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Using the TIDieR Checklist to Standardize the Description of a Functional Strength Training Intervention for the Upper Limb After Stroke

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Background and Purpose: Published reports of intervention in randomized controlled trials are often poorly described. The Template for Intervention Description and Replication (TIDieR) checklist has been recently developed to improve the reporting of interventions. The aim of this article is to describe a therapy intervention used in the stroke rehabilitation trial, “Clinical Efficacy of Functional Strength Training for Upper Limb Motor Recovery Early After Stroke: Neural Correlates and Prognostic Indicators” (FAST-INDICATE), using TIDieR.

Methods: The functional strength training intervention used in the FAST-INDICATE trial was described using TIDieR so that intervention can be replicated by both clinicians, who may implement it in practice, and researchers, who may deliver it in future research. The usefulness of TIDieR in the context of a complex stroke rehabilitation intervention was then discussed.

Results and Discussion: The TIDieR checklist provided a systematic way of describing a treatment intervention used in a clinical trial

of stroke rehabilitation. Clarification is needed regarding several aspects of the TIDieR checklist, including in which section to report about the development of the intervention in pilot studies, results of feasibility studies; overlap between training and procedures for assessing fidelity; and where to publish supplementary material so that it remains in the public domain.

Summary: TIDieR is a systematic way of reporting the intervention delivered in a clinical trial of a complex intervention such as stroke rehabilitation. This approach may also have value for standardizing intervention in clinical practice.

Video abstract is available for more insights from the authors (see Supplemental Digital Content 1, <http://links.lww.com/JNPT/A131>).

Key words: *evidence-based practice, physical therapy, rehabilitation, standardization*

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INTRODUCTION

Implementation of research-evidenced therapies into clinical practice requires a comprehensive description of both the experimental and comparator interventions evaluated in clinical trials. Such descriptions are required not just for reliable implementation of therapies but also to allow replication in subsequent research.^{1,2} Regrettably, sufficient description is often lacking in reports of randomized controlled trials.^{1–3} The Template for Intervention Description and Replication (TIDieR) checklist and guide were therefore produced to improve and enable the reporting of sufficiently detailed interventions in the public domain, such as in peer-reviewed journals. The checklist and guide were developed by an international panel of experts and stakeholders, by a process incorporating a literature review, Delphi survey and panel meetings,¹ and is an official extension of the Consolidated Standards of Reporting Trials (CONSORT) 2010 statement⁴ and the Standard Protocol Items (SPIRIT) 2013 statement.⁵ Item 5 of the CONSORT statement suggests that authors should report on “The interventions for each group with sufficient details to allow replication, including how and when they were actually administered”, and item 11 of the SPIRIT statement recommends describing interventions in protocols. However, it was apparent that more comprehensive guidance was needed as reporting of interventions is still deficient, so TIDieR was developed as an extension of these 2 items.¹ Because inclusion of all intervention details is not always possible in the primary

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On behalf of the FAST-INDICATE trial investigators: A list of the FAST-INDICATE trial collaborators is provided in the Appendix.

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The authors declare no conflict of interest.

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report of a trial, there is a move toward reporting in a separate article.^{6,7} This might be especially necessary for complex therapy interventions, such as those for people after stroke, as these consist of several detailed procedures, modified for different patients and contexts.

A complex stroke rehabilitation intervention has recently been developed for the FAST-INdICATE trial,⁸ a randomized controlled trial of functional strength training (FST) for upper limb recovery after stroke compared with movement performance therapy (MPT). The key elements of MPT, initially called conventional physical therapy (CPT), have already been detailed in the public domain.^{6,7} Briefly, these include joint and soft tissue mobilization, facilitation of muscle activity and functional movement patterns, retraining of selective movement, sensory stimulation, positioning, and education for patient/carer. MPT emphasizes intervention that facilitates and guides movement (therapist hands-on) to provide sensory input to optimize joint alignment in preparation for voluntary movement and to improve the quality of movement performance. The trial protocol for the FAST-INdICATE trial is also available.⁸ As part of the reporting of the conduct of this trial, it is necessary to report the FST intervention in detail, to allow replication and potential future implementation. This need provides an opportunity to report the intervention according to the TIDieR checklist.¹ The aims of this report are to describe the FST intervention for the FAST-INdICATE trial, using TIDieR; and to explore the feasibility of using TIDieR for a complex stroke rehabilitation intervention.

Description of FST According to the TIDieR Checklist

The TIDieR checklist includes 12 items ranging from intervention name to adherence and fidelity, which are reported here.

Item 1. Brief Name

Functional strength training.

Item 2. Why: Rationale, Theory, or Goal of the Elements Essential to the Intervention

2.1. Development of the Intervention. A treatment schedule, consisting of a clear description of the types of techniques, exercises/activities, and strategies for delivering a progressive FST program, was produced along with a manual containing detailed operating procedures (see Supplemental Digital Content 2, <http://links.lww.com/JNPT/A132>). Development of a treatment schedule fits within the modeling phase of the published Medical Research Council framework for the development of complex interventions.⁹ Modeling (phase I) involves the identification and description of key aims and content of therapy interventions for a characterized patient group, and the defining of appropriate attributes of the intervention.⁹ Modeling the treatment in this way allows evaluation of a standardized intervention in explanatory (phase II) and subsequently, definitive trials (phase III), and gives clinicians the knowledge required to implement the intervention according to the results.

The first stage of modeling of the FST intervention was undertaken before carrying out a feasibility trial.¹⁰ The process

involved was generation of a treatment list from consultation with clinical experts and the literature, refinement of the list into a treatment schedule by consulting expert clinicians, development of a treatment manual, and piloting the treatment in clinical practice. The people involved in the generation of the treatment list for FST included 5 physiotherapists, each with more than 10 years of experience in the treatment of neurological patients in the UK or Australia, all of whom were also active in the education of undergraduate physiotherapists in this topic. These therapists also were experienced in conducting research trials of arm recovery after stroke and using neuroscience findings to inform the content of rehabilitation interventions. The team also included a clinical physiotherapist who was engaged in doctoral study, and a psychologist with expertise in recovery of motor control.

During the second stage of modeling, the schedule was refined in preparation for the phase II FAST-INdICATE multicenter, randomized controlled trial, which is due to finish recruitment in January 2016.⁸ The research team consulted the literature on task-specific training,^{11–13} motor learning,^{14–17} and motor recovery from stroke.^{7,18–21} Details of exercises were listed and recommendations made for how exercises should be delivered and progressed to maximize motor learning procedures (see Supplemental Digital Content 2, <http://links.lww.com/JNPT/A132>).

2.2. Rationale for the Intervention. Problems performing everyday activities of daily living persist at 6 months after stroke for 95% of stroke survivors,²² largely due to 60% of stroke survivors with severe impairment and 30% with mild to moderate impairment still having a nonfunctional arm and/or hand.²³ Consequently, ability to perform everyday tasks is limited, for example, using a fork, unscrewing a coffee jar, and putting on shoes. Stroke survivors report that loss of upper limb function adversely affects their quality of life and well-being²⁴ and rate the question “What are the best treatments for arm recovery and function?” as one of the top 10 stroke research priorities.²⁵

Systematic reviews indicate that repetitive functional task-specific activity can enhance motor recovery.^{26,27} Several small exploratory studies have indicated initial gains compared with placebo or comparator treatment. One trial, for example, compared 22 participants receiving “functional” training in addition to usual care with 21 receiving only usual care, and found an advantage for functional training.²⁸ Such task-specific training can be provided as part- and whole-task practice. Biomechanical analysis of the whole task underpins choice of part-practice to facilitate transfer of learning to the whole task. Practice is composed of innovative and engaging exercises using interesting task goals for motivation. Repetitions are high (aim for 100–300 reps/session: a dose level that patients with stroke can achieve²⁹) to increase the likelihood of promoting the neuroplastic changes necessary for motor learning to occur in the specific neural networks that mediate motor functions.^{30,31} A considerable advantage is that task-specific training can be done by patients with severe impairment, in contrast to other treatments. For example, constraint-induced movement therapy, which includes up to 6 hours per day of task-specific training combined with constraint of the ipsilesional

upper limb, is suitable only where at least 10° of active movement is present in the paretic thumb and 2 or more paretic fingers.³² This high level of function and large dose excludes many early stroke survivors.³³ Furthermore, constraint-induced movement therapy is effective between 3 and 9 months after stroke³⁴ but less so when given early after stroke.³⁵

Loss of muscle strength,³⁶ defined as “the capacity of a muscle or of group of muscles to produce the force necessary for initiating, maintaining and controlling movement,”³⁷ may have the largest impact on upper limb functional recovery after stroke. Upper limb strength is related to the ability to perform activities of daily living.³⁸ Consequently, functional recovery could be further enhanced by strength training, which consists of voluntary, active exercises against resistance (weights, gravity-resisted exercises, or resistance bands) using isometric, isotonic, or isokinetic contractions.³⁹ Indeed, systematic reviews have found that strength training improves grip strength and upper limb functional recovery after stroke.^{39,40} Effect sizes were higher for those with moderate than with mild impairment, and there was a significant benefit for individuals in both the subacute and chronic phases of recovery.³⁹

Daily activities include other components of motor control such as coordination within the limb and with the eyes, head, and trunk, including postural adjustments. Therefore, combining strength training with task-specific training could boost recovery from stroke, and may well result in an improvement in functional ability through different mechanisms. Task-specific training may enhance the neuroplastic changes that accompany motor skill learning,^{30,41} and strength training will ensure that muscle power is adequate to the task performed, thus together enhancing recovery.

Initial proof-of-concept support for FST was found in the feasibility trial conducted before the phase II FAST-INDICATE multicenter, randomized controlled trial.¹⁰ This was a randomized, observer-blind, phase II trial, in which subjects within 3 months of stroke were randomized to conventional physiotherapy (CPT) (no extra therapy), CPT + CPT, or CPT + FST. Thirty subjects were recruited for the 6-week intervention. Postintervention results indicated that the CPT + FST group had the largest median increase in Action Research Arm Test score between baseline and outcome. This increase was above the clinically important level of 5.7 points. Median (interquartile range) increases were 11.5 (21.0) for CPT, 8.0 (13.3) for CPT + CP, and 19.5 (22.0) for CPT + FST.

Item 3. Materials: Physical and Informational Materials Used in the Intervention, Including Those Provided to Participants or Used in Intervention Delivery or in Training of Intervention Providers

A standardized treatment manual describing the detailed procedures involved is used by the FAST-INDICATE trial research therapists procedures (see Supplemental Digital Content 2, <http://links.lww.com/JNPT/A132>). The manual consists of 3 parts: a brief introduction, general principles underlying FST, and details of exercises. For each task-related activity, the manual includes instructions, a line drawing of the exercise where needed, part practice exercises (ie, the activity broken down into its components), and examples of how to progress

each exercise. Instructions for increasing resistance were embedded in the instructions for each activity. The interventions have been described as simply and clearly as possible so that they could be learned by therapists with minimal training; this has been important in the context of the FAST-INDICATE multicenter trial, with a number of research therapists delivering the intervention across 3 sites.

Item 4. Procedures, Activities, and/or Processes Used in the Intervention

FST combines functional task-specific exercise and strength training. It involves repetitive, progressive, resistive exercise during goal-directed functional activity, with the therapist providing verbal prompting and feedback, but only providing hands-on contact to maintain safety. FST is based on the key elements of normal upper limb function (ie, positioning the hand and then using it to manipulate an object) with an emphasis on producing appropriate muscle force for the functional activity being practiced. The focus is on improving the power of shoulder/elbow muscles to enable appropriate placing of the hand, improving the production of appropriate force in arm and hand muscles to achieve the specific grasp, and specific interventions for the wrist and finger muscles to maximize ability to manipulate objects. The manual is provided as supplemental material.

Item 5. Description of the Expertise, Background, and Specific Training Given to Intervention Providers

In the FAST-INDICATE trial, FST has been delivered by research therapists who are qualified physiotherapists and occupational therapists, registered with the appropriate professional bodies who ensure quality of clinical professionals. The research therapists were trained in provision of FST in accordance with the standardized manual before they saw participants. Therapists attended a 2-day training course, where they learned how to deliver and adjust FST treatment for different levels of movement ability, sensation, and cognition; and how to manage self-directed practice and record content and amount of therapy provided for participants in home, outpatients, and inpatient settings. Therapists were also given opportunities to observe therapy delivered by a trained and experienced research therapist and then to deliver therapy under the observation of a trained and experienced research therapist, followed by feedback and discussion. At various points throughout the trial, this initial training has been augmented through meetings of the research therapists and key members of the trial team to discuss case scenarios (devised by either SH or VP, without reference to trial participants), and agree appropriate FST treatment activities. In addition, the research therapists frequently communicated with each other to discuss their anonymized caseload. These procedures were devised to minimize potential for deviation from the manual and differences in interpretation between clinical centers.

Item 6. Mode of Delivery

FST was provided individually to participants either face-to-face, or with therapist-directed and participant self-administered practice.

Item 7. Type(s) of Location(s) Where the Intervention Occurred, Including Any Necessary Infrastructure or Relevant Features

FST was delivered in the inpatient or outpatient hospital setting, or in participants' homes.

Item 8. Number of Times the Intervention Was Delivered and Over What Period of Time Including the Number of Sessions, Their Schedule, and Their Duration, Intensity or Dose

The FST intervention was delivered for up to 1.5 hours, 5 days a week, for 6 weeks. Thus, the maximum possible dose was 45 hours for any individual. Research therapists endeavored to provide as much intervention as an individual could tolerate (up to the maximum 1.5 hours per day), but it was recognized that some people experience fatigue after stroke. Other factors reducing the maximum dose include participant illness, bank holidays, participant family commitments, and staff absence. The amount of FST for each participant was recorded on a specific case report form. These data will be reported together with the clinical efficacy data at the end of the trial.

Item 9. Tailoring of the Intervention

FST is designed for participants with a score of at least 11 of 33 for the Motricity Index pinch section⁴² but who are unable to complete the Nine Hole Peg Test⁴² in 50 seconds or less.⁴² The initial level of load/resistance used was the maximum load that still permits 5 repetitions of action through the available range of muscle length. Tailoring was built into the intervention. The description of the treatment in the manual details procedures for tailoring practice activities for particular movement problems and level of participant skill (see supplement).

Item 10. Modifications of the Intervention During the Study

Modifications were made after a feasibility study¹⁰ was conducted (described in item 11), and before the FAST-INDICATE trial. No further modifications were made to the standardized manual after participant recruitment began in the FAST-INDICATE trial.

Item 11. Planned Procedures for How Adherence or Fidelity Was Assessed, Describe How and by Whom, and if Any Strategies Were Used to Maintain or Improve Fidelity, Describe Them

The initial and ongoing training for the intervention providers is given within item 5 earlier. The text in this section therefore relates to adherence to FST by trial participants.

Before the current FAST-INDICATE trial, a feasibility study was conducted,¹⁰ within which fidelity to the FST treatment manual was assessed. A single physiotherapist, who received training in delivery of the schedule and who was closely supervised to ensure fidelity to the manual, administered FST. The aim was to deliver a total of 24 hours of FST over 6 weeks for each participant. The trial data showed that a median 17.7 hours of FST treatment over 6 weeks was delivered to partici-

pants. This fell 6 hours short of the 24 hours planned, but was approximately 4 hours more than that received by the comparator experimental group. The duration also exceeded the 16 hours of additional exercise therapy (compared with a control group), shown to be required to significantly improve activities of daily living.⁴³ These data indicate that use of the recording form to collect FST dose was feasible. Therefore, this procedure continues to be used in the ongoing FAST-INDICATE trial. A larger dose of FST is being delivered in the FAST-INDICATE trial, than in the feasibility trial, made possible by the fact that there are multiple therapists delivering treatment in FAST-INDICATE.

In addition to recording details of dose, the FAST-INDICATE research therapists have recorded details of the content of FST. The procedure followed has been shown to provide useful information.⁴⁴

11.1. Planned Procedures to Assess Feasibility in the Ongoing FAST-INDICATE Trial. There were no specific procedures to assess feasibility in the FAST-INDICATE trial, as this was already examined in the feasibility trial.¹⁰

Item 12. Actual Adherence or Fidelity

To measure fidelity to treatment protocol in the FAST-INDICATE trial, the treatment recording form used in the feasibility trial was used in the FAST-INDICATE trial to record both dose and content of intervention. The data concerning dose and content will be reported along with the clinical efficacy data in an article to be submitted to a peer-reviewed scientific journal after trial closedown.

DISCUSSION

Description of FST Intervention

The detail provided in the description of FST, using the TIDieR checklist, should ensure that FST, as it is delivered in the FAST-INDICATE trial, is replicable for clinicians and researchers.

The treatment manual used in the trial is available as supplementary material. However, we recommend that clinicians delay implementation of the treatment described in the manual until the results of the study are reported, so that an informed decision may be made about implementation.

Feasibility of TIDieR

The TIDieR checklist provided a systematic way to describe the FST intervention, inclusive of rationale (why); materials that were used (what); procedures (what); how, where, when, how much, and by whom training was provided, how it was tailored and modified and how well planned it was. With respect to the feasibility of TIDieR to describe a complex stroke rehabilitation intervention, several points arose that are worthy of discussion. First, it was unclear in which section pertinent information about the development of the intervention in pilot studies should be inserted. In the case of development of the FST intervention, this included generation of a treatment list from consultation with clinical experts and the literature, refinement of the list into a treatment schedule by consulting expert clinicians, development of a treatment

manual, and piloting the treatment in clinical practice. Because information from such pilot studies may help to explain the nature or conduct of the intervention, and an intervention may be better understood by knowing how the intervention was developed, we suggest that this information should be included in TIDieR. We judged that this information should be inserted into the most relevant parts of TIDieR: item 2, where we inserted information concerning development of the intervention, and item 11, describing assessment of fidelity to the treatment schedule in the pilot trial.

Second, TIDieR also does not contain a specific section in which to communicate results from feasibility studies. In the case of FAST-INDICATE, the feasibility study aimed to investigate potential recruitment and attrition rates, seek proof-of-concept data regarding potential effect size of FST, and assess the adequacy of trial procedures such as recording of the content and dose of FST. It would be useful to be able to include brief detail of relevant findings in TIDieR because (a) initial proof-of-concept evidence of efficacy could usefully inform the clinician's decision about whether to implement the intervention and (b) the information about procedures such as recording of the content and dose of FST is relevant to delivery of the intervention in clinical practice. In the case of FST, the feasibility study conducted before the phase III trial was published as a separate paper from the main trial.¹⁰ However, small feasibility studies do not always result in a publication, and it would be easier for clinicians to have all the information needed in the 1 article describing the intervention. Therefore, we included reference to the proof-of-concept data in item 2 (rationale for the intervention), and included information about recording of the content and dose of FST in item 11 (assessment of adherence and fidelity).

Third, there appears to be overlap in the items of TIDieR concerning training for treatment providers. Training for providers is mentioned in 2 sections of the explanatory article describing TIDieR: in item 5, "description of . . . specific training given to intervention providers"; and item 11, "strategies used to maintain or improve fidelity". In our description of the FAST-INDICATE trial, ongoing training for research therapists was described in item 5. We recommend that specific training be included in item 5, and omitted from item 11, which would be then devoted to assessment of fidelity.

Fidelity was not assessed in the FAST-INDICATE trial because it had already been assessed in the feasibility trial, and resources did not allow a more thorough assessment of fidelity, for example by checking samples of actual treatment delivered against criteria from the manual, by observation or from videotape.

Item 12 of TIDieR is different to other items in the checklist. The first 11 items are essentially about the intervention itself and details of its implementation. Item 12 however, "the extent to which intervention was delivered as planned," reports the actual fidelity, and so it would be more appropriate to report this information within the article reporting the results of the trial.

There is also an important choice to be made by authors of trials as to whether key additional information for implementation, such as the treatment manual, should be made available as supplementary information accompanying the pub-

lished article at the journal Web site, or whether it should be reported in a separate journal publication. The latter choice would ensure that the information is available in perpetuity for readers; however, it may prove difficult to find editors willing to publish what is essentially only a descriptive piece of work. Keeping treatment manual information in the public domain is particularly important for stroke rehabilitation interventions because, despite the importance of evidence-based practice, therapists do not identify research evidence as a primary source of information for use in clinical practice.⁴⁵ The timing of release of detailed information about an intervention, such as a treatment manual, also needs to be carefully considered. Trialists may wish to delay the release of such information (a) prevent the uptake of an intervention before its effectiveness is known, or (b) to minimize the risk of trial contamination—for example, usual care changing over time as a result of the details of the experimental intervention being in the public domain.

CONCLUSION

TIDieR provides much needed guidance for reporting a comprehensive description of interventions evaluated in clinical trials. The FAST-INDICATE trial provided an early opportunity to evaluate TIDieR to report a complex rehabilitation intervention. Using TIDieR will do much to resolve the problem of insufficiently detailed reporting of trial interventions. The existence of TIDieR should help alleviate this important barrier to implementation of new interventions in clinical practice. Therefore, we recommend its use by clinical trialists. However, trialists could bear in mind the minor shortcomings highlighted here.

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