

Rehabilitation of patients with a moderately to severely affected arm-hand in the sub-acute phase after stroke

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Chapter 10

Valorization

In stroke, the loss of the ability to move the arm and hand is a very common, and often persistent and disabling symptom [1]. Stroke patients who have a prospect on recovery of arm-hand function should be facilitated in creating an optimal retention of how to use the full potential of their affected hand in their own daily life pursuits. Organizing and structuring clinical treatment supporting stroke patients with a moderately or severely affected hand in regaining an optimal level of arm-hand function and arm-hand skill performance is difficult.

This thesis provides a perspective on how to clinically manage sub-acute stroke patients with a moderately to severely affected arm-hand, regularly seen in stroke rehabilitation settings.

The findings of this thesis may contribute to an increase in quality, efficacy and efficiency of treatment from both the perspective of health care professionals and patients. Furthermore, this research also provides some suggestions how to systematically implement novel insights in daily clinical practice.

Most important deliverables of this thesis are:

- 1) a clearly defined clinical pathway, aimed at the moderately to severely affected arm-hand of subacute stroke patients, which may lead to a more efficient way of communication between clinicians and patients, as well as between clinicians and scientists with respect to *how* therapy content relates to the patients' goals, and to clearly describe and communicate the treatment steps that are *actually* taken during arm-hand therapy [2];
- 2) reference data, obtained from the single-armed prospective cohort study, describing how stroke patients, who were admitted to CARAS, actually perform during and after rehabilitation;
- 3) suggestions on how to incorporate and systematically investigate technological and/or pharmacological interventions within the existing CARAS treatment, which may facilitate patients and/or clinicians during arm-hand rehabilitation in improving patients' performance. In addition, the information on how technological and/or pharmaceutical interventions that are used in conjunction with the designed clinical care pathway can be assessed, may also be beneficial to other stakeholders like innovative companies and knowledge institutes.

Valorization potential towards clinical experts and scientists

The multitude and complexity of information regarding the treatment of the patients' affected arm and hand in the post-stroke phase requires an efficient treatment policy. Facilitating knowledge exchange among clinical experts and between scientists is an important first step to take [3]. Here, four steps for further valorisation are proposed:

Step 1: Setting a reference frame

CARAS contains a well-defined form of therapy-as-usual, substantiated with outcome data at AHF and AHSP level [4, 5]. CARAS' transparent nature and related data may be used to, 1) strengthen insight into effects and changes at outcome level, process level and structure level, and 2) provide insight into complex arm-hand impairments and concomitant interventions. In summary, information obtained can be used as a *frame of reference* for clinicians and scientists to discuss clinical and scientific questions with respect to this field. Sharing knowledge and experiences may accelerate consensus on how to develop and/or improve knowledge, skills and outcomes with respect to arm-hand interventions that are currently offered in stroke rehabilitation practice. Experiences acquired in the stroke population may also be applicable in rehabilitation of patients who experience arm-hand problems due to other forms of central neurologic disorders.

Step 2: Combining expertise across disciplines

Strengthening the connection between care and research, and creating an on-going interaction between clinical experts and researchers is critical in order to facilitate the exchange of relevant knowledge with respect to the field [6]. To develop and adjust arm-hand interventions to the patient's individual needs, and to design the set-up of evaluation studies with respect to novel arm-hand interventions in moderately to severely affected patients is considered to be complex. This complexity reflects the importance and need for clinicians and (clinical) scientists to formalize exchange of knowledge and learning, which would necessitate the development of a (so-called) *Specialty*, focused on bringing together expertise on arm-hand rehabilitation in patients with a central nervous system disorder.

Step 3: Education program

Following chapter 2 of this thesis, in which CARAS has been described, an education and training program of arm-hand rehabilitation has been developed (in Dutch: "Opleidingsplan arm-hand revalidatie na centraal neurologisch letsel" (unpublished)). The training program has primarily been built to support clinical experts in their clinical

decision-making process in patients with different levels of arm-hand impairment after stroke. The main part of the training program contains 1) a module with respect to the analysis and observation of arm-hand skill performance, 2) a module containing the development of interventions in arm-hand skill performance training, and 3) a toolbox with supportive information, including various documents, such as the actual treatment program, a patient workbook, assignments and a manual.

Furthermore, throughout the Netherlands, the majority of the stroke survivors are discharged from the hospital to their home situation or are admitted to a nursing home [7]. Part of these patients also has to cope with a moderately to severely affected arm hand. Therefore, it is also relevant for clinical experts, who work in hospitals, nursing homes and/or home-based health-care centers to exchange and structure information with respect to the clinical management of the affected arm and hand in post-stroke phase. In fact, based on the complex nature of arm-hand rehabilitation, creating a network for arm-hand rehabilitation in central neurological disorders involving clinicians from a broad spectrum of rehabilitation care delivery organisations may optimize the quality of treatment, research and guidance of patients with an affected arm and hand. The description of CARAS and scientific output, as has been outlined in this thesis, may be used as supportive information in conjunction with the training course, thus valorizing the knowledge gathered in our research as presented in this thesis.

Step 4: Consortium building

Between 2014 and 2019 CARAS has been implemented in a number of stroke rehabilitation units in the Netherlands which now are united in a consortium (see Figure 1). The consortium provides a platform for discussion and learning methods with respect to topics related to arm-hand rehabilitation in post-stroke phase. Internationally, several stroke rehabilitation centers have implemented parts of CARAS. A step-wise implementation plan was developed in order to facilitate the implementation process of CARAS in other rehabilitation centers. An example of this implementation process is outlined in Figure 2.



Figure 1. Rehabilitation centers in the Netherlands who joined the CARAS Consortium between 2014 and 2019

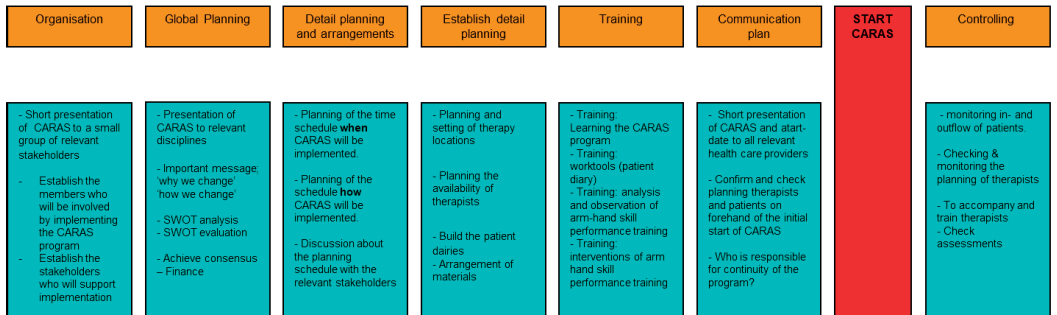


Figure 2. Example of an implementation schedule of CARAS.

Valorization regarding technological innovations

The use of (rehabilitation) technology as part of regular treatment may be a solution in optimizing and improving treatment outcome in AHF and AHSP during rehabilitation [8, 9]. From the perspective of manufacturers and distributors of technological and medical devices, there are several challenges with respect to the incorporation of technology in (daily) rehabilitation treatment. Many innovations do not mature and are not implemented in rehabilitation care. Also, impact assessments with respect to (cost-) effectiveness often are missing and technology can be used erroneously.

To exchange knowledge and intensifying the collaboration between the development and manufacturing of technological devices with rehabilitation experts may lead to a more optimal use of a device and could even accelerate the approval process of a medical device.

A substantial part of technological devices, developed with the purpose to be used as a medical device are subject to a systematic clinical evaluation, according to the Medical Device Regulation (MDR) [10]. This procedure is required *before* the product is provided with a (CE) certificate. Only once the product is certified, it can be distributed to end-users, as for instance healthcare providers or patients. These regulatory requirements and obtaining the approval process, is likely to make the transition to stroke rehabilitation services a complicated and time-consuming process. Data with respect to the development of arm-hand function and arm-hand skill performance of patients who were allocated to CARAS can be used as a reference database and can be used as a route to (systematically) assess and evaluate new technological innovations with respect to arm-hand rehabilitation in post-stroke phase. An example of an international initiative in which the reference data of this thesis will be used for further (technological) developments is the European Interreg EMR project "*Innovation and Implementation acceleration of Complex Rehabilitation Technology*" (acronym: i2-CoRT) (<https://www.i2-CoRT.eu/>). For example, the CARAS program is being used in conjunction with a novel, 'remote handling concept'-based, task-oriented arm-hand skill performance training approach (ReHab-TOAT) for patients with a moderately to severely impaired arm-hand in the subacute and chronic stage after a stroke. Results from this combination of existing treatment (CARAS) and novel, technology-assisted training aspects may be used by companies developing new

technologies in improving their product, bringing it in alignment with current training principles, thus valorising the (clinical) knowledge gathered.

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