materials need to be in enough detail to allow replication, or otherwise authors need to explicitly state where further details can be sought (e.g. contacting corresponding author).

Reporting of the research intervention setting/location in over half of the trials is similar to previous studies (Abell et al., 2015; Hoffmann et al., 2013). Although tailoring was more highly reported in these paediatric trials of upper limb interventions and reflected individualisation related to collaborative goal setting, the specific details of how tailoring was done and how interventions were progressed was not thoroughly described. Reporting of modifications between the study protocol and duration of the study were absent in all but one study. Authors might consider reporting modification if they were made, or alternatively stating that the intervention delivered as per protocol.

Intervention fidelity was not comprehensively planned, evaluated or reported in most studies. Strategies to optimize and measure treatment fidelity include the training of intervention providers, methods and measurement of delivery and receipt of therapy and enactment of intervention skills (Borrelli, Sepinwall, Ernst, Bellg, Czajkowski, Breger et al., 2005). Training of intervention providers was mentioned in 21 (35%) studies, however measurement of the provider knowledge and skill acquisition post training was not considered, nor how provider skills were maintained throughout the duration of the study. Intervention in 60% of included studies was delivered by more than one provider, further reinforcing the need for strategies to monitor and maintain fidelity. The main aspect considered when measuring fidelity in 48% of trials was recording the intervention dose. No study adequately addressed the aspect of therapist competence. Fidelity is a vital consideration particularly for complex interventions included in the current study. Reporting fidelity aids in interpretation of results and understanding the essential components of

complex interventions. The lack of methodological strategies to enhance and monitor delivery of research interventions decreases confidence in both the internal and external validity of the studies (Borrelli et al., 2005).

To our knowledge, this is the first study that has analysed the completeness of descriptions of control interventions in randomized trials. Inadequacy of reporting was even greater when the comparison to a research intervention was “usual care”. “Usual care” is likely very different between studies and highly dependent on factors such as the clinician involved, clinical setting and country in which the care is provided. Hence this lack of detail limits accurate interpretation of the magnitude of treatment effects of the research intervention being evaluated, and hampers comparison of effect sizes across studies.

A number of factors contribute to the lack of adequate description of interventions in randomized trials. A recent cross sectional study investigated the extent to which journals’ instructions to authors provided adequate details on how to report interventions and whether they allowed supplementary online materials to be published (Hoffmann, English, & Glasziou, 2014a). Across 106 journals, only 14% mentioned intervention reporting, although most gave non-specific instructions such as “describe methods, including interventions”; 58% referred to the CONSORT statement; and whilst 74% of journals offered supplementary online options, only 4% mandated their use (Hoffmann et al., 2014a). Word/page restrictions in journals challenge authors’ abilities to furnish adequate details on the interventions in the published report (Glasziou, Chalmers, Altman, Bastian, Boutron, Brice et al., 2010). However, greater use of the supplementary online options offered by journals can provide authors with additional scope to report interventions in greater detail. Another contributing factor is the lack of awareness of authors, reviewers and editors on the importance of complete reporting of interventions (Schulz, Altman, & Moher, 2010). Development of the TIDieR checklist (Hoffmann et al., 2014b), if adopted consistently by journals, editors and

authors of protocols and trials, has the potential to improve the quality of reporting of intervention and control conditions.

A strength of this study is the evaluation of the description of not only the research intervention, but also the control intervention. Additionally, this study included all randomised trials of upper limb therapy irrespective of publication year (Hoffmann et al., 2013) or journal quality (Glasziou et al., 2008). Unlike previous studies (Abell et al., 2015; Hoffmann et al., 2013), however, we did not approach authors to gain additional information to determine whether the completeness of interventions details could be improved. Previous studies have shown that additional information can be gained directly from authors (Hoffmann et al., 2013) and researchers and clinicians should contact authors to determine if there is more detailed information available to assist with knowledge translation processes. Additionally, we only included randomised controlled trials in the current study, however, the TIDieR checklist should would be a valuable tool to assist with reporting of interventions using other research designs.

5. Conclusion

Few research interventions of upper limb therapies for children with unilateral cerebral palsy were described with sufficient detail to enable replication of the intervention, with crucial details missing in many. Even poorer reporting was observed for control interventions. Lack of comprehensive reporting of interventions contributes to a worldwide waste in research funding, limits the uptake of research findings in clinical practice, and hampers evidence synthesis. Authors, reviewers, and editors all share a responsibility for improving the quality of intervention reporting in published trials. Mandating use of the TIDieR checklist and guide in reporting interventions is a potential solution for making it easier to structure accounts of intervention.

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Figure 1. Percentage of adequate reporting of research interventions, comparison interventions and usual care according to the TIDieR Checklist.

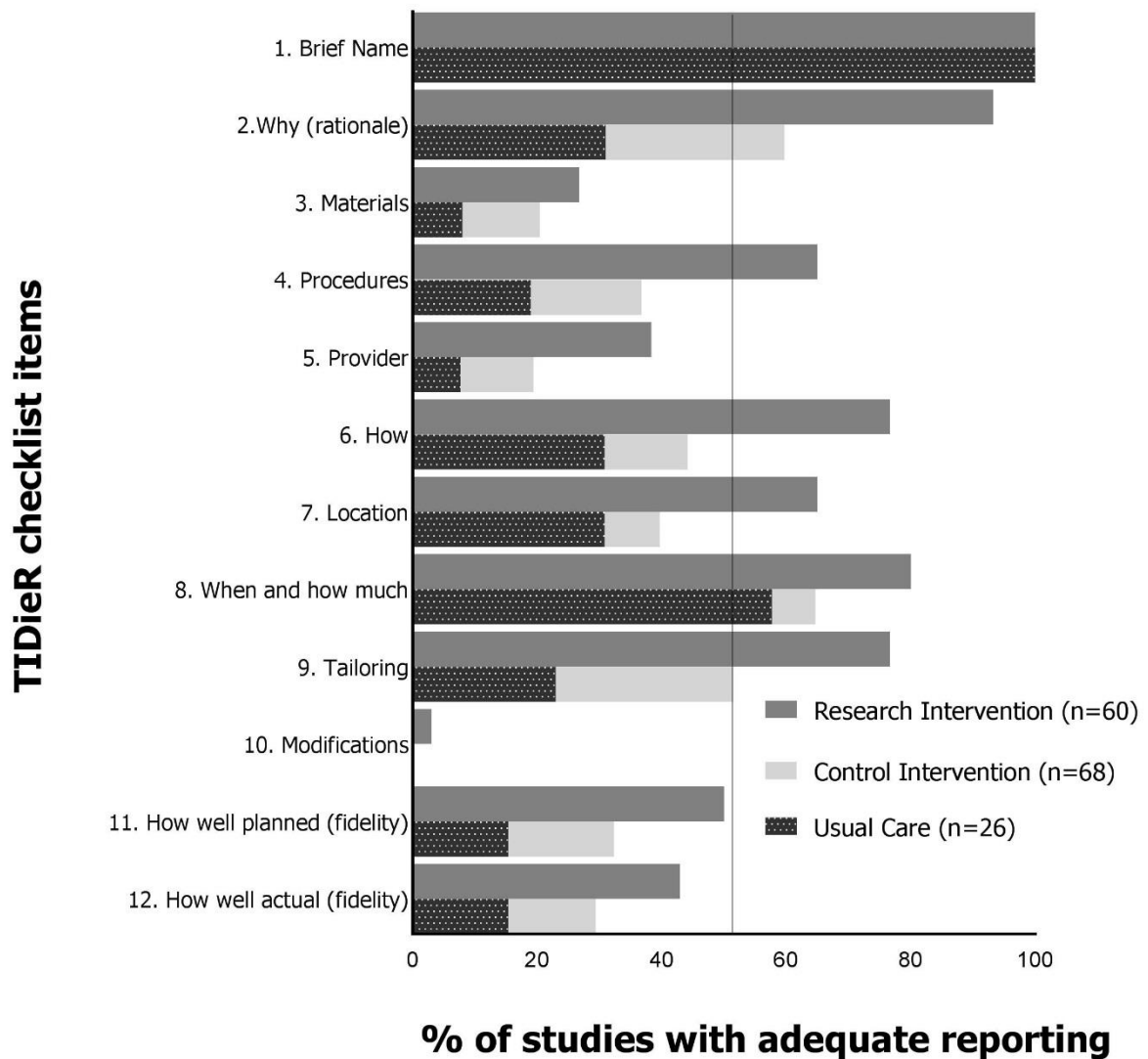


Table 1. Description of TIDieR items and examples of adequate reporting in included studies

TIDieR Item	Item description	Examples of adequate reporting
1. Brief Name	Provide the name or a phrase that describes the intervention.	<i>“Modified constraint induced movement therapy (mCIMT)”</i> (Hoare, Imms, Villanueva, Rawicki, Matyas, & Carey, 2013; Klingels et al., 2013; Wallen, Ziviani, Naylor, Evans, Novak, & Herbert, 2011).
2. Why	Describe any rationale, theory, or goal of the elements essential to the intervention.	<i>“...both imagery and actual execution of hand actions activate similar structures of the sensorimotor cortex....action observation, combined with actual replication of the observed action, induces a strong activation of the MNS, along with marked improvement in motor learning efficacy. These results have fostered the development of rehabilitation protocols based on the observation of meaningful actions followed by their execution (Observation to Imitate).”</i> [Action Observation Training (Sgandurra et al., 2013)].
3. What: Materials	Describe any physical or informational materials used in the intervention, including those provided to participants or used in the intervention delivery or training of intervention providers. Provide information on where the materials can be accessed.	<i>“Most treatment was undertaken with the child sitting at a height adjustable table (see Figure 1)...The child’s chair, with footrest, armrest and pommel was adjusted so that the table was at waist height.”</i> [mCIMT and BoNT-A (Hoare et al., 2010)].
4. What: Procedures	Describe each of the procedures, activities, and/or processes used in the intervention, including any enabling or support activities.	<i>“After baseline assessment, a trained therapist casted the child’s stronger or non-involved arm from the axillary area to the end of the fingertips with the elbow positioned in 90° flexion....The therapist removed the cast once a week during the intervention period to check skin integrity and allow the child 15-20 min of active range of motion.... The therapist structured the practice of arm and hand movements into activities of daily living (e.g., dressing and undressing, eating, grooming) and play activities....At the end of the intervention Day 18, the therapist removed the cast and shifted the focus of the intervention</i>

5. Who Provided	For each category of intervention provider (e.g. psychologist, nursing assistant), describe their expertise, background and any specific training given.	<p><i>for the final 3 days to bimanual activities” [CIMT (Case-Smith, DeLuca, Stevenson, & Ramey, 2012)].</i></p> <p><i>“Three occupational therapists and one physiotherapist will plan and lead all intervention groups.... Volunteer occupational therapists, physiotherapists, human movement scientists, therapy students and sports recreation staff (YMCA) will assist with program delivery with a ratio of 2 participants to one staff member....Professional circus trainers will lead the two hour circus workshops” [INCITE- mCIMT (Boyd et al., 2010)].</i></p> <p><i>“The pretreatment training, administered by the supervisors, was standardized based on the established manual of procedures for each treatment and reinforced by supervisors and during daily meetings.” [mCIMT and HABIT (Gordon et al., 2011)].</i></p>
6. How	Describe the modes of delivery (e.g. face to face or by some other mechanism, such as internet or telephone) of the intervention and whether it was provided individually or in a group.	<p><i>“Participants worked individually with their interventionist or in groups (1:1 interventionist to participant ratio always maintained). Interventionists were paired with children prior to randomization using family-centered approaches considering caregiver and supervisors’ best judgement based on the child’s age and gender” [mCIMT and HABIT (Gordon et al., 2011)].</i></p>
7. Where	Describe the type(s) of location(s) where the intervention occurred, including any necessary infrastructure or relevant features.	<p><i>“The intervention ...during which participating children visit the out-patient rehabilitation unit of the Sint Maartenskliniek, Nijmegen, the NetherlandsThe rooms for the intervention are decorated as a pirate island with all kinds of pirate attributes.” [The Pirate Group: hybrid-CIMT (Aarts et al., 2012)].</i></p>
8. When and How Much	Describe the number of times the intervention was delivered and over what period of time including the number of sessions, their schedule, and their duration, intensity of dose.	<p><i>“The individual-based treatment sessions of 45 to 60 minutes were conducted ...twice weekly for 8 weeks in an outpatient paediatric treatment room. In addition, children in the mCIMT experimental group were required to complete 3 hours of home program (with mitt on), 7 days a week for the 8 week treatment period” [mCIMT and BoNT-A (Hoare et al., 2010)].</i></p>

9. Tailoring	If the intervention was planned to be personalised, titrated or adapted, then describe what, why, when and how.	<i>“Task difficulty was graded as the child’s performance improved by requiring greater speed or accuracy, or by providing tasks that required more skilled use of the involved hand and arm (e.g. moving from activities in which the involved limb acted as a stabilizer to activities that required manipulative skills). Interventionists altered constraints to grade tasks according to desired target movements (e.g. they built up the grasp surface of an object by adding tape and removed it as grasp improved). Emphasis was placed on completing each movement with the involved upper extremity in the same way as the non-dominant hand of a typically developing child (i.e. as a stabilizer or manipulator).” [HABIT] (Gordon et al., 2007)].</i>
10. Modifications	If the intervention was modified during the course of the study, describe the changes (what, why, when and how).	<i>“When children took naps or had an unexpected disruption of their treatment, the therapist was responsible for ensuring that the full dose of 6 hours of active treatment per day was provided (e.g. by staying longer that day or by scheduling treatment for 3 hours before naptime and 3 hours after naptime)” [signature CIMT (DeLuca et al., 2006)].</i>
11. How Well Planned	If intervention adherence or fidelity was assessed, describe how and by whom, and if any strategies were used to maintain or improve fidelity, describe them.	<i>“A clearly defined classification of intervention strategies was developed for each intervention approach to ensure that they were indeed different.... To measure therapist adherence, children’s attendance was monitored throughout the study. All therapists completed a log after each session to document therapy, and these were analysed to determine procedural reliability” [Context-focused intervention (Law, Darrach, Pollock, Wilson, Russell, Walter et al., 2011)].</i>
12. How Well Actual	If intervention adherence or fidelity was assessed, describe the extent to which the intervention was delivered as planned.	<i>“Therapist log notes were coded to record the five most frequent intervention strategies in order to explore treatment differentiation between groups. In the child-focused group, they were practice of upper extremity motor activities..... In the context-focused group they were modifying physical characteristics of environment.....The most frequent intervention strategies were distinct for each group except for the practice of functional mobility activities.” [Context-focused intervention (Law et al., 2011)].</i>

Table 2. Categories of interventions (n=60 research interventions published in 71 articles, 3 feasibility studies, and 12 protocols) and publication sources of included studies

Category of intervention	Number and proportion of published studies for each intervention N (%)	Number of published feasibility studies, protocols, supporting articles for the intervention	Category of control/comparison interventions	Number of control/comparison interventions N
Constraint induced movement therapy	26 (43)	8	Bimanual therapy/OT/PT Usual Care NDT Control CIMT (diff dose/context)	9 10 1 4 5
Botulinum Toxin A and occupational therapy ± splint, FES	14 (23)	1	Control OT/PT Placebo ± PT BoNT-A (diff dose) BoNT-A + OT	1 8 2 1 3
Virtual reality/robotics	4 (6)	1	Usual care	4
Neurodevelopmental Therapy + casting	2 (3)	0	Intensive NDT Regular NDT OT	1 1 1
Forced use therapy	2 (3)	0	Usual Care Control	1 1
Action observation training	2 (3)	1	Watching other video	1
Hand-Arm Bimanual Intensive Training (± intensive LE)	3 (5)	2	Control Usual Care Unstructured bimanual	1 1 1

Mirror therapy	1 (2)	0	Bimanual therapy	1
Occupational therapy home programs	1 (2)	1	Home program (diff dose)	1
Acupuncture + occupational therapy	1 (2)	0	Control	1
Context-focused intervention	1 (2)	1	Intensive therapy	1
Splinting	1 (2)	0	Child focused therapy	1
Sensory cuing	1 (2)	0	Goal directed training	1
Kinesiotape	1 (2)	0	Sham	1
			Usual care	1

Diff, different; OT, occupational therapy; PT, physiotherapy; NDT, neurodevelopmental therapy; BoNT-A, Botulinum Toxin A; LE, lower extremity; FES, functional electrical stimulation.