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The Rehabilitation Treatment Specification System: Implications for improvements in research design, reporting, replication, and synthesis

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Abstract

Despite significant advances in measuring the outcomes of rehabilitation interventions, little progress has been made in specifying the therapeutic ingredients and processes that cause the measured changes in patient functioning. The general approach to better clarifying the process of treatment has been to develop reporting checklists and guidelines that increase the amount of detail reported. However, without a framework instructing researchers in how to describe their treatment protocols in a manner useful to or even interpretable by others, requests for more detail will fail to improve our understanding of the therapeutic process. In this paper, we describe how the Rehabilitation Treatment Specification System (RTSS) provides a theoretical framework that can improve research intervention reporting and enable testing and refinement of a protocol's underlying treatment theories. The RTSS framework provides guidance for researchers to explicitly state their hypothesized active ingredients and targets of treatment; as well as how the individual ingredients in their doses directly affect the treatment targets. We explain how theory-based treatment specification has advantages over checklist approaches for intervention design, reporting, replication, and synthesis of evidence in rehabilitation research. A complex rehabilitation intervention is used as a concrete example of the differences between an RTSS-based specification and the Template for Intervention Description and Replication (TIDieR)

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checklist. The RTSS's potential to advance the rehabilitation field can be empirically tested through efforts to use the framework with existing and newly developed treatment protocols.

Keywords

Rehabilitation; Therapeutics; Methods; Translational Research; Outcome Assessment (Health Care); Meta-Analysis as Topic

Over the past 50 years, the field of rehabilitation has seen substantial advances in defining and measuring outcomes and quantifying patient characteristics associated with those outcomes. However, treatment research seldom provides specific information as to which aspects of treatment contribute to patient outcomes, and how they contribute.[1–3] A significant barrier to identifying effective aspects of treatment is the lack of a comprehensive system or framework for defining and describing the interventions used in rehabilitation.[4] Most often, treatments are defined by either discipline ("X hours of occupational therapy") or the problem being treated ("gait training"), neither of which describes what the clinician actually does to affect functioning. Research reports that include detailed protocols often lack information about how a treatment was administered; e.g., instead of reporting what quantities of active treatment ingredients were provided, treatment dose descriptions simply state the duration or number of sessions. Even published treatment manuals frequently lack sufficient details to enable other researchers to replicate findings or build on previous results, or for clinicians to confidently implement published treatments in everyday care.

The most comprehensive effort to date to characterize rehabilitation treatments in multiple disciplines was a series of multicenter Practice-Based Evidence (PBE) studies that aimed to identify effective rehabilitation methods for stroke,[5, 6] joint replacement,[7] spinal cord injury,[8] and traumatic brain injury.[9] In these studies, front-line clinicians documented the contents of their treatments using point of care (POC) forms that included menus of "activities" (e.g., bed mobility, gait, community mobility) that clinicians could associate with "intervention" codes (e.g., balance training, motor learning, biofeedback).[10] Entries listed on the POC forms, however, suffered from the same limitations as can be noted for other treatment studies: labeling interventions by the targeted impairments (e.g., gait training), types of equipment (e.g., parallel bars), or modalities (e.g., biofeedback), so the resulting data provide little information about specific actions clinicians performed to achieve the targets of treatment. Also, since the POC forms were developed by diagnosis and discipline-specific workgroups, cross-discipline and cross-diagnosis differences in labeling and categorizing treatments obscured any common treatment themes.

To help improve the quality of intervention descriptions in clinical research, multiple individuals and committees have developed reporting guidelines. Examples include the Consolidated Standards of Reporting Trials extension for Non-Pharmacological Treatment interventions (CONSORT-NPT),[11] the Template for Intervention Description and Replication (TIDieR),[12] the Guideline for Reporting Evidence-Based Practice Education Interventions and Teaching (GREET),[13] and the Consensus on Exercise Reporting Template (CERT).[14] Guidelines typically list categories of information that should be described (e.g., components of the intervention, procedures for tailoring the intervention to individual

patients), but do not explicitly require authors to identify the aspects of treatment that are thought to bring about functional change. Reporting guideline authors presume that clinicians and researchers can reliably identify which aspects of a treatment carry the intended effects and that research authors have a standard method to articulate these aspects in a manner useful to others. Because standard reporting methods are agnostic to therapist actions, intervention describers could satisfy reporting guideline requirements by including anything that occurred during therapy, regardless of its significance in achieving the desired change in patient functioning (e.g., the color of the therapist's scrubs or the temperature of the room) while omitting the clinician's actions that are crucial (e.g., the instructional methods used, how practice was structured, the type of feedback used). For example, use of external memory aids is a recommended practice for patients with traumatic brain injury because of strong evidence that using these aids can improve relevant patient outcomes.[15] Studies have identified patient characteristics associated with successful device use (e.g., adequate dexterity and vision) and general principles of intervention (e.g., that it is individualized and includes practice), but methods for teaching patients to use these aids are inconsistently reported, and rarely to the level of detail needed for replication.[16]

In summary, our ability to characterize rehabilitation treatments has been challenging due to [1] a lack of clear guidance about which details are directly related to changes in patient function, making it difficult to determine what is important for research reporting; [2] a tendency to describe treatments by either the type of therapist or the problem that was addressed, instead of what was done in therapy; and [3] lack of a uniform, standard, cross-discipline system for describing treatment. To address these challenges, an interdisciplinary team of rehabilitation clinicians and researchers developed the Rehabilitation Treatment Specification System (RTSS).* The purpose of this paper is to describe how the RTSS can advance the design, reporting, replication, and synthesis of evidence in rehabilitation research. In this issue, Hart and colleagues[17] provide a general introduction to the RTSS. Also, the Manual for Rehabilitation Treatment Specification (which is available at http://mrri/.org/innovations/manual-for-rehabilitation-treatment-specification/) describes specification* in detail. When first used, an asterisk is present after all terms that have RTSS-specific definitions and their definitions are provided in the online Glossary at [editors insert]. We argue that the RTSS, which uses a common language and systematic approach to describing treatment, will offer solutions to the problems noted above, encourage collaboration, permit aggregation of data across disciplines, and foster development of overarching treatment theories that inform all of rehabilitation.

The Rehabilitation Treatment Specification System

Specification, as used here, refers to descriptions of the specific actions that clinicians take to achieve a particular change in patient or client functioning. The RTSS endeavors to specify therapeutic interventions based on the smallest unit of treatment, called a treatment component*. Most treatments are comprised of multiple treatment components and each treatment component has a tripartite structure*: [1] a singular treatment target*, the precise proximal aspect of patient functioning that is to be changed by the ingredients provided; [2] one or more ingredients*, what the therapist does or selects to achieve the target; and [3] a

mechanism of action*, the causal chain through which the treatment is known or hypothesized to work (i.e., how the ingredients affect the target).

The RTSS postulates that there are 3 broad groups of treatment components: Organ Functions*, Skills and Habits*, and Representations*. Organ Functions treatment components are concerned with changes in the efficiency, functioning, or replacement of an organ or organ system (e.g., exercise, habituation, prosthetics). Skills and Habits components involve modifying mental or behavioral skills through providing ingredients such as practice, repetition, feedback, etc. Representations[18, 19] components are intended to change mental representations related to cognition, affect, motivation, and volitional behavior. Table 1 outlines a few examples of each treatment component category from selected common rehabilitation treatments.[20–30]

The RTSS also defines the concept of treatment aims*, which are distal ("downstream") effects of treatment that may or may not result from achieving a single or even multiple targets. For example, if an aim is to reduce frequency of falling, therapy might include multiple targets that are thought to contribute to that aim (e.g., improved balance, increased use of fall prevention strategies, increased leg strength). The distinction between targets and aims is critical because it explicitly differentiates changes in function that are expected to result directly from an intervention from those that occur indirectly because of changes in one or more aspects of function.

Another important emphasis in the RTSS is the concept of volition*, which can be roughly equated with effort expended by the treatment recipient*. It is important to consider volition in a treatment specification system because the success of many rehabilitation treatments depends on the patient's voluntary actions as elicited, if necessary, by clinician actions[31] (e.g. in goal setting[32], establishing rapport[33], using shared decision-making[34]). The RTSS posits that there are two sources of treatment success or failure for volitional treatments: 1) the degree to which ingredients chosen affect the selected treatment target (e.g., do tongue-hold swallow exercises decrease residual food in the epiglottic/base-of-tongue valleculae after swallowing?); and 2) the degree to which ingredients result in the patient's performance of the therapeutic activity as directed (e.g., do instructional/ motivational ingredients improve the probability that the patient will perform the tongue-hold exercise program the prescribed number of times per day, with correct execution?). That is, the RTSS encourages clinicians and researchers to consider both the ingredients that are thought to change the patient's functioning and also the ingredients that enhance the likelihood that the prescribed therapeutic activities are done correctly.

Potential benefits of the RTSS for conducting research and disseminating findings

Example of RTSS specification

To illustrate the potential benefits of the RTSS for research, we chose an article by Tiedemann et al.[27] We chose this article because it provided the most comprehensive description of a multi-component rehabilitation intervention in our searches for publications

that used the TIDieR checklist. Table 2 shows the TIDieR elements provided by Tiedemann et al. for their intervention, as well as added treatment information that was in the main text but missing from their TIDieR table. Based on the RTSS guidelines, we identified treatment components in the protocol (Table 3). As the TIDieR checklist does not ask for a tripartite structure, we used the RTSS rules to guide our identification of treatment components and linking of ingredients with a target. In some cases, entire treatment components (numbers 4 and 5) were inferred because the TIDieR table listed fall prevention strategies that were not further explained or described in the main text. We realize that the authors may have a more extensive protocol for use by their therapists, but we based our analysis of the case example on what they published. Dosing parameters* for most treatment ingredients were missing from the TIDieR table, so we hypothesized parameters for individual treatment ingredients to complete the example. Note that these parameters do not reflect the actual protocol implemented in the cited investigation, but are included to provide examples of how relevant parameters would be articulated. All treatment components and information we added are italicized in Table 3.

Design of Experimental Interventions

The most obvious benefit of the RTSS is explication of the three aspects of a treatment component: ingredient(s) → mechanism of action → target. Existing guidelines mainly encourage researchers and research consumers to think critically about the aspect of patient function they are trying to change with a particular intervention, but do not encourage hypothesis development regarding how the ingredients directly or indirectly create that change. For example, “improved gait” would need to be more specific when considered as a target in the RTSS. This is because one would likely use different ingredients to affect targets like “improved gait speed” versus “improved gait symmetry.” However, the TIDieR guidelines do not explicitly provide a means for asking key questions such as, “What am I trying to change in the patient’s functioning with these specific ingredients?” or “Which ingredients drive the effects demonstrated in the study?” By contrast, the RTSS-based Table 2 specification allows the answers to these questions to be expressed in an empirically testable manner. Making the treatment components and targets explicit allows researchers to generate informed hypotheses about why their treatment worked or did not work. In reference to Table 2, if patients did not decrease their frequency of falls after the intervention (an aim of the treatment), was it because the practice schedule prescribed was insufficient to increase automaticity in performing fall prevention strategies (target in row 4); because the clinician’s explanation regarding the importance of using fall prevention strategies did not influence the patient’s volitional behavior enough to practice the strategies as directed (target in row 5); or because the intervention failed to address other targets that are closely related to the aim of fall prevention (e.g., prevention of orthostatic hypotension)? Answers to these questions could direct the researcher to revise the approach to fall prevention (e.g., add more opportunities for practice) or add more treatment ingredients to increase the likelihood the participants practice using the prescribed strategies (e.g. add phone calls to query the patient on their at-home practice). This closely relates to the issue of treatment appropriateness versus treatment adherence that is frequently encountered in effectiveness studies.[35–37] Treatment appropriateness refers to whether the researcher-selected ingredients are likely to have a clinically meaningful effect on the desired change in patient functioning, while

treatment adherence refers to whether the selected ingredients ever had a chance to change patient behavior (i.e., did the patient engage in the therapeutic activities that would effect the desired change?).

Use of the RTSS can improve the design of an intervention at the initial stages of protocol development. Before applying the research treatment protocol to patients, protocol developers could use the RTSS framework to guide the development of their treatment methods, phrasing such questions as: should the protocol have additional ingredients for associated targets, do the ingredients match the target(s), should the protocol have additional targets for associated aims, and how will the ingredient dosages, targets, and aims be measured? Once the research is completed, if treatment effects are weak, the stated relationships among ingredients, targets, and aims will be specific enough that researchers can decide if 1) future studies require larger doses of current ingredients, or 2) future studies require different treatment ingredients for specific targets, or 3) additional targets (with associated ingredients) need to be added, or 4) underlying theories regarding the connections among ingredients, targets, and aims are incorrect.[38] Many rehabilitation treatments are considered complex interventions[39] (i.e., they contain multiple interacting treatment components addressing different behaviors that can be difficult to measure), so development of a set of theories connecting specific ingredients with their respective targets will allow researchers to determine the sequence and combination of treatment components that optimizes outcomes.

Selection of Measures

The RTSS concepts of targets and aims have advantages over the current measurement focus on primary and secondary outcomes. Specifically, instead of the researcher solely considering the outcome of primary importance and additional secondary effects, the concept of treatment components directs him or her to identify the outcomes that can be hypothetically achieved as a direct result of the ingredients provided. Tiedemann et al.[27] list 3 primary outcomes of their intervention (physical activity as measured by ActiGraph over 7 days, and 2 individualized physical activity goals based on Goal Attainment Scaling), and 5 secondary outcomes (reduced falls, and patient-reported measures of quality of life, fear of falling, mood, and mobility). However, as is common in studies of rehabilitation interventions, the outcome measures do not match all of the listed targets: the 3 primary outcome measures would quantify only the row 1 target in Table 2, and all secondary outcomes appear to be aims that will require changes across multiple targets, not directly addressed by this treatment. This leaves all other targets (Table 2, rows 2 through 5) without an explicitly stated outcome measure.

The RTSS can help researchers choose appropriate outcome measures. As the treatment target is an aspect of patient functioning to be directly changed by the ingredients, proof-of-concept research should use a primary outcome measure aligned with change in that target. If the impact of treatment is weak on a primary outcome measure aligned with a target, researchers should consider one or both of two possibilities: 1) the selected outcome measure is a correct representation of the target but the ingredients are not right, or are administered in insufficient dose; 2) the selected outcome measure is an aim (rather than a

target), or something else weakly related to the target, and another primary outcome must be selected or developed. Later in the progress of a translational research agenda, it may be important to address broader and more clinically meaningful aims of treatment.[38] Often, effective treatment of one target in isolation is not sufficient to result in a meaningful functional impact on broader treatment aims. If this is the case or can be anticipated, the researcher should consider one or more of these possibilities: 1) the ingredient dosage for one or more targets is not optimal (e.g., too much, too little); 2) the link between the treated targets and the clinical aim is too weak; 3) one or more targets that are crucial to achievement of the aim have not been addressed (i.e., more causal links in the researcher's theory of what targets affect the aim are needed); 4) a more narrow population of patients should be selected for this treatment, specifically those patients where the treated target(s) *are* strongly linked to the clinical aim. For example, strengthening the leg muscles may contribute to independent ambulation, but ambulation also may also be affected by factors such as balance deficits. Thus, a strengthening treatment may be "effective" in terms of a change in the strength target, but "ineffective" in achieving independent ambulation (a possible aim of treatment). One could potentially achieve the aim of ambulation by adding an effective treatment targeting balance *or* by selecting only patients with weakness but good balance skills for the strengthening treatment. Use of the RTSS will help reveal problems like this, by focusing the investigator on specific functions that are targets of treatment and the clinician actions that can directly affect the target.

Reporting, Replication, and Clinical Translation

Replication of treatment protocols for purposes of scientific validation requires that they are reported with sufficient specificity to allow those not involved in the research to implement them in their local setting. Reporting checklists are meant to help replication by providing detailed descriptions of treatment protocols, but as noted above, the type of details required by these checklists may not improve either replicability or everyday clinical implementation of study protocols. As stated earlier, it is not simply more detail that is needed, but detail regarding administration of the active ingredients and treatment dosage, and clear identification of the function that these ingredients are hypothesized to change.

When researchers are identifying treatment ingredients for a given target, the RTSS requires them to also specify the ingredient dosage with reference to theoretically important dimensions of the ingredient (e.g., tension and duration for soft tissue stretch vs. practice schedule for skill development). This is a significant conceptual and practical advance over the typical practice of describing dose as total time or number of sessions, which conveys little meaningful information about the individual ingredients provided.[40–42] This practice is exemplified by the TIDieR checklist Item 8, "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, or dose." The resulting TIDieR description does not tell readers which ingredients were provided during specific treatment sessions, how much of each ingredient was provided per session (dose), and what the target was for which ingredients (e.g., see our reworking of the Tiedemann, et al. protocol in Table 2). The actual measurement of ingredient dosages is not necessarily a straightforward endeavor[43, 44]—especially ingredients for Skills and Habits targets, and Representation targets that include

notions such as the number of opportunities to practice, amount of feedback provided, type and amount of information conveyed in educational materials, and goal-setting parameters. Using the RTSS to specify dosage, even if that specification is incomplete, will help unpack the black box of rehabilitation treatments and ultimately improve the replicability of research interventions.

The specification of ingredients and their dose is critically important for the concept of treatment progression, which is a key feature of many treatments. The term “progression” refers to the clinician following a predetermined schedule of varying the quantity of ingredients over time to change function by increasing physical or cognitive task difficulty. Like dosage in general, progression is frequently underspecified. For example, in a recent systematic review of intervention descriptions in exercise for breast cancer survivors, only 29% of studies described progression of dose or intensity over the course of treatment.[45] Furthermore, reporting of progression parameters did not improve over the time period between the authors’ original systematic review in 2012[46] and their 2016[45] updated review.

Lack of specificity regarding targets, ingredients, and doses is a major barrier to knowledge translation into clinical practice. Because ingredients are not explicitly identified or described in a standard fashion in published treatments (especially the ingredients that were vital to the reported improvements in patient functioning), front-line clinicians often struggle to pinpoint what he or she should be doing to accurately implement these treatments. The RTSS directly addresses this problem because research reporting would identify and describe ingredients in a standardized manner, and tie them directly to specific targets. Therefore, if a clinician has a patient who needs to be more physically active, Table 2 row 1 can point to specific treatment ingredients that may help achieve that target (e.g., the number and schedule of practice sessions needed to develop a habit; provision of a step monitoring smartphone app). If the patient is not pursuing opportunities to increase physical activity in the community, Table 2 row 2 can point to specific treatment ingredients that may help increase the probability that the patient will engage in the recommended activity (e.g., provide the patient with an individually-tailored list of activity opportunities in their community or written materials on the dangers of inactivity).

Evidence synthesis and meta-analyses

Meta-analysis of clinical trials requires that all included studies are the same or at least very similar with respect to Population, Intervention, Comparator, Outcome, Time after intervention, and Setting of care (PICO-TS).[47] The terms Intervention and Comparator (the comparison intervention) would include ingredients as defined by the RTSS, and Outcome would correspond to measures of either targets or aims. Meta-analysis authors judge similarity of ingredients and outcome measures initially qualitatively, and any presumed similarities are evaluated using a measure of heterogeneity such as I-squared. However, only infrequently does a high I-squared lead to the decision not to perform a meta-analysis; typically the meta-analysts judge that apples and oranges can be combined. The RTSS emphasizes that substantial heterogeneity is hiding under the labels we put on rehabilitation interventions (e.g., memory therapy, gait treatment), including heterogeneity in specific targets and in the nature and quantity of the ingredients used to achieve those targets.

The current approach to describing treatments is a significant obstacle to evidence synthesis and meta-analysis, because it groups treatments that differ in their targets and active ingredients, and fails to group treatments that are very similar in targets and active ingredients but go by different names. Without a clear description of a treatment's active ingredients, it is difficult to ensure that replication attempts actually delivered the same ingredients as the original study. As an example, grouping together executive function interventions for meta-analysis would be inappropriate as recent clinical practice guidelines note at least two different sub-types, each with different targets: *metacognitive strategy instruction* targets the consistent, accurate use of a strategy; and *use of alerting or prompting aids* targets the correct performance of a specific task.[48] Viewing these two types of executive function interventions through the RTSS lens illustrates several benefits of using this system: 1) although these two treatments have different names, both metacognitive strategy instruction and use of alerting or prompting aids require ingredients related to practice or habit formation; 2) both treatments are likely to require ingredients to increase the patient's effort (the likelihood of using the strategy or aid as directed). Thus, specification of treatments using the RTSS can shed light on the differences and commonalities amongst treatments to guide appropriate grouping for analysis and potentially reduce the number of studies necessary to establish treatment benefits.

The grouping of targets into three categories (Organ Functions, Skills and Habits, and Representations) is relevant to all rehabilitation disciplines, and viewing targets from this perspective can enable evidence synthesis across a wide variety of interventions and disciplines. These broad categories could facilitate novel questions like "How are ingredient doses related to the achievement of habits across a range of different behaviors?" and "What ingredients are associated with improved volitional engagement in a wide range of treatments?" For example, the skills of speaking with better voice quality, walking with a cane, and using adapted utensils all require the clinician to provide opportunities for the patient to practice (an ingredient from the Skills and Habits group). In other words, use of the tripartite structure and target groups of the RTSS might reveal general principles that govern treatments across a wide variety of Skills and Habits targets and Representations targets. Therefore, the effort to specify treatments using the RTSS can have major benefits in aggregating/ integrating information across studies, ultimately to provide a stronger evidence base.

Adoption of the RTSS does not guarantee that researchers will use the same treatments in their studies. However, the RTSS can improve the field's knowledge of what treatment type is being provided and how the treatment varies from study to study, which is currently impossible due to the lack of a standardized specification system. Once the field can adequately describe its interventions, the development of treatment labels representing a host of ingredients and their associated targets becomes possible; which would be beneficial for meta-analysis.

Next steps for implementing the Rehabilitation Treatment Specification System

In this paper, we described the major concepts of the RTSS and the potential benefits of adopting this system for intervention reporting, replication, knowledge translation, and evidence synthesis. The RTSS provides a theory-based framework that is useful across disciplines and diagnoses, provides a standard procedure for identifying treatment components, and links ingredients to specific targets to facilitate investigation of the mechanisms by which ingredients cause changes in a target (i.e., mechanisms of action). Categorization of treatments into three treatment groups (Organ Functions, Skills and Habits, and Representations) helps emphasize commonalities across rehabilitation disciplines, and their use could have a significant positive effect on evidence synthesis. The recognition of the importance of volitional behavior provides opportunities to assess the extent to which observed outcomes are driven by effects of the ingredients on the target versus the successful “delivery” of ingredients themselves (i.e., patient adherence). Finally, the distinction between targets and aims moves the field toward a closer match of outcome measures to the targets of the therapy provided, which could help pose testable theory-based questions regarding whether and how treatments exert their effects.

What would it take to successfully implement the RTSS in rehabilitation research reporting? Practically, funding agencies and journal editors would need to require that authors adopt the specification system in their treatment grant proposals or manuscript submissions. However, we first must empirically demonstrate the potential benefits of the RTSS for research reporting. In collaboration with an Advisory Board consisting of rehabilitation stakeholders, we have initiated implementation projects that focus on two main knowledge translation steps: 1) collaboration between RTSS specialists and developers of rehabilitation treatment protocols to examine the impact and value of RTSS application, and 2) developing and implementing training to help future users of the RTSS acquire skill in applying the framework.

The collaborative process to specify treatment protocols using the RTSS will entail a back-and-forth between the RTSS specialists and treatment developers. An iterative approach is needed because the identification of treatment components, discriminating targets versus aims, and describing ingredients and targets requires both skill in using the RTSS rules and concepts (which the RTSS specialists have acquired) and knowledge of the hypothesized relationship between ingredients and targets (which requires the content expertise of the treatment developer). Creating and refining the specification of research protocols will provide opportunities for qualitative assessments of the value of the RTSS. Protocol developers and clinicians who would use their protocols can be directly asked about how the two treatment descriptions (original protocol versus its RTSS specification) differ in terms of replicability, opportunity for assessment of fidelity, and clarity of implementation instructions. RTSS specifications of research protocols could be immediately impactful by allowing front line clinicians increased insight into how the protocols may be adapted for their patients, facilitating increased use of evidence-based practice in rehabilitation.

For the RTSS to be useful as a research reporting tool, authors and reviewers will need to acquire some skill in using and applying the framework. Even without extensive training in the RTSS, the framework makes it possible for peer reviewers and authors—during their limited interchange—to bring up theoretically and clinically important concepts that were not easily accessible before the RTSS's development. These include: 1) whether or not the protocol has/ needs a treatment component to affect the patient's volition, 2) whether the measured outcomes match the hypothesized targets, and even 3) how ingredients affect targets (via mechanisms of action). Therefore, the contribution of the RTSS is not just the production of a new type of "correct" treatment specification, but also the facilitation of a process of theory refinement in a field composed almost entirely of complex interventions, delivered largely without theoretical underpinnings. Without a process for theory refinement, rehabilitation will be limited to individual empirical studies showing efficacy or effectiveness, without a means to systematically evaluate why a treatment works or how a treatment can work better.

The RTSS Manual contains a proposed list of formal rules for describing all rehabilitation treatments, from simple to complex. It is likely that applying the RTSS to complex treatments (e.g., treatment to increase independence in dressing) will be more challenging than application to simpler treatments (e.g., treatment to increase upper limb strength). However, it can be argued that using the RTSS for more complex treatments will result in more benefit, comparatively. Our current and future work is focused on implementation of the RTSS to demonstrate its usefulness, which work may also provide opportunities to determine the need for RTSS revision or the development of extensions.

Conclusion

The RTSS can provide much-needed guidance on how to describe a treatment protocol, as well as improve study replication and evidence synthesis. Additionally, because RTSS-based specifications can link ingredients with their targets, and foster discussions related to the association of outcome measures with targets or aims, researchers can systematically investigate how and why treatments fail, and revise them to achieve better outcomes. Adoption of the RTSS in research reporting will require the support of researchers, funders, and editors, and the broader dissemination of the skill of performing treatment specifications within this system. However, this effort has great potential to advance the development of evidence-based rehabilitation practice.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Abbreviations

POC	Point of care
PBE	Practice-Based Evidence
RTSS	Rehabilitation Treatment Specification System
TIDieR	Template for Intervention Description and Replication

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Table 1.

Treatment group examples using the Rehabilitation Treatment Specification System

Group	Treatment example	Target for treatment	Ingredient(s) for target
Organ Functions	Prism adaptation training[1]	Improved line bisection or circle crossing on the patient's left side	20-diopter, right-shifting by 11.4°, goggle-mounted, wedge prism lenses
	Mallet finger treatment[2]	Increased passive range of motion of the distal interphalangeal joint	Graded protective mobilization after four weeks of joint immobilization via splinting
	Circumlaryngeal manual therapy[3]	Decreased tension in suprahyoid muscles	Apply light circular pressure via the thumb and top finger on the posterior horns of the hyoid bone, within the thyro-hyoid space, and posterior borders of the thyroid cartilage.
	Exercise training[4]	Increased strength in bilateral knee extensors	1–2 sets of 6–8 repetitions at 65% of the patient's one-repetition maximum voluntary contraction.
Skills & Habits	Constraint induced movement therapy[5]	Improved accuracy in a functional reaching task with the more impaired limb	Perform a certain number of reaching repetitions with the more impaired limb while the less impaired limb is restrained
	Cognitive Orientation to Occupation Performance[6]	Formation of habit: use of the 4 step global strategy "Goal, Plan, Do, Check"	Provide goal sheets for each goal trained in the session, which are to be completed in daily life to document successful or non-successful implementation of a plan.
	Resonant Voice Therapy[7]	Formation of habit: use of forward focus resonance	Perform a certain number of voicing trials, at various difficulty levels (vowels, syllables, speech, etc.), with subsequent clinician feedback on correctness.
	Physical activity and fall prevention intervention[8]	Formation of habit to increase physical activity	Provide a practice schedule and provide feedback on daily activity with a Fitbit™
Representations	Frazier free water protocol[9]	Increased knowledge of oral hygiene protocol	Oral and written information was provided to the patient regarding how to properly perform oral hygiene.
	Motivational interviewing[10]	Increased positive attitude towards behavior change	Gather motivation-related information, cue patient to think about meaning of change, and elicit change talk
	Anger self-management training[11]	Modified beliefs regarding anger	Verbally describe anger as a normal adaptive emotion and discuss the specifics of the patient's anger response in this normalized context
	Physical activity and fall prevention intervention	Patient to engage in recommended physical activity on a daily basis as directed	Tell the patient about specific individually-tailored opportunities to increase physical activity in the community and provide website for searching for local active opportunities

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Table 2.

Intervention description using the Template for Intervention Description and Replication (TIDieR) checklist provided by Tiedemann et al.[1,2]

1. Brief name

Combined physical activity promotion and fall prevention intervention enhanced with health coaching and pedometers to increase older adults' physical activity levels and mobility-related goals.

2. Why

Physical inactivity and falls in older people are important public health problems. Health conditions that could be ameliorated with physical activity are particularly common in older people. One in three people aged 65 years and over fall at least once annually, often resulting in significant injuries and ongoing disability. These problems need to be urgently addressed as the population proportion of older people is rapidly rising.

3. What- materials

Participants will receive:
- The "Staying Active and On Your Feet" fall prevention booklet developed by the NSW Ministry of Health
- A pedometer enhanced with a web-interface ("Fitbit™") to give feedback on the amount of daily physical activity achieved. *The Fitbits™ will also be provided as a motivational tool to encourage ongoing physical activity participation.*

4. What- procedures

Telephone or email-based health coaching will be used to identify barriers and facilitators to physical activity participation, and to provide education and support to assist participants to reduce their risk of falling and to achieve their physical activity goals. *The health coach will … monitor and facilitate progress towards physical activity goals and assist participants to overcome any participation barriers that arise. Participants will be encouraged to wear the pedometer during waking hours on a daily basis for the whole 6 month intervention period to record their daily steps and provide feedback and motivation to increase their physical activity participation. Participants will be encouraged to synchronise and download their data on a weekly basis or more often if desired. During the home visit to implement the intervention, participants will be taught how to use the Fitbit™ device and the associated internet based feedback and monitoring technology. The research team will have access to all intervention participants' Fitbit™ data and will monitor individual adherence with the intervention.*

5. Who provided

Three health coaches with professional backgrounds in physiotherapy will deliver the intervention.

6. How

The tailored fall prevention and physical activity plan will be delivered during one face to face interview. Health coaching will be delivered via telephone or email contact.

7. Where

The intervention will be delivered to community dwelling people in Sydney and surrounds, Australia.

8. When and how much

The telephone-based health coaching will occur after the face to face assessment and interview, once every 2 weeks for approximately 20 minutes for a total duration of 6 months.

9. Tailoring

The fall prevention aspect of the intervention will be tailored to individual need with reference to the fall risk assessment results. The physical activity plan will be tailored to participant goals, current physical ability and preferences. *Health coaches will also enquire about the circumstances of any falls that participants may have experienced and they will discuss strategies for reducing the risk of future falls. Intervention participants will also be assisted to find suitable local exercise opportunities (e.g. Tai Chi, balance and strength training) that will be identified using the NSW Ministry of Health's Active and Healthy online database (http://www.activeandhealthy.nsw.gov.au/). If participants have not uploaded their Fitbit™ data to their computer or internet-connected tablet device in the past week, during the fortnightly contact their health coach will enquire about any problems encountered with the pedometer and they will encourage participant compliance with the intervention protocol.*

[1] Assessment has been identified with strikethrough font (because the RTSS does not address assessment) and added information from the article's narrative description has been identified with italic font. All italicized text is directly quoted from page 3, section "Intervention Group" of the Tiedemann et al. article.

[2] TiDieR items 10 (Modifications), 11 (How well – Planned) and 12 (How well – Actual) are not addressed by Tiedemann et al., and are omitted here.

Table 3.

RTSS description of a rehabilitation intervention protocol based on Tiedemann et al.[1]

TARGETS		**INGREDIENTS**	
What/In What Way	**Group**	**Ingredient**	**Dosing Parameter**
1.Increased physical activity/ Formation of habit	Skills & Habits	• Provide a practice schedule suitable for developing a habitual activity pattern • Feedback provided by Fitbit™ on the amount of daily physical activity achieved	• *Multiple times/day in identified context # 1* • *Number of times/day Fitbit™ feedback provided*
2.Engage in recommended physical activity on a daily basis/ Perform as directed	Representations	• Tell the patient about specific individually-tailored opportunities to increase physical activity in the community • Provide website for searching for local active opportunities (http://www.activeandhealthy.nsw.gov.au/) • Provide information to support patient goal setting (physical activity goals) • Provide written materials on dangers of inactivity and benefits of activity • Tell the patient to synchronize and download data on (at minimum) a weekly basis. If no Fitbit™ data have been uploaded within the past week: [1] inquire about any problems encountered with the pedometer, [2] provide verbal encouragement to comply with the intervention protocol	• N/A • N/A • Two goals at a time • N/A • Once per week
3.Knowledge of strategies to reduce the risk of falling/ Increased amount	Representations	• Offer and verbally explain strategies for decreasing fall risk • Give patient written materials on fall risks and strategies	• *Repeated presentation until verbal recall was 90% accurate* • *N/A*
4.Performance of fall prevention strategies/ Formation of habit	*Skills & Habits*	• *Provide a schedule for practicing fall prevention strategies*	• *Number of times per day and number of repetitions per strategy*
5.Use recommended fall prevention strategies on a daily basis/ Perform as directed	*Representations*	• *Suggest opportunities to practice daily fall prevention strategies in a # of specific contexts* • *Instruct patient on how to perform strategies correctly* • *Instruct patient to use a written tracking method to cue and measure patient performance* • *Give patient written materials on the potential major health consequences of falls* • *Explain need to practice use of strategies for habit formation*	• *Multiple times per day in identified context #1, #2, etc…* • *Repeated presentation until performance was 90% accurate* • *N/A* • *N/A* • *N/A*

[1]Each row is a treatment component. As this chart reflects only aspects of treatment that are observable/ measureable, the Mechanisms of Action linking ingredients to targets are excluded. In cases where targets, ingredients or dosing parameters relevant to a particular component were not part of the treatment description provided by Tiedemann et al., these were filled in by the present authors to provide examples of what these might be and how they might be articulated. These do not reflect the actual protocol implemented by Tiedemann et al.