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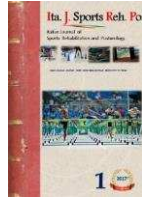
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# Ita. J. Sports Reh. Po.

Italian Journal of  
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## How evident are the guidelines for stroke 2014?

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### **Abstract**

*In May of this year there was a "Round Table" conference, where specialists working in the area of rehabilitation for individuals following a stroke were brought together to discuss the current levels of investigations, published works and evidence based practice in care delivery.*

*This resulting discussions identified concerns with the reporting accuracy and provision of replicatable data from the knowledge base on the subject, which also impacted on the validity and reliability of the current best practice guidelines available to practitioners.*

*The outcome from these group identify the need to develop a greater level of clarity and transparency in the reporting of research to ensure programs designed to improve the therapy for individuals following a stroke are more robust and go further to inform practice into better guidelines for future care.*



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## Introduction.

The first “Stroke recovery and rehabilitation round table” took place in May 2016<sup>(1)</sup>. Scientists from all parts of the world convened to discuss the current evidence with regards investigating Stroke. The round table discussions helped to confirm a series of general agreements in relation to this topic.

It was felt that a great number of the investigations considered at the roundtable along with the respected publications identifying these approaches lacked a particular depth of clarity when it came to providing physical therapists with the right depth of information with regards to how and what would need to be carried out when undertaking such investigations.

In the article: “Moving rehabilitation research forward: Developing consensus statements for rehabilitation and recovery research” Bernhardt, et al, (2016) helped to provide some insight into the need for authors to identify what is wrong with the current sharing of information along with some considerations as to what could be done, to improve the situation for the future.

This article considers the views of the scientists who took part in the “Round Table”-conference. Those present at the conference included:

1. Julie Bernhardt (Australia) Investigated the effects of early mobilisation after stroke with the AVERT – program<sup>(2)</sup>.
2. Karin Borschmann (Australia)
3. Lara Boyd (Canada)
4. S.Thomas Carmicheal (USA)
5. Dale Corbett (Canada) EBRSR = Evident-based Review of Stroke Rehabilitation.
6. Steven C Cramer (USA)
7. Tammy Hoffman (Australia) one of the people that had develop the TiDieR list.
8. Gert Kwakkel (Netherlands) The driving force behind the development of the guidelines for stroke 2004 and 2014 in the Netherlands.
9. Sean I Savitz (USA)
10. Gustavo Saposnik (Canada)
11. Marion Walker (UK)
12. Nick Ward (UK)

For this article the authors came to the conclusion that all the research on the area of rehabilitation isn't beneficial for individuals following a stroke because the investigation element was not transparent enough therefore resulting in the implementation phase of care being almost impossible to achieve. The article identifies with a number of point where the research itself was inadequate.

## Theme 1.

### Pre-clinic recovery research.

The purpose is to develop a better understanding about the neuro-biological events that happen in the recovery of stroke survivors. This includes developing the knowledge about the



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molecular mechanisms that can be influenced through different kind of therapy, such as rehabilitation or stem -cell therapy. Also looking towards how these mechanisms can influence the brains plasticity and therefore aid recovery following a stroke.

Further investigation was felt necessary to develop a better understanding of the profile for the clinical group of stroke survivors especially the older individual with co-morbidities who tend not to recover as quickly as others over a period of a few weeks.

## **Theme 2.** **Recovery of the Bio-Markers.**

Development of a new therapy that can stimulated recovery. It remains a paramount importance for research scientists to understand what the best treatment possible is, which remains a mystery at this current time.

Over the last decade it has become clear that there is a period of spontaneous recovery that can be stimulated through therapy. Although how this happens is still to be identified.

There are still only a few valid bio-markers which are currently identified, although more promising material currently being developed.

Especially TMS (Trans-cranial Magnetic Stimulation) has been found to provide beneficial effects within treatment of individuals following a stroke.

## **Theme 3.** **The developmental of therapeutic interventions especially the description in research articles.**

The narrative description of the interventions and treatments used along with the management of a control group in stroke rehabilitation remains incomplete. Too often poor amounts of reporting and misinterpretation of the descriptions written in the articles results in the value of the data becoming almost useless for fellow practitioners. Studies with clear guidance remains few and far between, with insufficient attention being afforded to providing information on the amount of training that is necessary or when it is best to carry out the interventions to maximize the potential for stimulation required for neurological recovery. The mantra “more is better” apart from being very ‘simple’ can to some degree be more harmful on some points in the recovery pad.

For instance there may be insufficient description of the intervention which in turn creates a barrier to reliably implementing and replicating the investigation itself. Therefore an extra guideline designed specifically to help to clearly describe the interventions and improve the overall transparency of its content for fellow practitioners to follow.

The Template for Intervention Description and Replication TIDieR<sup>(3)(4)(5)</sup> (see attachment), provides investigators with a guideline to help develop an investigation/trial in preparation for being published in an article that will ensure the best description of the intervention is included.



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#### **Theme 4. Measurements in clinical trials.**

The number of investigations on the subject of stroke rehabilitation has hugely increased over the last decade, although 98% of the published works do not meet with the TIDieR guidelines. Therefore the results of the different investigations are not comparable making it impossible to undertake a meta-analysis of the data.

Consequently by introducing a tool such as the TIDieR guidelines would help to make the presented evidence more systematic, therefore enabling a meta-analysis to be completed. Until such changes are implemented the volume of publications on investigations will remain high, although the quality of the evidence will continue to be poor which has a knock on effect towards having a comprehensive evidence based guidelines for stroke rehabilitation. Through the collaboration of 60 experts in the field of stroke rehabilitation, the need for change is evident, and this provides the base from which to develop our understanding of investigations and treatments for individuals following a stroke, which can then go to inform a more comprehensive practice guideline in the future.

#### **Test**

After reading the article by Julie Bernhardt<sup>(2)</sup> For the purposes of exploring the benefits of applying the TIDieR guidelines to an existing article I have decided to use Veerbeek, Kwakkel (2014) “What is the evidence for physical therapy Post Stroke? A Systematic Review and Meta-Analysis.”<sup>(6)</sup> and applied the fundamental principles of these guidelines to it. When meta-analysis was applied prior to using the TIDieR guideline it became evident quite quickly that a lot of unanswered questions presented themselves regarding the level of evidence.

For the purpose of scrutiny in this review I decided to apply the TIDieR list alongside only 1 piece of literature to help demonstrate the point of its usefulness.

Especially when applied to individuals following a severe stroke. Only this article presents with such a high Pedro score which was the rationale for its selection (see attachment).

#### **Item 1 Sit – Balance Training.**

In the article the treatment of the control group was described as “Conventional rehabilitation program”. Furthermore the intervention group received additional balance training as part of the treatment. When looking at replicating this method as described in the article it is almost impossible to demonstrate effectively to test the potential results. This is mainly due to the ambiguity of the term “Conventional rehabilitation program” which appears to be described different across different practitioners in various countries with the Netherlands being no exception to this.

#### **Item 2 Electro assistance in walking – training.**



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Besides 40 minutes of electro assistance there was also an additional 1.5 hours multidisciplinary treatment, although what this entails has not been described. When applying the TIDieR value's the individual elements of the electro assistance appeared to include intensity, frequency and length (time), but the base – which involved 1,5 hours treatment was not describe. Due to this lack of description it is again impossible to test the results and therefore restricts the possibility of implementing the treatment is significantly reduced.

### **Item 3 Overground Walking.**

An investigation with the intervention group - TIDieR – proof, the information was very explicit allowing for treatment to commence the following day. It involved a 4 weeks' intensive locomotor training in which the treadmill was set on the highest speed for the individual on a fixed time period. Over the treatment the period of time was increased, resulting in the individual developing a degree of stamina when using the treadmill on the highest speed for longer periods of time as they improved. Additionally, the weight support decrease from 40% at the beginning to only 10% at the end of the investigation. The result was that the intervention group increased their speed on the treadmill with less weight support when compared with the control group who did not improve over the same time period. After 4 weeks the control group became the intervention group and the intervention group was the control group and the treatment was repeated with similarly positive results. One issue with this was that it was not completely TIDieR aligned because the second control group had no treatment but was still capable of walking faster.

### **Item 4 Virtual reality.**

Often investigations tend to using a small group of individual following a stroke. In this article only 10 participants were identified, and the control group was noted to have something to achieve as part of the treatment but this was not identified in the article. Consequently, a comparison wasn't could not be identified.

### **Item 5 Circuit class.**

Sometimes the intervention group receive a 'task orientation resistance therapy' whilst the control group has no treatment. This isn't always as clear for physical therapists to follow and therefore difficult to perform in a clinical setting.

### **Items 6 Hydro.**

The experimental group receive exercises in the water especially cardio-vascular training with a clear framework to follow, whilst the control group undertook arm and leg exercises whilst in a seated position. What was less obvious was where the control group performed the exercises, for instance were the participants still in water, or just sat on a chair whilst doing this. This poor level of transparency prevent its immediate use within clinical practice?

### **Item 7 Electromyography biofeedback for the paretic leg.**



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#### **Item 8 Air splint.**

This group of 20 individuals received an intervention which was clear described, but the control group receive over the same time period was described as a “conventional” therapy. Therefore, comparison between the two groups was impossible and resulted in the potential for this to be repeated in clinical practice being significantly reduced too.

In this article the intervention group receive standard physical therapy in combination with changing pressure in the air splint. Time and intensity of the pressure was described. The control group receive as placebo short wave on the shoulder (although the tuning wasn't identified) and conventional therapy. Consequently, what was the significant difference between standard and conventional physical therapy. Without knowing the difference between standard and conventional it is difficult to then apply this knowledge into a clinical setting to produce any meaningful comparisons of the two sets of results.

#### **Item 9 Support Technics too prevention or treatment of the sublux of the shoulder.**

The Intervention was therapeutic strapping compared with placebo strapping with standard care? No clear description offered of what this involved limits the possibility of replication.

#### **Item 10 Bilateral arm training.**

An investigation where 3 groups were formed. A CIMT group, A bilateral training group and a control group. The length of time was identified for each day along with how often in the week it was needed to be performed. Although this was done by the first two groups, what the control group did in this time was not clearly defined. This limited the possibility to map out the progression of each of the three groups, to provide data of comparative performances.

#### **Item 11 CIMT**

Another investigation where CIMT group was used, with an intensive therapy program being used over a period of 2 hours. The question which was left unanswered was:” What does intensive therapy actually involve? Comparatively the individuals in the control group had their unaffected arms restricted, but no therapy appeared to be identified as part of this treatment. So the question remained about what the control group actually did over the same 2 hour period.

#### **Item 12 Mental practice.**

In this investigation 2 therapy groups clearly described. Repetitive Task Specific training encompassing ADLs with increasing levels of difficulty as the individual improves. Increasing





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### **Item 13 Mirror therapy.**

Intervention group did mirror therapy and the control group completed the same tasks without a mirror. The exercises was identified as 'bimanual training' (which was poorly defined), along with no additional description was offered identifying either the heaviness and/or the intensity of the exercises, and if there was any increase in the intensity as the individual improved.

### **Item 14 Virtual reality training for the paretic arm.**

There were 3 groups focusing on making extensions of their paretic fingers. Group 1 had assistance with a 'cable system', group 2 had assistance with a 'pneumatic system' and group three had no assistance. Other than providing information on what was used there was no further description of how the training was delivered.

### **Item 15 Trunk Restraint.**

This article provided a good investigation, in which the description of the exercises were clear, including information on the intensity , time and frequency. Training with this intervention group was easily transferrable into other clinical practices areas because of the information provided. The intervention group utilised a trunk restraint whilst the control group didn't. What was lacking from this study was any information about increasing intensity once the individual showed improvement.

### **Item 16 Strength training paretic been.**

Group 1 (the intervention group) received PRT training which is a community-based Progressive Resistance Training, unfortunately this is not a common practice and with limited description practitioners do not know what is involved in this. With strength training it is possible to describe everything clearly, such as the level of intensity, the number of rehearsals, the frequency of delivery, the number of session and the amount of time for each individual session and the exercise themselves with as much detail as possible. In the article about muscle recovery training this information was readily available for practitioners to copy, but the "Community-based Progressive Resistance Training" failed to offer this and there was no description at all when it came to the control group.

### **Item 17 Combination of strength and cardio-vascular training.**





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This combination of training appears to have good results for individuals with dementia. The description of the intervention group was based around a cardio-vascular function which was well written but the strength training part lacked any depth of information. The difference between the two groups was down to receiving a level of supervision with the intervention group whilst the control group had none.

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#### **Item 18 High intensity exercise therapy.**

This investigation's approach was based on the principle of "More is better" when considering the exercise regime for participants.

The intervention group had a high intensive exercise program with a core 17 hours of dedicated therapy divided over a period of 10 weeks, plus an additional piece of therapy running alongside this. Whereas the control group had a regular exercise program with no additional therapy. The information provided for both of these studies does not allow for differentiation between what makes it regular or high intensity? When it came to considering what the main consideration was with the focus of more intense exercise stimulating a greater level of recovery there was never any indication as to why this was considered in place of perhaps more traditional approaches which are developed over a longer period of time for instance.

#### **Item 19 Final Article.**

##### **The judgement of the Neurological treatment methods**

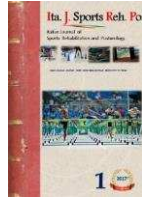
This approach distinguished between two groups, with one group including individuals who following a stroke, received therapy from a group of physical therapists, that were educated in the NDT- concept which was delivered for 40 minute periods each day.

Group two also included individuals following a stroke but they received a therapeutic program based MRP Motor Relearning Program, which was also delivered by a group of physical therapists educated in this approach for periods of 40 minutes each day.

The information on the therapy itself neglected to identify what the contents of the exercise programme involved, and the location where the therapy was delivered. There was no recognition to indicate the initial intensity and any adjustments which were made over the program such as when the intensity levels were increased. There was also no identification of how qualified or experienced the physical therapists delivering the programme needed to be following receiving the educational support for each respected approach.

The results of all the treatments for both groups with individuals following a stroke is often determined through the severity of the stroke itself and the degree of damage caused to the brain. Therefore, this information is useful to provide as a baseline for measuring improvements. Unfortunately this was not identified as part of the study.

As part of the Round Table Group Discussions the point of identifying baselines was considered to have a particular significance, not simply because the diversity of individuals following a stroke can be extremely complex, there is also a differentiation of how older individuals in particular appear to follow a different recovery curve, and as such this would have needed to be considered as part of the selection process, so that the similarities of severity of condition and age were reflected in both of the groups to help improve the validity of the results generated.



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Here are some examples differing Baseline - Characteristics comparisons from another investigation.

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Group 1 Severe Level 27 % compared with group 2 10%  
Group 1 Moderate Level 33 % compared with group 2 12%  
Group 1 Low Level 40% compared with group 2 57%  
Group 1 “Neglect” 33% compared with group 2 10 %

Group 1 receive NDT whilst group 2 receive conventional therapy! The descriptions offered in the study wasn't very clear when it came to describing what the therapy was, how heavy it was performed, which frequency and length of time. Even the concept of using NDT- Bobath therapy differed not only within different centres of physical therapy but also in its interpretation from country to country. Therefore like so many of the other interventions identified above, the lack of transparency reduced the potential of replicating the study in clinical practice settings to test the hypothesis and results.

#### **And Now? Are we back at the beginning?**

From 2000 a lot has been accomplished with regards to changes in treatment for individuals receiving rehabilitation following a stroke. This has especially help to try and inform a set of common principles which were adopted in many guidelines across the world, such as a considered timescale of support with 48 minutes being dedicated to physical therapy and 23 minutes to occupational therapy as a base.

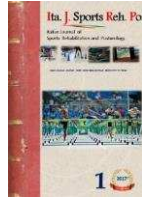
Unfortunately as this paper has tried to highlight, when it comes to the interpretation of the content of the therapy provision, this still remains confusing and somewhat conflicted in its approach.

The Intensity or how heavy the exercise is undertaken must provide information on how much is required to stimulate a reaction in the brain that will provoked the damaged areas to start to recover to help improve its overall control. This in turn would suggest the approach ( mantra) ‘More is Better’ should be reconsidered due to its potential to actually hinder effective recovery. <sup>(7)</sup>

On the other hand therapist already recognise that training can in some instances promote recovery or develop adaptation only when the body is challenged. This certainly accounts for muscle development but may also impact on the brain function itself.

New approaches according the TIDieR guideline should therefore require the need to clearly outline the level of for intensity along with the benefits of searching for bio-markers which will provide a more systematic approach for promoting improvement for individuals in the future. Practitioners are now considering the need to review their own practices and to submit for a review which can only be good when we consider the need for developing a best practice standard for therapy.

Are we back at the start?



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I think not, although I do feel that the real search of the “Holy Grail” is now looking like a more realistic outcome, so once it is available individuals are more likely to receive the most effective approaches to treatment in all stage of stroke.

Until that is achieved, practitioners should consider how to make the treatment more challenging considering how heavy the impact is and using variation in approaches, because this helps with brain stimulation when it searches for solutions to develop or re-develop its overall functional control.

The treatment must consider all aspect of the ADL, not only walking and balance but also getting out of a bed and on IADL, because these are the real issues of what individual following a stroke need, to start addressing the process of recovery towards independent function. This therefore requires the therapist to be capable of providing training programs which incorporate these aspects fully.

Many therapist continue to treat individuals following a stroke, therefore the need to continue to look at learning and developing your practices is paramount as we search for the best evidence to inform future guidelines.

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