

# Towards improved organisation of care

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# Towards improved organisation of care

Improving compression therapy for patients with DVT and  
CVD (CEAP 3-5)

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Rachel Hellen Petra Schreurs

**Promotor:**

Dr. A.J. ten Cate-Hoek

**Co-promotores:**

Prof. Dr. M.A. Joore

Prof. Dr. H. ten Cate

**Beoordelingscommissie:**

Prof. Dr. C. D. Dirksen (chair)

Prof. Dr. F.A. Klok (LUMC, Leiden)

Prof. Dr. R.P. Koopmans

Dr. M. R. De Maeseneer (Erasmus MC, Rotterdam)

Dr. R.T.A. Willems

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# Chapter 1

General introduction



## Introduction

The IDEAL-DVT trial showed that for patients with deep venous thrombosis (DVT) an individualized therapy with elastic compression stockings (ECS) using the Villalta-score was non-inferior to a standardized treatment duration of 24 months in preventing post-thrombotic syndrome.<sup>1</sup> By using this approach, it is possible to distinguish patients who benefit from long-term use of ECS from patients for whom long-term use has no added benefits. A cost-effectiveness analysis showed that this approach could save at least 30 million for this population per treatment episode of two years.<sup>2</sup> As a result of these findings, a dissemination and implementation proposal (VIMP) was developed to improve implementation of this individualized approach. This also included identifying and addressing other barriers in compression therapy. This VIMP was the basis for the current thesis. The granting organization (ZonMW) requested to also include patients with chronic venous disease (CVD) that are treated conservatively with compression therapy without other interventions. The rationale for this request was twofold: 1). There are many similarities in how compression therapy is organized for DVT and CVD, and 2). The largest part of the compression therapy care pathways and involved health care professionals is similar for both DVT and CVD. However, except for those similarities and the fact that both diseases affect the venous system, DVT and CVD are different entities of venous diseases with other underlying pathologies, complications, as well as other outcomes to be managed.

Deep venous thrombosis affects 1-2 per 1000 persons annually worldwide.<sup>3</sup> The mechanisms contributing to thrombus formation are defined by the Virchow triad as stasis, injury to the vessel wall and hypercoagulability; any combination of these mechanisms can lead to the formation of a thrombus. In the acute phase of DVT, the thrombus causes an acute obstruction of the deep venous system, which triggers an inflammatory response.<sup>4</sup> As a result of this response, damage to the valves and reflux can develop. The combination of outflow restriction and reflux, in turn, leads to venous hypertension. Although the exact pathophysiology of post-thrombotic syndrome is not clarified yet, especially outflow restriction is assumed to contribute to its development.<sup>5-7</sup> Up to 50% of DVT patients develop the post-thrombotic syndrome with manifestations such as oedema and skin problems.<sup>8,9</sup> These patients experience symptoms like pain, cramps, heaviness, and paraesthesia. Unfortunately, when the post-thrombotic syndrome has developed, it cannot be treated curatively. Although some controversy remains on the preventive properties of ECS therapy for DVT, the latest Cochrane review indicated a significant reduction in the incidence of the post-thrombotic syndrome associated with ECS therapy [RR 0.62 (95% CI=0.38–1.01, P=0.05)].<sup>10</sup>

Chronic venous disease is an overarching term that includes the full spectrum of long-term abnormalities affecting the venous system.<sup>11</sup> The prevalence of CVD (all stadia) in

the population ranges from 45.6% to 83.6%. Where COs (no visible or palpable varicose veins) was excluded, C1-C6 (patient with at least varicose veins) estimates ranged from 38.3-90.4% and disease severity generally increased with age.<sup>12</sup> The disease pathology is complex and involves genetic susceptibility and environmental factors. Symptoms are variable and include itching, aching, heaviness, tiredness, cramps and swelling of the leg, and skin manifestations such as hyperpigmentation and lipodermatosclerosis.<sup>13-15</sup> Chronic venous disease covers primary abnormalities of the venous wall and/or valves, but also secondary abnormalities as a complication of DVT. These abnormalities can lead to reflux and an alteration in hemodynamic properties with consequent venous hypertension. Venous hypertension most likely activates a number of inflammatory pathways which contributes to remodeling of the venous walls and valves leading to markedly dilated, elongated and tortuous capillaries. Venous hypertension also causes increased hydrostatic pressure in the capillaries which ultimately causes edema. All these changes are likely to prevent normal nutrition to skin cells predisposing to ulceration.<sup>15,16</sup> Chronic venous disease can be divided in different clinical stages according to the clinical, etiologic, anatomic and pathophysiologic (CEAP) classification.<sup>17</sup> Most stages of CVD are invasively treated since there is insufficient evidence that compression therapy prevents progression of CVD<sup>18,19</sup> and only limited evidence that supports reduction of symptoms for the lower CEAP-stadia.<sup>20</sup> Patients with a healed ulcer, however, should use elastic compression stockings for the long-term to prevent the development of new ulcers.<sup>20,21</sup> The incidence of venous leg ulcers in CVD patients is estimated at around 0.73 to 3.12 per 1000 persons per year.<sup>22</sup> The development of a venous leg ulcer is associated with long-term treatment and a decreased quality of life.<sup>23-26</sup> For the current thesis, we focus on CVD-patients that are treated conservatively, and have venous edema and/or a healed venous ulcer.

As described, compression therapy is part of the treatment of all patients with DVT, and patients with CVD treated conservatively. The therapy can roughly be divided into three parts: initial compression therapy and elastic compression stocking (ECS) therapy, which can be divided in the subacute and the long-term treatment phase. Initial compression therapy should be provided directly after diagnosis and reduces leg symptoms and swelling by counteracting the increased venous pressure and improving the venous flow.<sup>27-29</sup> For patients with DVT, adequate compression in the acute phase may also enhance thrombus resolution.<sup>30</sup> Different types of initial compression therapy are available: temporary compression hosiery, multilayer compression bandages, and adjustable compression devices. The type of initial compression may affect the patient's possibilities to remain self-reliant. Therefore, selecting the most suitable form of compression for each patient is essential. Initial compression (with or without home care assistance) is indicated until swelling of the leg has receded and the ECS can be fitted (the subacute treatment phase of ECS). The long-term treatment with ECS varies for patients with DVT who have a limited treatment duration based on clinical assessments, and patients with CVD that continue ECS for life.

Compression therapy is a complex process in which various healthcare professionals (internists, general practitioners, dermatologists, medical stocking suppliers, occupational therapists and home care nurses) can be involved. These collaborating healthcare professionals constantly adjust their performances to each other's and the patient's situation. To achieve optimal results for the patient it is important that this process is well-coordinated and that consensus is reached regarding how compression therapy should be optimally organized. In the Netherlands, a cross domain protocol to guide these interactions and to describe optimal care is currently missing. A recent report 'Verbetersignalement Diep veneuze trombose en longembolie' e.g. showed that, for DVT patients, the organisation of compression therapy could be optimized. This report recommended amongst others, to optimize patient information regarding assistive devices and treatment duration, and to implement the individualized ECS treatment for patients with DVT nationally.<sup>31</sup>

The organisation of compression therapy shows a large variability in current practice, which may lead to suboptimal care with probable consequences for the patient's access and adherence to compression therapy. Adherence to therapy is known to be an important predictor for compression treatment efficacy.<sup>32,33</sup> However, over 50% of DVT patients do not experience any problems with the leg in the sub-acute phase after DVT. For these patients the risk of developing PTS might be hard to imagine or understand. A discrete choice experiment in this population showed that patients are willing to accept an increase in future risk of PTS of 29% if that meant that they would be self-reliant now.<sup>34</sup> Especially elderly and overweight patients are facing difficulties in applying and removing the ECS. One smaller study found that in this specific group approximately 14.6% of patients relied on home care for assistance.<sup>35</sup> Other factors decreasing patients' adherence include a lack of understanding the goals of compression therapy, feeling that ECS is not helpful, cosmetic reasons and uncomfortable feelings by using the ECS (tight and hot).<sup>36,37</sup>

Home care organizations are already confronted with an increased care demand due to the aging population which becomes hard to manage. The prognosis is that, in the Netherlands alone, 26.100 extra home care nurses are necessary to provide care in 2030 compared to 2020.<sup>38</sup> Increasing patients' self-reliance, and decreasing home care demands in patients with ECS therapy is therefore important to contribute to the sustainability of the system. Furthermore, few studies focused on the economic burden of compression therapy. Most of these studies focused on total costs for treatment or only costs associated with pharmacological therapy.<sup>2,29,39-41</sup> One study showed that healthcare costs are significantly higher when prescribing multilayer compression bandages are prescribed compared to temporary compression hose.<sup>29</sup> In addition, a cost-effectiveness analysis of the IDEAL-DVT trial showed that an individually shortened duration of ECS therapy based on clinical assessments was non-inferior and cost-effective compared to standard ECS treatment duration.<sup>2</sup> However, detailed insight into

the costs and resource use associated with the entire organization of compression therapy process and the budget impact of various critical treatment decisions is currently missing.

As a base to identify targets for improvement, we first aimed to gain a detailed understanding of current practice in the Netherlands. For this purpose, we selected two regions in the Netherlands (North-Holland and Limburg) with a different geographical localization and different hospital setting (a general hospital in North-Holland and an academic hospital in Limburg) and we performed a Functional Resonance Analysis Method (FRAM). Consequently, a realist evaluation was used to better understand the mechanisms leading to both desirable or undesirable outcomes. We thereby identified several improvement themes for the organization of ECS therapy from a local multiple stakeholder' perspective. Subsequently, we used these insights as a base for propositions which were than assessed by the national stakeholders in a modified Delphi analysis. The main improvement themes identified in the modified Delphi analysis were, in turn, used as inputs in a budget impact analysis. This budget impact analysis aimed to assess the impact of these improvements on resource use and budget. The budget impact analysis only targeted DVT patients since this was the focus of the original VIMP, and because follow-up for DVT patients was already common general practice nationally whereas the conduction of follow-up for CVD patients was largely variable.

## Aims and outline of the present thesis

In this thesis we describe the development of a national cross-domain protocol compression therapy, in the context of a VIMP, that guides healthcare professionals on how to optimize compression therapy not only for patients with DVT, but also for patients with CVD that are treated conservatively (excluding patients with active venous leg ulcers). To create this protocol, we followed a stepwise approach. **Chapter 2** provides a general overview of the role of compression therapy in DVT, the underlying evidence and the role of compression in the post-thrombotic syndrome. In **chapter 3** we provide a detailed insight into how compression therapy is currently organized in the Netherlands, which health care professionals are involved in the process, and how they collaborate using a FRAM. Ultimately, we identified barriers and improvement targets from a multi-stakeholder perspective. In **chapter 4** the improvement targets identified in chapter 3 were further refined by using a Realist Evaluation. This method identifies causal explanations between contextual factors (such as interpersonal relationships or institutional settings), health care professionals' reactions to these contextual factors (mechanisms) and their combined link to desirable or undesirable outcomes. In this way, a theoretical framework of how outcomes are achieved is created and targets for improvement are identified. **Chapter 5** describes the results of a modified Delphi study. In this study, statements regarding the improvement targets found in chapters 3 and 4

are assessed by national stakeholders from all disciplines and patients to reach consensus on optimal collaboration and critical issues of compression therapy. **Chapter 6** elucidates the costs and resource use of compression therapy in current practice, and the impact on resource use and budget impact of three important improvement themes as identified by the modified Delphi study (chapter 5). **Chapter 7** presents the final cross-domain protocol. Finally, **chapter 8** reflects on the proposed barriers and facilitators of the protocol's implementation and presents an initial implementation model for implementing the protocol in the complex context of compression therapy.

## References

1. Ten Cate-Hoek AJ, Amin EE, Bouman AC, Meijer K, Tick LW, Middeldorp S, et al. Individualised versus standard duration of elastic compression therapy for prevention of post-thrombotic syndrome (IDEAL DVT): a multicentre, randomised, single-blind, allocation-concealed, non-inferiority trial. Lancet Haematol. 2018;5(1):e25-e33.
2. Amin EE, Ten Cate-Hoek AJ, Bouman AC, Meijer K, Tick L, Middeldorp S, et al. Individually shortened duration versus standard duration of elastic compression therapy for prevention of post-thrombotic syndrome: a cost-effectiveness analysis. Lancet Haematol. 2018;5(11):e512-e9.
3. Naess IA, Christiansen SC, Romundstad P, Cannegieter SC, Rosendaal FR, Hammerstrøm J. Incidence and mortality of venous thrombosis: a population-based study. Journal of thrombosis and haemostasis : JTH. 2007;5(4):692-9.
4. Thomas DP, Merton RE, Hockley DJ. The effect of stasis on the venous endothelium: an ultrastructural study. Br J Haematol. 1983;55(1):113-22.
5. Phillips LJ, 2nd, Sarkar R. Molecular characterization of post-thrombotic syndrome. J Vasc Surg. 2007;45 Suppl A:A116-22.
6. Henke PK, Comerota AJ. An update on etiology, prevention, and therapy of postthrombotic syndrome. J Vasc Surg. 2011;53(2):500-9.
7. ten Cate-Hoek AJ, Henke PK, Wakefield TW. The post thrombotic syndrome: Ignore it and it will come back to bite you. Blood Rev. 2016;30(2):131-7.
8. Prandoni P, Lensing AW, Cogo A, Cuppini S, Villalta S, Carta M, et al. The long-term clinical course of acute deep venous thrombosis. Ann Intern Med. 1996;125(1):1-7..
9. Cucuruz B, Kopp R, Pfister K, Noppeney J, Tripal K, Korff T, et al. Risk and protective factors for post-thrombotic syndrome after deep venous thrombosis. J Vasc Surg Venous Lymphat Disord. 2020;8(3):390-5.
10. Appelen D, van Loo E, Prins MH, Neumann MH, Kolbach DN. Compression therapy for prevention of post-thrombotic syndrome. Cochrane Database Syst Rev. 2017;9(9):CD004174.
11. Eklof B, Perrin M, Delis KT, Rutherford RB, Goliczki P. Updated terminology of chronic venous disorders: the VEIN-TERM transatlantic interdisciplinary consensus document. J Vasc Surg. 2009;49(2):498-501.
12. Salim S, Machin M, Patterson BO, Onida S, Davies AH. Global Epidemiology of Chronic Venous Disease: A Systematic Review With Pooled Prevalence Analysis. Ann Surg. 2021;274(6):971-6.
13. Perrin M, Eklof B, A VANR, Labropoulos N, Vasquez M, Nicolaides A, et al. Venous symptoms: the SYM Vein Consensus statement developed under the auspices of the European Venous Forum. Int Angiol. 2016;35(4):374-98.
14. Langer RD, Ho E, Denenberg JO, Fronek A, Allison M, Criqui MH. Relationships between symptoms and venous disease: the San Diego population study. Arch Intern Med. 2005;165(12):1420-4.
15. Eberhardt RT, Raffetto JD. Chronic venous insufficiency. Circulation. 2014;130(4):333-46.
16. Raffetto JD. Pathophysiology of Chronic Venous Disease and Venous Ulcers. Surg Clin North Am. 2018; 98(2):337-47.
17. Lurie F, Passman M, Meisner M, Dalsing M, Masuda E, Welch H, et al. The 2020 update of the CEAP classification system and reporting standards. J Vasc Surg Venous Lymphat Disord. 2020;8(3):342-52.
18. Palfreyman SJ, Michaels JA. A systematic review of compression hosiery for uncomplicated varicose veins. Phlebology. 2009;24 Suppl 1:13-33.
19. Shingler S, Robertson L, Boghossian S, Stewart M. Compression stockings for the initial treatment of varicose veins in patients without venous ulceration. Cochrane Database Syst Rev. 2013; 9(12):CD008819.
20. Rabe E, Partsch H, Hafner J, Lattimer C, Mosti G, Neumann M, et al. Indications for medical compression stockings in venous and lymphatic disorders: An evidence-based consensus statement. Phlebology. 2018;33(3):163-84.
21. Nelson EA, Bell-Syer SE. Compression for preventing recurrence of venous ulcers. Cochrane Database Syst Rev. 2014;2014(9):CD002303.
22. Kolluri R, Lugli M, Villalba L, Varcoe R, Maleti O, Gallardo F, et al. An estimate of the economic burden of venous leg ulcers associated with deep venous disease. Vasc Med 2022;27(1):63-72.

23. Franks PJ, McCullagh L, Moffatt CJ. Assessing quality of life in patients with chronic leg ulceration using the Medical Outcomes Short Form-36 questionnaire. *Ostomy Wound Manag.* 2003;49(2):26-37.
24. Franks PJ, Moffatt CJ, Doherty DC, Smithdale R, Martin R. Longer-term changes in quality of life in chronic leg ulceration. *Wound Repair Regen.* 2006;14(5):536-41.
25. Heinen MM, Persoon A, van de Kerkhof P, Otero M, van Achterberg T. Ulcer-related problems and health care needs in patients with venous leg ulceration: a descriptive, cross-sectional study. *Int J Nurs Stud.* 2007;44(8):1296-303.
26. Furtado K, Pina E, Moffatt CJ, Franks PJ. Leg ulceration in Portugal: quality of life. *Int Wound J.* 2008;5(1):34-9.
27. Mosti G, Iabichella ML, Partsch H. Compression therapy in mixed ulcers increases venous output and arterial perfusion. *J Vasc Surg.* 2012;55(1):122-8.
28. Flour M, Clark M, Partsch H, Mosti G, Uhl JF, Chauveau M, et al. Dogmas and controversies in compression therapy: report of an International Compression Club (ICC) meeting, Brussels, May 2011. *Int Wound J.* 2013;10(5):516-26.
29. Amin EE, Joore MA, Ten Cate H, Meijer K, Tick LW, Middeldorp S, et al. Clinical and economic impact of compression in the acute phase of deep vein thrombosis. *Journal of thrombosis and haemostasis : JTH.* 2018 Jun 1. PMID: 29856509.
30. Amin EE, Bisterveld IM, Meijer K, Tick LW, Middeldorp S, Mostard G, et al. Reduced incidence of vein occlusion and postthrombotic syndrome after immediate compression for deep vein thrombosis. *Blood.* 2018;132(21):2298-304.
31. Zinnige Zorg; Verbetersignalement Diepe veneuze trombose en longembolie <https://www.venvn.nl/media/hecghpzh/zinnig-1.pdf2021>.
32. Prandoni P, Lensing AW, Prins MH, Frulla M, Marchiori A, Bernardi E, et al. Below-knee elastic compression stockings to prevent the post-thrombotic syndrome: a randomized, controlled trial. *Ann Intern Med.* 2004;141(4):249-56.
33. Kahn SR, Shapiro S, Wells PS, Rodger MA, Kovacs MJ, Anderson DR, et al. Compression stockings to prevent post-thrombotic syndrome: a randomised placebo-controlled trial. *Lancet.* 2014;383(9920):880-8.
34. Bouman AC, Ten Cate-Hoek AJ, Dirksen CD, Joore MA. Eliciting patients' preferences for elastic compression stocking therapy after deep vein thrombosis: potential for improving compliance. *Journal of thrombosis and haemostasis : JTH.* 2016;14(3):510-7.
35. Reich-Schupke S, Murmann F, Altmeyer P, Stucker M. Compression therapy in elderly and overweight patients. *VASA.* 2012;41(2):125-31.
36. Dawson AJ, Akaberi A, Galanaud JP, Morrison DR, Kahn SR, investigators SOXT. Patient-reported reasons for and predictors of noncompliance with compression stockings in a randomized trial of stockings to prevent postthrombotic syndrome. *Res Pract Thromb Haemost.* 2020;4(2):269-77.
37. Raju S, Hollis K, Neglen P. Use of compression stockings in chronic venous disease: patient compliance and efficacy. *Ann Vasc Surg.* 2007;21(6):790-5.
38. Prognosemodel Zorg en Welzijn. Ministerie van Volksgezondheid, Welzijn en Sport. Available from: <https://prognosemodelzw.databank.nl/dashboard/dashboard-branches/totaal-zorg-en-welzijn--breed-/>.
39. MacDougall DA, Feliu AL, Bocuzzi SJ, Lin J. Economic burden of deep-vein thrombosis, pulmonary embolism, and post-thrombotic syndrome. *Am J Health Pharm.* 2006;63(20 Suppl 6):S5-15.
40. Guanella R, Ducruet T, Johri M, Miron MJ, Roussin A, Desmarais S, et al. Economic burden and cost determinants of deep vein thrombosis during 2 years following diagnosis: a prospective evaluation. *J Thromb Haemost.* 2011;9(12):2397-405.
41. Bullano MF, Willey V, Hauch O, Wygant G, Spyropoulos AC, Hoffman L. Longitudinal evaluation of health plan cost per venous thromboembolism or bleed event in patients with a prior venous thromboembolism event during hospitalization. *J Manag Care Pharm.* 2005;11(8):663-73.



# Chapter 2

The role of compression in deep vein thrombosis, post thrombotic syndrome prevention and treatment

Rabe E, Pannier F, Milic JD, Da Matta ES, Schreurs R, Ten Cate AJ

*Indications for compression according to venous disease.*  
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## Introduction

The post thrombotic syndrome (PTS) is the most prevalent complication of deep vein thrombosis (DVT) occurring in up to 50% of patients.<sup>1,2</sup> PTS is a type of secondary chronic venous disease with manifestations such as edema and skin changes (e.g., hyperpigmentation, redness, venous ectasia) and in its appearance similar to primary chronic venous disease (CVD).<sup>3</sup> However, the aetiology is quite different, although in a subset of patients both disease entities may overlap. The prevalence of CVD in the population ranges from 13.7% to 19.7% and is age dependent with gradually increasing prevalence over time.<sup>4-9</sup> The onset of PTS is much more sudden with an immediate onset of venous hypertension due to the obstructing thrombus in the deep venous system which is associated with a relatively rapid appearance of edema and skin manifestations.<sup>10</sup> The incidence of PTS is highest in the first year following DVT and much lower in the second year and even lower thereafter.<sup>1,11</sup> Patients experience typical symptoms such as pain, cramps, heaviness, itching and paraesthesia.<sup>12</sup> The impact on patients' quality of life<sup>13</sup> and the health care burden associated with PTS is substantial.<sup>14</sup> Currently, there is no curative treatment for PTS, prevention of the disorder is therefore crucial.

It is thought that impaired thrombus resolution plays a central role in the onset of PTS.<sup>15-17</sup> Swift recanalization of the vein with restoration of flow may thereby be critical to minimize residual venous obstruction (RVO), valvular damage and inflammatory vein wall remodelling.<sup>18</sup> Current conservative management for DVT is based on two pillars: anticoagulant treatment and compression therapy. Adequate suppression of coagulation is needed to limit thrombus propagation and to promote endogenous fibrinolysis. Several studies have shown the importance of adequate anticoagulation especially in the initial phase after DVT, with increased incidences of PTS associated with sub-therapeutic INR.<sup>19-21</sup> Anticoagulant drugs with a more stable mode of action such as LMWH have been associated with reduced incidences.<sup>22</sup> Direct oral anticoagulant drugs (DOACs) also exert a stable thrombin inhibition and it was therefore assumed that this class of drugs would also be associated with less PTS. However, until now only treatment with rivaroxaban has shown consistent better outcomes for PTS.<sup>23-27</sup> For Dabigatran no difference compared to vitamin K antagonists was observed for the outcome PTS (OR 1.1(0.6-1.8)).<sup>28</sup> The long-term outcomes for PTS with edoxaban were found to be less favourable than those for warfarin.<sup>29</sup> It may therefore be concluded that for the prevention of PTS, the type of anticoagulant as well as stable initial anticoagulation is important. Anticoagulant treatment for the prevention of PTS thereby seems to be most critical in the acute phase of the DVT as duration of treatment is not associated with the occurrence of PTS.<sup>30,31</sup>

This chapter will further focus on compression therapy in the management of lower extremity DVT.

## Initial compression in the acute phase of DVT

In the acute phase of DVT, patients often experience pain and swelling of the leg due to the obstruction of the deep venous system by the thrombosis and its associated inflammatory response.<sup>18</sup> Initial compression therapy is thought to counteract this increased venous pressure, and to improve venous flow thereby reducing edema and restoring the calf muscle function.<sup>32,33</sup> Restoration of flow might be important for optimal thrombus resolution in the initial phase of DVT, as suggested by the results from animal experimental research showing that thrombus resolution is impaired under conditions of low flow.<sup>34</sup> Therefore, in the acute phase of the thrombosis patients might benefit from compression therapy not only to reduce complaints but maybe also to enhance flow and thereby facilitate thrombus resolution. Adverse events associated with compression therapy are infrequent (2-6%) and are usually mild, mainly involving itching and minor skin changes.<sup>35</sup> Adverse effects are however more frequently reported (25%-40.7%) with thigh-length compression.<sup>36,37</sup> Contraindications to compression are infrequent and concern mostly patients with severe arterial insufficiency ( $ABI < 0.50$ ) or absolute ankle pressure  $< 60 \text{ mmHg}$  or severe congestive heart failure.<sup>38</sup>

Initial compression therapy is usually realized with multi-layer bandaging and is continued until the acute edema has resolved. Elastic compression stockings are prescribed and fitted to be worn consecutively. This implies that patients need to have follow-up visits or need to be adequately instructed to assess the development of their symptomatology.<sup>39</sup> The value of immediate compression for the reduction of acute symptomatology in the very early stage of the thrombosis was assessed in four randomized controlled trials<sup>10,40-42</sup> and one sub study of a trial.<sup>43</sup> Two trials assessed the impact on symptomatology in the first 7-9 days in respectively 45 patients<sup>40</sup> and 69 patients<sup>41</sup> and showed a significant reduction in pain and swelling, with one also showing an improvement in clinical severity scores.<sup>40</sup> There were no significant benefits observed beyond this early observation period. The impact of immediate compression on quality of life was assessed in another much larger trial (IDEAL DVT trial).<sup>37</sup> In this trial (864 patients) signs and symptoms were assessed based on the Villalta score<sup>44,45</sup> 6 weeks after the acute DVT in patients that were either treated with multi-layer bandaging or elastic compression hosiery (both thigh high) compared with those not initially treated with any form of compression; a significant reduction in the incidence of irreversible skin signs was observed with compression (both for multi-layer bandaging and compression hosiery). Improved quality of life was observed in patients initially treated with compression hosiery compared to those treated with multi-layer bandaging.<sup>10</sup> Time to compression was within 24 hours of the diagnosis. Compression therapy with hosiery had a significant and clinically relevant positive effect on all quality-of-life measures (46). Bandaging had a negative impact on quality of life as it involved a substantial loss of autonomy, which is an important trade-off for treatment efficacy.<sup>47</sup>

The impact of external compression on recanalization in the early stage of the thrombosis was assessed in three trials.<sup>41-43</sup> One trial (73 patients) compared acute initiation of compression hosiery with hosiery starting after 14 days. Better recanalization of the thrombus was detected (after 14 and 90 days) in patients in whom acute initiation of hosiery was applied (COMPRE-trial).<sup>42</sup> Another trial (69 patients) assessed venous outflow resistance, thrombus score and reflux (after 7, 30 and 90 days) but did not find differences between the groups. Also, no differences were found for PTS incidences after 1 year based on either the CEAP classification (RR 0.91; 95% CI 0.50–1.66) or the Villalta score (RR 0.87; 95% CI 0.41–1.8).<sup>41</sup> The largest study (692), a substudy of the IDEAL DVT trial, showed however that early compression was not only associated with a significant risk reduction for residual venous obstruction at a mean of  $5.3 \pm 1.9$  months (OR 0.46; 95% CI 0.27–0.8;  $P=.005$ ), but also for the subsequent development of PTS in relation to venous obstruction (OR 0.65; 95% CI 0.46–0.92;  $P=0.013$ ), with absolute risk reductions of 20.4% and 8% for residual venous obstruction and PTS, respectively.<sup>43</sup> These outcomes were independent of the severity of symptoms and similar for multi-layer compression bandaging and compression hosiery. Based on these data it may be concluded that quality of life can be enhanced, and costs can be greatly reduced when compression hosiery is used in the acute phase.

Residual venous obstruction has been previously associated with (a moderate) increased risk of recurrent thrombosis.<sup>48</sup> Reduction of residual venous obstruction may therefore also be beneficial for optimal treatment outcomes after DVT. However, two studies that specifically studied the effect of compression in the acute phase on thrombus resolution<sup>42,43</sup> did not find any effect of compression therapy on the risk of recurrent DVT.

## Compression stocking therapy following initial compression

Once the edema has resided initial compression is usually replaced by therapeutic elastic compression stockings (ECS). Compliance to therapy is a major determinant for the effectiveness of this therapy.<sup>49,50</sup> A discrete choice experiment conducted in a cohort of 300 patients with recent DVT, showed that for optimal use of ECS the most important determinants of patient preference were the probability of reducing the risk of PTS and the ability to put the ECS on by themselves.<sup>47</sup> Patients were willing to increase the duration of therapy by 1 year if this would reduce their risk with an additional 10%. On the other hand, patients were willing to accept an even greater increase in the risk of PTS (29%) if that meant that they would be self-reliant. This illustrates the high value that patients attach to being self-reliant as well as the importance of providing information on the effectiveness of this intervention. Therefore, in order to improve compliance to ECS therapy care should be taken to support patients in their ability to put on and take off the ECS independently, but also to inform patients on the mode of action and the expected risks and benefits associated with this therapy. The evidence

underlying the use of ECS in DVT in order to prevent PTS is derived from five trials.

**Table 2.1.** Two medium sized clinical trials (194 and 180 patients) that initially showed strong preventive properties with relative risk reductions of 58% (RR 0,42 (0,27-0,66)) and 48% (RR 0,52 (0,35-0,79)) respectively for the risk of PTS with ECS (knee high; 30-40mmHg) started in the subacute phase (within 10 days of the DVT) and continued for about 2 years.<sup>49,51</sup> These two trials had high compliance rates (>80%). The third trial started compression in the acute phase and found an even better risk reduction (RR 0,38 (0,20-0,71)).<sup>40,52</sup> The fourth trial (SOX trial) was much larger (803 patients) and compared ECS (knee high;30-40mmHg) with placebo stockings (5 mmHg) for two years and did not find a reduction of PTS (RR 1,01 (0,86-1,18)).<sup>50</sup> The outcomes of this trial changed the attitude of many doctors (and guidelines) towards the value of ECS. This trial however has received criticism concerning the late onset of therapy and the lack of compliance in patients. After two years only 56% of patients used their compression stocking for at least 3 days a week compared to >80% of patients for at least 4 days a week in the two previous trials. An additional very small negative trial (69 patients) with suboptimal compliance (60%) was published in 2015 (1,17 (0,62-2,20); the quality of this trial is however uncertain as there is a lack of detail in its publication.<sup>53</sup> For the prevention of PTS, knee length ECS appears to be equally effective as thigh length ECS. One study with 267 participants (CANANO study) reported that there is no clear difference in effectiveness of knee length ECS vs. thigh length ECS (RR 0.92, 95% CI 0.66-1.28;  $P=0.60$ ). More patients experienced adverse effects with thigh length ECS (40.7%) vs. knee length ECS (27.3%;  $P=0.017$ ).<sup>54</sup> Several meta-analyses have been performed all showing substantial heterogeneity between trials, but also in the selection of studies for the meta-analysis, the diagnostic criteria for PTS used, the emphasis (or lack thereof) on compliance, and the methodological quality of the trials. Varying methodologies have been applied in the selection of studies and the presentation of data, with outcomes varying from significant reductions in PTS incidence to no effect of ECS. A recent Cochrane meta-analysis reviewing ECS initiated in the acute and subacute phase concluded that although there is significant heterogeneity between studies the overall effect of ECS for the prevention of PTS is more likely to favor compression, showing a 38% RR reduction for the occurrence of PTS (RR 0,62; 95%-BI=0,38-1,01;  $P=0,05$ ).<sup>55</sup> This would probably be more so when only trials with good compliance were assessed. The overall conclusion was that more research into this clinical problem is needed. The CHAPS (Compression hosiery to avoid post thrombotic syndrome) trial (*NCT04103112*) was planned to fill this need and plans to assess the value of ECS, as compared to no compression, for the prevention of PTS with an intended inclusion of 864 participants.

Recently, data from the Celeste trial was presented. This trial addressed an important question whether low compression strength is equal to higher compression strength for the prevention of PTS. This trial also assessed compliance. From 2012 to 2017, 350 patients were randomly assigned to receive either 25mmHg (20-30 mmHg) or 35mmHg ECS (20-30 mmHg). Cumulative incidence of PTS was 31.0% in 25mmHg ECS

versus 33.3% in 35 mmHg ECS (absolute difference -2.3%, (90%CI -12.1;7.4),  $P=0.006$  for non-inferiority). The predefined non-inferiority margin for the difference in success rates was set at 12.5%. It was concluded that 25mmHg ECS (20-30 mmHg) is non-inferior to 35 mmHg ECS (30-40 mmHg) for the prevention of PTS and that compliance is better with 25 mmHg (20-30 mmHg) ECS.<sup>56</sup>

**Table 2.1** Trials assessing the value of ECS for the prevention of PTS.

Author, year (n)	ECS 30-40mmHg		No ECS		Effect RR (95% CI)
	PTS incidents	Number of patients	PTS incidents	Number of patients	
Brandjes, 1997 (194)	19	96	46	98	0,42(0,27-0,66)
Prandoni, 2004 (180)	23	90	44	90	0,52(0,35-0,79)
Partsch, 2004 (37)	8	26	9	11	0,38(0,20-0,71)
Kahn, 2014* (803)	176	409	168	394	1,01(0,86-1,18)
Jayaram, 2015 (69)	14	36	11	33	1,17(0,62-2,20)
<b>Total</b>	<b>240</b>	<b>770</b>	<b>278</b>	<b>626</b>	<b>0,82(0,72-0,94)</b>

\* Kahn (SOX trial) compared ECS to sham stockings with compression of 5 mmHg. Abbreviations ECS: elastic compression stockings, PTS: post-thrombotic syndrome.

## Duration of compression stocking use

Standard duration of treatment for the prevention of PTS following acute DVT is 24 months. There is however no evidence underlying this treatment duration. Therefore, three trials focused on establishing the optimal duration of treatment.<sup>37,57,58</sup>

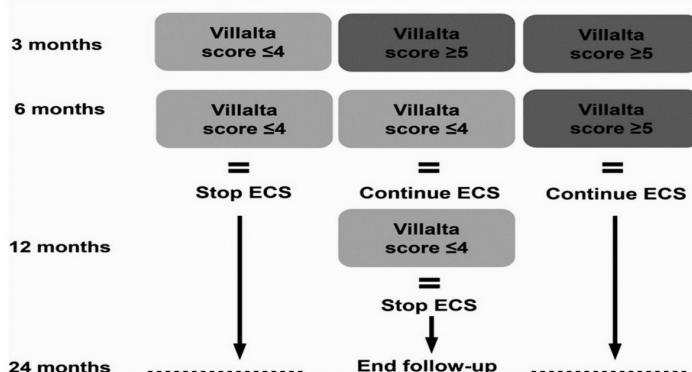
**Table 2.2.** The trial by Aschwanden randomised patients after 6 months of initial ECS treatment to either continuation of treatment for another 18 months or to stop treatment at that point in time. Overall, there was no difference in efficacy of ECS between treatment durations of 6 months or 24 months (RR 0,65 (0,33-1,31). However, a large gender-specific reduction of PTS (diagnosed according to the CEAP classification) using ECS was found (HR 0.11 95% CI 0.02-0.91) and no reduction in males (HR 1.07, 95% CI 0.42-2.73), most probably due to a high degree of non-compliance to therapy in male patients. Men were 4 times more often incompliant than women (OR 4.1;95% CI 1.0-16.0).<sup>57</sup> Another trial (OCTAVIA trial) selected patients with high compliance to ECS therapy (85% adherence for 6-7 days a week) during the first 12 months of treatment. Patients (518) were then randomised to either continue ECS treatment or to stop treatment. This trial could not show non-inferiority between the treatment arms; the incidence of PTS was 19% and 13% respectively, with an absolute difference of 6.9% and a relative risk reduction of 35% (RR ,0.65 (0,44-0,97)).<sup>58</sup> More recently, the IDEAL-DVT trial (865 patients) showed that treatment duration for ECS can be individually shortened without significant differences in effectiveness.<sup>37</sup> It was found that it is possible to select patients who can stop treatment as early as six months after the acute

DVT, PTS incidence based on the Villalta score was 28.9% for individualised duration vs. 27.8% for standard duration, for an absolute difference of 1.1% (OR 1.06, 95% CI 0.78-1.44). Compliance to allocated treatment was good till the end of study in both treatment arms (80%). The strategy proved to be highly efficient as treatment could be stopped at six months in 54.6% of patients and in an additional 10% of patients at 12 months, and it was also highly cost effective.<sup>59</sup> The assessment of PTS in the IDEAL DVT trial was based on the original Villalta score using two assessments at least 3 months apart to make the diagnosis. This approach guarantees diagnosis in a more stable situation. Individualised shortened duration of treatment requires the involvement of professionals that can do the assessment both practically and timewise. A practical algorithm to support contemporary practice should be unrestricted and easily available.<sup>60</sup>

**Table 2.2** Standard duration of ECS treatment (usually 24 months) versus shortened duration of 6 months or 12 months.

Therapy duration	Standard duration		Shortened duration		Effect
	PTS incidents	Number of patients	PTS incidents	Number of patients	
Aschwanden, 2008	11	84	17	85	0,65(0,33-1,31)
Mol, 2014	34	262	51	256	0,65(0,44-0,97)
Ten Cate-Hoek, 2017*	118	424	125	432	0,96(0,77-1,19)
Total	163	770	193	773	0,84(0,71-1,02)

\*The IDEAL DVT trial tailored duration of treatment using the Villalta scale. Abbreviations PTS (post-thrombotic syndrome).



**Figure 2.1** Algorithm for individualisation of treatment with elastic compression stockings. Patients with two consecutive low (4) Villalta scores six months after the deep vein thrombosis are instructed to stop elastic compression stocking (ECS) treatment. Those with one low and one high (5) score are instructed to continue treatment. There is an additional assessment at 12 months, and those with two consecutive low scores can stop treatment at that point. Those with scores of five or higher continue treatment for 24 months or longer if necessary. Reproduced from ten Cate-Hoek et al., 2014.<sup>211</sup> ESVS 2021 Clinical Practice Guidelines on the Management of Venous Thrombosis.

## Compression for the treatment of PTS

Once PTS is diagnosed treatment options are limited. The main treatment options are conservative and are directed at reduction of edema and improving calf muscle pump action. Elastic compression therapy is at the heart of all treatment options. Even though, there is very low- certainty evidence regarding the use of ECS for treatment of PTS. In a recent update of a Cochrane review on this subject, four trials were identified. Two trials reported on ECS and two other trials on intermittent mechanical compression devices.<sup>61</sup> Only two trials with short duration assessed ECS in PTS. One evaluated pain and oedema<sup>62</sup> this trial showed a lack of improvement or even a worsening of pain and swelling in about 60% of patients which was similar to those without ECS. Another trial only evaluated hemodynamic parameters.<sup>63</sup> The hemodynamic parameters: venous filling index, filling time and venous volume difference were evaluated in association with different types and dosages of ECS (AK, BK, class II and III). A significant improvement for all parameters was found with all forms of ECS. The two other identified studies assessing the role of compression in PTS, were on intermittent compression devices. Quality of life was improved in those using an intermittent compression device even though 9% of patients experienced adverse effects. More research is needed to assess whether ECS can provide long-term relief of symptoms and/or prevent leg ulceration. Despite the current lack of evidence, compression is a commonly accepted treatment modality in PTS. The evidence to support the use of ECS is entirely extrapolated from CVD literature. Especially for ulcer healing the value of compression is undisputed.<sup>64</sup>

## References

1. Prandoni P, Lensing AW, Cogo A, Cuppini S, Villalta S, Carta M, et al. The long-term clinical course of acute deep venous thrombosis. *Ann Intern Med.* 1996;125(1):1-7.
2. Cucuruz B, Kopp R, Pfister K, Noppeney J, Tripal K, Korff T, et al. Risk and protective factors for post-thrombotic syndrome after deep venous thrombosis. *J Vasc Surg Venous Lymphat Disord.* 2020;8(3):390-5.
3. Ten Cate-Hoek AJ. Prevention and treatment of the post-thrombotic syndrome. *Res Pract Thromb Haemost.* 2018;2(2):209-19.
4. Serra R, Grande R, Butrico L, Fugetto F, Stefano d. Epidemiology, diagnosis and treatment of chronic venous disease: A systematic review. *Chirurgia.* 2015 07/15;29.
5. Andreozzi GM, Signorelli S, Di Pino L, Garozzo S, Cacciaguerra G, Leone A, et al. Varicose symptoms without varicose veins: the hypotonic phlebopathy, epidemiology and pathophysiology. The Acireale project. *Minerva Cardioangiolog.* 2000;48(10):277-85.
6. Andreozzi G. Prevalence of patients with chronic venous disease-related symptoms but without visible signs (described as C0s in the CEAP classification): The Italian experience. *Phlebolymphology.* 2006 01/01;13:28-35.
7. Langer RD, Ho E, Denenberg JO, Fronek A, Allison M, Criqui MH. Relationships between symptoms and venous disease: the San Diego population study. *Arch Intern Med.* 2005;165(12):1420-4.
8. Gux J, Rabe E, Escotto I, Escudero JR, Scuderi A, Yuwono HS. The "C0s" patient: Worldwide results from the vein consult program. *Phlebolymphology.* 2012 01/01;19:182-92.
9. Vuylsteke ME, Colman R, Thomis S, Guillaume G, Degrande E, Staelens I. The influence of age and gender on venous symptomatology. An epidemiological survey in Belgium and Luxembourg. *Phlebology.* 2016;31(5):325-33.
10. Amin EE, Joore MA, Ten Cate H, Meijer K, Tick LW, Middeldorp S, et al. Clinical and economic impact of compression in the acute phase of deep vein thrombosis. *J Thromb Haemost.* 2018 Jun 1. doi: 10.1111/jth.14163.
11. Phillips LJ, 2nd, Sarkar R. Molecular characterization of post-thrombotic syndrome. *J Vasc Surg.* 2007;45 Suppl A:A116-22.
12. Villalta SBP PA, Lensing A, Prins M, Prandoni P. Assessment of validity and reproducibility of a clinical scale for the post-thrombotic syndrome. *Haemostasis.* 1994;24:158a
13. Kahn SR, Hirsch A, Shrier I. Effect of postthrombotic syndrome on health-related quality of life after deep venous thrombosis. *Arch Intern Med.* 2002;162(10):1144-8.
14. Prandoni P. Healthcare burden associated with the post-thrombotic syndrome and potential impact of the new oral anticoagulants. *Eur J Haematol.* 2012;88(3):185-94.
15. Prandoni P, Frulla M, Sartor D, Concolato A, Girolami A. Vein abnormalities and the post-thrombotic syndrome. *J Thromb Haemost.* 2005 Feb;3(2):401-2.
16. Vedovetto V, Dalla Valle F, Milan M, Pesavento R, Prandoni P. Residual vein thrombosis and trans-popliteal reflux in patients with and without the post-thrombotic syndrome. *Thromb Haemost.* 2013;110(4):854-5.
17. Galanaud JP, Holcroft CA, Rodger MA, Kovacs MJ, Betancourt MT, Wells PS, et al. Predictors of post-thrombotic syndrome in a population with a first deep vein thrombosis and no primary venous insufficiency. *J Thromb Haemost.* 2013;11(3):474-80.
18. ten Cate-Hoek AJ, Henke PK, Wakefield TW. The post thrombotic syndrome: Ignore it and it will come back to bite you. *Blood Rev.* 2016;30(2):131-7.
19. Chitsike RS, Rodger MA, Kovacs MJ, Betancourt MT, Wells PS, Anderson DR, et al. Risk of post-thrombotic syndrome after subtherapeutic warfarin anticoagulation for a first unprovoked deep vein thrombosis: results from the REVERSE study. *J Thromb Haemost.* 2012;10(10):2039-44.
20. van Dongen CJ, Prandoni P, Frulla M, Marchiori A, Prins MH, Hutten BA. Relation between quality of anticoagulant treatment and the development of the postthrombotic syndrome. *J Thromb Haemost.* 2005;3(5):939-42.
21. Ziegler S, Schillinger M, Maca TH, Minar E. Post-thrombotic syndrome after primary event of deep venous thrombosis 10 to 20 years ago. *Thromb Res.* 2001;101(2):23-33.

22. Hull RD, Liang J, Townshend G. Long-term Low-Molecular-Weight Heparin and the Post-Thrombotic Syndrome: A Systematic Review. *Am J Med.* 2011;124(8):756-65.
23. Prandoni P, Ageno W, Mumoli N, Zanatta N, Imberti D, Visonà A, et al. Recanalization rate in patients with proximal vein thrombosis treated with the direct oral anticoagulants. *Thromb Res.* 2017;153: 97-100.
24. Cheung YW, Middeldorp S, Prins MH, Pap AF, Lensing AW, Ten Cate-Hoek AJ, et al. Post-thrombotic syndrome in patients treated with rivaroxaban or enoxaparin/vitamin K antagonists for acute deep-vein thrombosis. A post-hoc analysis. *Thromb Haemost.* 2016;116(4):733-8.
25. Søgaard M, Nielsen PB, Skjøth F, Kjældgaard JN, Coleman CI, Larsen TB. Rivaroxaban Versus Warfarin and Risk of Post-Thrombotic Syndrome Among Patients with Venous Thromboembolism. *Am J Med.* 2018; 131(7):787-94.e4.
26. Utne KK, Dahm A, Wik HS, Jelsness-Jørgensen LP, Sandset PM, Ghanima W. Rivaroxaban versus warfarin for the prevention of post-thrombotic syndrome. *Thromb Res.* 2018;163:6-11.
27. Rinfret F GS, Vedantham S, Kahn S. Predictors of the Development of the Post-thrombotic Syndrome: A Sub-analysis of the ATTRACT TrialAbstract Number: LPB0091, ISTH 2021 Congress.
28. Wik HS, Kahn SR, Eriksson H, Morrison D, Ghanima W, Schulman S, et al. Post-thrombotic syndrome in patients with venous thromboembolism treated with dabigatran or warfarin: A long-term cross-sectional follow-up of RE-COVER study patients. *J Thromb Haemost.* 2021;19(10):2495-503.
29. Bavalia R, Bistervels IM, Boersma WG, Quere I, Brisot D, Falvo N, et al. Quality of life in patients with pulmonary embolism treated with edoxaban versus warfarin. *Res Pract Thromb Haemost.* 2021; 5(5):e12566.
30. Bradbury C, Fletcher K, Sun Y, Heneghan C, Gardiner C, Roalfe A, et al. A randomised controlled trial of extended anticoagulation treatment versus standard treatment for the prevention of recurrent venous thromboembolism (VTE) and post-thrombotic syndrome in patients being treated for a first episode of unprovoked VTE (the ExACT study). *Br J Haematol.* 2020;188(6):962-75.
31. Schulman S, Ogren M. New concepts in optimal management of anticoagulant therapy for extended treatment of venous thromboembolism. *Thromb Haemost.* 2006;96(3):258-66.
32. Mosti G, Iabichella ML, Partsch H. Compression therapy in mixed ulcers increases venous output and arterial perfusion. *J Vasc Surg.* 2012;55(1):122-8.
33. Flour M, Clark M, Partsch H, Mosti G, Uhl JF, Chauveau M, et al. Dogmas and controversies in compression therapy: report of an International Compression Club (ICC) meeting, Brussels, May 2011. *Int Wound J.* 2013;10(5):516-26.
34. Cooley BC, Chen CY, Hess R, Schmeling G. Incomplete resolution of deep vein thrombosis under reduced flow conditions. *Thromb Res.* 2013;131(1):55-8.
35. Rabe E, Partsch H, Morrison N, Meissner MH, Mosti G, Lattimer CR, et al. Risks and contraindications of medical compression treatment - A critical reappraisal. An international consensus statement. *Phlebology.* 2020;35(7):447-60.
36. Kahn SR, Shapiro S, Ducruet T, Wells PS, Rodger MA, Kovacs MJ, et al. Graduated compression stockings to treat acute leg pain associated with proximal DVT. A randomised controlled trial. *Thromb Haemost.* 2014;112(6):1137-41.
37. Ten Cate-Hoek AJ, Amin EE, Bouman AC, Meijer K, Tick LW, Middeldorp S, et al. Individualised versus standard duration of elastic compression therapy for prevention of post-thrombotic syndrome (IDEAL DVT): a multicentre, randomised, single-blind, allocation-concealed, non-inferiority trial. *Lancet Haematol.* 2018;5(1):e25-e33.
38. Gloviczki P, Comerota AJ, Dalsing MC, Eklof BG, Gillespie DL, Gloviczki ML, et al. The care of patients with varicose veins and associated chronic venous diseases: clinical practice guidelines of the Society for Vascular Surgery and the American Venous Forum. *J Vasc Surg.* 2011;53(5 Suppl):2s-48s.
39. Schreurs RHP, Joore MA, Ten Cate H, Ten Cate-Hoek AJ. Using the Functional Resonance Analysis Method to explore how elastic compression therapy is organised and could be improved from a multistakeholder perspective. *BMJ Open.* 2021;11(10):e048331.
40. Partsch H, Blättler W. Compression and walking versus bed rest in the treatment of proximal deep venous thrombosis with low molecular weight heparin. *J Vasc Surg.* 2000;32(5):861-9.
41. Roumen-Klappe EM, den Heijer M, van Rossum J, Wollersheim H, van der Vleuten C, Thien T, et al. Multilayer compression bandaging in the acute phase of deep-vein thrombosis has no effect on the development of the post-thrombotic syndrome. *J Thromb Thrombolysis.* 2009;27(4):400-5.

42. Arpaia G, Cimminiello C, Mastrogiacomo O, de Gaudenzi E. Efficacy of elastic compression stockings used early or after resolution of the edema on recanalization after deep venous thrombosis: the COM.PRE Trial. *Blood Coagul Fibrinolysis*. 2007;18(2):131-7.
43. Amin EE, Bisterveld IM, Meijer K, Tick LW, Middeldorp S, Mostard G, et al. Reduced incidence of vein occlusion and postthrombotic syndrome after immediate compression for deep vein thrombosis. *Blood*. 2018;132(21):2298-304.
44. S Villalta PB, A Piccioli, A Lensing, M. Prins, P Prandoni, S Villalta, AW Lensing, MH Prins, AW Lensing, C Piccioli, AWA Lensing. Assessment of validity and reproducibility of a clinical scale for the post thrombotic syndrome. *Haemostasis*. 1994;24: 158a.
45. Kahn SR, Partsch H, Vedantham S, Prandoni P, Kearon C. Definition of post-thrombotic syndrome of the leg for use in clinical investigations: a recommendation for standardization. *J Thromb Haemost*. 2009;7(5):879-83.
46. Walters SJ, Brazier JE. Comparison of the minimally important difference for two health state utility measures: EQ-5D and SF-6D. *Qual Life Res*. 2005;14(6):1523-32.
47. Bouman AC, Ten Cate-Hoek AJ, Dirksen CD, Joore MA. Eliciting patients' preferences for elastic compression stocking therapy after deep vein thrombosis: potential for improving compliance. *J Thromb Haemost*. 2016;14(3):510-7.
48. Donadini MP, Ageno W, Antonucci E, Cosmi B, Kovacs MJ, Le Gal G, et al. Prognostic significance of residual venous obstruction in patients with treated unprovoked deep vein thrombosis: a patient-level meta-analysis. *Thromb Haemost*. 2014;111(1):172-9.
49. Prandoni P, Lensing AW, Prins MH, Frulla M, Marchiori A, Bernardi E, et al. Below-knee elastic compression stockings to prevent the post-thrombotic syndrome: a randomized, controlled trial. *Ann Intern Med*. 2004;141(4):249-56.
50. Kahn SR, Shapiro S, Wells PS, Rodger MA, Kovacs MJ, Anderson DR, et al. Compression stockings to prevent post-thrombotic syndrome: a randomised placebo-controlled trial. *Lancet*. 2014;383(9920): 880-8.
51. Brandjes DP, Buller HR, Heijboer H, Huisman MV, de Rijk M, Jagt H, et al. Randomised trial of effect of compression stockings in patients with symptomatic proximal-vein thrombosis. *Lancet*. 1997; 349(9054):759-62.
52. Partsch H, Kaulich M, Mayer W. Immediate mobilisation in acute vein thrombosis reduces post-thrombotic syndrome. *Int Angiol*. 2004;23(3):206-12.
53. Jayaraj A, Meissner M. Impact of graduated compression stockings on the prevention of post-thrombotic syndrome - results of a randomized controlled trial. *Phlebology*. 2015;30(8):541-8.
54. Prandoni P, Noventa F, Quintavalla R, Bova C, Cosmi B, Siragusa S, et al. Thigh-length versus below-knee compression elastic stockings for prevention of the postthrombotic syndrome in patients with proximal-venous thrombosis: a randomized trial. *Blood*. 2012;119(6):1561-5.
55. Appelen D, van Loo E, Prins MH, Neumann MH, Kolbach DN. Compression therapy for prevention of post-thrombotic syndrome. *Cochrane Database Syst Rev*. 2017;9:Cd004174.
56. Galanaud JP, Genty-Vermorel C, Barrelier MT, Becker F, Bertaina I, Blaise S, Bura Riviere A, Comte A, Grange C, Guenneguez H, Maufus M, Ouwy P, Richaud C, Rolland C, Schmidt J, Sevestre MA, Verrière F, Bosson J-, CELEST Trial Investigators . 25mmHg vs. 35mmHg Elastic Compression Stockings to Prevent Post Thrombotic Syndrome after Deep Vein Thrombosis: The CELEST Double-blind Trial [abstract]. *Res Pract Thromb Haemost*. 2021; 5 (Suppl 2). <https://abstracts.isth.org/abstract/25mmhg-vs-35mmhg-elastic-compression-stockings-to-prevent-post-thrombotic-syndrome-after-deep-vein-thrombosis-the-celest-double-blind-trial/>. Accessed November 15, 2022.
57. Aschwanden M, Jeanneret C, Koller MT, Thalhammer C, Bucher HC, Jaeger KA. Effect of prolonged treatment with compression stockings to prevent post-thrombotic sequelae: a randomized controlled trial. *J Vasc Surg*. 2008;47(5):1015-21.
58. Mol GC, van de Ree MA, Klok FA, Tegelberg MJ, Sanders FB, Koppen S, et al. One versus two years of elastic compression stockings for prevention of post-thrombotic syndrome (OCTAVIA study): randomised controlled trial. *BMJ*. 2016;353:i2691.
59. Amin EE, Ten Cate-Hoek AJ, Bouman AC, Meijer K, Tick L, Middeldorp S, et al. Individually shortened duration versus standard duration of elastic compression therapy for prevention of post-thrombotic syndrome: a cost-effectiveness analysis. *Lancet Haematol*. 2018;5(11):e512-e9.

60. Kakkos SK, Gohel M, Baekgaard N, Bauersachs R, Bellmunt-Montoya S, Black SA, et al. Editor's Choice - European Society for Vascular Surgery (ESVS) 2021 Clinical Practice Guidelines on the Management of Venous Thrombosis. *Eur J Vasc Endovasc Surg.* 2021;61(1):9-82.
61. Azirar S, Appelen D, Prins MH, Neumann MH, de Feiter AN, Kolbach DN. Compression therapy for treating post-thrombotic syndrome. *Cochrane Database Syst Rev.* 2019;9(9):CD004177.
62. Ginsberg JS, Hirsh J, Julian J, Vander Laan Vries M, Magier D, MacKinnon B, et al. Prevention and treatment of postphlebitic syndrome: results of a 3-part study. *Arch Intern Med.* 2001;161(17):2105-9.
63. Lattimer CR, Azzam M, Kalodiki E, Makris GC, Geroulakos G. Compression stockings significantly improve hemodynamic performance in post-thrombotic syndrome irrespective of class or length. *J Vasc Surg.* 2013;58(1):158-65.
64. Shi C DJ, Cullum N, Connaughton E, Norman G. Compression bandages or stockings versus no compression for treating venous leg ulcers. *Cochrane Database of Systematic Reviews* 2021, Issue 7 Art No: CD013397.



# Chapter 3

Using the Functional Resonance Analysis Method to  
explore how elastic compression therapy is organized  
and could be improved from a multi-stakeholder  
perspective

Schreurs RHP, Joore MA, Ten Cate H, Ten Cate-Hoek AJ

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## Summary

### Objectives

Elastic compression stocking (ECS) therapy is an important treatment for patients with deep venous thrombosis (DVT) and chronic venous disease (CVD). This study aimed to provide insight into the structure and variability of the ECS therapy process, its effects on outcomes, and to elicit improvement themes from a multiple stakeholder perspective.

### Design

Thirty semi-structured interviews with professionals and patients were performed. The essential functions for the process of ECS therapy were extracted to create two work-as-done models using the Functional Resonance Analysis Method (FRAM). These findings were used to guide discussion between stakeholders to identify improvement themes.

### Setting

Two regions in the Netherlands, region Limburg and region North-Holland, including an academic hospital and a general hospital and their catchment region.

### Participants

The interviewees were purposely recruited and included 25 health care professionals (i.e. GPs, internists, dermatologists, nurses, doctor's assistants, occupational therapists, home care nurses, and medical stocking suppliers) and five DVT- or CVD patients.

### Results

Two FRAM models were created (one for each region). The variability of the functions and their effect on outcomes, as well as interdependencies between functions were identified. These were presented in stakeholder meetings to identify the structure of the process and designated variable and uniform parts of the process and its outcomes. Ultimately six improvement themes were identified: dissemination of knowledge of the entire process; optimizing and standardizing initial compression therapy; optimizing timing to contact the medical stocking supplier (when edema has disappeared); improving the implementation of assistive devices; harmonizing follow-up duration for CVD patients; personalizing follow-up and treatment duration in DVT patients.

### Conclusions

This study provided a detailed understanding of how ECS therapy is delivered in daily practice by describing major functions and variability in performances and elicited six improvement themes from a multi-stakeholder perspective.

## Introduction

Elastic compression stocking (ECS) therapy is the cornerstone for the prevention and treatment of post-thrombotic syndrome after deep venous thrombosis (DVT) and the major conservative treatment modality for patients with chronic venous disease (CVD).<sup>1-5</sup> Practically, it was our impression that there is a substantial variation in how ECS therapy is implemented. We assume this to result in heterogeneous and suboptimal care. However, a good understanding of this assumed variability is lacking. This study aimed to provide insight into the variability of the process as well as interactions between healthcare professionals and patients concerning ECS therapy in daily practice and to elicit improvement themes from a multi-stakeholder perspective.

From the moment ECS therapy is indicated, patients first need initial compression therapy to reduce edema and to bridge the time until the start of definitive ECS therapy, which has to be fitted and delivered by a medical stocking supplier.<sup>5-6</sup> Choosing optimal ECS therapy appears to be challenging since several decisions have to be made regarding the ECS characteristics (for example pressure class, stiffness and ECS type) to optimally match the patient's clinical characteristics.<sup>7-9</sup> Patients then are expected to apply and remove their ECS themselves. However, a large proportion of both DVT and CVD patients are non-compliant to ECS therapy.<sup>10-11</sup> One of the reasons for non-compliance include difficulties putting ECS on and/or removing the ECS.<sup>12-16</sup> Some patients need assistive devices to preserve self-reliance, and a smaller proportion of patients rely on home care to assist with the application and removal of the ECS. The proportion of patients needing home care for this indication is not well known. One study found that, in elderly and overweight CVD patients, 14.6% of patients relied on home care to either put on and/or remove the ECS.<sup>17</sup> A recent trial in patients with acute DVT showed that 16.1% of patients received home care, though this included patients that required home care for the initial compression phase.<sup>18</sup> Finally, a decision regarding ECS therapy duration will be made during regular outpatient clinic visits (only in DVT) whereas ECS therapy is permanent for CVD patients.

ECS therapy is a complex process, with various healthcare professionals and patients collaborate and constantly, purposely or not, adjust their performances to each other and the working conditions (for example restrictions in time, information, or resources).<sup>19</sup> This complexity results in a process of dynamic performances and interactions between healthcare professionals that can lead to both desirable, but also unwanted or unexpected outcomes that can spread through the whole system.<sup>20</sup> As a consequence, a difference exists between work-as-done (which represents how work is done in daily practice), and work as imagined (which represents how work is supposed to be done as stated in clinical guidelines and protocols).<sup>21</sup> These insights have created a growing awareness of the importance of both context and practical applicability of recommendations and guidelines to optimize care<sup>22-25</sup>, rather than a focus on guideline

characteristics. Therefore, establishing specific facilitators and targets for improvements and gaining insight into how ECS therapy is managed and performed in clinical practice is essential to optimize current care.

To date, studies concerning ECS therapy have mainly focused on the duration and efficacy of ECS therapy to prevent post-thrombotic syndrome in the case of DVT<sup>1-4, 26-27</sup>, reasons for non-compliance to ECS therapy<sup>10, 16, 28</sup>, quality of life<sup>29</sup>, and improvement of self-reliance<sup>30-32</sup> for patients with either DVT or CVD. To the best of our knowledge, no empirical studies to date have addressed the entire process of ECS therapy with gaps, interdependencies, and variability across settings. Only four studies have focused on specific parts of daily practice (prescription patterns and patients' perspectives): three on DVT<sup>13, 28, 33</sup>, and one on venous disease in general.<sup>34</sup> These studies consistently show a lack of consensus and considerable variation in practice among physicians regarding timing of initiation ECS, duration of therapy (in DVT patients), and compression strength. However, in complex care as ECS therapy, it is especially important to assess the entire process.

A useful method to analyze complex socio-technical systems is to utilize the functional resonance analysis method (FRAM). FRAM arrives from the relatively new safety-II perspective. Whereas the safety-I primarily focused on finding the source for failures and reasons for non-adherence to guidelines to improve care, this promising perspective focuses on what can be learned from daily practice.<sup>35</sup> FRAM thereby uses the idea of resonance arising from the variability of everyday performance, which pro-actively results in improvement themes to reduce unwanted variability and strengthen performances leading to desired results.<sup>21</sup> It follows a stepwise approach to create a model that provides clear insight into work-as-done, including all variability in performance as well as interactions and the consequences thereof on outcomes. Ultimately the FRAM determines whether, and how far, work-as-done corresponds with work-as-imagined. The method has been widely applied in many work fields (e.g. aviation, railway and airway traffic management, and construction), but its implementation in health care research remains more limited.<sup>36-46</sup>

Hence, this study aims to provide an overview of how ECS therapy is organized and to define suggestions for improvement using FRAM. It is the first step in developing a general cross-domain protocol to improve ECS therapy for patients with either DVT or CVD, matching daily practice, and in adherence to guidelines and scientific evidence.

## Methods

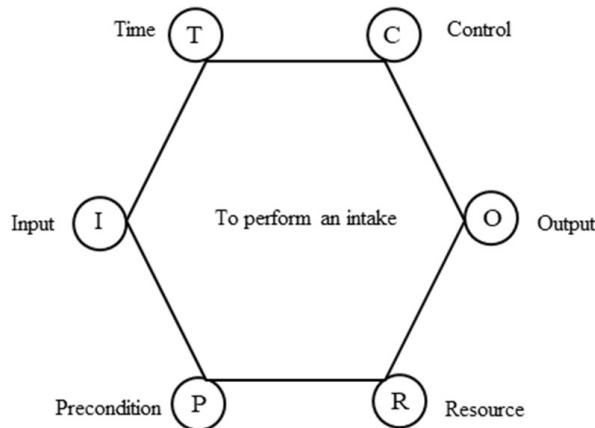
### Setting and population

The study was conducted in two regions in the Netherlands (Limburg and North-Holland). These settings were chosen considering their geographical spread (Limburg in the most southern part of the Netherlands and North-Holland in the northern part) and because in North-Holland several interventions to improve self-reliance in compression care have already been implemented. The hospital settings differ too, with a general hospital in North-Holland (on two locations) and an academic hospital in Limburg. To access care and appropriate diagnostic processes in both settings, patients may present at a general practitioner's (GP) practice. After clinical assessment, the GP determines whether the patient can be managed in primary care for further diagnosis and treatment or whether secondary care assessment is necessary.

The scope of this study is to identify the complete process of ECS therapy, from the moment ECS is indicated until the moment ECS can be stopped, for DVT- and CVD patients (stage C4 and C5 according to the CEAP (Clinical-Etiological-Anatomical-Pathophysiological) classification system<sup>47</sup>). Stadium C6 patients (with an active venous ulcer), were excluded since these patients are generally not able to be self-reliant as they depend on home care for wound management. These patients are therefore expected to have fewer benefits from optimizing care.

### Study design

FRAM consists of four steps. The first step has a dual objective: first to explore work-as-imagined based on work instructions, guidelines, and recent literature to globally identify the system's main activities (called functions) and the healthcare professionals that are involved; second, to visualize work-as-done and to systematically identify the functions that constitute ECS therapy in its entirety. These functions are identified based on interviews with involved healthcare professionals. Functions are divided into foreground functions (the system's main functions, whose variability may have consequences for its other functions) and background functions (those functions that are considered to be more stable and are on themselves not the focus of the current study, although they may introduce variability into the main functions). The functions are then visualized as hexagons using the FRAM Model Visualizer (FMV) software (version 0.4.1)<sup>48</sup>. Thereafter, the foreground functions are characterized by six aspects necessary to realize the function: input, output, precondition, resource, control, and time (see Figure 3.1).



**Figure 3.1** Functional resonance analysis method (FRAM) activity hexagon.

The six aspects represent: Input (I): what the function activates, acts on, or changes. Time (T): any time constraints that might affect the function. Control (C): how the function is monitored or controlled. Output (O): the output or change of state that emerges from the function. Resource (R): materials or people needed to carry out the function or materials consumed during the function. Precondition (P): a condition that must be satisfied before the function can be started.

The second step is to identify and characterize the variability in output of the individual functions in the FRAM model based on the information provided in the interviews. This output variability can be internal (variability in the function itself) or external (variability in working condition, i.e., the conditions under which the function is performed). The third step is to identify how the aspects can connect different functions and identify interdependencies (also called couplings). For example, if the output of function A is also defined as a precondition for function B, then these functions are coupled (a so-called 'upstream-downstream coupling') since variability in the output of function A impacts the performance of function B. The variability in each function's output can be identified as well as its effect on the performance of other downstream functions (i.e. functions performed later in the process). Finally, it is possible to develop recommendations on how to monitor and influence the variability by attenuating the variability that can lead to undesirable results or by enhancing the variability that can lead to desired results.<sup>49</sup>

## Data collection and analysis

### *Identification of system functions and aspects (step 1)*

To identify the systems main functions, a work-as-imagined model was created based on local protocols of the two selected regions, guidelines<sup>50-53</sup>, and recent literature.<sup>4</sup> Healthcare professionals involved in the system were identified for each region and semi-structured interviews were planned to identify main functions and aspects for the

work-as-done models. The interviewees were purposely recruited starting with a senior policy adviser from a home care organization in Limburg, and a senior project manager from a home care organization in North-Holland. Other experienced professionals were recruited through consecutive interviewees until data saturation was reached, defined as three consecutive interviews during which no new functions or output emerged.<sup>54</sup>

The healthcare professionals were contacted by phone or email and all agreed to participate and consented verbally. One interviewer (RS) conducted the audio-recorded interviews with each interviewee either at the healthcare professional's workplace or the patient's home (Limburg) or by telephone (North-Holland). Interviews were guided by an interview template based on questions of the FRAM method, in which the interviewer was trained before start of the interviews.<sup>49</sup> Afterward, the interviews were transcribed verbatim. Follow-up questions were used to clarify any unclear descriptions and no repeat interviews were performed. A deeper understanding of the process was obtained from the interviews and the essential functions, including the six aspects of the function's hexagon required for ECS therapy, were extracted using an iterative modeling process to create the work-as-done models. Both the identified aspects and functions were discussed with two co-authors (AtC, MJ) until consensus was reached. Subsequently, the functions and aspects were uploaded to the FRAM Model Visualizer software (FMV).

#### *Assessment of variability of function output and interdependencies (step 2 and 3)*

To determine how the output variability of each function affected the process, functions were analyzed based on whether they varied internally, externally, or due to couplings reported in the interview data. Additionally, it was possible to consider variability between different healthcare professionals performing the same function in the process. Variability was primarily assessed by the interviewer (RS) and discussed with co-authors (AtC, MJ) until consensus was reached. Afterward, a list of potential improvement themes was compiled following a thematic analysis based on improvement suggestions from interviewees, the described variability in the interviews, and the presumed effects on undesirable outcomes. This list was provided to all stakeholders before the discussion meeting.

#### *Validation of the FRAM model and to identify opportunities for improvement to optimize current care (step 4)*

A meeting of local key stakeholders, involving a selection of interviewees (one per discipline) as well as local policymakers, was organized for both regions separately. In these meetings, the work-as-done models were presented to reflect on the FRAM findings and validate the models. Responses from stakeholders were used to adjust the presented FRAM models. Thereafter, the FRAM models and the list of the potential improvement themes were used to reconcile improvement suggestions with work-as-

done until consensus regarding the main improvement themes was reached. After the meetings, the adjusted models were sent to the stakeholders for final validation.

#### *Patient and public involvement*

Patients were viewed as equally important stakeholders and from the start of the project involved as interviewees ( $n=5$ ) in order to integrate their perspectives on work-as-done. Subsequently, their perspectives were included in the final FRAM models and improvement themes.

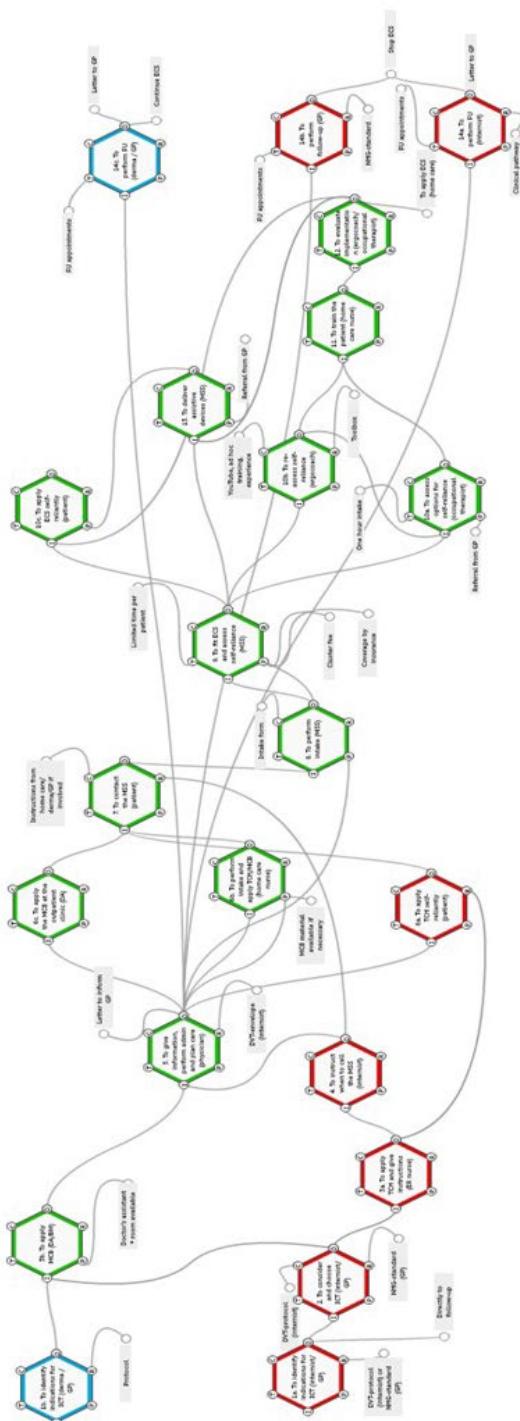
## Results

### FRAM model

A total of 30 interviews: 15 face-to-face interviews for Limburg, and 15 telephonic interviews for North-Holland, were performed. Interviews lasted between 30 and 90 minutes. The profiles of interviewees are listed in Table 3.1. Initially, separate models for DVT and CVD were created per region. Ultimately, as most functions for the DVT and CVD processes were equal, functions were combined and modeled in one FRAM model per region (Figures 3.2 and 3.3). The Limburg model consisted of 14 foreground functions and the North-Holland model of 18. Four time-consecutive phases were empirically identified from the interviews, which were similar for both models.

**Table 3.1** Number of interviewees per stakeholder group.

Interviewees	Limburg (15)	North-Holland (15)
General practitioners	2	2
Internists	2	3
Dermatologist	1	1
Emergency room nurses	2	1
Doctor's assistant dermatology	Not applicable	1
Nurse dermatology	1	Not applicable
Medical stocking suppliers	2	1
Home care nurses	2	2
Occupational therapists	1	1
Deep venous thrombosis patients	1	1
Chronic venous insufficiency patients	1	2



**Figure 3.2** Functional resonance analysis method (FRAM) model CV/D and DVT region Limburg.

The red functions are specific functions for the process of deep venous thrombosis (DVT). The blue functions are specific functions for chronic venous disease (CV/D). The green functions can occur in both processes of DVT and CV/D, and activities and variability were observed to be the same for both DVT and CV/D. Abbreviations: ICT = initial compression therapy, NHS = Nederlandse Huisartsen Genootschap (Dutch general practitioner society), GP = general practitioner, MCB = multilayer compression bandages, DA = doctor's assistant, TCH = temporary compression hosiery, ER = emergency room, MSS = medical stocking supplier, physician = GP/dermatologist/internist, ECS = elastic compression therapy, admin = administration, FU = follow-up.

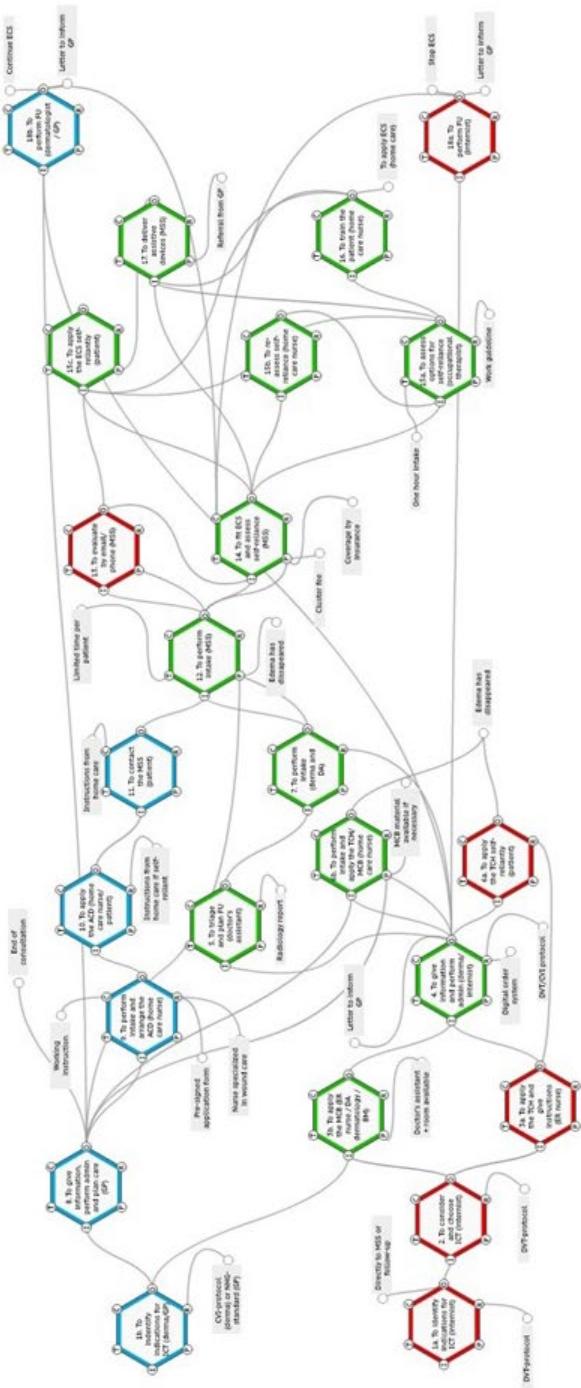


Figure 3.3

Functional resonance analysis method (FRAM) model DVT and CVD region North-Holland. The red functions are specific functions for the process of deep venous thrombosis (DVT). The green functions are specific functions for both processes of DVT and CVD, and activities and variability were observed to be the same for both DVT and CVD. Abbreviations: derma = dermatologist, GP = general practitioner, ICT = initial compression therapy, NHG = nederlands huisartsen genootschap (Dutch general practitioner society), ACD = adjustable compression devices, MCB = multilayer compression bandages, ER = emergency room, DA = doctor's assistant, TCH = temporary compression hosiery, physician = internist/dermatologist, MSS = medical stocking supplier, FU = follow-up.

Phase 1, the initial compression therapy includes identifying treatment indications; selecting the type of initial compression therapy; and implementing initial compression therapy either self-reliantly by the patient, provided by a caregiver at the outpatient clinic or general practice, or provided by home care nurses. Phase two is initiating ECS therapy. In this phase, the patient is expected to contact the medical stocking supplier who conducts an intake, a fitting consult, and delivers the ECS. Subsequently, the medical stocking supplier estimates the patient's ability to be self-reliant (with or without an assistive device) and implements an assistive device if possible. If the medical stocking supplier estimates that it is not possible to implement the assistive device at that moment, downstream functions can be activated (e.g. the occupational therapist for additional training) or the patient is advised to contact home care. In phase 3 some patients apply and remove their ECS self-reliantly, whereas others are trained to use the assistive device or home care is arranged to apply and remove the ECS. Phase four consists of maintenance ECS therapy and follow-up. A detailed description of the functions, the main aspects, and output variability is outlined in the Appendix 3.1 (Tables S3.1 and S3.2).

In both regions, the treating physician (i.e. internist, dermatologist, or GP) and the medical stocking supplier play key roles in the process. The treating physician (function 5 in the Limburg model and 4 and 8 in the North-Holland model) makes decisions regarding the type of initial compression therapy, affecting the course in downstream functions. Additionally, the treating physician generates prescriptions (e.g. for multilayer compression bandages), instructions (e.g. when to call the medical stocking supplier), and referrals (e.g. for definitive ECS), documents that play important roles in downstream functions. Furthermore, the medical stocking supplier (function 9 in the Limburg model and 14 in North-Holland) provides outputs (implementing an assistive device, referring the patient to the occupational therapist, or advising the patient to contact home care) affecting the patient's course in downstream functions. Finally, both models included downstream functions (i.e. the follow-up appointments with the internist, the dermatologist, or the GP, functions 14a-c in the Limburg model and 18a+b in the North-Holland model) that controlled the progress of the entire process.

### Main themes for improvement

In each region, a selection of potential improvement themes (n=11 for Limburg and n=12 for North-Holland, see Table 3.2) was made to guide two meetings with stakeholders (n=8 for Limburg and n=9 for North-Holland). Six major themes for improvement interventions were identified that were the same for both regions and are discussed in the next sections.

**Table 3.2** Selection of potential improvement themes.

Region Limburg (11)	Region North-Holland (12)
<b>Deep venous thrombosis</b>	
<ul style="list-style-type: none"> <li>• To harmonize the advice to use initial and/or definitive ECS therapy</li> <li>• To harmonize the advised duration of ECS therapy</li> <li>• To increase knowledge of emergency room nurses regarding the instruction and demonstration of the TCH</li> </ul>	<ul style="list-style-type: none"> <li>• To incorporate the advised duration of ECS therapy in the patient letter</li> <li>• To create clarity in who is responsible for advising ECS therapy duration between internists and dermatologists</li> </ul>
<b>Chronic venous insufficiency</b>	
<ul style="list-style-type: none"> <li>• To organize follow-up and optimize patient knowledge on when to contact the treating physician</li> </ul>	
<b>Deep venous thrombosis and chronic venous insufficiency</b>	
<ul style="list-style-type: none"> <li>• To optimize and harmonize initial compression therapy</li> <li>• To harmonize working methods for selecting and implementing assistive devices between medical stocking suppliers</li> <li>• To optimize the implementation of assistive devices in patients receiving home care for ECS therapy</li> <li>• To optimize the timing to contact the medical stocking supplier towards the end of the initial compression phase</li> <li>• To improve communication between medical stocking suppliers and home care nurses</li> <li>• To aim for uniformity in declaration requirements among insurance companies</li> <li>• To increase therapy adherence in patients using ECS therapy</li> </ul>	

Abbreviations ECS: elastic compression stockings.

*Theme 1: Dissemination of knowledge of the entire process among all healthcare professionals involved*

All stakeholders agreed that for the process to be optimized, instead of being knowledgeable only on the part in which they are directly involved, it is important that knowledge about the entire process is disseminated among all healthcare professionals involved. This is important to optimize the coordination among functions, provide uniform information to the patient, and to involve the patient in the decision-making process at all phases of the process. This is especially the case for the frontline professionals working in phase one (initiating initial compression therapy), which enables them to better inform patients on the entire process at an early point in time and in a personalized manner.

*Theme 2: Optimizing and standardizing initial compression therapy for both DVT and CVD patients*

The FRAM showed that nearly all DVT and CVD patients were treated with initial compression therapy, except for DVT patients without edema diagnosed by the GP in Limburg and DVT patients diagnosed at one hospital location in North-Holland. At this hospital location, even definitive ECS was omitted in DVT patients without complaints and no edema. Logistics problems at the outpatient clinic and suboptimal awareness of the consequences of the omission of therapy were identified as the main drivers for these differences in approach. However, stakeholders agreed that initial and definitive

compression therapy should be standardized for all DVT patients, regardless of accompanying symptoms, to reduce the risk of post-thrombotic syndrome.

Further variation was observed regarding the type of initial compression therapy prescribed by GPs, dermatologists, and internists in both regions for both DVT and CVD patients. Initial therapy included multilayer compression bandages, adjustable compression devices (only for CVD patients from the GP in North-Holland), or temporary compression hosiery (only for DVT patients in both regions). Although all treating physicians did use some kind of standardized methods to select initial compression therapy, these methods were not aligned among the different disciplines, which can have severe consequences for patients' chances to maintain self-reliance depending on the treating physician. Consensus was reached that in the context of preserving and promoting patients' self-reliance adjustable compression devices or temporary compression hosiery should be considered as the preferred therapy instead of multilayer compression bandages for DVT as well as CVD patients. Additionally, stakeholders agreed that maintaining self-reliance early in the process can facilitate the success rate for implementation of assistive devices since it appeared more challenging to ensure self-reliance for the use of ECS if patients were already using home care.

*Theme 3: Optimizing timing to contact the medical stocking supplier towards the end of the initial compression phase*

In both regions, the exact timing of the intake at the medical stocking supplier was mentioned as a point for improvement. In an estimated 10-30% of patients, edema had not disappeared sufficiently at the time of intake, preventing the ECS to be fitted. Subsequently, a new appointment had to be made resulting in a delay in the downstream functions. Proposed strategies to guide this problem differed per region. One suggestion was that the speed and efficiency of the process could be further enhanced by providing better support to self-reliant patients on when to contact the medical stocking supplier. Another suggestion was to actively question the patient regarding the presence of edema when the patient contacts the medical stocking supplier. Both suggestions were assessed to be practically feasible and were expected to help prevent unnecessary additional appointments and delays in the process.

*Theme 4: Improving the implementation of assistive devices to maintain patient's self-reliance*

It was recognized by stakeholders that maintaining patient self-reliance and starting the implementation of assistive devices from the start of ECS therapy were key factors for increasing adherence to therapy.

The medical stocking supplier is initially responsible for estimating self-reliance abilities, and if necessary, select an assistive device and provide training. They perceive the

assessment of patient's abilities, and the selection of a suitable assistive device challenging, in particular for elderly patients. Most importantly, since it has to be done in a short period (during the fitting consult, with an average duration of 10-15 minutes). The assessment of a patient's abilities at this point is essential because if patients eventually turn out to be less self-reliant as previously expected, the expense of the assistive device will not be covered by the insurance company. Additionally, most elderly patients require additional time to be trained in the use of the assistive device. Furthermore, the cluster fee that medical stocking suppliers receive is a set amount that will not be increased if additional activities are performed to keep patients self-reliant. For either of these reasons, medical stocking suppliers can decide to not select and implement an assistive device themselves but instead refer patients to the occupational therapist or advise patients to contact the home care organization to apply and remove the ECS.

Home care nurses mentioned that, in their experience, there is a low threshold for referral to the home care organization, which probably results in more patients than necessary, using home care. This is an important concern as the home care organizations are already facing a high and increasing workload due to the aging population and subsequent higher need for home care, which becomes hard to manage. Both home care organizations developed solutions to reduce the proportion of patients requiring home care for ECS therapy. In North-Holland, home care nurses re-assess the patient's ability for self-reliance and refer selected patients to the occupational therapist to select and train an assistive device when indicated. In Limburg, specialized home care nurses select and implement assistive devices themselves. However, this adds to the workload of home care nurses, and the proportion of patients that become self-reliant following the intervention through home care nurses was noted to be low.

#### *Theme 5: Harmonizing follow-up duration CVD patients*

In CVD patients there was variability in conducting follow-up appointments among GPs, and between dermatologists and GPs in both regions. Most GPs mentioned that they did not plan any follow-up appointments but relied on the patient's responsibility to alert them if problems occurred, whereas dermatologists standardized a follow-up appointment after 6 weeks. Dermatologists emphasized the importance of a prespecified follow-up appointment to repeat information regarding treatment goals and adherence to ECS therapy and to estimate the patient's risk for future problems. Ultimately, consensus was reached that follow-up appointments for CVD patients are essential.

#### *Theme 6: Personalizing follow-up and treatment duration in DVT patients*

In DVT patients, considerable variations were found in both follow-up frequency and duration (6 weeks to 24 months), as well as the advice when to stop ECS therapy among

internists between the two hospital locations in North-Holland and between internists and GPs in both regions. In Limburg, internists gave individualized advice on when to stop ECS therapy (based on Villalta scores, see function 14a in the Limburg model) following local protocol. In North-Holland, some internists and dermatologists (dermatologists also conduct one consultation for DVT patients at hospital location A, see function 7 in the North-Holland model) advised to stop the ECS therapy after 6 months if no complaints existed based on their most recent knowledge of literature, while others advised to stop ECS after 2 years according to the local protocol. Internists and dermatologists in North-Holland acknowledged that they were not aware of each other's instructions. As a result, patients in North-Holland mentioned that they received different advice regarding the duration of ECS therapy from dermatologists and internists. Moreover, as the moment of ECS therapy to be stopped generally takes place after follow-up appointments have ended, and no health care professionals were involved in this decision anymore, patients mentioned that it was especially difficult for them to understand the correct duration of therapy. It was stated that a longer follow-up duration and a more uniform, personalized method to substantiate the advice when to stop ECS therapy is necessary in DVT patients.

## Discussion

This study provides important insight into the complex structure of the organization of ECS therapy for DVT and CVD patients in daily practice in the Netherlands, from a multiple stakeholder perspective. By using FRAM, we were able to identify the essential functions of ECS therapy. Since the majority of essential functions were equal for DVT and CVD patients, especially for phase 1 (the initial compression therapy), phase 2 (initiating ECS therapy), and phase 3 (definitive ECS therapy), we were able to merge the processes and developed two models (one per region). Based on these models, we identified major sources of variability in the performance of the different functions and assessed the influence of variability on outcomes for patient care in discussion with the stakeholders. This ultimately resulted in five themes for improvement: dissemination of knowledge of the entire process among all health care professionals involved; optimizing and standardizing initial compression therapy; optimizing timing to contact the medical stocking supplier (when edema has disappeared); improving the implementation of assistive devices to maintain patient's self-reliance; harmonizing follow-up duration for CVD patients, and personalizing follow-up and treatment duration in DVT patients.

Previous studies on the implementation of improvement interventions have mainly focused on the individual (single component) performances instead of focusing on 'a system approach'. A review by Lau et al revealed that, in general, such strategies directed at individual professionals only achieved a small to modest improvement (range 2-9%) compared to no strategy.<sup>55</sup> It is suggested that the use of a system approach,

focusing on incorporating an understanding of how systems work as a whole from different perspectives could facilitate implementation of improvement interventions.<sup>56</sup>

The large variation in the advised duration of therapy for DVT patients observed in our study is consistent with data from previous studies, although none of the studies was performed in The Netherlands. Kahn et al showed that 38% of physicians recommended ECS to be worn until symptoms improved, 18% recommend it to be worn for a defined period, 26% recommended its indefinite use, and 18% provided other advice regarding ECS therapy duration.<sup>28</sup> Roche-Nagel et al. also highlighted that there is a large variety in the advised duration of therapy (ranging from 1 month to 2 years).<sup>13</sup> Additionally, the OTIS-DVT trial showed variable durations of therapy ranging from a median of 92 days in private practices to 364 days in patients treated in hospitals.<sup>33</sup>

Furthermore, our results emphasize the importance of maintaining patient's self-reliance for both initial compression therapy and definitive ECS therapy. We identified that, for the medical stocking supplier, time pressure, the reimbursement system of insurance companies, and the cluster fee received are barriers to optimally select and implement assistive devices for definitive ECS. We hypothesize that these barriers result in an excess of patients receiving home care, with major consequences for the patient's self-reliance, home care burden, and healthcare costs. An earlier study of Sippel et al. showed that the use of an assistive device could increase the ability of elderly patients with CVD to apply the ECS (closed-toe, pressure 40 mmHg) self-reliantly from 60% to 90%, which again emphasizes the importance of optimal selection and implementation of assistive devices. Future studies should focus on creating transparency in health care costs regarding the implementation of assistive devices, and improvement interventions to optimize this care.

Additionally, our results showed the importance of dissemination of knowledge and skills among the different healthcare professionals involved in ECS therapy. The degree of knowledge about the process in its entirety was perceived to have strong implications for the alignment of functions in the process. This is in line with previous findings that sharing knowledge and interaction between different professionals is essential to deliver high-quality patients care in complex contexts.<sup>57</sup>

With this study, we provided a detailed insight into how ECS therapy care is organized and delivered in daily practice for all patients receiving ECS therapy. The major strength of this study is the interdisciplinary and inter-organizational design, which shows the multicenter applicability of the FRAM providing the possibility to compare challenges and strengths across different settings. Furthermore, the study enabled a first insight into the reproducibility of the FRAM between regions, which is an area that is not yet extensively explored. The large number of interviewees included from each professional group, and the participation of stakeholders from all groups in the discussion meetings

are also strengths of the current study. This made it possible to integrate different perspectives and to provide a detailed understanding of the process in its entirety including the six themes for improvement.

However, it is possible that with more participants more variability could have been identified, providing a wider range of perspectives for improvement interventions even though data saturation appeared to be achieved and the models and discussion points were presented and validated by all stakeholders involved in the process. Additionally, due to COVID-19, we were forced to perform several interviews by telephone. Which prevented us from interviewing the participants in their working context, which could have provided further understanding of specific working conditions. Furthermore, since the interviews were conducted by a single researcher (RS) with a medical background, the possibility of observer bias arises. Pre-understanding of the context may have advanced data collection, but it might also have influenced how the interviews were conducted. We tried to control this bias by discussing the content of the interviews with also non-medical co-authors to incorporate different views into the interpretation of the results.

## Conclusion

In this study conducted among multiple stakeholders, we used the FRAM to integrate different perspectives and to provide a detailed insight into how the complex process of ECS therapy is delivered in daily practice in the Netherlands. We identified six major themes for improvement, which can be used to direct future intervention strategies. Furthermore, these themes can also be used as a foundation for a general cross-domain protocol for all health care professionals involved.

## References

1. Prandoni P, Lensing AW, Prins MH, et al. Below-knee elastic compression stockings to prevent the post-thrombotic syndrome: a randomized, controlled trial. *Ann Intern Med.* 2004;141(4):249-56.
2. Brandjes DP, Buller HR, Heijboer H, et al. Randomised trial of effect of compression stockings in patients with symptomatic proximal-vein thrombosis. *Lancet.* 1997;349(9054):759-62.
3. Mol GC, van de Ree MA, Klok FA, et al. One versus two years of elastic compression stockings for prevention of post-thrombotic syndrome (OCTAVIA study): randomised controlled trial. *BMJ.* 2016;353:i2691.
4. Ten Cate-Hoek AJ, Amin EE, Bouman AC, et al. Individualised versus standard duration of elastic compression therapy for prevention of post-thrombotic syndrome (IDEAL DVT): a multicentre, randomised, single-blind, allocation-concealed, non-inferiority trial. *Lancet Haematol.* 2018;5(1):e25-e33.
5. Wittens C, Davies AH, Baekgaard N, et al. Editor's Choice - Management of Chronic Venous Disease: Clinical Practice Guidelines of the European Society for Vascular Surgery (ESVS). *Eur J Vasc Endovasc.* 2015;49(6):678-737.
6. Rabe E, Partsch H, Hafner J, et al. Indications for medical compression stockings in venous and lymphatic disorders: An evidence-based consensus statement. *Phlebology.* 2018;33(3):163-84.
7. Berszakiewicz A, Sieroń A, Krasiński Z, et al. Compression therapy in venous diseases: current forms of compression materials and techniques. *Postepy Dermatol Alergol.* 2020;37(6):836-41.
8. Berszakiewicz A, Sieroń A, Krasiński Z, et al. Compression therapy in venous diseases: physical assumptions and clinical effects. *Postepy Dermatol Alergol.* 2020;37(6):842-7.
9. Dahm KT, Myrhaug HT, Strømme H, et al. Effects of preventive use of compression stockings for elderly with chronic venous insufficiency and swollen legs: a systematic review and meta-analysis. *BMC Geriatr.* 2019;19(1):76.
10. Raju S, Hollis K, Neglen P. Use of compression stockings in chronic venous disease: patient compliance and efficacy. *Ann Vasc Surg.* 2007;21(6):790-5.
11. Kankam HKN, Lim CS, Fiorentino F, et al. A Summation Analysis of Compliance and Complications of Compression Hosiery for Patients with Chronic Venous Disease or Post-thrombotic Syndrome. *Eur J Vasc Endovasc Surg.* 2018;55(3):406-16.
12. Dawson AJ, Akaberi A, Galanaud JP, et al. Patient-reported reasons for and predictors of noncompliance with compression stockings in a randomized trial of stockings to prevent postthrombotic syndrome. *Res Pract Thromb Haemost.* 2020;4(2):269-77.
13. Roche-Nagle G, Ward F, Barry M. Current prescribing patterns of elastic compression stockings post-deep venous thrombosis. *Phlebology.* 2010;25(2):72-8.
14. Bouman AC, Ten Cate-Hoek AJ, Dirksen CD, et al. Eliciting patients' preferences for elastic compression stocking therapy after deep vein thrombosis: potential for improving compliance. *J Thromb Haemost.* 2016;14(3):510-7.
15. Carolyn C. Post-thrombotic syndrome patient education based on the health belief model: self-reported intention to comply with recommendations. *J Wound Ostomy Continence Nurs.* 2011;38(6):648-54.
16. Gong JM, Du JS, Han DM, et al. Reasons for patient non-compliance with compression stockings as a treatment for varicose veins in the lower limbs: A qualitative study. *PloS One.* 2020;15(4):e0231218.
17. Reich-Schupke S, Murmann F, Altmeyer P, et al. Compression therapy in elderly and overweight patients. *VASA.* 2012;41(2):125-31.
18. Amin EE, Ten Cate-Hoek AJ, Bouman AC, et al. Individually shortened duration versus standard duration of elastic compression therapy for prevention of post-thrombotic syndrome: a cost-effectiveness analysis. *Lancet Haematol.* 2018;5(11):e512-e9.
19. The Health Foundation. Evidence scan: Complex adaptive systems. London: The Health Foundation. 2010.
20. Plsek PE, Greenhalgh T. Complexity science: The challenge of complexity in health care. *BMJ.* 2001;323(7313):625-8.
21. Hollnagel E. FRAM: The Functional Resonance Analysis Method: Modelling Complex Socio-Technical Systems2012.

22. Rubenstein LV, Pugh J. Strategies for promoting organizational and practice change by advancing implementation research. *J Gen Intern Med.* 2006;21 Suppl 2:S58-64.
23. Murphy GJ, Reeves BC, Rogers CA, et al. Increased mortality, postoperative morbidity, and cost after red blood cell transfusion in patients having cardiac surgery. *Circulation.* 2007;116(22):2544-52.
24. May CR, Johnson M, Finch T. Implementation, context and complexity. *Implement Sci.* 2016;11(1):141.
25. Campbell NC, Murray E, Darbyshire J, et al. Designing and evaluating complex interventions to improve health care. *BMJ (Clinical research ed).* 2007;334(7591):455-9.
26. Kahn SR, Shapiro S, Wells PS, et al. Compression stockings to prevent post-thrombotic syndrome: a randomised placebo-controlled trial. *Lancet.* 2014;383(9920):880-8.
27. Azirar S, Appelen D, Prins MH, et al. Compression therapy for treating post-thrombotic syndrome. *Cochrane Database Syst Rev.* 2019;9(9):CD004177.
28. Kahn SR, Elman E, Rodger MA, et al. Use of elastic compression stockings after deep venous thrombosis: a comparison of practices and perceptions of thrombosis physicians and patients. *J Thromb Haemost.* 2003;1(3):500-6.
29. Berszakiewicz A, Kasperekzyk J, Sieron A, et al. The effect of compression therapy on quality of life in patients with chronic venous disease: a comparative 6-month study. *Postepy Dermatol Alergol.* 2021;38(3):389-95.
30. Sippel K, Seifert B, Hafner J. Donning devices (foot slips and frames) enable elderly people with severe chronic venous insufficiency to put on compression stockings. *Eur J Vasc Endovasc Surg.* 2015;49(2):221-9.
31. Mosti G, Cavezzì A, Partsch H, et al. Adjustable Velcro Compression Devices are More Effective than Inelastic Bandages in Reducing Venous Edema in the Initial Treatment Phase: A Randomized Controlled Trial. *Eur J Vasc Endovasc Surg.* 2015;50(3):368-74.
32. Gelderblom G, Hagedoorn-Meuwissen EAV. Kousen uitbrekhulpmiddel Easy-Lever. Een onderzoek naar bruikbaarheid, effecten en belemmeringen. . 2005.
33. Spirk D, Banyai M, Jacomella V, et al. Outpatient management of acute deep vein thrombosis: results from the OTIS-DVT registry. *Thromb Res.* 2011;127(5):406-10.
34. Dua A, Desai SS, Heller JA. Heterogeneity in venous disease practice patterns amongst primary healthcare practitioners. *Vascular.* 2015;23(4):391-5.
35. Hollnagel E. Safety-I and Safety-II. The Past and Future of Safety Management. . Farnham, UK: Ashgate Publishing Limited; 2014.
36. Damen NL, de Vos MS, Moesker MJ, et al. Preoperative Anticoagulation Management in Everyday Clinical Practice: An International Comparative Analysis of Work-as-Done Using the Functional Resonance Analysis Method. *J Patient Saf.* 2021;17(3):157-65.
37. Clay-Williams R, Hounsgaard J, Hollnagel E. Where the rubber meets the road: using FRAM to align work-as-imagined with work-as-done when implementing clinical guidelines. *Implement Sci.* 2015;10:125.
38. McNab D, Freestone J, Black C, et al. Participatory design of an improvement intervention for the primary care management of possible sepsis using the Functional Resonance Analysis Method. *BMC Med.* 2018;16(1):174.
39. Raben DC, Bogh SB, Viskum B, et al. Learn from what goes right: A demonstration of a new systematic method for identification of leading indicators in healthcare. *Reliability Engineering & System Safety.* 2018 2018/01/01/;169:187-98.
40. O'Hara JK, Baxter R, Hardicre N. 'Handing over to the patient': A FRAM analysis of transitional care combining multiple stakeholder perspectives. *Appl Ergon.* 2020;85:103060.
41. Laugaland K, Aase K, Waring J. Hospital discharge of the elderly—an observational case study of functions, variability and performance-shaping factors. *BMC Health Serv Res.* 2014;14:365.
42. Furniss D, Nelson D, Habli I, et al. Using FRAM to explore sources of performance variability in intravenous infusion administration in ICU: A non-normative approach to systems contradictions. *Appl Ergon.* 2020;86:103113.
43. Schutijser BCFM, Jongerden IP, Kłopotowska JE, et al. Double checking injectable medication administration: Does the protocol fit clinical practice? *Safety Science.* 2019 2019/10/01/;118:853-60.
44. Pickup L, Atkinson S, Hollnagel E, et al. Blood sampling - Two sides to the story. *Appl Ergon.* 2017;59(Pt A):234-42.
45. Kaya GK, Ovalı HF, Ozturk F. Using the functional resonance analysis method on the drug administration process to assess performance variability. *Safety Science.* 2019 2019/10/01/;118:835-40.

46. Buikstra E, Strivens E, Clay-Williams R. Understanding variability in discharge planning processes for the older person. *Safety Science*. 2020;2020/01/01;121:137-46.
47. Eklof B, Rutherford RB, Bergan JJ, et al. Revision of the CEAP classification for chronic venous disorders: consensus statement. *J Vasc Surg*. 2004;40(6):1248-52.
48. Hill R. FRAM Model Visualizer version 0.4.1. Available at: <http://functionalresonance.com/the%20fram%20model%20visualiser.html>.
49. Hollnagel E, Hounsgaard J, Colligan L. FRAM- The Functional Resonance Analysis Method - A Handbook for Practical Use of the Method. 2014. Available from: [https://functionalresonance.com/onewebmedia/FRAM\\_handbook\\_web-2.pdf](https://functionalresonance.com/onewebmedia/FRAM_handbook_web-2.pdf).
50. Kwaliteitsinstituut voor de Gezondheidszorg CBO. CBO Richtlijn Diagnostiek Preventie en behandeling van veneuze trombo-embolie en secundaire preventie van arteriële trombose 2008 [September 17, 2020]. Available from: <https://www.nvr.nl/cbo-richtlijnen>.
51. Nederlands Huisartsen Genootschap. NHG-standaard Diepveneuze trombose en longembolie 2017. sept 17, 2020]. Available from: <https://richtlijnen.nhg.org/standaarden/diepveneuze-trombose-en-longembolie>.
52. Nederlands Huisartsen Genootschap. NHG standaard Varices 2009 [Sept 17, 2020]. Available from: <https://richtlijnen.nhg.org/standaarden/varices>.
53. Nederlandse Vereniging voor Dermatologie en Venereologie (NVDV). Richtlijn veneuze pathologie 2014 [Sept 17, 2020]. Available from: <https://www.huidziekten.nl/richtlijnen/richtlijn-veneuze-pathologie-2014.pdf>.
54. Mason M. Sample Size and Saturation in PhD Studies Using Qualitative Interviews <http://www.qualitative-research.net/index.php/fqs/article/view/14282010> [cited 2020 Sept 17].
55. Lau R, Stevenson F, Ong BN, et al. Achieving change in primary care--effectiveness of strategies for improving implementation of complex interventions: systematic review of reviews. *BMJ Open*. 2015;5(12):e009993.
56. Greenhalgh T, Papoutsis C. Studying complexity in health services research: desperately seeking an overdue paradigm shift. *BMC Med*. 2018;16(1):95.
57. Nancarrow SA, Booth A, Ariss S, et al. Ten principles of good interdisciplinary team work. *Hum Resour Health*. 2013;11:19.

## Appendix 3.1

**Table S3.1** Functions from the Functional Resonance Analysis Method (FRAM) model Limburg

Function*	Description of function	Variability
1a. To identify indications for initial compression therapy (internist/GP)	The indication for initial compression therapy in the acute phase after a diagnosis of DVT is made by the GP at the general practice or the internist in the ER.	Variations occur since GPs are not always aware of the treatment indications for initial compression therapy in patients without edema. Patients are then directly referred to the medical stocking supplier for definitive ECS without initial compression therapy. The result of omitting initial compression therapy is a delay in the onset of compression therapy and preventing function 3b from occurring.
1b. To identify indications for initial compression therapy (dermatologist/GP)	The indication for initial compression therapy after a diagnosis of CVI can be made by the GP or the dermatologist. Thereafter the physician informs the doctor's assistant to apply the multilayer compression bandages.	Variation is not mentioned due to the use of clear protocols and similarities in recommendations.
2. To consider and choose initial compression therapy (internist/GP)	When the indication for compression therapy is made, the treating physician (GP/internist) needs to decide what type of initial compression therapy is indicated. The GP chooses multilayer compression bandages, based on the NHG-standard, and informs the doctor's assistant to apply them. The internist chooses a temporary compression hosiery unless there are contra-indications and informs the ER nurse to apply them. If contra-indications exist, the internist chooses multilayer compression bandages based on the DVT-protocol and contacts the bandage master to apply them.	Variations occur since internists and GPs are using different protocols. GPs are not always aware of the different possibilities for initial compression therapy and there is a lack of detailed information in their current guideline (NHG-standard). Patients automatically become dependent on home care or need to visit the outpatient clinic for the application of the multilayer compression bandages. This affects function 6a-c.
3a. To apply the temporary compression hosiery and give instructions (ER nurse)	The ER nurse measures the leg circumference at different places and determines the requested size for the temporary compression hosiery. Thereafter the nurse fits the hosiery and instructs the patient on how to apply it independently at home using a disposable donning slide which the patient can take home. Thereafter the nurse informs the internist.	Variation occurs based on the nurses' experience to apply the temporary compression hosiery, give instructions, and the knowledge of their role and responsibilities in the process. Thereby time constraints may affect the extent of the patient's instruction. This may affect function 6a.

**Table 33.1** (continued)

<b>Function*</b>	<b>Description of function</b>	<b>Variability</b>
3b. To apply the multilayer compression bandages (doctor's assistant/bandage master)	In the general practice and at the dermatology department, the doctor's assistant applies the multilayer compression bandages. In the ER, the ER nurse contacts the bandage master to apply the bandages within office hours. Afterward, the nurse/doctor's assistant informs the physician.	Variation occurs when there is no doctor's assist with the appropriate experience and/or room available to apply the multilayer compression bandages. Thereby, the bandage master is only available to apply the bandages within office hours in the ER. Outside office hours, home care is arranged for the next day. Both these variabilities could lead to a delay in the onset of initial compression.
4. To instruct when to call the medical stocking supplier (internist)	The internist instructs the patient when to call the medical stocking supplier to schedule an appointment to fit the definitive ECS when edema has disappeared.	The quality of instructions can vary based on a lack of time due to other patient care related duties and the experience of the internist. This may affect function 6a.
5. To give information and perform administration (physician)	The treating physician informs the patient about the aim of the compression therapy. Then the physician performs administrative tasks including:	Variation occurs since some GPs are not aware that a referral is necessary for the medical stocking supplier to start function 8.
	1. Prescribing a referral for the definitive ECS 2. Planning a follow-up appointment 3. Contacting the home care organization if necessary 4. Prescribing multilayer compression bandages if necessary. The patient collects the materials at the pharmacy.	Variability is reduced by the availability of the DVT-envelope in the ER, which contains all the necessary pre-completed forms to perform administration.
6a. To apply the temporary compression hosiery self-reliantly (patient)	The patient applies the temporary hosiery self-reliantly at home based on instructions given at the ER. Thereby, the patient needs to check if the leg is still containing edema.	Variability occurs based on the adherence and accuracy of applying the temporary compression hosiery and the awareness of the patient to assess if the leg is still containing edema and how to assess this. When the hosiery is not applied or not applied correctly, this could lead to a delay in disappearing edema and a delay in downstream functions. This affects function 7 and 8.

Table S3.1 (continued)

Function*	Description of function	Variability
6b. To perform an intake and apply the temporary compression hosiery/multilayer compression bandages (home care nurse)	When the physician contacts the home care organization, a nurse contacts the patient and arranges an appointment on the same day or the day after to perform an intake. The nurse makes a care plan and plans home visits. The compression materials must be complete and present at the patient's home.	Variability occurs since multilayer compression bandages are regularly incomplete when the home care nurse visits the patient at the intake appointment, the nurse needs to call the treating physician to arrange the missing materials causing a delay of the function itself.
6c. To apply the multilayer compression bandages at the outpatient clinic (doctor's assistant)	Patients using multilayer compression bandages prescribed by the GP/dermatologist can visit the outpatient clinic twice a week to have them applied.	Variability occurs when there is no doctor's assistant/nurse or room available to deliver care twice a week. This could result in a delay in Function 7 and further downstream functions.
7. To contact the medical stocking supplier (patient)	When edema has disappeared, the patient is supposed to contact the medical stocking supplier to make an appointment for an intake. This can be initiated by either the patient based on the information provided by the internist, the GP, or dermatologist when multilayer compression bandages are applied in the outpatient clinic, or home care when involved.	A delay in function 8 and further downstream functions appears if the appointment is made even too late or too early (as a consequence edema has not yet disappeared and the definitive ECS cannot be fitted).
8. To perform an intake (medical stocking supplier)	The patient visits the medical stocking supplier. At the intake appointment, the medical stocking supplier checks the referral, evaluates the patient based on the intake form, and measures leg size at specific points to select the definitive ECS. Afterward, the medical stocking supplier orders the definitive ECS and claims the expenses with the insurance company.	Variability reduces when home care is involved or the multilayer compression bandages are applied in the outpatient clinic, then the home care nurse/GP/dermatologist controls this function.
		Variation occurs if the referral from the physician is imprecise or missing. This delays the function or can lead to variability when the medical stocking supplier adds the missing information based on information provided by the patient. This can affect all downstream functions.

Table S3.1 (continued)

<b>Function*</b>	<b>Description of function</b>	<b>Variability</b>
9. To fit the ECS and assess self-reliance (medical stocking supplier)	When the definitive ECS is delivered, a new appointment is made to either fit the ECS and select and train 'uncomplicated'** assistive devices if the patient is not self-reliant. When patients are not self-reliant with these assistive devices, the occupational therapist is contacted to introduce 'complicated***' assistive devices. When patients are self-reliant with or without using the 'uncomplicated' assistive device, they apply the ECS self-reliantly at home. The medical stocking supplier thereafter implements the expenses of the assistive device with the insurance company.	Variability in the implementation of 'uncomplicated' assistive devices between medical stocking suppliers occurs mainly due to time pressure, especially in elderly who often require more training before they can use the assistive device. Other sources of variability are financial constraints and regulation of coverage of the expenses by the insurance. For either of these reasons, the medical stocking supplier can decide not to refer the patient to the occupational therapist (function 10a) or to advise contacting the home care organization (function 10b).
10a. To assess options for self-reliance (occupational therapist)	Once contacted, the occupational therapist calls the patient and arranges an appointment for an intake visit. The therapist visits the patient and selects an assistive device based on prior experience combined with the needs and possibilities of the patient. The therapist instructs the patient and demonstrates how the selected assistive device is used. When the patient learned how to use the assistive device self-reliantly, the therapist reclaims the training device and sends a report to the medical stocking supplier to arrange a new device. When additional practice is necessary, a new appointment is made, or home care is contacted for additional practice.	Variation occurs mainly based on the patient's motivation to willingness to learn how to be self-reliant using an assistive device. If patients are unmotivated, e.g. since they are used to the social contact from home care, it is perceived as exceedingly difficult to train them successfully.

**Table S3.1** (continued)

<b>Function*</b>	<b>Description of function</b>	<b>Variability</b>
10b. To re-assess self-reliance (ergocoach)	Patients contact the home care organization when ECS is delivered. The ergocoach (a home care nurse specialized in making patients self-reliant) visits the patient and assesses options for implementing assistive devices. The ergocoach selects an assistive device based on experience and written instructions in the 'toolbox' available at main home care locations. The toolbox contains different assistive devices. Thereafter, the ergocoach trains the patient to use assistive devices based on experience, ad-hoc training, and YouTube instructions. The ergocoach then contacts the regular home care nurses to additionally train the patient in how to use the assistive device during a prespecified period.	Variability can occur based on the experience of the ergocoach in selecting and demonstrating the appropriate assistive device for the specific patient. If the chosen assistive device is unsuitable for the patient, this can affect the output of function 12.
10c. To apply the ECS self-reliantly (patient)	The patient applies the ECS at home daily until the treating physician advises to stop the treatment.	Variability in output can occur based on the patient's adherence to therapy. If patients do not use the ECS as prescribed or stop the therapy on their initiative, this results in an increased risk of developing post-thrombotic syndrome in DVT patients and a higher risk of developing ulcers in CVI patients.
11. To train the patient (home care nurse)	Regular home care nurses train the patient twice daily on how to use the assistive device self-reliant. This process lasts for an estimated week (occupational therapist) and two weeks (ergocoach).	Variation occurs based on time constraints affecting the extensiveness of the training and the nurse's experience to instruct and train the patient. Further variation occurs based on the patient's motivation and abilities to learn how to use the assistive device self-reliantly. This could both affect the duration of the function and the outcome of function 12.

Table S3.1 (continued)

<b>Function*</b>	<b>Description of function</b>	<b>Variability</b>
12. To evaluate implementation (ergocoach/occupational therapist)	The ergocoach or occupational therapist evaluates the implementation. When the patient learned how to use the assistive device self-reliantly, the occupational therapist reclaims the training device and sends a report to the medical stocking supplier to arrange a new device. In patients who required additional training by home care, home care should be continued until the assistive device is delivered. The ergocoach can leave the assistive device with the patient and stops home care. When the assistive device is not successfully implemented, home care needs to continue for the duration of therapy.	Variability in the availability of the assistive device for the patient occurs based on differences in reimbursement agreements with insurance companies. A delay in function 10c occurs if the occupational therapist implements the assistive device since it is not directly available to the patient since the therapist has to reclaim the assistive device and order a new device.
13. To deliver assistive devices (medical stocking supplier)	When a suitable assistive device is selected, medical stocking suppliers claim the expenses with the patient's insurance company. Therefore, they need to deliver a declaration along with a report from the occupational therapist (for more expensive assistive devices) and an indication letter from the GP. Assistive devices are usually delivered between 1-14 days depending on the type.	Variability occurs since the requirements for reimbursements different insurance companies have are variable. This can result in a delay in the function itself and function 10c if the claim is not submitted correctly. Further variation occurs when the GP does not directly respond to a referral request. The medical stocking supplier than cannot claim the expenses and deliver the assistive device. This results in a delay in the function itself and function 10c.
14a. To perform follow-up (internist)	The internist performs standard follow-up appointments after three weeks, three months, six months, one year, and two years based on the 'clinical pathway DVR'. At each appointment, the internist checks the progress of the process, compliance to therapy, and determines a Villalta score. The Villalta score is a scoring system to assess the presence of post-thrombotic syndrome. The internist advises the patient to stop ECS therapy if the Villalta score is four or less at two consecutive visits. The internist writes a patient letter to inform the GP if changes in medical approaches are made and at the end of follow-up.	Variability can occur based on the experience of the internist in using the Villalta score. When the Villalta score is not used correctly, the patient might get incorrect advice to either stop or continue ECS therapy. Variability in activities performed at the follow-up appointments and the frequency of these appointments is reduced using the clinical pathway.

**Table S3.1** (continued)

<b>Function*</b>	<b>Description of function</b>	<b>Variability</b>
14b. To perform follow-up (GP)	If the GP has diagnosed the DVT, a standard follow-up appointment is planned after a few days to check the progress and compliance to therapy. Further follow-up is planned a few weeks after diagnosis and at the end of the pharmacological therapy. The GP advises the patient to stop the ECS after one year, when complaints re-occur the GP advises to resume ECS therapy for another year based on their national guideline (NHG-standard).	Variation can occur when patients do not adhere to therapy; this can result in adjustments of follow-up or duration of therapy.
14c. To perform follow-up (dermatologist/GP)	The dermatologist performs a follow-up visit after a few weeks. Further follow-up appointments are only planned in patients with expected problems. When the dermatologist does not expect problems, a patient letter is sent to the GP including the advice to perform a follow-up visit. Some GPs standardize this follow-up visit whereas others rely on the patient's responsibility to alert them if problems exist. Both the dermatologist and GP advise the patient to wear ECS for life.	Variation in follow-up occurs since it is mainly based on personal preferences and experiences.

\* The numbers of the functions refer to Figure 3.2; \*\* Uncomplicated assistive devices: e.g. resistance reducing assistive devices and cuffs and cones;  
 \*\*\* Complicated assistive devices: e.g. arm extending devices, frames, and ECS pistol. Abbreviations: GP = general practitioner, DVT = deep venous thrombosis, ECS = elastic compression therapy, CVI = chronic venous insufficiency, NHG = nederlandse huisartsen genootschap (Dutch general practitioner society), ER = emergency room.

**Table S3.2** Functions from the Functional Resonance Analysis Method (FRAM) model North-Holland.

<b>Function*</b>	<b>Description of function</b>	<b>Variability</b>
1a. To identify indications for initial compression therapy (internist)	The indication for initial compression therapy in the acute phase after a diagnosis of DVT is made by the internist, either at the emergency department (hospital location A) or the outpatient clinic (hospital location B). At hospital location A, all patients are treated with initial compression therapy by default.  At hospital location B, initial compression therapy is omitted by default. Even definitive ECS therapy can be omitted in selected patients without complaints and no edema.	Variations occurred since the two hospital locations were using different protocols with different recommendations regarding initial compression therapy until one month ago. A new protocol was designed covering both locations. However, this protocol is lacking information regarding initial compression therapy. This results in internists relying on their own experiences and clinical judgment to estimate if (initial) compression therapy is necessary. This places patients at risk for not being treated with initial compression therapy and/or definitive compression. Patients at hospital location B are directly referred to the medical stocking supplier (function 12) or follow-up (function 18a) if even definitive ECS therapy is omitted, preventing the intermediate functions from occurring.
1b. To identify indications for initial compression therapy (dermatologist/GP)	The indication for initial compression therapy after a diagnosis of CVI is made by the dermatologist or the GP. The dermatologist informs the doctor's assistant to apply multilayer compression bandages while the GP contacts the home care organization to initiate therapy using adjustable compression devices.	Variation regarding the type of initial compression therapy between the dermatologist and the GP occurs since the implementation of adjustable compression devices by home care organizations only comprises the general practice.
2. To consider and choose initial compression therapy (internist)	When the indication for compression therapy in DVT patients is made, the internist needs to decide what type of initial compression therapy is indicated. At hospital location A, the internist chooses a temporary compression hosiery unless there are contra-indications based on the developed DVT-protocol. If multilayer compression bandages are chosen, the internist asks the ER nurse to apply the multilayer compression bandages. In most cases, an ER nurse with the right skills and experience is available. In other cases (within office hours) the internist calls the dermatology department to apply multilayer compression bandages.	At hospital location A, this function may vary based on pressure at the ward and experience of the internist.

**Table S3.2** (continued)

Function*	Description of function	Variability
3a. To apply the temporary compression hosiery and give instructions (ER nurse)	<p>See function 3a FRAM model region Limburg. Instead of using a disposable donning slide, the ER nurses use a non-disposable donning slide which may not be taken home by the patient. The ER nurse instructs the patient to buy the slide at the home care shop.</p> <p>The ER nurse, doctor's assistant at the dermatology department, or bandage master applies multilayer compression bandages.</p>	<p>Time constraints may affect the extent of patient instruction, affecting function 6a.</p>
3b. To apply the multilayer compression bandages (ER nurse/doctor's assistant dermatology/bandage master)	<p>The ER nurse, doctor's assistant at the dermatology department, or bandage master applies multilayer compression bandages.</p>	<p>Variation occurs if the professional responsible for applying the multilayer compression bandages is occupied, this prevents function 3b from occurring. In some of these cases, home care has to be arranged to apply the multilayer compression bandages the next day.</p>
4. To give information and perform administration (internist/dermatologist)	<p>The treating physician informs the patient about the aim of the compression therapy. The treating physician (internist/dermatologist) then plans follow-up:</p> <ol style="list-style-type: none"> <li>1. The internist plans a follow-up appointment after 3 or 6 weeks (depending on location) in DVT patients at the department of internal medicine. At hospital location A, the internist additionally informs the dermatology outpatient clinic either by telephone or by digital order to schedule a follow-up appointment with the dermatologist. The dermatologist plans a follow-up appointment after 6 weeks in CVI patients.</li> <li>2. If necessary, the home care organization is contacted by phone or digital order. Whereas the internist at the ER calls the home care nurse who is available at the ER (24/7) to visit the patient and plan care.</li> <li>3. Prescribing materials for multilayer compression bandages if necessary. If the dermatologist prescribes multilayer compression bandages, the prescription can be ordered digitally and is automatically delivered at the patient's home the next day. Whereas the internist issues a conventional prescription, and the patient collects the materials at the pharmacy.</li> <li>4. Additionally, the internist and dermatologist write a patient letter to inform the GP.</li> </ol>	<p>The digital order used in the dermatology department can improve the speed of the process and decreases time variability in patients collecting the materials for multilayer compression bandages. Additionally, the availability of the home care nurse at the ER can reduce variability since the nurse is directly involved with the patient, estimates the needs, and plans care.</p>

Table S3.2 (continued)

Function*	Description of function	Variability
5. To triage and plan follow-up (doctor's assistant)	The doctor's assistant triages the phone call or digital order by acquiring additional information either through supplementary questions or accessing the radiology report. Based on this information the assistant then estimates when edema is thought to have disappeared to schedule the first follow-up appointment.	Variability occurs if the doctor's assistant responsible for the triage is not informed about how to determine the appropriate period to schedule the patient or the patient is not adhering to therapy. If the appointment is made when the edema has not yet disappeared, the definitive ECS cannot be measured (function 12), and a new appointment has to be made. See function 6a FRAM model region Limburg.
6a. To apply the temporary compression hosiery self-reliantly (patient)	See function 6a FRAM model region Limburg.	Variability occurs since the materials are regularly incomplete, resulting in a delay of the intake appointment.
6b. To perform intake and apply the temporary compression hosiery/multilayer compression bandages (home care nurse)	See function 6b FRAM model region Limburg. Additionally, the leg circumflex is measured once a week.	The output of this function is a precondition for function 12, but the two functions are not coupled. The intake with the medical stocking supplier is planned without the active input regarding the actual situation of the edema.
7. To perform intake (dermatologist + doctor's assistant)	The doctor's assistant prepares the intake by retrieving information from the letter written in the emergency department. The assistant completes this information by obtaining a comprehensive medical history. Thereafter, the assistant determines whether the edema has disappeared, and calls the dermatologist who co-assesses the patient.	The advised duration of therapy is subject to variation since dermatologists and internists are unaware of other's instructions. This could result in patients receiving different advice regarding the duration of ECS.
8. To give information, perform administration, and plan care (GP)	If the dermatologist agrees that the ECS can be fitted, the dermatologist issues a referral for definitive ECS. Subsequently, the patient visits the medical stocking supplier (at the same location). The patient is generally advised to wear ECS for six months to two years. If the GP diagnoses CVI, the GP calls the home care organization to schedule care to apply the adjustable compression devices and makes a referral for definitive ECS. Some GPs schedule a follow-up appointment.	Variation occurs since some GPs are unaware that a referral is necessary for the medical stocking supplier to start function 12.

**Table S3.2** (continued)

Function*	Description of function	Variability
9. To perform intake and arrange the adjustable compression devices (home care nurse)	<p>When the GP contacts the home care organization regarding CVI, a nurse contacts the patient and arranges an intake appointment for that day or the day after. The nurse then measures the leg and determines the size of the adjustable compression devices. All nurses followed an online course to learn how to determine the size of the device and how to apply them. Afterward, the device is ordered by completing a pre-signed application form. This form is then sent to the medical stocking supplier and delivered within 24-48 hours. If in exceptional cases difficulties occur in measuring the leg to determine the size of the adjustable compression device, a nurse specialized in wound care is contacted to support this.</p>	<p>Variation is not mentioned, mostly because of the use of clear protocols, the pre-signed application form, and the support by the nurse specialized in wound care if necessary.</p>
10. To apply the adjustable compression devices (home care nurse)	<p>After the adjustable compression devices have been delivered, the home care nurse visits the patient again to demonstrate how they can be applied, and how an enclosed measuring tape can be used to apply them with the right pressure. With the patient now able to apply the adjustable compression devices self-reliantly, the home care nurse visits once per week to measure leg circumference. If the patient is unable to apply the devices, the home care nurse visits two to four times a week to apply them.</p>	<p>If in exceptional cases, the adjustable compression device is ordered at the weekend it will be delivered the next working day, resulting in a delay of first compression.</p>
11. To contact the medical stocking supplier (patient)	<p>If the leg circumference is stable at two consecutive measuring moments, the home care nurse instructs the patient to contact the medical stocking supplier to plan an intake. Except for DVT patients at hospital location A, who already received an appointment for the intake planned at the moment of diagnosis.</p>	<p>Variation in instructions to contact the medical stocking supplier is not mentioned, mainly since clear agreements have been made and captured in the patient's care plan.</p>
12. To perform intake (medical stocking supplier)	<p>See function 8 FRAM model region Limburg. Additionally, information concerning assistive devices is given.</p>	<p>Variation occurs if the referral from the GP is imprecise or missing. This delays the function. Further variation occurs since time constraints may affect the extensiveness of the information provided regarding assistive devices. This could affect function 13a-14c.</p>

Table S3.2 (continued)

Function*	Description of function	Variability
13. To evaluate by email/phone (medical stocking supplier)	For patients referred from the hospital, the ECS is delivered after two to ten days. Three to four weeks after delivery, a telephonic or automatic email evaluation is made to check whether there are problems. If there are problems, a follow-up appointment is scheduled.	Variability occurs when the patient ignores the email evaluation or did not admit problems, this results in the medical stocking supplier not being completely informed about the performances of the patient.
14. To fit ECS and assess self-reliance (medical stocking supplier)	For patients referred from the GP, a standard follow-up appointment is arranged to fit ECS and assess self-reliance. See function 9 FRAM model region Limburg.	See function 9 FRAM model region Limburg. Instead of affecting function 10a and 10b in the FRAM model region Limburg, this affects function 15a and 15b.
15a. To assess options for self-reliance (occupational therapist)	See function 10a FRAM model region Limburg. In region North-Holland, the occupational therapist uses a designed working guideline in addition to prior experience and needs and possibilities of the patient to select an assistive device.	No variation is mentioned, mainly because of the clear working guidelines implemented in clinical practice.
15b. To re-assess self-reliance (home care nurse)	Patients contact the home care organization when ECS is delivered. The home care nurse re-assesses self-reliance, if the nurse estimates that the patient can be self-reliant with the use of assistive devices, the occupational therapist is contacted.	Variation in output occurs based on the experience of the home care nurse to assess the patient's abilities to be self-reliant.
15c. To apply the ECS	See function 10c FRAM model region Limburg.	See function 10c FRAM model region Limburg.
16. To train the patient (home care nurse)	If the occupational therapist indicates that additional practice is necessary, home care nurses train the patient twice a day on how to use the assistive device self-reliantly for a pre-specified time range. For this reason, the indicated time per consult is extended. If the patient can use the assistive device self-reliantly, the occupational therapist writes a report and sends it to the medical stocking supplier. If the assistive device is not successfully implemented, home care needs to continue for the duration of therapy.	See function 11 FRAM model region Limburg. Additionally, variation decreases by extending the time per consult, giving the nurses enough time to train the patient.

**Table S3.2** (continued)

Function*	Description of function	Variability
17. To deliver assistive devices (medical stocking supplier)	See function 13 FRAM model Region Limburg. Assistive devices are usually delivered within a few days to weeks depending on the selected type and stock supply.	The duration of delivery is subject to variability since it depends on the medical stocking suppliers stock supply. For more advanced assistive devices, the delivery can take up to a few weeks. This enables the patient to be self-reliant directly and extends the duration of home care. Time variation is reduced since GPs and dermatologists already ask to implement assistive devices on their referral for the definitive ECS, making another referral for assistive devices unnecessary.
18a. To perform follow-up (internist)	The internist performs a follow-up appointment between three to six weeks (depending on location) after diagnosis. At this appointment, the internist checks the progress of the process and dermatologists. Some internists omit to advise on the duration of compliance to therapy. Furthermore, some internists advise the patient to stop ECS therapy after six months (if the patient has no leg complaints), whereas others advise a treatment duration of two years. The duration of follow-up differed too; some internists perform only one follow-up visit while others plan a consecutive visit after three months. At the last follow-up visit, the internist writes a patient letter to inform the GP. This patient letter generally does not contain the advice of any consecutive follow-up appointments with the GP or advice regarding the duration of ECS therapy.	The advised duration of therapy is subject to variation since internists are unaware of each other's instructions nor of the therapy since they suppose this is the responsibility of the dermatologist. Others adjust their advice to their most recent knowledge of literature instead of following the protocol. This subsequently could affect the duration of function 15c.
18b. To perform follow-up (dermatologist/GP)	In CVI patients, the dermatologist standardized a follow-up appointment after six weeks. In patients at risk for complications, a consecutive follow-up appointment is planned after six months. When the dermatologist does not expect problems, a letter is sent to the GP and the referral is completed. Some GPs standardize the follow-up visit for CVI patients whereas others rely on the patient's responsibility to alert them if problems exist. Both the dermatologist and GP advise the patient to wear ECS for life.	See function 14c FRAM model region Limburg.

\* The numbers of the functions refer to Figure 3.3. Abbreviations: DVT = deep venous thrombosis, CVI = chronic venous insufficiency, GP = general practitioner, ER = emergency room, FRAM = functional resonance analysis method, ECS = elastic compression stocking g,



# Chapter 4

A realist evaluation to identify targets to improve the organization of compression therapy for deep venous thrombosis- and chronic venous disease patients

Schreurs RHP, Joore MA, De Brujin-Geraets DP, Ten Cate H, Ten Cate-Hoek AJ

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## Summary

### Background

Although compression therapy is well established for patients with deep venous thrombosis (DVT) and chronic venous disease (CVD), considerable variation exists in its organization in clinical practice which may impact patient outcomes. The current study aims to deepen our understanding of the main drivers of the complex care organization for compression therapy and to identify targets for improvement.

### Methods

This realist evaluation includes a mixed-method design consisting of semi-structured interviews with patients and health care professionals involved in compression therapy (n=30), stakeholder meetings (n=2) and surveys (n=114). Data were collected to create the content of context-mechanism-outcome-configurations (CMOcs) important in compression therapy. Based on these CMOcs, targets for improvement to optimize the organization of compression care were identified.

### Results

We identified overarching context factors and mechanisms targeting four optimal outcomes for the organization of compression therapy: selecting initial compression therapy types that support patient's self-reliance (1), evidence based selection of elastic compression stocking type and class (2), patient-based selection of assistive devices (3), individualizing treatment duration for DVT patients (4a) and providing follow-up for CVD patients (4b). We found that increasing health care professionals' knowledge of compression therapy, the availability of unambiguous protocols and guidelines, increasing patient involvement (and if applicable their informal care giver) in the decision making process, the accessible availability of resources, and increasing interdisciplinary consultation enhanced desirable outcomes. These targets triggered mechanisms such as increased health care professionals' willingness, confidence and motivation to provide patient-based care and increased patients' self-confidence and self-efficacy.

### Conclusions

This study provides a detailed insight into what needs to be in place to optimize compression care and identified five main targets for improvement.

## Introduction

Compression therapy is an effective therapy used to treat acute symptomatology and prevent complications such as post-thrombotic syndrome for deep venous thrombosis (DVT)<sup>1-3</sup> and ulcer development for chronic venous disease (CVD).<sup>4,5</sup> Both diseases are frequently encountered worldwide; 1-2 per 1000 persons annually develop a DVT<sup>6</sup> and the prevalence of CVD in the population ranges from 13.7% to 19.7%.<sup>7-9</sup>

The organization of compression therapy is complex and involves collaboration between the patient and various healthcare professionals. There is considerable variation in how compression therapy is organized for both DVT and CVD patients.<sup>10</sup> In this study, this variability was found to affect patient's chances to remain self-reliant, the advised treatment duration for DVT patients, and was expected to affect compliance with compression therapy. Compliance with compression therapy is a major determinant of effectiveness.<sup>3,11</sup> Not being able to independently apply or remove the elastic compression stockings (ECS) was found to be an important reason for non-compliance.<sup>12</sup> On the other hand, it was found that in some regions a subset of all patients is treated longer than necessary without added benefits.<sup>2,10</sup> Decreasing variability in the organization of compression therapy is necessary to improve therapy and is likely to result in an increase in desirable outcomes.

With this study we used a realist evaluation to deepen our understanding of the main drivers in the complex organization of compression therapy for patients with DVT and CVD and identify targets for improvement. Realist evaluation acknowledges and identifies the complexity of a system by identifying how outcomes are achieved.<sup>13,14</sup> It is shown that a realist evaluation is a well suited approach to investigate complex causal pathways, and can advance understanding of the best circumstances for increasing improvement strategies' impact.<sup>15,16</sup>

## Methods

### General study design

We performed a realist evaluation using a mixed-methods design. In this evaluation, we explore how different patterns result in specific outcomes by asking the explanatory question: what works (or does not work), for whom, and under which circumstances. This was achieved by the identification of causal explanations in the complex dynamics among context and mechanisms that interact and contribute to context-mechanism-outcome configurations (CMOcs).<sup>13,16-19</sup> We used the definitions for context, mechanism, and outcome as introduced by Pawson and Tilley.<sup>14</sup> Context includes all individual capacities of the patients and professionals, their interpersonal relationships,

institutional settings, and infrastructural or welfare systems affecting daily practice. Mechanisms generate outcomes and include causal forces as well as choices, reasoning, and decisions made in response to the context and resources provided. Outcomes are the effects produced by causal mechanisms triggered in a specific context. We reported this evaluation using the RAMESES publication standards.<sup>20</sup>

We only included CVD patients that were conservatively treated and excluded CVD patients with an active venous ulcer since these patients have different care- and treatment needs compared to the patients selected for the current study. Our study was assessed by the Ethics Board of Maastricht University Medical Center (MUMC), Maastricht (2019-1125), and was considered not to be subject to the Medical Research involving Human Subjects Act (WMO).

### Data collection: interviews, stakeholder meetings, and surveys

The study context, selection of interviewees and stakeholders were described in the FRAM (Functional Resonance Analysis Method) study we previously conducted.<sup>10</sup> We performed the study in two regions in the Netherlands: Limburg and North-Holland. We purposively selected these regions based on their geographical spread and the differences in hospital setting (an academic hospital in Limburg and a general hospital with two locations in North-Holland). Furthermore, several interventions to improve self-reliance had already been implemented in North-Holland, while a tailored ECS treatment duration was implemented by internists in Limburg. This allowed us to evaluate factors contributing to the differences in implementation of these specific interventions in the two regions.

RS conducted thirty semi-structured interviews (n=15 for each region) with purposively recruited experienced professionals (n=25) and patients (n=5) from the two selected regions. Professionals were recruited beginning with a senior policy adviser from a home care organization in Limburg, and a senior project manager from a home care organization in North-Holland. Consecutive interviewees recruited other experienced professionals and patients until during three consecutive interviews no new context factors or mechanisms emerged indicating that data was saturated.<sup>21</sup> Patients were selected by health care professionals and included self-reliant patients and patients who required home care assistance for both DVT and CVD. Interviews with professionals were conducted by telephone whereas patients were interviewed either by telephone or at the patient's home. All interviewees were informed regarding the goal of the interview and consented verbally to participate. We audio-recorded and transcribed the interviews verbatim.

A predesigned interview template was used to guide the interviews as presented in Appendix 4.1. In brief, interviewees were asked to define important process outcomes that enhance treatment effect and patients' self-reliance. To better understand how

context and generative mechanisms affected these outcomes, interviewees were asked how they explained these outcomes, and what factors affected their actions in different contexts. Following the interviews, we selected key stakeholders among the interviewees (one per discipline) based on clinical experience. Two stakeholder meetings were organized (n=8 participants for Limburg and n=9 for North-Holland) to refine and validate the CMOcs as identified in the interviews and discuss potential new insights.

To quantify the main process outcomes, we used Qualtrics (Qualtrics, Provo, UT, version September 2020) to administer online surveys among a larger sample of professionals. For these surveys, we purposively sampled the professional groups based on the extent and influence of their activities within the entire process, and the degree of variability in the performance of the activity described. These professionals included occupational therapists, medical stocking suppliers, home care nurses, and general practitioners (GPs). Although internists and dermatologists also contributed significantly to the process, we decided to not include them in the survey, since only a small proportion of internists and dermatologists perform DVT- or CVD care in the selected hospitals (these professionals were included in the semi-structured interviews and stakeholder meetings).

In total 14 practices for occupational therapy, 9 medical stocking companies, the main home care organization of each region, and 33 GP-practices were invited to participate in the online surveys. As there is no registration or centrally held record of professionals working in compression care, clinical practices were found by searching Google Maps and subsequently contacted by email or telephone. They were asked whether they were willing to participate, to give an indication of the number of professionals providing compression care in their organization, and to distribute the survey among these professionals. Two reminders were sent after the initial invitation.

The first author (RS) developed the questions and response options in the survey in discussion with co-authors (ATC, MJ) and aimed to quantify the process outcomes. The surveys consisted of 8-19 questions depending on the professional group (as presented in Appendix 4.2). Pilot testing was undertaken by sending the survey to one stakeholder per professional group, feedback was incorporated in the final survey designs.

### Data-analysis

The semi-structured interviews, the stakeholder meetings, and the responses to the open-ended survey questions were coded and categorized as context (C), mechanism (M), or outcome (O) using a codebook based on the definitions as described by Pawson and Tilley.<sup>14</sup> Outcomes were selected if stakeholders considered them to be important for further exploration to optimize the organization of care and if they were expected to improve treatment effect and/or patient's self-reliance.

RS summarized and coded all interviews, stakeholder meetings, and open-ended survey questions after which the results were repeatedly discussed with MJ, ATC, and DDB. If information was missing or not clear, stakeholders were contacted to provide further information. Common links and consistent patterns between context, mechanisms, and outcomes across the data were identified to generate the CMOcs. All CMOcs targeted one of the four phases of compression therapy being: initial compression therapy (in which the patient uses either multilayer compression bandages, temporary compression hosiery or adjustable compression bandages until edema has receded), onset of ECS therapy (in which the ECS is fitted and delivered), implementation of assistive devices (in which the patient is trained how to use assistive devices upon indication), and long-term maintenance of ECS therapy (in which follow-up takes place and ECS duration is determined).<sup>10</sup>

When patient volumes showed large variation within a region, local stakeholders were asked to indicate whether patient volumes were representative in their opinion and how these results could be explained.

To identify what works or does not work, for whom, and under which circumstances, we identified overarching contextual factors and mechanisms that occurred multiple times in our CMOcs and resulted in desirable outcomes. Next, we identified the CMOcs that covered the same subject and resulted in undesirable outcomes. We considered the context factors and mechanisms that differed between those CMOcs and the context factors and mechanisms resulting in desirable outcomes as targets for improvement. Moreover, we examined all other CMOcs to check whether additional targets could be identified.

We used descriptive statistics to analyze the quantitative survey results for rating scale questions in Microsoft Excel 2010.

## Results

In addition to the 30 semi-structured interviews and two stakeholder meetings (with a total of 17 participants), 114 surveys were received (overall response rate 74%). An overview of the interviewees per discipline and response rates to the survey are further specified in Appendix 4.3.

Seven CMOcs emerged from our data. A detailed description of these CMOcs can be found in Appendix 4.4. CMOcs were described in the context of the four phases of compression therapy: three CMOcs concerned process outcomes regarding initial compression therapy (treatment setting, start of initial compression therapy, and type of initial compression), one the onset of ECS therapy with selection of ECS class and type, one the implementation of assistive devices with selection and training of assistive

devices, one the long-term maintenance of ECS therapy with individualized treatment duration for DVT patients and another one the provision of follow-up for CVD patients. Quantitative results regarding these main outcomes can be found in Table 4.1, 4.2 and Appendix 4.4.

**Table 4.1** Means, ranges, and resources clinical pathways deep venous thrombosis.

	Limburg mean (%)	Range (%)	Source	North-Holland A mean (%)	Range (%)	North-Holland B mean (%)	Range (%)	Source
<b>Initial compression therapy</b>								
GP	17	0-75	S <sub>GP, L</sub>	0	-	0	-	S <sub>GP, NH</sub>
No initial compression	20	0-50	S <sub>GP, L</sub>	-	-	-	-	-
MCB GP	40	-	S <sub>GP, L</sub>	-	-	-	-	-
MCB home care	40	-	S <sub>GP, L</sub>	-	-	-	-	-
Internist	83	-	S <sub>GP, L</sub>	100	-	100	-	S <sub>GP, NH</sub>
MCB home care	10	5-15	1,2 L	10	-	-	-	1,2 NH
TCH home care	4	-	1,2 L	4	-	-	-	1,2 NH
TCH self-reliant	86	-	1,2 L	86	-	-	-	1,2 NH
No initial compression	0	-	1,2 L	0	-	100	-	1,2 NH
	Limburg mean (%)	Range (%)	Source	North-Holland mean (%)		Range (%)		Source
<b>Onset of ECS therapy</b>								
Custom-made ECS	61	-	-	67	-	-	-	-
Ready-made ECS	39	7-95	S <sub>MSS, L</sub>	33	10-50	S <sub>MSS,NH</sub>		
Class 2 ECS	30	0-90	S <sub>MSS, L</sub>	65	20-90	S <sub>MSS,NH</sub>		
Class 3 ECS	68	0-100	S <sub>MSS, L</sub>	35	10-79	S <sub>MSS,NH</sub>		
Other	2	0-10	S <sub>MSS, L</sub>	0	0-1	S <sub>MSS,NH</sub>		
<b>Implementation of assistive devices</b>								
Self-reliant without AD	23	0-60	S <sub>MSS, L</sub>	50	0-80	S <sub>MSS,NH</sub>		
Self-reliant with AD without training	56	-	-	35	-	-	-	-
Uncomplicated AD	53	15-80	S <sub>MSS, L</sub>	34	10-90	S <sub>MSS,NH</sub>		
Complicated AD	3	0-10	S <sub>MSS, L</sub>	1	0-3	S <sub>MSS,NH</sub>		
<b>Training by occupational therapist</b>								
Via medical stocking supplier	15	0-25	S <sub>MSS, L</sub>	7	0-20	S <sub>MSS,NH</sub>		
Additional training by home care	50	20-90	S <sub>OCCL</sub>	43	0-71	S <sub>OCCL</sub>		
Self-reliant with AD after training	68	10-90	S <sub>OCCL</sub>	66	36-95	S <sub>OCCL</sub>		
To long term home care after training	32	-	-	34	-	-	-	-
<b>Home care</b>								
Directly to long term home care	6	0-20	S <sub>MSS, L</sub>	8	1-20	S <sub>MSS,NH</sub>		
Training by occupational therapist	53	-	-	42	-	S <sub>HN,NH</sub>		
Training by home care	-	-	-	58	0-100	S <sub>HN,NH</sub>		
Self-reliant with AD after training	47	15-95	S <sub>HN,L</sub>	-	-	-	-	-
To long term home care after training	43	15-75	S <sub>HN,L</sub>	-	-	-	-	-
				-	-	-	-	-

**Table 4.1** (continued)

	Limburg mean (%)	Range (%)	Source	North-Holland mean (%)	Range (%)	Source
<b>Follow-up</b>						
FU GP	17	0-75	S <sub>GP,L</sub>	-	-	-
Standardized treatment duration	100	-	<sup>3</sup> L	-	-	-
Individualized treatment duration	0	-	<sup>3</sup> L	-	-	-
FU Internist	83	-	-	100	-	<sup>1,2</sup> NH
Standardized treatment duration	0	-	<sup>1,2</sup> L	0	-	<sup>1,2</sup> NH
Individualized treatment duration	100	-	<sup>1,2</sup> L	0	-	<sup>1,2</sup> NH

<sup>1</sup>: interview internist, <sup>2</sup>: interview ER-nurse, <sup>3</sup>: interview GPs. Abbreviations: L: Limburg, NH: North-Holland, GP: general practitioner, MCB: multilayer compression bandages, TCH: temporary compression hosiery, ECS: elastic compression stockings, AD: assistive device, S<sub>GP,L</sub>: survey GPs Limburg, S<sub>GP,NH</sub>: survey GPs North-Holland, S<sub>MSS,L</sub>: survey medical stocking suppliers Limburg, S<sub>MSS,NH</sub>: survey medical stocking suppliers North-Holland, S<sub>OCC,L</sub>: survey occupational therapists Limburg, S<sub>OCC,NH</sub>: survey occupational therapists North-Holland, S<sub>HN,L</sub>: survey home care nurses Limburg, S<sub>HN,NH</sub>: survey home care nurses North-Holland.

**Table 4.2** Means, ranges, and resources clinical pathways chronic venous disease.

	Limburg mean (%)	Range %	Source	North- Holland mean (%)	Range (%)	Source
<b>Initial compression therapy</b>						
GP	70	-	S <sub>GP,L</sub>	77	-	S <sub>GP,NH</sub>
No initial compression	10	0-50	S <sub>GP,L</sub>	8	0-50	S <sub>GP,NH</sub>
MCB GP	50	-	S <sub>GP,L</sub>	-	-	-
MCB home care	41	-	S <sub>GP,L</sub>	-	-	-
ACD self-reliant	-	-	-	44	5-80	S <sub>HN,NH</sub>
ACD not self-reliant	-	-	-	48	-	-
Dermatologist	30	5-75	-	23	0-100	-
Patients treated conservatively with ECS therapy	100	-	Assumption, no data available	100	-	Assumption, no data available
MCB by home care	50	-	<sup>1,2</sup> L	100	-	<sup>1,2</sup> NH
MCB at outpatient clinic	50	-	<sup>1,2</sup> L	0	-	<sup>1,2</sup> NH
No initial compression	0	-	<sup>1,2</sup> L	0	-	<sup>1,2</sup> NH
<b>Onset of ECS therapy</b>						
Custom-made ECS	24	-	-	25	-	-
Ready-made ECS	76	70-85	S <sub>MSS,L</sub>	75	61-95	S <sub>MSS,NH</sub>
Class 2 ECS	77	20-95	S <sub>MSS,L</sub>	87	80-99	S <sub>MSS,NH</sub>
Class 3 ECS	23	5-80	S <sub>MSS,L</sub>	13	1-20	S <sub>MSS,NH</sub>
Others	0	0-1	S <sub>MSS,L</sub>	0	0-1	S <sub>MSS,NH</sub>
<b>Implementation of assistive devices</b>						
Self-reliant without AD	25	0-50	S <sub>MSS,L</sub>	33	0-65	S <sub>MSS,NH</sub>
Self-reliant with AD without training	45	-	-	53	-	-
With uncomplicated AD	38	20-80	S <sub>MSS,L</sub>	50	25-90	S <sub>MSS,NH</sub>
With complicated AD	7	0-20	S <sub>MSS,L</sub>	3	0-5	S <sub>MSS,NH</sub>

**Table 4.2** (continued)

	Limburg mean (%)	Range %	Source	North- Holland mean (%)	Range (%)	Source
<b>Implementation of assistive devices</b>						
Self-reliant without AD	25	0-50	S <sub>MSS,L</sub>	33	0-65	S <sub>MSS,NH</sub>
Self-reliant with AD without training	45	-	-	53	-	-
With uncomplicated AD	38	20-80	S <sub>MSS,L</sub>	50	25-90	S <sub>MSS,NH</sub>
With complicated AD	7	0-20	S <sub>MSS,L</sub>	3	0-5	S <sub>MSS,NH</sub>
Training by occupational therapist						
Via medical stocking supplier	16	5-30	S <sub>MSS,L</sub>	7	0-20	S <sub>MSS,NH</sub>
Additional training by home care	50	10-90	S <sub>OCC,L</sub>	43	10-71	S <sub>OCC,L</sub>
Self-reliant with AD after training	68	10-90	S <sub>OCC,L</sub>	66	25-90	S <sub>OCC,L</sub>
To long term home care after training	32	-	S <sub>OCC,L</sub>	34	-	S <sub>OCC,L</sub>
Home care	14	0-35	S <sub>MSS,L</sub>	7	1-20	S <sub>MSS,NH</sub>
Directly to long term home care	53	-	-	42	-	S <sub>HN,NH</sub>
Training by occupational therapist	-	-	-	58	0-100	S <sub>HN,NH</sub>
Training home care	47	15-95	S <sub>HN,L</sub>	-	-	-
Self-reliant with AD after training	43	15-75	S <sub>HN,L</sub>	-	-	-
To long term home care after training	57	-	-	-	-	-
<b>Long-term maintenance of ECS therapy</b>						
FU by GP	70	-	S <sub>GP,L</sub>	77	-	S <sub>GP,NH</sub>
FU by default	40	-	S <sub>GP,L</sub>	20	-	S <sub>GP,NH</sub>
FU if problems exists	60	-	S <sub>GP,L</sub>	80	-	S <sub>GP,NH</sub>
Dermatologist	30	5-75	S <sub>GP,L</sub>	23	0-100	S <sub>GP,NH</sub>
FU by default	100	-	<sup>1</sup>	100	-	<sup>1</sup>
FU if problems exists	0	-	1	0	-	1

<sup>1</sup> interview dermatologist, <sup>2</sup> interview nurse dermatology department. Abbreviations: L: Limburg, NH: North-Holland, GP: general practitioner, MCB: multilayer compression bandages, ACD: adjustable compression therapy, ECS: elastic compression stockings, AD: assistive device, S<sub>GP,L</sub>: survey GPs Limburg, S<sub>GP,NH</sub>: survey GPs North-Holland, S<sub>MSS,L</sub>: survey medical stocking suppliers Limburg, S<sub>MSS,NH</sub>: survey medical stocking suppliers North-Holland, S<sub>OCC,L</sub>: survey occupational therapists Limburg, S<sub>OCC,NH</sub>: survey occupational therapists North-Holland, S<sub>HN,L</sub>: survey home care nurses Limburg, S<sub>HN,NH</sub>: survey home care nurses North-Holland.

## Initial compression therapy

### *CMoC 1: Treatment setting*

GPs generally have lower knowledge levels, exposure to compression therapy, and availability of diagnostic equipment compared to hospital specialists. These

shortcomings are more relevant for DVT than for CVD. This influenced the willingness and commitment to treat DVT patients in primary care. As a result, most GPs referred DVT patients to secondary care whereas they treated most CVD patients in primary care. Moreover, in some elderly CVD patients, referral is not desired which triggered a reticent attitude to refer patients to secondary care.

#### *CMOc 2: Start of initial compression therapy*

Physicians' knowledge levels and the extent to which they understood and valued the purposes of initial compression therapy influenced the willingness and commitment to prescribe it. Subsequently, variations exist in whether initial compression therapy was prescribed or omitted. In case physicians had insufficient knowledge, they relied on the local protocol or national guideline. If these provided unambiguous recommendations supporting the use of initial compression therapy, physicians' commitment to implement these recommendations increased. Subsequently, the number of initial compression therapy prescriptions also increased.

Internists, GPs and dermatologists indicated that the extent to which patients were informed and had knowledge of the purposes of initial compression therapy influenced patients' motivation to accept and use initial compression therapy. Additionally, it increased patients' self-confidence and self-efficacy which supported the treating physicians' prescribing behavior. Some CVD patients had a negative attitude or perception towards compression therapy since they anticipate difficulties in applying the materials. This attitude triggered patients' demotivation to accept and use compression therapy in general and physicians' demotivation to prescribe it. Finally, the availability of trained staff to fit and demonstrate the use of initial compression therapy decreased stress levels and time constraints and improved the treating physicians' motivation to prescribe it. Although treating physicians persistently perceived it to be difficult and time-consuming to manage initial compression therapy.

#### *CMOc 3: Type of initial compression*

Dermatologists (for CVD) and a minority of internists (for DVT) had sufficient knowledge regarding initial compression therapy types and their effects on maintaining self-reliance. This drove the willingness and commitment to prescribe the most suitable initial compression therapy. As a result, the number of self-reliant patients increased. Most internists and GPs lacked this knowledge treating DVT patients. Therefore, they relied on- and committed to the local protocol or national guideline. These protocols and guidelines provided diverse recommendations and guidance regarding the preferred initial compression therapy. This ambiguity in recommendations resulted in a diversity of treatment processes influencing the patient's opportunity to maintain self-reliance. Some GPs in region North-Holland were more focused on patient-based treatments for CVD patients since they experienced benefits for patients. In this case, the use of

adjustable compression devices was supported by local arrangements. In these arrangements it was agreed that management and reimbursement were covered by the home care organization. As a result, GPs were motivated and self-confident to prescribe adjustable compression devices which allowed approximately half of the patients to maintain self-reliance.

With increased availability of trained staff physicians' motivation to make use of the staff's capabilities to instruct and demonstrate how to apply the initial compression therapy increased. As a result, patients were better informed and their self-efficacy increased leading to a higher likelihood for patients to remain self-reliant. Additionally, patients' knowledge, aims, and desires regarding initial compression therapy were identified as conditional to achieve optimal patient involvement in the decision-making process. As a result, patients' likelihood to receive the most appropriate initial compression therapy increased with enhanced possibilities for self-reliance.

## Onset of ECS therapy

### *CMOc 4: Selection of ECS class and type*

Depending on the physician's knowledge levels in determining the treatment indication and ECS characteristics (class and type) the willingness, confidence, and commitment to include the ECS characteristics in the referral to the medical stocking supplier varied. If physicians had insufficient knowledge they committed to the local protocol or the national guideline (which in some cases were not up to date) or omitted including the ECS characteristics in the referral. This increased the number of ECS referrals that were not evidence-based or incomplete.

If referrals were complete, the medical stocking supplier generally delivered the ECS as indicated by the treating physician based on confidence and commitment to approach and instructions. In case referrals were incomplete, medical stocking suppliers decided to select the ECS characteristics themselves. Medical stocking suppliers are bound to financial constraints as they receive a fixed cluster fee per patient which is perceived to be insufficient. In some cases these constraints triggered a reticent attitude toward the implementation of more expensive ECS classes and types resulting in a decrease in evidence-based prescriptions.

The availability of accessible interdisciplinary communication and understanding of responsibilities as well as mutual expectations affected the willingness and motivation to improve interdisciplinary processes. Consequently, information transfers enhanced and the delivery of evidence-based ECS prescriptions increased.

## Implementation of assistive devices

### *CMOc 5: Selection and training of assistive devices*

The extent to which patients desired to be self-reliant to apply the ECS in combination with the physical and cognitive abilities they possess influenced the patient's motivation to use an assistive device, their involvement in the decision-making process, and their willingness to use their abilities. As a result, the likelihood of patients maintaining their self-reliance varied. The presence of an informal caregiver for patients lacking these abilities provided the opportunity to involve the caregiver in the selection and training process to support the patient. In turn, the number of patients requiring additional training or long-term home care decreased.

Furthermore, the extent to which medical stocking suppliers experienced time and financial constraints varied. As an effect, their motivation and willingness to invest time in the selection and training of patients to use an assistive device varied. If training duration was based on the patient's needs, their possibility to maintain self-reliance increased. If medical stocking suppliers experienced financial constraints, a reticent attitude to invest time and costs was triggered. As a result, the number of patients referred for additional training or long-term home care increased.

If patients were referred for additional training, differences in levels of training- and knowledge regarding assistive devices existed between occupational therapists and home care nurses. Occupational therapists generally applied patient-based methods to select an assistive device and training frequency and duration were based on the patient's needs. Most home care nurses selected an assistive device based on personal experience and training duration depending on the available time left during the visit. If a patient-based method was implemented, the patient's likelihood to maintain self-reliance with the use of an assistive device increased. Moreover, medical stocking suppliers and occupational therapists had well-established interdisciplinary communication whereas communication between medical stocking suppliers and home care nurses was spare or absent. This affected the ability, willingness, and motivation to collaborate and improve interdisciplinary processes and the extent to which patient information was transferred. In return, it affected the patient's opportunities to maintain self-reliance.

Finally, home care nurses perceived it to be more difficult to encourage patients to be self-reliant if they were already used to home care because patients were anxious to lose these services. This led to a lack of motivation in patients and decreased the patient's likelihood to be self-reliant with an assistive device.

## Long-term maintenance of ECS therapy

### *CMOc 6: Individualized duration of ECS therapy for DVT patients*

Internists'- and GPs' knowledge levels of individually tailored treatment duration and how to assess eligibility for shortened treatment duration influenced the extent to which physicians could commit to an individualized approach. This resulted in two outcomes: some physicians advised a standardized treatment duration of two years whereas others advised an individualized treatment duration.

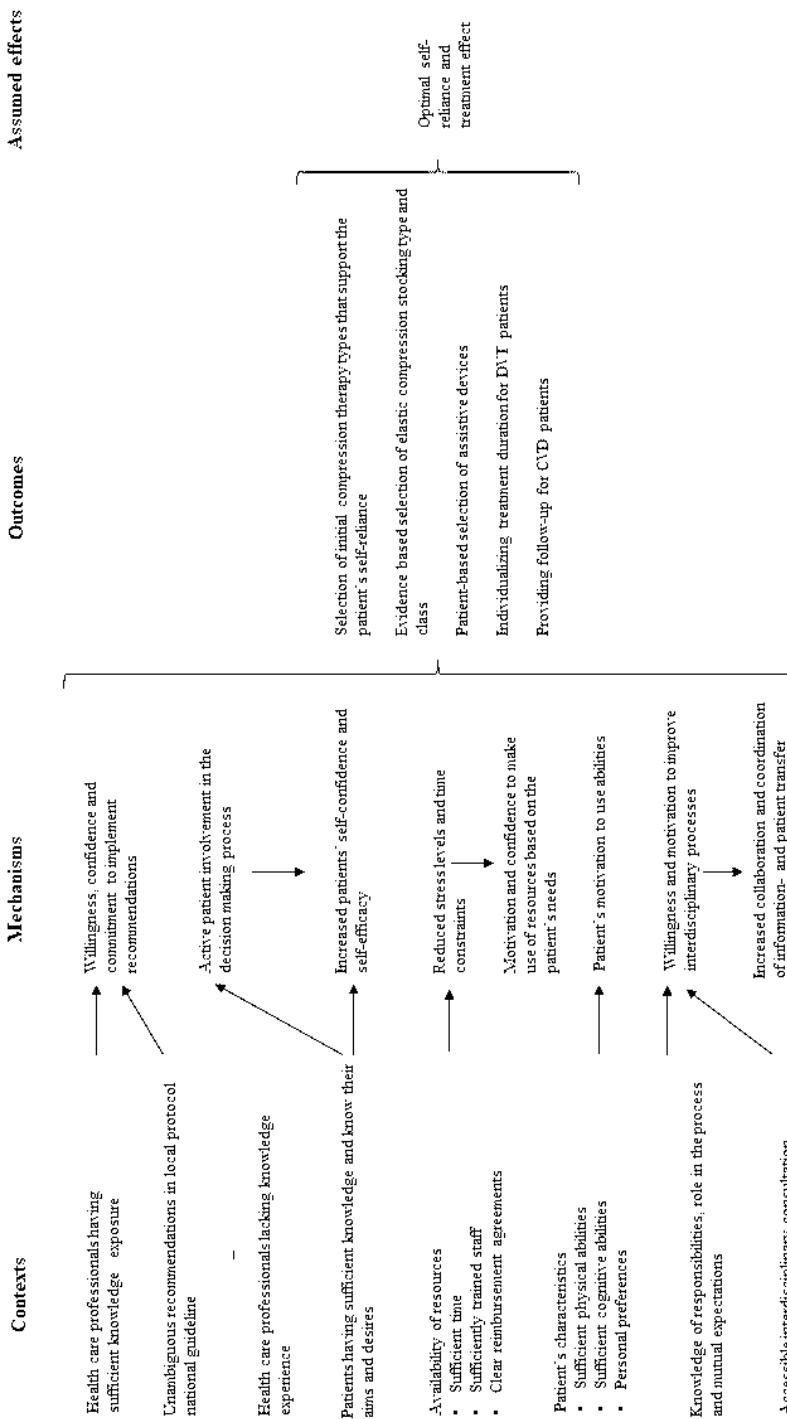
In case physicians lacked knowledge they relied on the local protocol or national guideline which showed ambiguity in their recommendations. This led to different treatment advice. Furthermore, depending on whether the GPs and internists felt responsible for follow-up, their motivation and willingness to invest time and effort in shaping this follow-up varied. Consequently, some physicians had a reticent attitude to implement individualized follow-up. Finally, individualized treatment duration cannot work without interdisciplinary cooperation and communication between all involved health professionals and patients. Currently, some patients received automated annual calls from the medical stocking supplier although their treatment was already terminated. In some cases this resulted in patients resuming ECS therapy without interference from the treating physician.

### *CMOc 7: Performing follow-up for CVD patients*

The degree to which physicians value the need for follow-up and the disease severity determined physicians' motivation and willingness to invest time in follow-up appointments. GPs often do not value this need when other health care professionals (i.e., edema therapists, home care nurses, or medical stocking suppliers) are involved in monitoring the process and contacting the GP when applicable. This induced a lack of involvement to perform follow-up. However, home care nurses and medical stocking suppliers experience these follow-up appointments as essential since they often encounter difficulties with patients who have additional questions or lack adherence to therapy that they cannot resolve.

## Overview of overarching CMOcs

In our CMOcs, we identified several overarching contextual factors and mechanisms resulting in desirable outcome as presented in Figure 4.1. Based on these overarching CMOcs, we ultimately identified five targets for improvement strategies: 1. Increase all health care professionals' knowledge of compression therapy, 2. Provide unambiguous recommendations in guidelines and protocols, 3. Involve patients (and if applicable the informal caregivers) in the decision-making process, 4. Provide access to resources (time, trained staff, and clear reimbursement agreements), and 5. Promote interdisciplinary consultation.



**Figure 4.1** Graphical overview of the overarching CMOs resulting in desirable outcomes. Abbreviations: ECS: elastic compression therapy, DVT: deep venous thrombosis, CVD: chronic venous disease.

## Discussion

This study used a realist evaluation to understand what works and does not work, for whom, and under which circumstances in the organization of compression therapy for DVT and CVD patients. Our results indicate a lack of knowledge among treating physicians regarding compression therapy in general, leading to incomplete referrals to medical stocking suppliers. For example, the level of class 3 ECS prescriptions for DVT patients was below what was to be expected from evidence.<sup>1,2,11,22</sup> Increasing knowledge most likely will result in more complete referrals. Consequently, as most medical stocking suppliers commit to the treating physicians referrals, financial incentives currently influencing the medical stocking supplier's choice for ECS-type will likely become less relevant. To further minimize the role of financial incentives, we suggest that the financial reward system for medical stocking suppliers needs to be reformed. Furthermore, the lack of knowledge among health care professionals not only resulted in suboptimal selection of compression therapy but also in suboptimal provision of assistive devices to promote patients' self-reliance.

Knowledge improvement will also likely increase the use of an individualized risk-based treatment duration and thus prevent unnecessary long treatment duration without benefits for the patients.<sup>2</sup> The prerequisite for successful implementation of individualized ECS treatment duration needs broad consensus on who is responsible for this type of management and follow-up. Additionally, it is important to communicate treatment duration between treating physicians, the medical stocking supplier, and the homecare organization.

However, health care professionals acknowledged that this specific knowledge rapidly declines since most stakeholders were working in broad disciplines covering a large variety of diseases. Therefore, detailed protocols and guidelines are mandatory to provide sustainable practical support to guide these decisions. It is shown that protocols and guidelines are especially useful if they pay attention to contexts.<sup>16</sup> In case of insufficient knowledge, our CMOcs showed that professionals used local protocols or the national guideline (GPs) by default. Currently there is ambiguity amongst protocols and because of different recommendations a variety of outcomes has been observed. Especially for the recommended initial compression therapy types and the level to which self-reliance is considered to inform the treatment decision. Making protocols unambiguous prioritizing temporary compression hosiery for DVT<sup>2,23</sup> and adjustable compression devices for CVD<sup>24,25</sup> will likely increase the number of self-reliant patients at this stage.

Furthermore, the role of the patient and (if present) the informal caregiver in the various stages of the decision-making process needs to be enhanced. This may be achieved by improved information transfer, shared decision making, and providing motivation and

support to better define patients' aims and desires. The involvement of patients in the decision-making process is of major importance since higher levels of involvement are positively correlated with clinical outcomes like adherence to therapy and coordination of care.<sup>26-28</sup> Furthermore, it is important to consider patients' characteristics (physical and cognitive abilities and personal preferences) in shared decision making.

The availability of sufficient resources is also important role for optimizing outcomes as it facilitates a patient-based approach to select compression materials and assistive devices. For this, clear reimbursement agreements, sufficient time and trained staff, and a sufficient reward system is necessary. These resources facilitated a patient-based approach to select compression materials and assistive devices. Finally, for all improvement opportunities, it is pivotal to create clarity among involved professionals concerning their specific role in the process and to improve knowledge of mutual expectations and responsibilities. This is supposed to increase the motivation to improve interdisciplinary processes resulting in overall optimization of outcomes.<sup>29-33</sup>

Although this study did not primarily focus on patient's adherence, which is one of the most important determinants for effectiveness of compression therapy, we expect that the proposed process improvement will be associated with increased patients' adherence. However, further research on long-term adherence and health care outcomes after implementation of the improvements is necessary. Multidimensional interventions to improve adherence were found to show promising results<sup>34</sup>, although further investigation with high-quality trials is warranted.

Some weaknesses of our study have to be considered. Although we identified a large variety of CMOcs based on interview data and stakeholder meetings, direct observations of the care delivered were not possible due to the COVID-19 pandemic. It is therefore possible that some contextual factors and mechanisms were missed since health care professionals were not aware of these factors and did not mention them. Furthermore, although we diligently approached stakeholder groups and received adequate response rates, response rates for occupational therapists and home care nurses in Limburg were lower. This might have biased our results. The main strength of this study is that it provides not only a detailed insight into how ECS therapy is organized, but also on how outcomes are influenced by contexts and mechanisms, resulting in the identification of targets for improvement. As previously observed in implementation science, many studies lack this attention to theory development preceding the implementation of complex interventions which is thought to limit implementation.<sup>35-37</sup> Finally, although the CMOcs are designed to be specific to DVT- and CVD patients, the configurations and targets for improvement are likely to be transferable to other patient groups using compression therapy such as patients with lymphedema. The degree to which the CMOcs are transferable to other countries depends on how compression therapy is organized locally. However, the approach we used to identify targets for improvement is

A realist evaluation to identify targets to improve the organization of compression therapy for DVT- and CVD patients

generalizable and could be used to evaluate and improve compression therapy in other counties as well.

## Conclusion

This realist evaluation gives a detailed insight into what works (and does not work), for whom, and under which circumstances for both patients and health care professionals in compression care. We identified five targets for improvement of compression care: increase health care professionals' knowledge of compression therapy, increase the availability of unambiguous protocols and guidelines, increase the involvement of patients in the decision making process, increase the accessibility of resources, and increase interdisciplinary consultation.

## References

1. Mol GC, van de Ree MA, Klok FA, Tegelberg MJ, Sanders FB, Koppen S, et al. One versus two years of elastic compression stockings for prevention of post-thrombotic syndrome (OCTAVIA study): randomised controlled trial. *BMJ*. 2016;353:i2691.
2. Ten Cate-Hoek AJ, Amin EE, Bouman AC, Meijer K, Tick LW, Middeldorp S, et al. Individualised versus standard duration of elastic compression therapy for prevention of post-thrombotic syndrome (IDEAL DVT): a multicentre, randomised, single-blind, allocation-concealed, non-inferiority trial. *Lancet Haematol*. 2018;5(1):e25-33.
3. Kahn SR, Shapiro S, Wells PS, Rodger MA, Kovacs MJ, Anderson DR, et al. Compression stockings to prevent post-thrombotic syndrome: a randomised placebo-controlled trial. *Lancet*. 2014;383(9920): 880-8.
4. Vandongen YK, Stacey M. Graduated Compression Elastic Stockings Reduce Lipodermatosclerosis and Ulcer Recurrence. *Phlebology*. 2000 08/01;15:33-7.
5. Franks PJ, Oldroyd MI, Dickson D, Sharp EJ, Moffatt CJ. Risk factors for leg ulcer recurrence: a randomized trial of two types of compression stocking. *Age Ageing*. 1995;24(6):490-4.
6. Naess IA, Christiansen SC, Romundstad P, Cannegieter SC, Rosendaal FR, Hammerstrøm J. Incidence and mortality of venous thrombosis: a population-based study. *Journal of thrombosis and haemostasis : JTH*. 2007 Apr;5(4):692-9.
7. Serra R, Grande R, Butrico L, Fugetto F, Stefano d. Epidemiology, diagnosis and treatment of chronic venous disease: A systematic review. *Chirurgia*. 2015 07/15;29.
8. Langer RD, Ho E, Denenberg JO, Fronek A, Allison M, Criqui MH. Relationships between symptoms and venous disease: the San Diego population study. *Archives of internal medicine*. 2005 Jun 27;165(12):1420-4.
9. Rabe E, Guex JJ, Puskas A, Scuderi A, Fernandez Quesada F. Epidemiology of chronic venous disorders in geographically diverse populations: results from the Vein Consult Program. *Int Angiol*. 2012;31(2): 105-15.
10. Schreurs RHP, Joore MA, Ten Cate H, Ten Cate-Hoek AJ. Using the Functional Resonance Analysis Method to explore how elastic compression therapy is organised and could be improved from a multistakeholder perspective. *BMJ Open*. 2021;11(10):e048331.
11. Prandoni P, Lensing AW, Prins MH, Frulla M, Marchiori A, Bernardi E, et al. Below-knee elastic compression stockings to prevent the post-thrombotic syndrome: a randomized, controlled trial. *Annals of internal medicine*. 2004;141(4):249-56.
12. Dawson AJ, Akaberi A, Galanaud JP, Morrison DR, Kahn SR, investigators SOXT. Patient-reported reasons for and predictors of noncompliance with compression stockings in a randomized trial of stockings to prevent postthrombotic syndrome. *Res Pract Thromb Haemosts*. 2020;4(2):269-77.
13. Pawson R, Tilley N. Realist evaluation. London: SAGE. 1997.
14. Pawson R, Tilley N. Realist Evaluation. 2004. Available from: [https://www.communitymatters.com.au/RE\\_chapter.pdf](https://www.communitymatters.com.au/RE_chapter.pdf).
15. Ridde V, Guichard A. Perception of each mechanism favorable to the reduction of social and health inequalities in France. *Glob Health Promot*. 2011;18(3):47-60.
16. Rycroft-Malone J, Fontenla M, Bick D, Seers K. A realistic evaluation: the case of protocol-based care. *Implement Sci*. 2010;5:38.
17. Alvarado N, Honey S, Greenhalgh J, Pearman A, Dowding D, Cope A, et al. Eliciting Context-Mechanism-Outcome configurations: Experiences from a realist evaluation investigating the impact of robotic surgery on teamwork in the operating theatre. *Evaluation*. 2017 2017/10/01;23(4):444-62.
18. McGaughey J, O'Halloran P, Porter S, Trinder J, Blackwood B. Early warning systems and rapid response to the deteriorating patient in hospital: A realist evaluation. *J Adv Nurs*. 2017;73(12):3119-32.
19. Dalkin SM, Greenhalgh J, Jones D, Cunningham B, Lhussier M. What's in a mechanism? Development of a key concept in realist evaluation. *Implement Sci*. 2015;10:49
20. Wong G, Greenhalgh T, Westhorp G, Buckingham J, Pawson R. RAMESES publication standards: realist syntheses. *J Adv Nurs*. 2013;69(5):1005-22.
21. Mason M. Sample Size and Saturation in PhD Studies Using Qualitative Interviews <http://www.qualitative-research.net/index.php/fqs/article/view/14282010> [cited 2020 Sept 17].

22. Brandjes DP, Buller HR, Heijboer H, Huisman MV, de Rijk M, Jagt H, et al. Randomised trial of effect of compression stockings in patients with symptomatic proximal-vein thrombosis. *Lancet.* 1997;349(9054):759-62.
23. Amin EE, Joore MA, Ten Cate H, Meijer K, Tick LW, Middeldorp S, et al. Clinical and economic impact of compression in the acute phase of deep vein thrombosis. *J Thromb Haemost.* 2018 Jun 1. PubMed PMID: 29856509.
24. Mosti G, Mancini S, Bruni S, Serantoni S, Gazzabin L, Bucalossi M, et al. Adjustable compression wrap devices are cheaper and more effective than inelastic bandages for venous leg ulcer healing. A Multicentric Italian Randomized Clinical Experience. *Phlebology.* 2020;35(2):124-33.
25. Mosti G, Cavezzi A, Partsch H, Urso S, Campana F. Adjustable Velcro Compression Devices are More Effective than Inelastic Bandages in Reducing Venous Edema in the Initial Treatment Phase: A Randomized Controlled Trial. *Eur J Vasc Endovasc Surg.* 2015;50(3):368-74.
26. Greene J, Hibbard JH. Why does patient activation matter? An examination of the relationships between patient activation and health-related outcomes. *J Gen Intern Med.* 2012;27(5):520-6.
27. Maeng DD, Martolf GR, Scanlon DP, Christianson JB. Care coordination for the chronically ill: understanding the patient's perspective. *Health Serv Res.* 2012;47(5):1960-79.
28. Schiøtz ML, Bøgelund M, Almdal T, Jensen BB, Willaing I. Social support and self-management behaviour among patients with Type 2 diabetes. *Diabet Med.* 2012;29(5):654-61.
29. Viejo A. American Association of Critical-Care Nurses. (2016). AACN standards for establishing and sustaining healthy work environments: A journey to excellence (2nd ed.) 2016.
30. Interprofessional Education Collaborative. (2016). Core competencies for interprofessional collaborative practice: 2016 update. Washington, DC: Interprofessional Education Collaborative.
31. Framework for Action on Interprofessional Education & Collaborative Practice. Health Professions Networks Nursing & Midwifery Human Resources for Health. World Health Organization 2010.
32. Lillebo B, Faxvaag A. Continuous interprofessional coordination in perioperative work: an exploratory study. *J Interprof Care.* 2015;29(2):125-30.
33. Martin JS, Ummenhofer W, Manser T, Spirig R. Interprofessional collaboration among nurses and physicians: making a difference in patient outcome. *Swiss Med Wkly.* 2010;140:w13062.
34. Bar L, Brandis S, Marks D. Improving Adherence to Wearing Compression Stockings for Chronic Venous Insufficiency and Venous Leg Ulcers: A Scoping Review. *Patient Prefer Adherence.* 2021;15:2085-102.
35. Kislov R, Pope C, Martin GP, Wilson PM. Harnessing the power of theorising in implementation science. *Implement Sci.* 2019;14(1):103.
36. Designing theoretically-informed implementation interventions. *Implement Sci.* 2006;1:4.
37. Rycroft-Malone J, Bucknall T. Models and Frameworks for Implementing Evidence-Based Practice: Linking Evidence to Action Oxford: Wiley-Blackwell2010.

## Appendix 4.1 Interview template

### Main questions for health care professionals

Can you tell me what your role in compression therapy exactly is?

Do you treat/assist patients with deep venous thrombosis, chronic venous disease, or both?

If you see compression therapy as a whole, which factors are important outcomes to patient care?

You mentioned (outcome named in the previous question) as an important outcome. Is there variation in outcomes in your practice or is the outcome always the same? How can health care professionals empower patients to achieve this outcome? Are there any treatment decisions that influence the patient's chances to achieve desirable outcomes? Practically, it was our impression that there is a substantial variation in how ECS therapy is organized in current care, with various effects on outcomes. Do you acknowledge this variation within the process? And within your discipline/your work?

If there is variation, how can you explain this variation? What factors influenced you had outcome x for patient 1 and outcome y for patient 2? How does this variation affect your work/how do you deal with this variation? How do you think other health care professionals in your discipline deal with this variation? Does this affect outcomes? Can you identify specific targets leading to desirable/undesirable outcomes?

If you could change something to make your current work more efficient and achieve higher desirable outcomes, what would you change and why?

### Main questions for patients

Are you currently being treated with compression therapy? For which disease are you being treated?

Have you been treated before with other types of compression therapy (for example, multilayer compression bandages, temporary compression hosiery, or adjustable compression devices)?

What are important factors/outcomes for you during treatment? Can you give an example of (outcome named in the previous question)? Did these important factors change during the process? Did you discuss these factors with your treating physician? If yes, did they support you in achieving these outcomes and how exactly did they help you?

Do you apply and remove the compression materials self-reliant or do you need home care assistance to assist you? If the patient required home care assistance, is it a problem for you that you require home care assistance? If yes, do you think health care professionals maximally empowered you to maintain self-reliance? If not, what do you think you need to function self-reliant?

Do you use your compression materials? If not, why not? If yes, do you use them daily? If not, why not?

## Appendix 4.2 Survey questions

Only the questions in bold were used in the current paper.

### 1.1 Survey medical stocking suppliers

In this survey, the term CVD refers to patients with a stage C4 and C5 CVD according to the CEAP (Clinical-Etiological-Anatomical-Pathophysiological) classification system.

- 1. Are you currently working for a company chain or an independent company? [MC]**
2. How long does an intake consult take? [slider 0-90 minutes]
- 3. What percentage of CVD-patients is treated with ready-made ECS? [slider 0-100%]**
- 4. What percentage of CVD-patients is treated with the following classes of ECS: [Must total 100%]**
  - Class 2
  - Class 3
  - Other
- 5. Which factors affect the chosen type (custom-made or ready-made), and compression strength for CVD-patients? [OQ]**
- 6. What percentage of DVT-patients is treated with confection ECS? [slider 0-100%]**
- 7. What percentage of DVT-patients is treated with the following classes of ECS: [Must total 100%]**
  - Class 2
  - Class 3
  - Other
- 8. Which factors affect the chosen type (custom-made or ready-made), and compression strength for DVT-patients? [OQ]**
9. What is the average delivery time for ready-made ECS? [slider 0-25 days]
10. What is the average delivery time for custom-made ECS? [slider 0-25 days]
11. How long does a fitting consult take in general? [slider 0-45 minutes]
12. What percentage of patients receive a fitting consult by default? [slider 0-100%]
13. What percentage of patients receive a physical follow-up appointment after one year? [slider 0-100%]
14. What percentage of patients receive a physical follow-up appointment in the subsequent years? [slider 0-100%]
- 15. After delivery of the definitive ECS, what percentage of CVD-patients applies the following situations: [Must total 100%]**
  - The patient is self-reliant without an assistive device
  - The medical stocking supplier implements an uncomplicated assistive device (i.e. resistance reducing device or a cuff and cone)
  - The medical stocking supplier implements a complicated assistive device (i.e. frames or arm-extending devices)
  - The patient is referred to the occupational therapist
  - The patient is advised to contact the home care organization
- 17. How do you explain these percentages? Which factors affect the patient's course? [OQ]**

18. After delivery of the definitive ECS, what percentage of DVT-patients applies the following situations: [Must total 100%]
  - The patient is self-reliant without an assistive device
  - The medical stocking supplier implements an uncomplicated assistive device (i.e. resistance reducing device or a cuff and cone)
  - The medical stocking supplier implements a complicated assistive device (i.e. frames or arm-extending devices)
  - The patient is referred to the occupational therapist
  - The patient is advised to contact the home care organization

19. How do you explain these percentages? Which factors affect the patient's course? [OQ]

Abbreviations: CVD: chronic venous insufficiency, DVT: deep venous thrombosis, ECS: elastic compression stockings, MC: multiple-choice, OQ: open question.

## 1.2 Survey occupational therapists

1. Are you currently working for a company chain or an independent company? [OQ]
2. How many hours do you spend, on average, to select and implement an assistive device with the patient (including the intake consult)? [slider 0-10 hours]
3. What percentage of patients ultimately succeeds to be self-reliant after training? [slider 0-100%]
4. Which factors affect the chosen assistive device? [OQ]
5. Which factors affect the patient's possibilities to be self-reliant with the use of an assistive device? [OQ]
4. For what percentage of patients do you ask the home care organization to provide additional training? [slider 0-100%]
5. For how long do you ask the home care organization to provide additional training on average in these patients? [slider 0-30 days]
6. For what percentage of patients do you implement the following assistive devices for training: [Must total 100%]
  - Resistance reducing devices
  - Cuffs and cones
  - Frames and arm-extending devices
  - Elastic compression stocking pistol
7. How do you choose and select the appropriate assistive device? Which factors affect your choice? [OQ]

Abbreviations: OQ: open question.

## 1.3 Survey home care nurses Limburg

1. What percentage of patients, referred back to home care after the definitive elastic compression stocking is delivered, is referred to the specialized home care nurse (ergocoach) to train an assistive device? [slider 0-100%]
2. How do you select patients for referral? Which factors affect your choice? [OQ]
3. How many hours do you spend, on average, to select and implement an assistive device with the patient (including the intake consult)? [slider 0-5 hours]
4. For what time frame do you ask regular home care nurses, on average, to provide additional training in these patients? [slider 1-6 weeks]

5. What percentage of patients ultimately succeeds to be self-reliant after training? [slider 0-100%]
6. Which factors affect the chance of successful implementation of an assistive device? [OQ]
7. For what percentage of patients do you use the following assistive devices for training: [Must total 100%]
  - Resistance reducing devices
  - Cuffs and cones
  - Frames and arm-extending devices
  - ECS pistol
8. How do you choose and select the appropriate assistive device? Which factors affect your choice? [OQ].

#### 1.4 Survey home care nurses North-Holland

1. How long does an ACD fitting consult takes on average (including instruction)? [slider 0-120 minutes]
2. What percentage of patients can self-reliantly apply and adjust the ACD after the instruction consult in the initial compression phase? [slider 0-100%]
3. Which factors affect the patient's possibilities to self-reliantly apply and adjust the ACD? [OQ]
4. What percentage of patients require a footwrap in addition to the adjustable compression device? [slider 0-100%]
5. What percentage of patients require another adjustable compression device as type A? [slider 0-100%]
6. How long do you generally apply ACD before the patient is instructed to call the medical stocking supplier to fit the definitive ECS? [slider 1-9 weeks]
7. What percentage of patients, referred back to home care after the definitive elastic compression stocking is delivered, is referred to the occupational therapist to train an assistive device? [slider 0-100%]
8. How do you select patients for referral to the occupational therapist? Which factors affect your choice? [OQ]

Abbreviations: ACD: adjustable compression device, ECS: elastic compression stocking, OQ: open question.

#### 1.5 Survey general practitioners

In this survey, the term CVD refers to patients with a stage C4 to C5 according to the CEAP (Clinical-Etiological-Anatomical-Pathophysiological) classification system.

Questions regarding DVT:

1. Do you treat DVT-patients independently at your general practice? Yes/no  
If not: 1a. What are the reasons you do not treat these patients? [OQ]  
If yes:
  - 1b. What percentage of patients do you refer to secondary care? [slider 0-100%]
  - 1c. Which factors affect whether you refer a patient to secondary care for the treatment of DVT? [OQ]
  - 1d. For what percentage of DVT-patients do you prescribe initial compression therapy? [slider 0-100%]

- 1e. Which factors affect whether you prescribe initial compression therapy? [OQ]
- 1f. Do you ever use other types of initial compression therapy than multilayer compression bandages? Yes/no

Questions regarding CVD:

2. What percentage of CVD patients are referred to secondary care? [slider 0-100%]
3. Which factors affect whether you refer the patient to secondary care? [OQ]
4. If you decide to treat the patient at the general practice, for what percentage of CVD patients do you prescribe initial compression therapy? [slider 0-100%]
5. Which factors affect whether you prescribe initial compression therapy? [OQ]
6. Only for GPs in Limburg: Do you ever use other types of initial compression therapy than multilayer compression bandages? Yes/no.  
If yes
  - 6a. What other types of initial compression therapy do you prescribe? [OQ]
  - 6b. For what percentage of patients do you prescribe other types of initial compression therapy? [slider 0-100%]
7. Only for GPs in North-Holland: Do you ever use other types of initial compression therapy than adjustable compression devices? Yes/no.  
If yes
  - 7a. What other types of initial compression therapy do you prescribe? [OQ]
  - 7b. For what percentage of patients do you prescribe other types of initial compression therapy? [slider 0-100%]
8. What percentage of CVD patients receive a follow-up appointment by default?
9. Which factors affect whether you plan a follow-up appointment?

Abbreviations: CVD: chronic venous insufficiency, DVT: deep venous thrombosis, GP: general practitioner, OQ: open question

## Appendix 4.3

**Table S4.3.1** Distribution of interviewees per stakeholder group.

Interviewees	Limburg (15)	North-Holland (15)
General practitioners	2	2
Internists	2	3
Dermatologist	1	1
ER nurses	2	1
Doctor's assistant dermatology	n/a	1
Nurse dermatology	1	n/a
Medical stocking suppliers	2	1
Home care nurses	2	2
Occupational therapists	1	1
Deep venous thrombosis patients	1	1
Chronic venous insufficiency patients	1	2

Adopted from Schreurs RHP, Joore MA, Ten Cate H, Ten Cate-Hoek AJ. Using the Functional Resonance Analysis Method to explore how elastic compression therapy is organised and could be improved from a multistakeholder perspective. BMJ open. 2021 Oct 12;11(10):e048331. PubMed PMID: 34642192. Pubmed Central PMCID: PMC8513256. Epub 2021/10/14. eng.

**Table S4.3.2** Response rate per professional group (survey).

Professionals	Limburg					North-Holland			
	Invited practices (n)	Practices agreed to participate (n)	Invited professionals (n)	Response rate (%)	Invited practices (n)	Practices agreed to participate (n)	Invited professionals (n)	Response rate (%)	
Occupational therapists	7	6	34	47	7	6	21	67	
Medical stocking suppliers	5	5	8	88	4	5	5	100	
Home care nurses	1	1	24	67	1	1	40	85	
General practitioners	18	12	12	100	15	10	10	100	

## Appendix 4.4 Context-mechanism-outcome-configurations (CMOcs)

### Initial compression therapy

**Table S4.4.1** Referral behavior.

Context (+)	Mechanism (=)	Distal outcome
<b>In favor of referral</b>		
DVT		DVT <i>Primary care</i>
<u>Lack of knowledge/exposure:</u> Most GPs have limited knowledge regarding the treatment of DVT and limited exposure to DVT-patients <u>Lack of diagnostic equipment:</u> Most GPs lacked an ultrasound (L, NH-A), or even the possibility to direct order a diagnostic ultrasound without interference of the internist (NH-B).	<u>Lack of confidence, and commitment</u> to treat DVT-patients. <u>Lack of motivation and commitment</u> to use resources	L: 11%, NH: 0% <i>Secondary care</i> L: 89%, NH: 100%
DVT and CVD		
<u>Patient characteristics:</u> Younger and patient's with a higher risk for complications (e.g. with multiple comorbidities, known bleeding disorders, or recurrent DVT's) are more likely to be referred to exclude underlying pathology	<u>Risk management:</u> In younger and complicated patients, GPs do not tolerate any risk of missing an underlying disease	CVD <i>Primary care</i> L: 70%, NH: 76% <i>Secondary care</i> L: 30%, NH: 24%
<b>In favor of treatment in primary care</b>		
DVT	<u>Willingness and commitment</u> to treat DVT-patients	
<u>Knowledge/exposure:</u> Specialized GPs have sufficient knowledge regarding the treatment of DVT and sufficient exposure to DVT-patients		
DVT and CVD		
<u>Patient characteristics:</u> In some elderly interference of secondary care is not desired by the GP or the patient	<u>Reticent attitude</u> regarding referrals in some elderly	
CVD		
<u>Knowledge/exposure:</u> All GPs have sufficient knowledge regarding the treatment of CVD and sufficient exposure to CVD-patients <u>Availability of diagnostic equipment:</u> GPs have the appropriate equipment to diagnose CVD	<u>Willingness and commitment</u> to treat CVD-patients <u>Motivation and commitment</u> to make use of resources	

Abbreviations L: Limburg, NH: North-Holland, GP: general practitioner, DVT: deep venous thrombosis, CVD: chronic venous disease

**Table S4.4.2** Start of initial compression therapy.

Context (+)	Mechanism (=)	Proximal outcome	Distal outcome
<b>Enhancing</b>			DVT <i>Initial compression therapy:</i> GP L: 90 % Internist L/NH-A: 100%, NH-B:0%
DVT and CVD			
<u>Knowledge levels:</u> Most internists (L+NH-A), dermatologists (L+NH), and GPs (L+NH) have sufficient knowledge to treat DVT patients, they understand and value the underlying purpose of initial compression therapy	<u>Willingness, confidence and commitment to prescribe initial compression therapy</u>	Increased number of initial compression therapy prescription	
<u>Lack of knowledge:</u> Some internists (L+NH-A), dermatologists (L), and GPs (L+NH) lack knowledge regarding initial compression therapy. The local protocol provides unambiguous recommendations for using initial compression therapy	<u>Commitment to implement recommendations</u>	Increased number of initial compression therapy prescription	<i>No initial compression therapy:</i> GP L: 10% Internist L/NH-A: 0%, NH-B: 100%
<u>Patient's knowledge:</u> Sufficiently informed patients who want to prevent complications or reduce symptoms	<u>Patients' motivation to accept and use initial compression therapy</u> <u>Increased self-efficacy and self-confidence</u>	Increased number of initial compression therapy prescriptions	CVD <i>Initial compression therapy:</i> GP L: 90%, NH: 88%
<u>Trained staff:</u> Availability of trained staff to fit and demonstrate initial compression therapy	<u>Physician's motivation to use staff's capabilities</u> <u>Professionals experiencing less stress and less time constraints</u>	Increased number of initial compression therapy prescriptions	Dermatologist L+NH: 100% <i>No initial compression therapy:</i> GP L: 10%, NH: 12% Dermatologist L+NH: 0%
<b>Inhibiting</b>			
DVT			
<u>Lack of knowledge:</u> Internists are not aware, or lack knowledge, regarding the effectiveness of initial compression therapy for DVT (NH-B). The local protocol does not provide recommendations for using initial compression therapy	<u>Lack of willingness and commitment to prescribe initial compression therapy</u>	Omission of initial compression therapy	
<u>Lack of trained staff:</u> Available staff is not trained to fit and demonstrate the initial compression therapy for DVT (NH-B). If no trained staff is available, it is perceived as difficult and inefficient to arrange care.	<u>Reticent attitude regarding the use of initial compression therapy</u>	Omission of initial compression therapy	
CVD			
<u>Patient characteristics:</u> Some patients expect difficulties in applying compression therapy in general, i.e. due to a lack of strength. Furthermore, compression therapy generally has a negative image to most patients	<u>Patient's demotivation, reticent attitude</u>	Decreased number of initial compression therapy prescription	

Abbreviations L: Limburg, NH-A: North-Holland location A, NH-B: North-Holland location B, GP: general practitioner, DVT: deep venous thrombosis, CVD: chronic venous disease

**Table S4.4.3** Type of initial compression.

Context (+)	Mechanism (=)	Proximal outcome	Distal outcome
<b>Enhancing DVT</b>			DVT <i>TCH self-reliant:</i> L: 77%, NH: 86% <i>TCH home care</i> L: 4%, NH: 4% <i>MCB not self-reliant</i>
<u>Lack of knowledge:</u> Some internists lack knowledge regarding the different types of initial compression therapy (L+NH-A). The local protocol provides unambiguous recommendations as regards preference for TCH	<u>Commitment</u> to prescribe the recommended initial compression therapy	TCH is prescribed, the largest part of patients remains self-reliant	
<u>Knowledge:</u> Some internists (for DVT) and dermatologists (for CVD) know the different types of initial compression therapy, their effectiveness, and their effects on the ability of patients to maintain their self-reliance (L+NH-A)	<u>Willingness and commitment</u> to prescribe the most suitable initial compression therapy	Patients receive the most suitable type of initial compression therapy, increased number of self-reliant patients	L: 19%, NH: 10% <i>No initial compression therapy:</i> L: 1%, NH-A: 0%, NH-B: 100% CVD
<u>Trained staff:</u> At the ER and the dermatology department, trained staff is available to fit and demonstrate the initial compression therapy (L + NH-A)	<u>Motivation</u> to make use of staff's capacities and experience  <u>Professionals experiencing less stress and less time constraints</u>	Patients are sufficiently instructed to use the initial compression therapy, increased number of self-reliant patients	<i>MCB not self-reliant</i> L: 94%, NH: 24% <i>ACD self-reliant</i> NH: 32% <i>ACD not self-reliant</i>
<u>Patient characteristics:</u> Patients who have the sufficient strength and cognitive abilities to apply and remove the initial compression therapy self-reliantly  <u>Patient's knowledge:</u> Sufficiently informed patients who know their aims and desires regarding initial compression therapy	<u>Motivation</u> to make use of their abilities  <u>Active patient involvement</u> in the decision-making process <u>Increased self-efficacy and self-confidence</u>	The likelihood of the patient maintaining self-reliance increases  Increased likelihood that the patient receives the most suitable type of initial compression therapy	NH: 35 % <i>No compression</i> L: 7 %, NH: 9 %
<b>CVD</b>			
GPs (NH) have <u>knowledge</u> regarding the use of ACD and know that chances to remain self-reliance increase compared to MCB.	<u>Fixed (written) arrangements</u> regarding the management of adjustable compression devices as preferred compression therapy completely executed by home care organizations are available.  <u>GPs motivation</u> to make use of arrangements, decreased stress-levels and increased confidence that ACD are reimbursed without problems for the patient.	Adjustable compression devices are prescribed which increases the possibility to maintain self-reliant	

**Table S4.4.3** (continued)

Context (+)	Mechanism (=)	Proximal outcome	Distal outcome
<b>Inhibiting</b> DVT and CVD <u>Lack of knowledge:</u> Most GPs have insufficient knowledge regarding the different types of initial compression therapy (L). The national guideline recommends using MCB	<u>Commitment</u> to guideline recommendations	MCB is prescribed, patients depend on home care or outpatient clinic for assistance	
<u>Patient characteristics:</u> Patients who have insufficient strength and/or cognitive abilities to apply and remove the initial compression therapy self-reliantly	<u>Lack of ability</u>	Patients depend on home care or outpatient clinic for assistance	
CVD <u>Reimbursement constraints and perceived lack of evidence regarding ACD by dermatologists and internists (L + NH) and GPs (L)</u>	<u>Reticent attitude</u> regarding the use of ACD	Omission of ACD	

Abbreviations L: Limburg, NH-A: North-Holland location A, GP: general practitioner, DVT: deep venous thrombosis, CVD: chronic venous disease, ACD: adjustable compression devices, TCH: temporary compression hosiery, MCB: multilayer compression bandages.

## Selection of ECS type and class

**Table S4.4.4** Information and patient transfer.

Context (+)	Mechanism (=)	Proximal outcome	Distal outcome
<b>Enhancing</b>			
DVT			<u>Delivered ECS</u>
<u>Knowledge:</u> Most internists and specialized GPs have sufficient knowledge to determine the indication and ECS class based on evidence (L+NH)	<u>Willingness and commitment</u>	Complete referrals including the ECS indication and class based on evidence	DVT <i>Custom-made</i> L: 39%, NH: 33% <i>Ready-made</i> L: 61%,
<u>Lack of knowledge:</u> Some internists have insufficient knowledge to determine the ECS class based on evidence.	An evidence-based <u>printed recipe</u> for class 3 ECS is available at the workplace.  <u>Increased confidence and self-efficacy</u> in prescribing the ECS	Complete referrals including the ECS indication and class based on evidence	NH: 67% <i>Class 2</i> L: 30%, NH: 65%  <i>Class 3</i> L: 68%, NH: 35%
CVD	<u>Willingness and commitment</u>	Complete referrals including the ECS indication and class based on evidence	Other L: 2%, NH: 0%  CVD <i>Custom-made</i>
DVT + CVD	<u>Increased efficacy, alignment and knowledge</u> regarding each other's needs and wishes  <u>Medical stocking supplier's confidence and commitment</u> to the treating physician's approach and instructions  <u>Willingness and motivation</u> to collaborate and improve interdisciplinary processes	Increased ECS deliveries as intended by the treating physician	L: 24%, NH: 25% <i>Ready-made</i> L: 76%, NH: 75% <i>Class 2</i> L: 77%, NH: 87%  <i>Class 3</i> L: 23%, NH: 13%
<b>Inhibiting</b>			
DVT			
<u>Lack of knowledge:</u> dermatologists (NH) lack evidence-based knowledge regarding how to determine the indicated ECS class for DVT. The local protocol does provide recommendations that are not evidence-based	<u>Commitment</u> to the local protocol	ECS class included in the referral is not evidence-based	

**Table S4.4.4** (continued)

Context (+)	Mechanism (=)	Proximal outcome	Distal outcome
DVT + CVD			
<u>Lack of knowledge/exposure:</u> most GPs have insufficient knowledge to determine the indicated ECS class based on evidence. The national guideline provides evidence-based recommendations	Evidence regarding the ECS class is difficult to find in the national guideline	Incomplete referrals lacking the ECS indication and/or class	
<u>Incomplete referrals and financial constraints:</u> if ECS referrals are incomplete and lack patient information, ECS indication, and/or ECS class the medical stocking supplier selects the indicated ECS. Medical stocking suppliers generate income based on a fixed cluster fee per patient, which is a set amount and is perceived to be insufficient	<u>Lack of time to rigorously search the guideline and lack of self-confidence</u> to commit to the national guideline  <u>Reticent attitude</u> to implement expensive ECS types, increased risk of selection of ECS based on financial incentives	Decreased ECS deliveries as intended by evidence	Lack of coordination of information transfer
<u>Lack of understanding of responsibilities and mutual expectations</u> among treating physicians and medical stocking suppliers	<u>Lack of willingness to invest time and motivation</u> to collaborate and improve interdisciplinary processes		

Abbreviations L: Limburg, NH: North-Holland, GP: general practitioner, DVT: deep venous thrombosis, CVD: chronic venous disease, ECS: elastic compression stockings.

## Patient-based selection of assistive devices

**Table S4.4.5** Selection and training of assistive devices.

Context (+)	Mechanism (=)	Proximal outcome	Intermediate outcome	Distal outcome
<b>Enhancing</b>				
DVT and CVD				DVT <i>Self-reliant without AD</i> L: 23%, NH: 50%
<u>Patient characteristics:</u> younger patient's generally possess more strength and cognitive abilities	<u>Motivation and ability to use their abilities</u>	-	Increased number of self-reliant patients	<i>Self-reliant with AD</i> <i>without</i> L: 56%, NH: 35%
<u>Informal caregiver:</u> availability of an informal caregiver which can support and train the patient with the use of an AD	<u>Active involvement of the caregiver in the process.</u> Patients are <u>feeling in control</u> and safe since their caregiver is informed to support them.	Less referrals to home care, less/no additional training needed	Increased implementation rate AD, increased number of self-reliant patients	<i>Self-reliant with AD after training</i> L: 11%, NH: 8% <i>Long term home care for ECS</i> L: 10%, NH: 7%
<u>Patient's knowledge and perspectives:</u> appropriately informed patients who are aware of their desires and aims, and aspire to maintain self-reliance	<u>Active patient involvement</u> in the process. Patients are <u>feeling in control</u> of the situation and are <u>more confident</u> in directing care.	Patient trains most suitable AD	Increased implementation rate AD, increased number of self-reliant patients	CVD <i>Self-reliant without AD</i> L: 25%, NH: 33%
<u>Time constraints:</u> occupational therapists have sufficient time to select and train AD	<u>Patient-based adjustment</u> of time	Training duration based on patient's needs	Increased implementation rate AD, increased number of self-reliant patients	<i>Self-reliant with AD</i> <i>without training</i> L: 45%, NH: 53%
<u>Trained staff*:</u> occupational therapists are sufficiently trained to select and train AD based on patient's characteristics; desires and aims.	<u>Patient-based selection</u> of AD	Patient trains most suitable AD	Increased implementation rate AD, increased number of self-reliant patients	<i>Self-reliant with AD after training</i> L: 14%, NH: 7% <i>Long term home care for ECS</i> L: 16%, NH: 7%
<u>Accessible interdisciplinary consultation*:</u> direct peer consultation among medical stocking suppliers and occupational therapists	<u>Increased efficacy, alignment and knowledge</u> regarding each other's needs  <u>Willingness and ability</u> to collaborate and improve interdisciplinary processes	The occupational therapist is better informed of the patient's situation	Increased implementation rate AD, increased number of self-reliant patients	
	<u>Improved continuity of care</u>			
<b>Inhibiting</b>				
DVT and CVD				
<u>Time constraints:</u>	<u>Prioritizing tasks, reticent attitude</u> to invest time	1. Short explanation of AD/omission of implementation AD 2. Decreased training time	1. Increased number of referrals to home care and occupational therapists 2. Decreased implementation rate AD	
1. Medical stocking suppliers (L+NH) and 2. Home care nurses (NH+L) experience high time pressure and workload demands				

**Table S4.4.5** (continued)

Context (+)	Mechanism (=)	Proximal outcome	Intermediate outcome	Distal outcome
<b>Inhibiting</b>				
<u>Financial constraints:</u> Training consults provided by the medical stocking supplier are financially included in the cluster fee, which is not extended if additional time is invested	Reticent attitude to invest time for training	Increased referrals - to home care and occupational therapist		
<u>Patient characteristics:</u> elderly and obese patients are less likely to apply and remove the ECS self-reliantly	<u>Lack of strength and physical abilities</u>	-	Decreased implementation rate AD	
<u>Lack of patient's knowledge</u> regarding different assistive devices and their aims and desires regarding these assistive devices	Patients <u>not actively involved</u> in the decision-making process or patients are <u>feeling overwhelmed</u> by the variety of choices which makes them <u>feel losing control</u>	Higher risk to select an AD less suitable for the patient	Decreased implementation rate AD	
<u>Lack of understanding of responsibilities and mutual expectations</u> among involved professionals	<u>Lack of willingness and motivation</u> to collaborate and improve interdisciplinary processes	Lack of coordination of patient transfer	Decreased implementation rate AD	
<u>Lack of trained staff*:</u> home care nurses are not sufficiently trained to select and train AD based on patient's characteristics; desires and aims (L)	Selection of AD based on <u>personal experience</u>	Higher risk to select an AD less suitable for the patient	Decreased implementation rate AD, decreased number of self-reliant patients	
<u>Lack of accessible interdisciplinary consultation*</u> : lack of communication among medical stocking suppliers and home care nurses to discuss options to maintain patient's self-reliance. It is perceived to be difficult and time-consuming to contact each other.	<u>Lack of willingness and motivation to collaborate</u>	Home care nurses are suboptimally informed/prepared AD for the patient's situation	Decreased implementation rate	
<u>Patient characteristics*:</u> occupational therapists and home care nurses perceive it to be more difficult to encourage patients to be self-reliant when they were already used to home care.	Patients feel <u>anxious</u> that the use of an assistive device indicates they will lose home care contacts and are <u>not motivated</u> for training	Decreased patients selected for training	Decreased implementation rate AD	

\* Context factors related to patients who require additional training. Abbreviations L: Limburg, NH: North-Holland, AD: assistive device, DVT: deep venous thrombosis, CVD: chronic venous disease.

## Individualized treatment duration for DVT patients

**Table 4.4.6** Individualized duration of ECS therapy for DVT patients.

Context (+)	Mechanism (=)	Proximal outcome	Distal outcome
<b>Enhancing</b>			
<u>Knowledge:</u> Most internists have sufficient knowledge regarding the individualization of treatment duration for DVT-patients, value the added value for the patient, and how to determine Villalta scores (L)	<u>Confidence and motivation to individualize treatment duration</u>	Individualized ECS treatment duration	<i>Standardized treatment duration</i> L: 17%, NH: 100% <i>Individualized treatment duration</i> L: 83%, NH: 0%
<u>Lack of knowledge:</u> Some internists lack knowledge regarding the possibility to individualize treatment duration (L). They are aware of the local protocol providing unambiguous recommendations to individualize the ECS treatment duration	<u>Increased self-confidence and commitment to use the local protocol</u>	Individualized ECS treatment duration	<i>Individualized ECS treatment duration</i> L: 100%, NH: 0%
<u>Perspectives:</u> internists feel responsible for leg assessments and risk assessment for the post-thrombotic syndrome (L)	<u>Internists motivation and willingness to invest time</u>	Individualized ECS treatment duration	<i>Individualized ECS treatment duration</i> L: 100%, NH: 0%
<u>Lack of knowledge:</u> Internists (NH) and GPs (L) lack knowledge, experience, and training in estimating Villalta-scores since they rarely assess legs. A tool is available to stepwise guide health care professionals on how to determine a Villalta score	<u>Increased self-confidence and self-efficacy to determine Villalta-scores</u>	Individualized ECS treatment duration	<i>Individualized ECS treatment duration</i> L: 100%, NH: 0%
<b>Inhibiting</b>			
<u>Lack of knowledge:</u> GPs lack knowledge regarding the possibility to individualize treatment duration (L+NH). The national GPs guideline recommends a standardized treatment duration and does not provide support on how to individualize ECS treatment duration	<u>Rely back on acquired (lack of) knowledge</u>	Standardized treatment duration without formal leg assessments	
Internists and dermatologists are aware of the possibility to individualize treatment duration, however, they have insufficient knowledge of the content of this approach (NH). The local protocol recommends a standardized treatment duration and does not provide support on how to individualize ECS treatment duration			
<u>Lack of knowledge:</u> Internists (NH) and GPs (L) lack knowledge, experience, and training in estimating Villalta-scores since they rarely assess legs	<u>Reticent attitude and lack of self-confidence to determine Villalta scores</u>	Standardized ECS treatment duration without formal leg assessments	
<u>Perspectives:</u> internists experience leg assessments and risk assessment for the post-thrombotic syndrome as a dermatological problem and do not feel responsible for this follow-up (NH)	<u>Lack of motivation and willingness to invest time for follow-up</u>	Standardized ECS treatment duration without formal leg assessments	
<u>Time constraints:</u> dermatologists' and internists' outpatient clinics are already fully booked, they experience a lack of time to perform more follow-up consults (NH)	<u>Lack of motivation and willingness to invest time for follow-up</u>	Standardized ECS treatment duration without formal leg assessments	
<u>Lack of interdisciplinary communication:</u> among the indicated ECS treatment duration among internists (L, NH-B) or dermatologists (NH-A), and medical stocking suppliers (L+NH).	Medical stocking suppliers send patients annual calls for follow-up regardless of the advised treatment duration. <u>Patient's interpretation</u> of the automated call as an indication to restart ECS therapy	Some patients resume ECS therapy regardless of the advised treatment duration	

Abbreviations L: Limburg, NH: North-Holland, NH-B: North-Holland location B, GP: general practitioner, DVT: deep venous thrombosis, ECS: elastic compression stockings.

## Provision of follow-up for CVD patients

**Table 4.4.7** Performing follow-up for CVD patients.

Context (+)	Mechanism (=)	Distal outcome
<b>Enhancing</b>		<i>FU only if problems exist</i>
<u>Perspective:</u> Dermatologists and approximately half of GPs value the need for a follow-up appointment to check adherence to therapy and provide additional information (L+NH)	<u>Motivation and willingness</u> to invest time	GP L: 42%, NH: 62%
<u>Patient characteristics:</u> In general, patients visiting the dermatologists have more severe, or complicated disease (L+NH)	<u>Motivation and willingness</u> to invest time	Dermatologist L/NH: 0%
<b>Inhibiting</b>		
<u>Time constraints:</u> Most GPs experience a high workload, and outpatient clinic appointments are already fully booked (L+NH)	<u>Prioritizing tasks, reticent attitude</u> to perform follow-up	FU by default GP L: 58%, NH: 38%
<u>Understanding of responsibilities, roles, and mutual:</u> Half of GPs do not value the need for a follow-up appointment. As they experience that, for most patients, different healthcare professionals (i.e. edema therapists or home care nurses) are involved in ECS therapy. These professionals monitor the process and contact the GP if problems exist. However, these professionals indicate patient problems that they cannot solve without interference of the GP	<u>Lack of GPs willingness and involvement in follow-up</u>	Dermatologist L/NH: 100%

Abbreviations L: Limburg, NH: North-Holland, GP: general practitioner, CVD: chronic venous disease.



# Chapter 5

Development of a consensus-based cross-domain protocol for the management of elastic compression stocking therapy in patients with deep venous thrombosis and chronic venous disease: a modified Delphi study

Schreurs RHP, Joore MA, Ten Cate H, Ten Cate-Hoek AJ  
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## Summary

### Objective

Elastic compression stocking (ECS) therapy is commonly used in patients with deep venous thrombosis (DVT) and chronic venous disease (CVD). The provision of ECS therapy is complex, and studies indicate a lack of practical guidance and suboptimal collaboration among health care professionals. We aimed to reach consensus on critical issues of ECS therapy among the involved health care professionals and patients.

### Methods

A three-round modified Delphi analysis was performed in the Netherlands in which 56 health care professionals (internists, dermatologists, general practitioners, emergency room nurses, home care nurses, medical stocking suppliers, and occupational therapists) and seven patients were invited. The 21 statements included in this analysis were based on information collected from a previously conducted Functional Resonance Analysis Method and Realist Evaluation. We used 7-point Likert scale questions and a 75% threshold for consensus.

### Results

Of the 63 persons invited for this study, 59 (94%) agreed to participate and responded in the first questionnaire round; of whom 52 were health care professionals and seven were patients (five DVT and two CVD). The overall response rate for the three questionnaire rounds was 91%. After completion of the rounds, full consensus was achieved on 19 out of 21 statements. No consensus was reached on the need for a follow-up appointment for CVD patients and who should be responsible to determine the ECS type (custom-made or standard).

### Conclusions

We identified 19 consensus-driven recommendations on treatment decisions and collaboration in ECS therapy among an interdisciplinary panel of health care professionals and patients. These recommendations form a basis for consensus-driven optimization of ECS therapy and should ideally be incorporated in a general cross-domain protocol for ECS therapy in patients with DVT and CVD.

## Introduction

Elastic compression stocking (ECS) therapy is a frequently prescribed treatment worldwide. It is indicated to reduce leg complaints in the acute phase of deep venous thrombosis (DVT)<sup>1-3</sup>, to prevent the occurrence of post-thrombotic syndrome which affects up to 50% of DVT patients, and to prevent the development of venous ulcers in patients with chronic venous disease (CVD). Although some controversy remain on the preventive properties of ECS therapy for DVT, the latest Cochrane review indicated a significant reduction in the incidence of the post thrombotic syndrome associated with ECS therapy (RR 0.62 (95% CI=0.38-1.01, p=0.05)).<sup>4</sup> Elastic compression stocking therapy in CVD has been associated with improved venous symptomatology, oedema, skin changes<sup>5-8</sup>, and with the prevention of ulcer recurrence.<sup>9</sup> The complications negatively impact patients' quality of life.<sup>10-12</sup> Furthermore, the associated health care burden is substantial and is expected to increase as a result of aging of the global population (especially for CVD).<sup>13-15</sup> Currently, there is no curative treatment for post-thrombotic syndrome once it has occurred, and treatment of venous ulcers is complicated. Prevention of these complications is therefore crucial.

During the process of ECS therapy, patients are confronted with various professionals from different organizations which may affect both the quality and continuity of care. This could hamper patients' chances to maintain self-reliance during different stages of the process and, subsequently, lead to an increased workload for home care organizations. Two recent studies described the structure of ECS therapy and identified what needs to be in place to maximally support patients and health care professionals to achieve optimal patient outcomes.<sup>16,17</sup> These studies indicated that there was a lack of unambiguous practical guidance regarding management decisions and collaboration among involved health care professionals in local, national, and international guidelines.

To this end, we aimed to reach interdisciplinary consensus on critical management decisions in ECS therapy and to propose consensus-based recommendations for collaboration among health care professionals across various disciplines together with patients involved in ECS therapy.

## Methods

For this study, we applied a consensus-based approach using a modified Delphi technique. With this technique, sequential questionnaire rounds are presented to an expert panel alternated with controlled feedback on the results collected from the prior rounds. The method allows participants to modify their opinion to achieve consensus regarding a specific topic or process.<sup>18,19</sup> Anonymity between participants is guaranteed, which prevents bias resulting from opinions from dominant participants influencing

group opinion.<sup>20,21</sup> We modified the procedure for the qualitative first round as used in the classic Delphi analysis and instead used the content derived from two of our earlier performed studies in this context (a Functional Resonance Analysis method and a Realist evaluation) to develop the questionnaire.<sup>16,17</sup> CREDES criteria were used to conduct and report the study.<sup>22</sup>

## Participants

We invited a panel of 56 Dutch health care professionals with a balanced representation of all professional groups involved in ECS therapy (i.e., internists, dermatologists, general practitioners, emergency room nurses, home care nurses, medical stocking suppliers, occupational therapists) and seven patients.<sup>16</sup> The participants included local stakeholders as well as national stakeholders to assure broad support of the consensus reached. National health care professionals were identified based on their involvement in the development of national guidelines regarding the treatment of DVT and CVD, their clinical and/or academic expertise in the field, or if they were representatives of national associations (i.e. the Dutch federation of occupational therapists and the Dutch association for general practitioners) with a special interest in ECS therapy. Experienced patients were purposely selected from the Dutch patient association for patients with cardiovascular diseases, 'Harteraad'. Each potential panel member was provided with comprehensive study information, outlining the aim of the modified Delphi analysis, an overview of the elements of ECS therapy, and the extent and timing of their expected involvement as presented in Appendix 5.1: Clinical care pathways of compression therapy for DVT patients.

## Delphi rounds

We performed a pre-established total of three questionnaire rounds. Each round consisted of statements classified as belonging to the four main stages of ECS therapy as identified by previous research: initial compression, the onset of ECS therapy, implementation of assistive devices, and follow-up.<sup>16</sup> For each round, participants were asked to indicate their level of agreement on each of the statements provided on a 7-point Likert scale (1= strongly disagree, 2= disagree, 3= somewhat disagree, 4= neutral, 5= somewhat agree, 6= agree, 7= strongly agree). All participants were encouraged to provide answers to all questions, a further option 'insufficiently informed' was available and participants were asked to use this score if they felt they lacked expertise on a specific topic, this answer option did not influence the level of consensus. In addition, each statement was provided with a textbox to allow participants to provide feedback on statements and/or written justification for their choices. Non-responders were reminded after one week. Participants who did not complete a questionnaire by the deadline of the round were considered to have withdrawn from the study and were not invited to take part in subsequent questionnaires. Qualtrics was used to administer, collect, and analyze the online questionnaires.

We used a predefined threshold of 75% of participants indicating at least a score of 6 or higher to reach consensus which is a threshold commonly used for Delphi consensus studies.<sup>23</sup> The analysis stopped when consensus was reached for a specific statement, or when the predefined end of study following three rounds was reached. Statements not reaching consensus in round three were deemed non-agreement.

Based on the outcomes of the two studies conducted earlier: the Functional Resonance Analysis Method and the Realist Evaluation, the research team (authors RS, MJ, AtC) developed the draft of the guiding statements for the first round of the modified Delphi study. Statements focused on interdisciplinary collaboration, professionals' roles and responsibilities, and treatment decisions in ECS therapy. Pilot testing was performed by distributing the draft questionnaire to three independent health care professionals and one patient who were not involved in the study design nor the analysis. Feedback was processed and incorporated in the final draft which comprised demographical questions and 21 statements.

The second round intended to reach further consensus by modification of the statements that lacked consensus as well as to validate possible barriers for implementation based on qualitative information gathered in round 1. These 'barrier statements' did not undergo modifications and were only presented to the experts once (round 2 or 3). The third round was used to achieve consensus on the remaining statements and to evaluate possible new barriers that arrived from the qualitative information gathered in round two.

We analyzed both the quantitative level of consensus results (using Microsoft Excel) and qualitative results (content analysis of the text box information) after each questionnaire round. Statements were either dropped or refined, and new statements for subsequent rounds were developed based on the quantitative and qualitative information gathered in the previous round. Participants received anonymized feedback on the results of the previous round at the start of rounds two and three. In this way, we aimed to inform the participants' judgments and provide them the possibility to amend answers during the next questionnaire round. Additionally, we provided an overview of the statements that already achieved consensus since these statements did not need further consideration in the subsequent round.

## Results

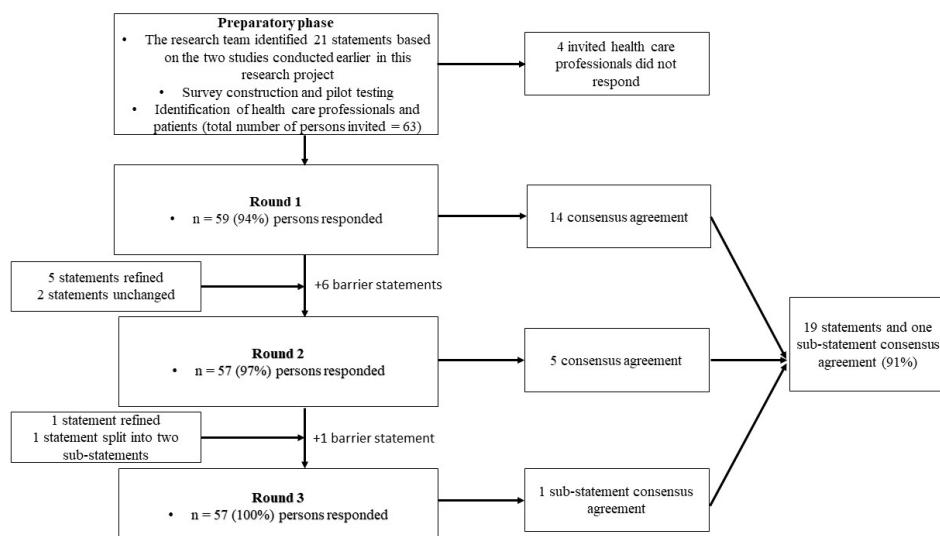
Of the 63 persons invited for this study, 59 (94%) agreed to participate and responded in the first questionnaire round, of whom 52 were health care professionals and 7 were patients (5 DVT and 2 CVD). Fifty-seven participants (97%), including all patients, also responded in the second and third rounds (overall response 91%). Participants'

characteristics can be found in Table 5.1. Responding health care professionals were equally distributed among the disciplines. Three-quarters of the participants had more than 10 years of clinical experience in the field of either DVT and/or CVD. The majority of health care professionals indicated treating DVT- and/or CVD patients in daily practice, although the number of patients varied.

**Table 5.1** Background characteristics of the participants responding in the first round.

<b>Healthcare professionals n=52</b>	<b>N</b>	<b>%</b>
Role in the process		
Health care professional	34	66
A combined health care professional and managerial/policy function	6	12
Managerial/policy function	12	23
Discipline		
Vascular internist	6	12
Hematologist	3	6
Dermatologist	7	14
General practitioner	8	15
Medical stocking supplier/skin therapist	8	15
Occupational therapist	6	12
Home care professional	8	15
Emergency room nurse	4	8
Emergency room doctor/resident internal medicine	2	4
Years' experience		
0-5 years	7	13
6-10 years	7	13
years	20	38
>20 years	19	36
Annually treated patients (only for health care professionals or combined functions)		
<i>Deep venous thrombosis</i>		
No patients	2	4
0-25 patients	21	46
25-50 patients	10	22
50-100 patients	8	17
>100 patients	5	11
<i>Chronic venous disease</i>		
No patients	5	11
0-25 patients	18	39
25-50 patients	9	20
50-100 patients	8	17
>100 patients	6	13
Earlier involvement in guideline development		
Yes	30	57
No	23	43
Earlier involved as a local stakeholder		
Yes	10	19
Region Limburg	5	10
Region North-Holland	5	10
No	42	81
<b>Patients n=7</b>	<b>N</b>	<b>%</b>
Indication elastic compression therapy		
Deep venous thrombosis	5	71
Chronic venous disease	2	29

A graphic representation of the modified Delphi process is presented in Figure 5.1, and the statements presented to the panelists can be found in Table 5.2. In the first round, we reached consensus on 14 statements (67%). Of the seven statements for which consensus was not obtained, five were refined and two were resubmitted without modifications in the second questionnaire round. Additionally, we introduced six statements targeting potential barriers for implementation. This questionnaire was sent to the 59 respondents who had responded in the first round. After round two, we reached consensus on five out of seven statements. The two statements for which consensus had not been reached were again refined. We simplified one of these statements (statement 6) by dividing it into two sub-statements which were assessed by the respondents in the last round. Finally, full consensus was reached on 19 statements (91%) and on one of the two sub-statements of statement six. A graphical representation of the consensus levels per round is shown in Figure 5.2. Detailed information on the statements, adaptations per round, feedback provided to the participants at the start and between each of the questionnaire rounds, and consensus levels can be found in Appendix 5.2 and 5.3.



**Figure 5.1** Graphic representation of the modified Delphi process.

**Table 5.2** Final statements and consensus levels per questionnaire round.

#### Statements

##### General statements

1. Active involvement of the patient and (if relevant) their informal caregiver in the decision-making process improves the probability of independence in the treatment process
2. It is important to improve collaboration and dissemination of knowledge among health care professionals involved in elastic compression therapy

**Table 5.2** (continued)

<b>Initial compression therapy</b>
3. Both patients with deep venous thrombosis and chronic venous disease (with edema) need to receive initial compression therapy
4. The treating physician should structurally ask patients about their goals and wishes regarding self-reliance in the process and consider them in the selection of a specific type of initial compression therapy
5. The treating physician needs to provide general information regarding the options of using assistive devices to maintain self-reliance during the use of elastic compression stockings at the time of diagnosis (either written or oral)
6. The treating physician is responsible for determining the indication, the pressure class, and the type of ECS. This information should be included in the referral to the medical stocking supplier
6.1. The treating physician is responsible for determining the indication, the pressure class, and determining if custom made or standard stockings are indicated
6.2. The treating physician is responsible for determining the indication and pressure class of ECS. This information should be included in the referral to the medical stocking supplier.
7. For patients who do not need home care assistance, the medical stocking supplier needs to assess the presence of edema during the use of initial compression therapy before fitting the ECS*
8. If home care nurses are involved to apply and remove the initial compression therapy, they are responsible to assess whether the edema has disappeared in direct consultation with the medical stocking supplier. And to subsequently instruct the patient to contact the medical stocking supplier
<b>The onset of the elastic compression stocking and implementation of assistive devices</b>
9. The medical stocking suppliers office should explicitly ask for the presence of edema during the first telephonic contact with the patient
10. At the moment the elastic compression stocking is delivered, a physical follow-up appointment with the medical stocking supplier needs to take place to fit the stocking and discuss possibilities for self-reliance
11. The medical stocking supplier is primarily responsible for assessing the patient's ability to maintain self-reliance in using an assistive device
12. The medical stocking supplier needs to instruct and train the patient in using an assistive device. If it appears that the patient is not functioning self-reliant at this time, the medical stocking supplier needs to assess whether additional training is useful
13. It is the medical stocking suppliers (primary) responsibility to discuss the referral to the occupational therapist for additional training with patients who are not directly functioning self-reliant after instruction and training of an assistive device
14. The most suitable approach to select an assistive device is based on the estimated patient's physical characteristics and cognitive functioning; goals and wishes; and (if relevant) possibilities to involve the informal caregiver in the process
<b>Follow-up</b>
15. For patients with chronic venous disease, it is important to schedule a follow-up appointment with the treating physician after the elastic compression stocking is delivered (only for the first prescription)*
16. It is important to individualize deep venous thrombosis patients' treatment duration with elastic compression stockings based on a risk assessment using Villalta scores with a minimum treatment duration of six months
17. Patients with deep venous thrombosis need to have follow-up appointments with the treating physician until the treatment duration with elastic compression stockings is established (generally after 6 or 12 months)
18. If the treating physician changes from secondary to primary care during the treatment period, the treating physician should send a letter to the general practitioner which minimally includes the advised treatment duration
19. All patients should have annual physical follow-up appointments with the medical stocking supplier (as long as the treatment indication lasts) to check and (if necessary) re-measure the elastic compression stocking
20. If the treating physician changes from secondary to primary care during the treatment period, the first treating physician should inform the patient, general practitioner, and home care organization (if involved)
21. When elastic compression therapy needs to be discontinued, the treating physician should inform the patient, the medical stocking supplier, and the home care organization (if involved)

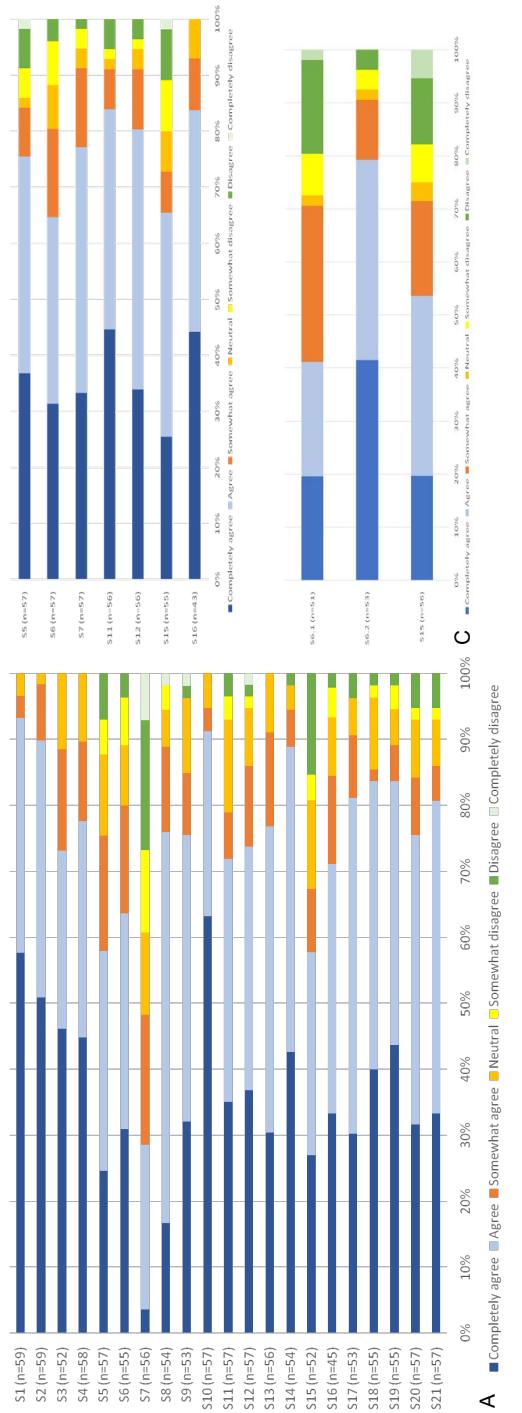
\* These statements underwent major modifications throughout the questionnaire rounds as presented in Appendix 5.2.

The Delphi panel agreed that collaboration and dissemination of knowledge among health care professionals involved in ECS therapy should be improved (90%) and active patient involvement in the decision-making process is important (93%). Consensus was reached for different treatment decisions concluding that: 1. Initial compression therapy should be offered to all patients (76%); 2. Involvement of the occupational therapist should be accessible to all patients who are not able to maintain self-reliance using an assistive device after instruction and demonstration by the medical stocking supplier (77%); 3. A tailored treatment duration should be implemented for all DVT-patients (84%).

The statement that did not reach consensus concerned the need for a follow-up appointment for CVD patients (statement 15). Although most respondents agreed that a follow-up appointment was necessary, heterogeneity existed in the opinions on who needs to perform these follow-up appointments: the medical stocking supplier or the treating physician. Furthermore, most general practitioners stated that a follow-up appointment was not necessary by default. In their opinion, default follow-up appointments do not add value since in most cases no problems exist. These GPs relied on the patient's responsibility to contact them if problems occurred.

Only partial consensus was reached for statement 6. Consensus (79%) was reached on responsibility of the treating physician for the determination of the ECS indication and pressure class (sub-statement 6.2). Hence, there was a large heterogeneity among respondents on who should determine the ECS type (sub-statement 6.1) and for this sub-statement consensus was not reached. Some respondents (mainly medical stocking suppliers and general practitioners) indicated that most treating physicians lack the knowledge to determine the correct ECS type. In their opinion, this role should be delegated to the medical stocking supplier. Other respondents stated that treating physicians should determine the type of ECS since financial barriers can influence medical stocking suppliers in selecting the type.

Finally, a high rate of agreement was found for most barrier statements, as represented in Table 5.3. These barriers included: the treating physicians' lack of knowledge, reimbursement constraints for assistive devices and training time, administrative burdens, and a lack of expertise regarding applying multilayer compression bandages.



**Figure 5.2** (A) Consensus levels statements Round 1. (B) Consensus levels statements Round 2. (C) Consensus levels statements Round 3.

**Table 5.3** Barrier statements.

	n	Strongly disagree n (%)	Disagree n (%)	Somewhat disagree n (%)	Neutral n (%)	Somewhat agree n (%)	Agree n (%)	Strongly agree n (%)	Insufficiently informed n
1. There is a lack of knowledge among treating physicians regarding different types of initial compression therapy	46	0 (0)	1 (2)	1 (2)	3 (7)	7 (15)	24 (52)	10 (22)	11
2. There is a lack of knowledge among treating physicians to inform patients about assistive devices at the moment of diagnosis	52	1 (2)	4 (8)	6 (12)	3 (6)	4 (8)	25 (48)	9 (17)	5
3. There is a lack of knowledge among treating physicians to determine the appropriate strength and type (circular or flat-knit) elastic compression stocking	46	0 (0)	4 (9)	0 (0)	2 (4)	6 (13)	26 (57)	8 (17)	11
4. Variable reimbursement criteria are a barrier to optimally select initial compression therapy and assistive devices	43	0 (0)	0 (0)	1 (2)	2 (5)	8 (19)	21 (49)	11 (26)	14
5. The administrative burden of achieving reimbursement for assistive devices is a barrier to optimal selection	45	0 (0)	2 (4)	0 (0)	5 (11)	9 (20)	16 (36)	13 (29)	12
6. Home care nurses and staff applying multilayer compression bandages at the general practice lack expertise to apply them with appropriate quality which extends the duration of initial compression therapy	36	0 (0)	4 (11)	5 (14)	3 (8)	10 (28)	9 (25)	5 (14)	21
7. The need to obtain prior permission from some insurance companies for the implementation of advanced assistive devices to receive coverage and delivery times are a barrier for optimal implementation of these devices	50	1 (2)	1 (2)	0 (0)	2 (4)	2 (4)	19 (38)	25 (50)	7

## Discussion

This study outlines a three-round modified Delphi procedure among experts across different disciplines as well as patients with experience of ECS therapy. We reached full consensus on 19 out of 21 statements (consensus rate 91%). These statements provide recommendations for tangible transitional care agreements that can be used to inform new guidance documents to support treatment decisions and collaboration among professionals involved in ECS care. These recommendations mainly target interdisciplinary collaboration, improving the use of initial compression therapy for all patients, accessible involvement of the occupational therapist at the start of ECS therapy to enhance the patient's self-reliance, and a tailored ECS treatment duration for DVT patients.

In general, this study shows the clear need for optimization of interdisciplinary collaboration, including dissemination of knowledge, and empowering patients to be involved in their treatment process. The need for this 'integrated care' is in line with developments in care worldwide as a response to the fragmented delivery of health care services in current practice.<sup>24-26</sup> The World Health Organization states that integrated care is important to ensure interdisciplinary collaboration, optimal outcomes, and appropriate research use.<sup>27,28</sup>

Our Delphi panel agreed that initial compression therapy should be offered to all DVT- and CVD patients. This recommendation is supported by several studies showing the positive short-term effects of immediate initial compression on the occurrence of the post-thrombotic syndrome, reduction of vein occlusion, and reduction of pain and edema for DVT patients.<sup>2,3,29</sup> However, evidence on the long-term effectiveness was lacking until a sub-study of the IDEAL-DVT showed an 8% absolute reduction for developing the post-thrombotic syndrome after immediate compression (<24 hours) at 24 months.<sup>30</sup> We could not identify studies specifically evaluating the effects of initial compression therapy for CVD patients, although there is some evidence showing a reduction in symptoms and an improved quality of life associated with compression therapy in general.<sup>31,32</sup>

Furthermore, the panel agreed that the occupational therapist should be actively involved if the patient is not self-reliant after a short introduction and demonstration by the medical stocking supplier. Different experts stated that they expected this intervention to improve the number of self-reliant patients; however, although these expert' statements are clinically comprehensible, there is a lack of evidence supporting this assumption. Therefore, this could be an important target for future studies.

Finally, our panel agreed that an individualized treatment duration based clinical assessments of the leg is indicated for DVT patients. This is in line with the latest large RCT in the field, showing that this individualized treatment approach is non-inferior

compared to standard treatment.<sup>33</sup> In the IDEAL-DVT trial, 66% of patients could terminate ECS treatment within 12 months which, in turn, enhanced patients' self-reliance (especially for patients needing home care assistance).

Reaching consensus on ECS treatment recommendations is the first step towards implementation in daily practice leading ultimately to improved processes and outcomes. Next, a consensus-based protocol endorsed by professional associations and health care authorities should be developed to facilitate implementation into daily practice. Special attention should be focused on health care professionals' knowledge gaps, reimbursement constraints, and reducing the administrative pressure since panelists rated these topics as important.

Some limitations to our study should be mentioned. Dermatologists accounted for four out of six non-responders. Although this might potentially have led to selection bias, the lack of response did not result in an underrepresentation of this professional group in the analysis. Furthermore, the final draft of the recommendations included in this modified Delphi study was not reviewed and approved by an external board as is recommended by the CREDES criteria.<sup>22</sup> We acknowledge that though some of the recommendations in our manuscript are likely to be transferable to other countries, the extent to which they are transferable completely depends on how compression therapy is organized. The major strength of this study is the broad representation of professionals from each participating discipline and contribution of patients, with a balanced composition of the groups, involving both participants with a policy-based background as well as participants with extensive clinical experience. We achieved high overall response rates (91%) as well as high consensus rates (95%) which implies a broad consensus and support base on the content and structure of a general cross-domain protocol to be created. Finally, the panelists had a good understanding of the topic as well as the realities of clinical practice and were therefore able to select elements that should be included in a general cross-domain protocol to optimally support and complement their practice.

## Conclusions

This study identified 19 consensus-driven recommendations for the optimization of ECS therapy in both DVT- and CVD-patients with broad interdisciplinary support. The main topics being: interdisciplinary collaboration, the use of initial compression therapy for all patients, improving patients' self-reliance, and tailored ECS treatment duration for DVT patients. These recommendations should be included in a general cross-domain protocol as the first step towards implementation in daily practice and are ultimately expected to improve processes and outcomes. Future research should focus on testing the feasibility of the recommendations and cost consequences in daily practice.

## References

1. Amin EE, Joore MA, Ten Cate H, Meijer K, Tick LW, Middeldorp S, et al. Clinical and economic impact of compression in the acute phase of deep vein thrombosis. *Journal of thrombosis and haemostasis : JTH*. 2018 Jun 1. PubMed PMID: 29856509. Epub 2018/06/02. eng.
2. Partsch H, Blättler W. Compression and walking versus bed rest in the treatment of proximal deep venous thrombosis with low molecular weight heparin. *J Vasc Surg*. 2000;32(5):861-9.
3. Roumen-Klappe EM, den Heijer M, van Rossum J, Wollersheim H, van der Vleuten C, Thien T, et al. Multilayer compression bandaging in the acute phase of deep-vein thrombosis has no effect on the development of the post-thrombotic syndrome. *J Thromb Thrombolysis*. 2009;27(4):400-5.
4. Appelen D, van Loo E, Prins MH, Neumann MH, Kolbach DN. Compression therapy for prevention of post-thrombotic syndrome. *Cochrane Database Syst Rev*. 2017;9(9):CD004174.
5. Mosti G, Picerni P, Partsch H. Compression stockings with moderate pressure are able to reduce chronic leg oedema. *Phlebology*. 2012;27(6):289-96.
6. Blättler W, Kreis N, Lun B, Winiger J, Amsler F. Leg symptoms of healthy people and their treatment with compression hosiery. *Phlebology*. 2008;23(5):214-21.
7. Vayssairat M, Ziani E, Houot B. Placebo controlled efficacy of class 1 elastic stockings in chronic venous insufficiency of the lower limbs. *J Mal Vasc*. 2000;25(4):256-62.
8. Benigni J-P, Sadoun S, Allaert F, Vin F. Efficacy of Class 1 elastic compression stockings in the early stages of chronic venous disease. A comparative study. *Int Angiol*. 2004;22:383-92.
9. Nelson EA, Bell-Syer SE. Compression for preventing recurrence of venous ulcers. *Cochrane Database Syst Rev*. 2014;2014(9):CD002303.
10. Kahn SR, Hirsch A, Shrier I. Effect of postthrombotic syndrome on health-related quality of life after deep venous thrombosis. *Arch Intern Med*. 2002;162(10):1144-8.
11. Lubberts B, Paulino Pereira NR, Kabrhel C, Kuter DJ, DiGiovanni CW. What is the effect of venous thromboembolism and related complications on patient reported health-related quality of life? A meta-analysis. *Thromb Haemost*. 2016;116(3):417-31.
12. Carradice D, Mazari FA, Samuel N, Allgar V, Hatfield J, Chetter IC. Modelling the effect of venous disease on quality of life. *Br J Surg*. 2011;98(8):1089-98.
13. Prandoni P. Healthcare burden associated with the post-thrombotic syndrome and potential impact of the new oral anticoagulants. *Eur J Haematol*. 2012;88(3):185-94.
14. Bergqvist D, Jendteg S, Johansen L, Persson U, Odegaard K. Cost of long-term complications of deep venous thrombosis of the lower extremities: an analysis of a defined patient population in Sweden. *Ann Intern Med*. 1997;126(6):454-7.
15. Lal BK. Venous ulcers of the lower extremity: Definition, epidemiology, and economic and social burdens. *Semin Vasc Surg*. 2015;28(1):3-5.
16. Schreurs RHP, Joore MA, Ten Cate H, Ten Cate-Hoek AJ. Using the Functional Resonance Analysis Method to explore how elastic compression therapy is organised and could be improved from a multistakeholder perspective. *BMJ Open*. 2021;11(10):e048331.
17. Schreurs RH, Joore MA, De Bruijn-Geraets D, Ten Cate H, Ten Cate-Hoek AJ. A Realist Evaluation on Therapeutic Elastic Compression Therapy Pathways for DVT- and CVD Patients to Develop Evidence-informed Improvement Strategies [abstract]. *Res Pract Thromb Haemost*. 2021;5 (Suppl 2). <https://abstracts.isth.org/abstract/a-realistic-evaluation-on-therapeutic-elastic-compression-therapy-pathways-for-dvt-and-cvd-patients-to-develop-evidence-informed-improvement-strategies/>. Accessed March 7, 2022.
18. Keeney S, Hasson, F., McKenna, H. . The Delphi technique in nursing and health research. Oxford, UK: John Wiley.2011.
19. Hsu C, Sandford BA. The Delphi Technique: Making Sense of Consensus. *Practical Assessment, Research, and Evaluation*. 2007;Vol. 12 , Article 10.
20. Biondo PD, Nekolaichuk CL, Stiles C, Fainsinger R, Hagen NA. Applying the Delphi process to palliative care tool development: lessons learned. *Support Care Cancer*. 2008;16(8):935-42.
21. De Vet E, Brug J, De Nooijer J, Dijkstra A, De Vries NK. Determinants of forward stage transitions: a Delphi study. *Health Educ Res*. 2005;20(2):195-205.

22. Jünger S, Payne SA, Brine J, Radbruch L, Brearley SG. Guidance on Conducting and REporting DElphi Studies (CREDES) in palliative care: Recommendations based on a methodological systematic review. *Palliative Medicine*. 2017;31(8):684-706.
23. Diamond IR, Grant RC, Feldman BM, Pencharz PB, Ling SC, Moore AM, et al. Defining consensus: a systematic review recommends methodologic criteria for reporting of Delphi studies. *J Clin Epidemiol*. 2014;67(4):401-9.
24. National Health Services (NHS). Five year forward view. October 2014. Available from: <https://www.england.nhs.uk/wp-content/uploads/2014/10/5yfv-web.pdf>. Accessed March 7, 2022.
25. Cardiovascular Disease Team. Cardiovascular Disease Outcomes Strategy. 05 March 2013. [https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/217118/9387-2900853-CVD-Outcomes\\_web1.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/217118/9387-2900853-CVD-Outcomes_web1.pdf)17-12-2021.
26. Gröne O, Garcia-Barbero M. Integrated care: a position paper of the WHO European Office for Integrated Health Care Services. *Int J Integr Care*. 2001;1:e21.
27. WHO. WHO global strategy on people-centred and integrated health services, interim report. Geneva; 2015. Available from: [http://apps.who.int/iris/bitstream/10665/155002/1/WHO\\_HIS\\_SDS\\_2015.6\\_eng.pdf](http://apps.who.int/iris/bitstream/10665/155002/1/WHO_HIS_SDS_2015.6_eng.pdf). Accessed March 7, 2022.
28. WHO. Strengthening people-centred health systems in the WHO European Region: Framework for action on integrated health services delivery. WHO Regional Office for Europe; 2016. Available from: [http://www.euro.who.int/\\_\\_data/assets/pdf\\_file/0004/315787/66wd15e\\_FFA\\_IHSD\\_160535.pdf?ua=1](http://www.euro.who.int/__data/assets/pdf_file/0004/315787/66wd15e_FFA_IHSD_160535.pdf?ua=1). Accessed March 7, 2022.
29. Arpaia G, Cimminiello C, Mastrogiacomo O, de Gaudenzi E. Efficacy of elastic compression stockings used early or after resolution of the edema on recanalization after deep venous thrombosis: the COM.PRE Trial. *Blood Coagul Fibrinolysis*. 2007;18(2):131-7.
30. Amin EE, Bistervels IM, Meijer K, Tick LW, Middeldorp S, Mostard G, et al. Reduced incidence of vein occlusion and postthrombotic syndrome after immediate compression for deep vein thrombosis. *Blood*. 2018;132(21):2298-304.
31. Andreozzi GM, Cordova R, Scomparin MA, Martini R, D'Eri A, Andreozzi F. Effects of elastic stocking on quality of life of patients with chronic venous insufficiency. An Italian pilot study on Triveneto Region. *Int Angiol*. 2005;24(4):325-9.
32. Özdemir Ö C, Sevim S, Duygu E, Tuğral A, Bakar Y. The effects of short-term use of compression stockings on health related quality of life in patients with chronic venous insufficiency. *J Phys Ther Sci*. 2016; 28(7):1988-92.
33. Ten Cate-Hoek AJ, Amin EE, Bouman AC, Meijer K, Tick LW, Middeldorp S, et al. Individualised versus standard duration of elastic compression therapy for prevention of post-thrombotic syndrome (IDEAL DVT): a multicentre, randomised, single-blind, allocation-concealed, non-inferiority trial. *Lancet Haematol*. 2018;5(1):e25-e33.

## Appendix 5.1 Invitation letter and participants information

Dear panelists,

Thank you for participating in our modified Delphi study!

The study is part of an implementation study on elastic compression stocking therapy for patients with deep venous thrombosis, and chronic venous diseases with a long-term indication for elastic compression stockings. A large variety of health care professionals are involved in elastic compression stocking therapy, requiring sufficient coordination and collaboration to achieve optimal outcomes. This study aims to achieve consensus regarding a national cross-domain protocol concerning elastic compression stocking therapy, matching daily practice.

The statements in the survey are based on an earlier performed analysis regarding elastic compression stocking therapy in daily practice in two regions in the Netherlands (Limburg and North-Holland). We kindly ask you to provide your answer based on your profession and work experience. The answers given by you and the other experts will be anonymously used as a basis for the subsequent questionnaires. A total of 3 questionnaire rounds will be performed. The first round aims to rate statements to create a basis for the cross-domain protocol. The second round aims to further deepen understanding of the statements that lacked consensus in the first round and to identify possible barriers for implementation. The last round will be used to achieve consensus on the remaining statements. Using this method, we will be working to a consensus for a national cross-domain protocol for elastic compression stocking therapy. For validity and reproducibility of the results, it is important that you participate in all rounds. The survey will take approximately 15 minutes of your time.

Instructions:

1. We kindly ask you to look at the 'overview of elastic compression therapy' figure added in the supplementary information. We recommend you use the figure to guide you through the time consecutive elements of the survey. Additionally, an explanatory list of medical terms can be found in the supplementary information.
2. Please answer all statements, you will be allowed to add comments after each statement. We encourage you to do so, especially if you do not agree with the statement.
3. If you feel like you lack the information to assess the statement, or it is not within your expertise please choose 'insufficiently informed'
4. The maximum response time for this survey is two weeks.

Explanatory word list:

Compression therapy: the entire process from diagnosis till the end of elastic compression stocking therapy

Edema: the leg contains fluid

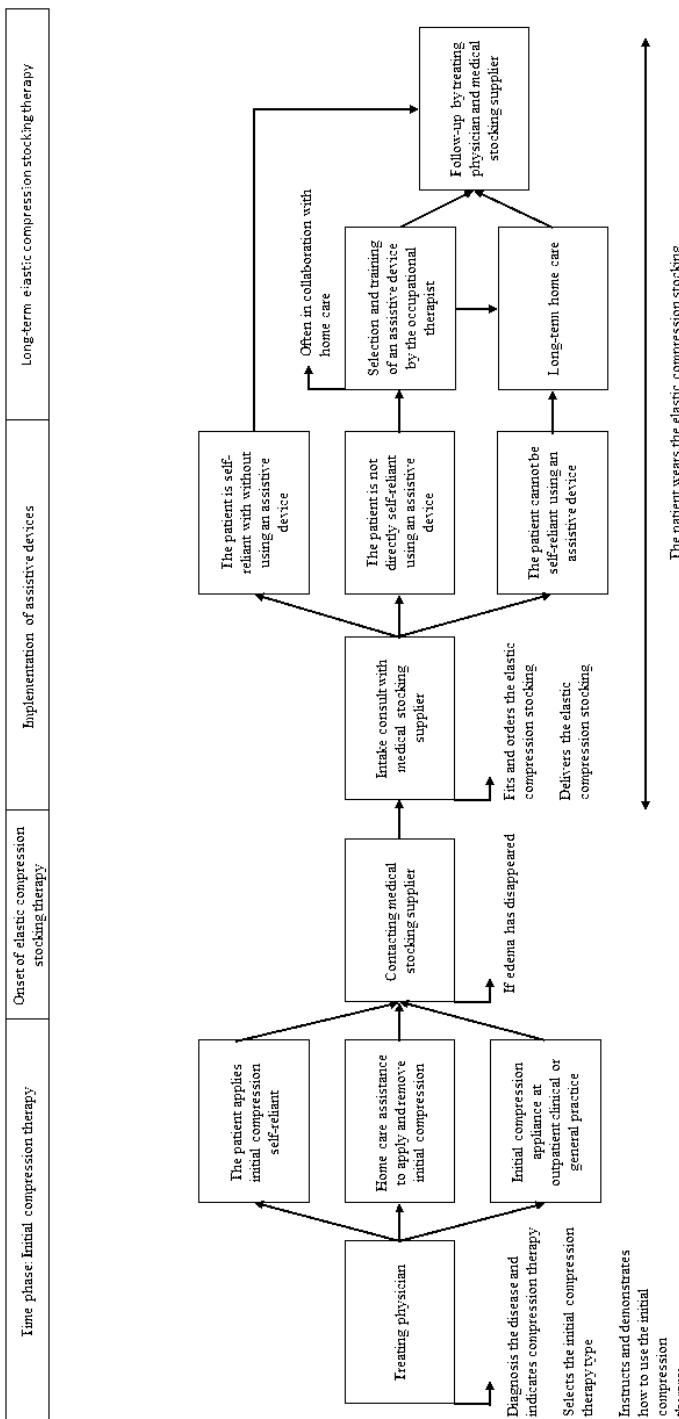
Chronic venous disease (stadium C4/C5): the leg contains varicose veins, fluid, and skin changes without an active wound

Treating physician: responsible physician (this could be either the general practitioner, the dermatologist, the physician assistant, specialized nurse or the internist depending on treatment setting)

Initial compression therapy: the initial form of compression therapy aiming to resolve edema (e.g. bandages, temporary compression hosiery, or adjustable compression devices). This type of compression is usually used until the elastic compression stocking is delivered.

Villalta scores: a clinical decision rule (CDR) combining items on patient's complaints, and findings of physical examination of the leg. This CDR makes the diagnosis when for post-thrombotic syndrome (a complication of deep venous thrombosis) when the total score is 5 or higher at least 6 months after the onset of DVT.

Medical stocking supplier/skin therapist: the medical stocking supplier and the skin therapist have the same function in the process.



**Figure S5.1** Process of elastic compression therapy: brief overview.

## Appendix 5.2 Modified Delphi questionnaires round 1-3

### Round 1

#### Participant Information

*Before starting the actual questionnaire we would like to ask you to answer the following questions regarding your background.*

**Do you agree to participate in this modified Delphi analysis?**

- Yes
- No → directed to the end of the survey

**Which function do you have in the process of elastic compression therapy?**

- Health care professional
- A managerial or policy-related function → directed to how many years of experience in the field of elastic compression stocking therapy do you have?
- Health care professional combined with a managerial or policy-related function
- Patient → directed to for what indication do you / did you wear elastic compression stockings?

**How many deep venous thrombosis patients do you assess annually?**

- No patients
- 0-25 patients
- 25-50 patients
- 50-100 patients
- > 100 patients

**How many chronic venous disease patients (CEAP stadium C4 or C5) who are conservatively treated do you assess annually?**

- No patients
- 0-25 patients
- 25-50 patients
- 50-100 patients
- > 100 patients

**How many years of experience in the field of elastic compression stocking therapy do you have?**

- 0-5 years
- 6-10 years
- 11-20 years
- > 20 years

**What is your discipline?**

- Vascular medicine
- Hematology
- Dermatology
- General practitioner
- Medical stocking supplier/skin therapist
- Occupational therapy
- Home care
- Emergency room nurse
- Resident internal medicine/emergency room physician

**Have you ever been involved in the development of a guideline?**

- Yes
- No

**For what indication do you / did you wear elastic compression stockings? (Only for patients)**

- Deep venous thrombosis
- Chronic venous disease
- I do not know

**Have you been involved in the earlier stages of this study as a local stakeholder?**

- Yes → directed to the end of participant information
- No

**In which region do you work?**

- Limburg
- North-Holland

**General statements\***

*The following two statements will be directed at the entire process of elastic compression stocking therapy. If a statement does not include a specific indication (deep venous thrombosis or chronic venous disease), the statement includes both diseases.*

1. Active involvement of the patient and (if relevant) their informal caregiver in the decision-making process improves the chance of independence in the treatment process
2. It is important to improve collaboration and dissemination of knowledge among health care professionals involved in elastic compression therapy

**Initial compression therapy\***

*The following statements will be directed at the initial compression phase. From the moment elastic compression therapy is indicated until the moment the patient visits the medical stocking supplier for an intake consult. The timeline indicates the time phase the statement is directed at.*

Initial compression therapy	Onset of elastic compression stocking therapy	Implementation of assistive devices	Follow-up
-----------------------------	---	-------------------------------------	-----------

3. It is important that both patients with deep venous thrombosis and chronic venous disease (with edema) receive initial compression therapy
4. It is important that the treating physician structurally asks patients about their goals and wishes regarding self-reliance in the process, and considers them in the selection of a specific type of initial compression therapy
5. The treating physician needs to provide general information regarding the options of using assistive devices to maintain self-reliance during the use of elastic compression stockings at the time of diagnosis
6. The treating physician is responsible for determining the indication, the pressure class, and the type of elastic compression stocking. This information should be included in the referral to the medical stocking supplier

Initial compression therapy		Onset of elastic compression stocking therapy	Implementation of assistive devices	Follow-up
-----------------------------	--	---	-------------------------------------	-----------

7. Patients who do not require home care assistance for initial compression therapy can assess whether edema has disappeared without the interference of a health care professional, and then make an appointment with the medical stocking supplier
8. If home care nurses are involved to apply and remove the initial compression therapy, they are responsible to assess whether the edema has disappeared and to instruct the patient to contact the medical stocking supplier

**Onset of the elastic compression stocking and implementation of assistive devices\***

*The following statements will be directed at the onset of the elastic compression stocking and the implementation of assistive devices. From the moment the first contact with the medical stocking supplier takes place until the implementation of assistive devices (including training if necessary).*

Initial compression therapy		Onset of elastic compression stocking therapy	Implementation of assistive devices	Follow-up
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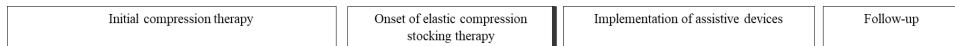
9. It is important that the medical stocking supplier explicitly asks for the presence of edema during the first telephonic contact with the patient

Initial compression therapy		Onset of elastic compression stocking therapy	Implementation of assistive devices	Follow-up
-----------------------------	--	---	-------------------------------------	-----------

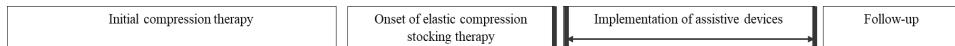
10. At the moment the elastic compression stocking is delivered, a physical follow-up appointment with the medical stocking supplier needs to take place to fit the stocking and discuss possibilities for self-reliance

Initial compression therapy		Onset of elastic compression stocking therapy	Implementation of assistive devices	Follow-up
-----------------------------	--	---	-------------------------------------	-----------

11. The medical stocking supplier is primarily responsible for assessing the patient's ability to maintain self-reliance in using an assistive device



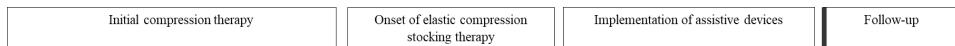
12. The medical stocking supplier needs to instruct and train the patient in using an assistive device. If it appears that the patient is not functioning self-reliant at this time, the medical stocking supplier needs to assess whether additional training is useful
13. It is the medical stocking suppliers (primary) responsibility to discuss the referral to the occupational therapist for additional training with patients who are not directly functioning self-reliant after instruction and training of an assistive device



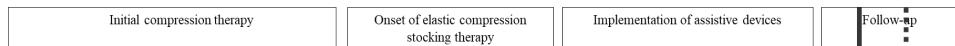
14. The most suitable approach to select an assistive device (with the medical stocking supplier or occupational therapist) is based on the patient's physical characteristics; goals and wishes, and (if relevant) possibilities to involve the informal caregiver in the process

#### Follow-up\*

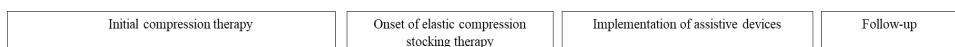
*The following statements will be directed at the follow-up phase. From the moment the patient applies the elastic compression stocking self-reliantly or with home care assistance until the moment the indication for elastic compression therapy ends (for patients with deep venous thrombosis).*



15. For patients with chronic venous disease, it is important to schedule a follow-up appointment with the treating physician after the elastic compression stocking is delivered



16. It is important to individualize deep venous thrombosis patients' treatment duration with elastic compression stockings based on a risk assessment using Villalta scores with a minimum treatment duration of six months
17. Patients with deep venous thrombosis need to have follow-up appointments with the treating physician until the treatment duration with elastic compression stockings is established (generally after 6 or 12 months)



18. When the treatment duration is established, the treating physician should send a letter to the general practitioner which minimally includes any additional follow-up appointments required and the advised treatment duration
19. All patients should have annual physical follow-up appointments with the medical stocking supplier (as long as the treatment indication lasts) to check and (if necessary) re-measure the elastic compression stocking
20. If the treating physician changes during the treatment period, the first treating physician should inform all involved professionals about this change
21. When elastic compression therapy needs to be discontinued (e.g. because of the development of contra-indications or end of treatment duration) the treating physician should inform all involved health care professionals

Thank you for filling out our survey. We will process all answers and soon invite you for the second round of this analysis.

\* All statements were provided with the following answer options and an open field text box.

Strongly disagree	Disagree	Somewhat disagree	Undecided	Somewhat agree	Agree	Strongly agree	Insufficiently informed
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## Round 2

### General information

Dear participant,

We would like to extend our gratitude to everyone for participating in the first questionnaire of our modified Delphi study. We reached consensus on 14 out of 21 statements. These statements are provided in the supplementary file.

In this second questionnaire, you will receive feedback from the non-consensus statements of the first questionnaire. Some statements underwent modifications based on the qualitative responses provided. We kindly ask you to re-assess the statements. Additionally, six statements regarding barriers to implementation were added to the current questionnaire. This questionnaire will take approximately 15 minutes of your time.

#### Instructions:

5. We kindly ask you to take a look at the 'overview of elastic compression therapy' figure added in the supplementary information. We recommend you use the figure to guide you through the time consecutive elements of the survey. Additionally, an explanatory list of medical terms can be found in the supplementary information.
6. Please answer all statements, you will be allowed to add comments after each statement. We encourage you to do so, especially if you do not agree with the statement.

7. If you feel like you lack the information to assess the statement, or it is not within your expertise please choose 'insufficiently informed'
8. The maximum response time for this survey is two weeks.

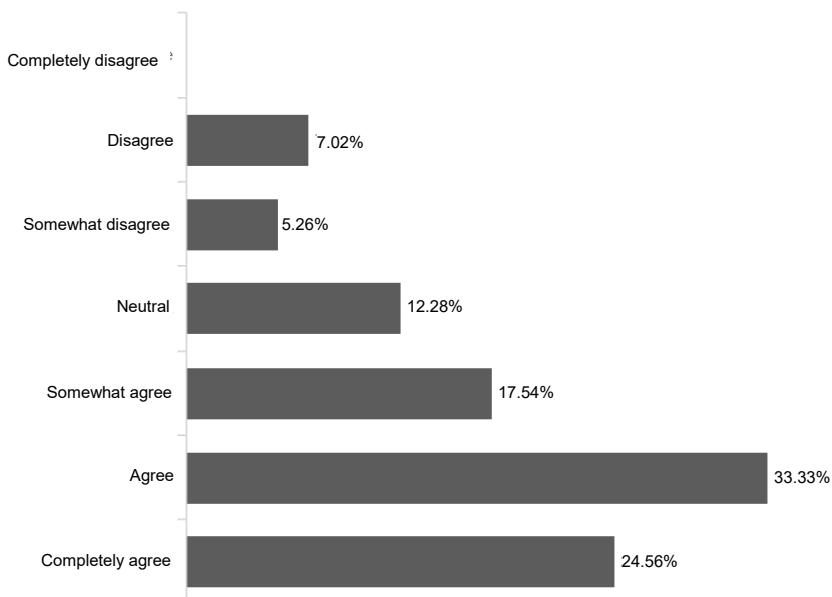
### Non-consensus statements round 1

The next 7 statements did not receive consensus in questionnaire 1 (defined as < 75% of participants scoring a 6 (agree) or 7 (totally agree) on the Likert score)). Both quantitative and qualitative feedback is given per statement. We ask you to re-assess the statement after reading this feedback.

#### Initial compression therapy\*

**Statement 5: It is important that the treating physician provides general information regarding the options of using assistive devices to maintain self-reliance during the use of elastic compression stockings at the time of diagnosis**

#### Response (n=57)



#### Summary of qualitative responses (n=30):

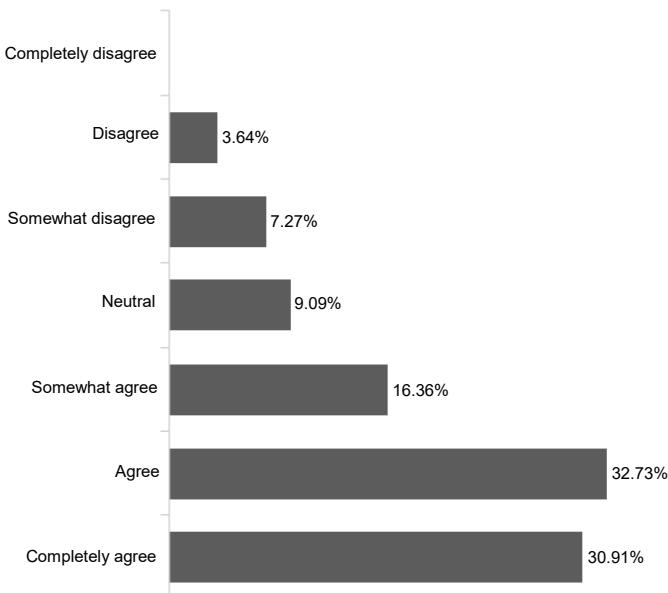
- 57.9% of the respondents agreed or completely agreed with the statement, including all patients.
- Respondents stated that giving this information early in the process could benefit the patient's acceptance of the ECS and repeating information during the process is necessary.

- Some respondents (n=3, mainly patients) stated that there is a lack of information regarding assistive devices during the entire process.
- Some respondents (n=5) stated that there is a lack of expertise and time to provide this information (especially at the emergency room) and it would be better to assign this task to the medical stocking supplier (n=6).
- Two professionals stated that they were concerned that patients receive too much information at the moment of diagnosis.

**Statement 5 (minor adaptation):** The treating physician needs to provide general information regarding the options of using assistive devices to maintain self-reliance during the use of elastic compression stockings at the time of diagnosis (either written or oral)

**Statement 6:** The treating physician is responsible for determining the indication, the pressure class, and the type of elastic compression stocking. This information should be included in the referral to the medical stocking supplier

Respons (n=55)



#### Summary of qualitative responses (n=23)

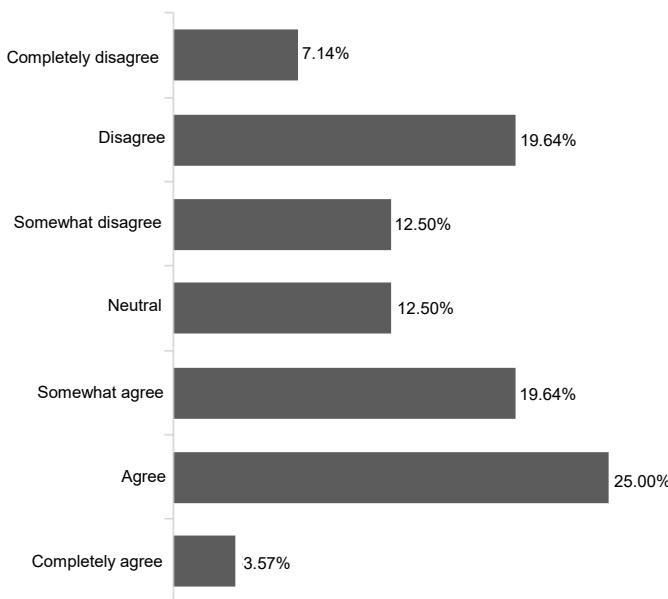
- 63.6% of the respondents agreed or completely agreed with the statement, of whom 87.5% of the medical stocking suppliers.
- Other respondents from different disciplines (n=12) stated that treating physicians lack the knowledge to determine the appropriate compression

strength and type and it would be better to assign this task with the medical stocking supplier.

- One medical stocking supplier indicated that external financial incentives trigger a reticent attitude towards implementing more expensive ECS for medical stocking suppliers.

**Statement 6 (without adaptations): The treating physician is responsible for determining the indication, the pressure class, and the type of ECS. This information should be included in the referral to the medical stocking supplier**

**Statement 7: Patients who do not require home care assistance for initial compression therapy can assess whether edema has disappeared without the interference of a health care professional, and then make an appointment with the medical stocking supplier**  
Respons (n=56)



**Summary of qualitative responses (n=27):**

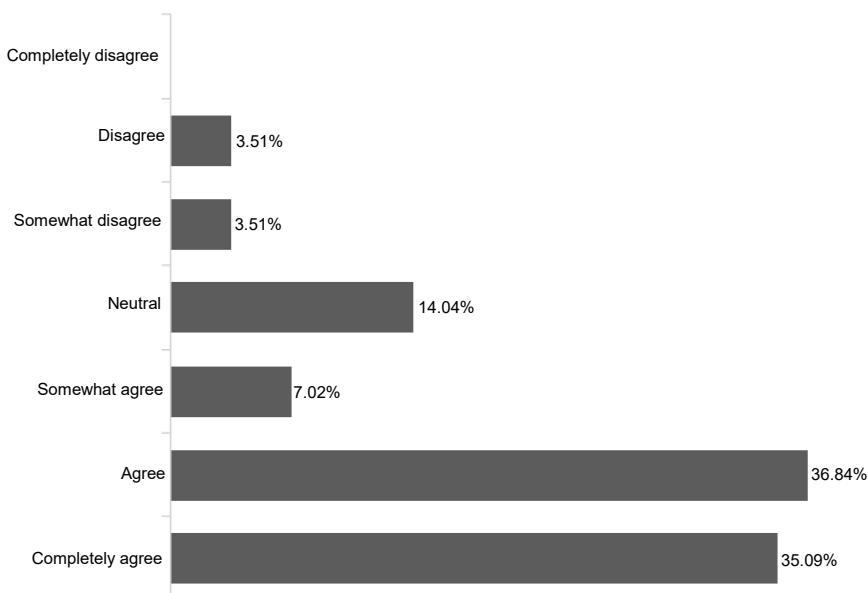
- The results on this statement vary, resulting in a small consensus rate (28.6%). Only 14.3% of patients and 0% of medical stocking suppliers agreed with the statement.
- Over 50% of respondents from different disciplines indicated that only some patients can assess the edema self-reliant (patients with sufficient cognitive functioning and awareness).
- Approximately 33% of respondents from different disciplines suggested that the medical stocking supplier or treating physician should be responsible to assess the edema.

**Statement 7 (major adaptation):** For patients who do not need home care assistance, the medical stocking supplier needs to assess the presence of edema during the use of initial compression therapy before fitting the ECS.

**The onset of the elastic compression stocking and implementation of assistive devices\***

**Statement 11:** The medical stocking supplier is primarily responsible for assessing the patient's ability to maintain self-reliance in using an assistive device

**Respons (n=57):**



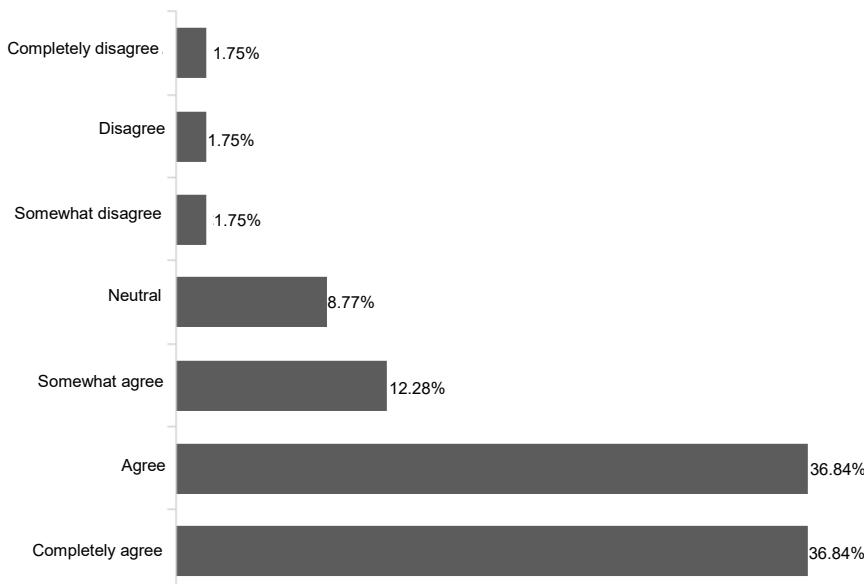
**Summary of qualitative responses (n=39)**

- 71.9% of the respondents agreed or completely agreed with the statement.
- Part of the respondents (n=7) stated that it is especially important that the medical stocking supplier globally assesses if the patient is self-reliant without an assistive device or by using a resistance-reducing device, and provides a single training and instruction moment. The patient needs to be referred to the occupational therapist to train more advanced assistive devices.
- Two professionals suggest that this assessment should be done by the occupational therapist.
- Some respondents (n=5; occupational therapists, general practitioners, and home care nurses) suggest that the medical stocking supplier should contact the home care nurse (if involved) to achieve further information regarding the patient's cognitive- and physical functioning before assessing the patient.

**Statement 11 (minor adaptation):** The medical stocking supplier needs to assess the patient's ability to maintain self-reliance without the use of an assistive device or by using a resistance-reducing device, and provide a single training and instruction moment.

**Statement 12:** The medical stocking supplier needs to instruct and train the patient in using an assistive device. If it appears that the patient is not functioning self-reliant at this time, the medical stocking supplier needs to assess whether additional training is useful

**Respons (n=57)**



**Summary of qualitative responses (n=17):**

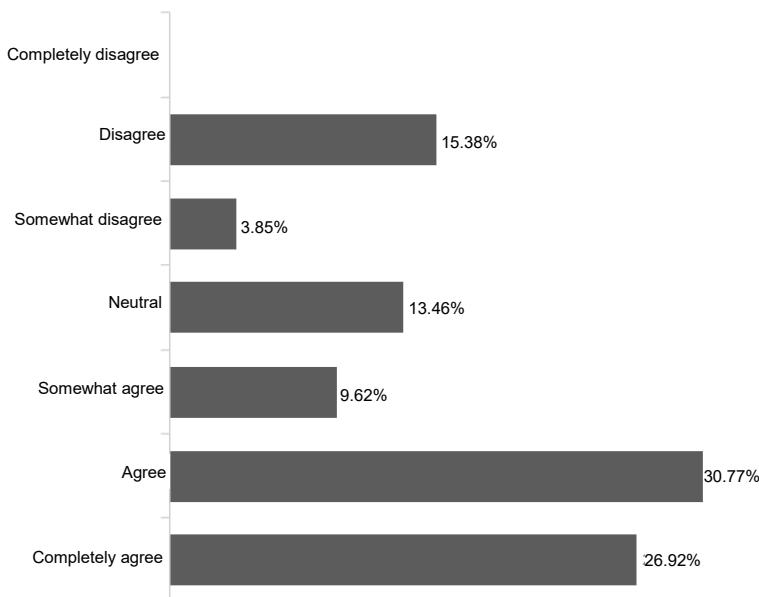
- 73.7% of the respondents agreed or completely agreed with the statement of whom 62.5% of medical stocking suppliers and 66.7% of occupational therapists.
- One medical stocking supplier indicated that with the current reimbursement system, reward, and available time, it is difficult to extensively train the patient in how to use an assistive device.
- Two respondents (one patient and one home care nurse) indicated that in current practice, some patients are referred back to the general practitioner or home care organization without any information or training in using an assistive device.

**Statement 12 (minor adaptation):** If it appears that the patient is not functioning self-reliant without an assistive device or with a resistance reducing assistive device, the medical stocking supplier needs to assess whether additional training is useful

**Follow-up\***

**Statement 15:** For patients with chronic venous disease, it is important to schedule a follow-up appointment with the treating physician after the elastic compression stocking is delivered

Respon (n=52)



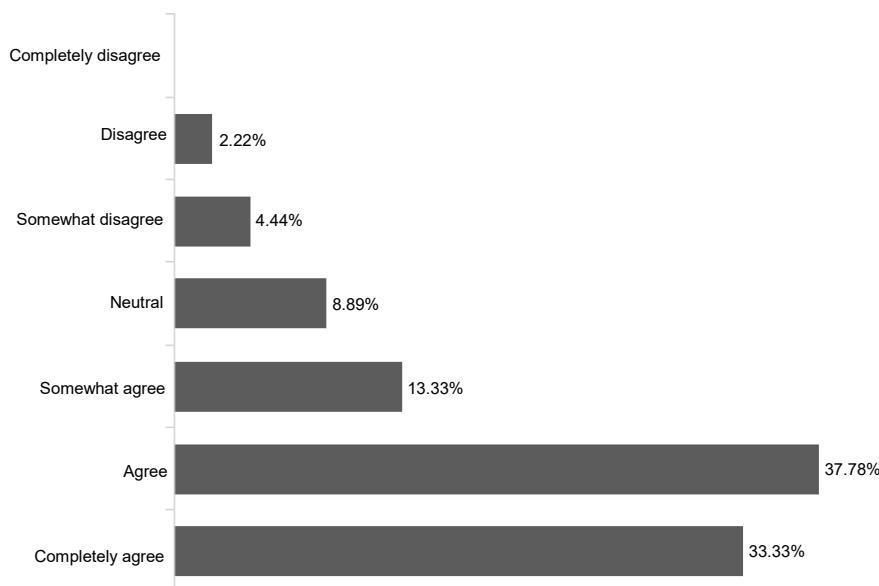
**Summary of qualitative responses (n=25):**

- 57.7% of the respondents agreed or completely agreed with the statement of whom 88.3% of patients.
- A large part of respondents stated that performing follow-up is important to assess treatment effects, evaluate sufficient use of the ECS, and enhance the patient's motivation and compliance therapy.
- One respondent suggested that follow-up could also be provided by the general practitioner instead of the treating physician (in case it is a dermatologist or internist), and follow-up is only necessary for the first ECS prescription.
- Another part of respondents from different disciplines (n=4 of whom one patient) indicated that follow-up is not necessary if patients can recognize problems themselves (and inform their physician) or if there are no problems.
- Some respondents from different disciplines (n=3) stated that follow-up should be performed by the medical stocking supplier.

**Statement 15 (minor adaptation): For patients with chronic venous disease, it is important to schedule a follow-up appointment with the treating physician after the elastic compression stocking is delivered (only for the first prescription)**

**Statement 16: It is important to individualize deep venous thrombosis patients' treatment duration with elastic compression stockings based on a risk assessment using Villalta scores with a minimum treatment duration of six months**

**Respons (n=45)**



**Summary of qualitative responses (n=18):**

- 71.1% of the respondents agreed or completely agreed with the statement.
- Some respondents (n=3, medical stocking supplier and internists) indicated that there is sufficient evidence to individualize the treatment duration based on Villalta scores.
- One respondent (dermatologists) is concerned about the long-term effects of this strategy in developing post-thrombotic syndrome.
- Two professionals (internist and general practitioner) are not convinced that a treatment duration of six months is necessary for all patients.
- Two professionals (dermatologists) suggested adding a duplex to the follow-up in addition to assessing Villalta scores.

**Statement 16 (without adaptation): It is important to individualize deep venous thrombosis patients' treatment duration with elastic compression stockings based on a risk assessment using Villalta scores with a minimum treatment duration of six months**

**New barrier statements round 2\***

1. There is a lack of knowledge among treating physicians regarding different types of initial compression therapy
2. There is a lack of knowledge among treating physicians to inform patients about assistive devices at the moment of diagnosis
3. There is a lack of knowledge among treating physicians to determine the appropriate strength and type (circular or flat-knit) elastic compression stocking
4. Variable reimbursement criteria are a barrier to optimally select initial compression therapy and assistive devices
5. The administrative burden of achieving reimbursement for assistive devices is a barrier to optimal selection
6. Home care nurses and staff applying multilayer compression bandages at the general practice lack expertise to apply them with appropriate quality which extends the duration of initial compression therapy

Thank you for filling out our survey. We will process all answers and soon invite you for the last round of this analysis.

\* All statements were provided with the following answer options and an open field text box.

Strongly disagree	Disagree	Somewhat disagree	Undecided	Somewhat agree	Agree	Strongly agree	Insufficiently informed
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### Round 3

#### General information

Dear participant,

We would like to extend our gratitude to everyone for participating in the first questionnaire of our modified Delphi study. We reached consensus on 5 out of the remaining 7 statements. These statements are provided in the supplementary file.

We kindly ask you to re-assess the statements two statements that did not reach consensus in round 2. Additionally, 1 new barrier statement was added to the current questionnaire. This questionnaire will take approximately 5 minutes of your time.

Instructions:

1. Please answer all statements, you will be allowed to add comments after each statement. We encourage you to do so, especially if you do not agree with the statement.

2. If you feel like you lack the information to assess the statement, or it is not within your expertise please choose 'insufficiently informed'
3. The maximum response time for this survey is two weeks.

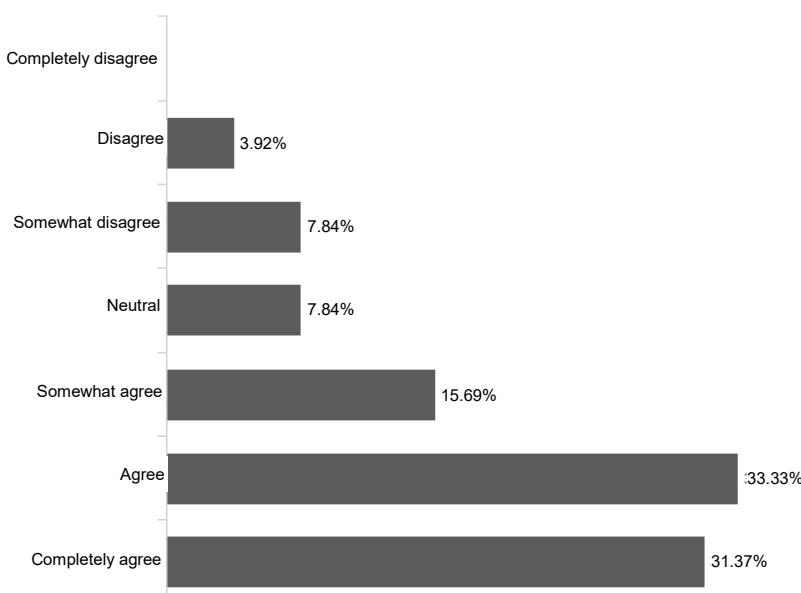
### Non-consensus statements round 2

The next 2 statements did not receive consensus in questionnaire 1 (defined as < 75% of participants scoring a 6 (agree) or 7 (totally agree) on the Likert score)). Both quantitative and qualitative feedback is given per statement. We ask you to re-assess the statement after reading this feedback.

#### Initial compression therapy\*

**Statement 6:** The treating physician is responsible for determining the indication, the pressure class, and the type of elastic compression stocking. This information should be included in the referral to the medical stocking supplier

Respons (n=51)



#### Summary of qualitative responses (n=27):

- 64.7% of the respondents agreed or completely agreed with the statement of whom 50% of the medical stocking suppliers and 71.43% of treating physicians.
- A large part of respondents (n=10) from different disciplines indicated that treating physicians (in particular general practitioners) lack the knowledge to determine the appropriate stocking type and in some cases even the appropriate pressure class.

They suggested that the medical stocking supplier should determine the stocking type.

- Another part of respondents (n=4) stated that treating physicians should determine the appropriate pressure class and stocking type since they are aware of the diagnosis, contraindications, etc. Even more, since treating physicians are (as opposed to medical stocking suppliers) not exposed to financial constraints.
- Two respondents indicated that treating physicians are responsible to include this information in the referral, if they lack this knowledge, they should not treat these patient groups (n=2).
- One respondent suggested that it should be considered to prescribe adjustable compression devices instead of prescribing elastic compression stockings (by default). However, treating physicians lack knowledge regarding this type of compression.

**Statement 6.1 (minor adaptation): The treating physician is responsible for determining the elastic compression stocking indication, the pressure class, and if a custom-made elastic compression stocking is necessary or if a ready-made elastic compression stocking is sufficient. This information should be included in the referral to the medical stocking supplier**

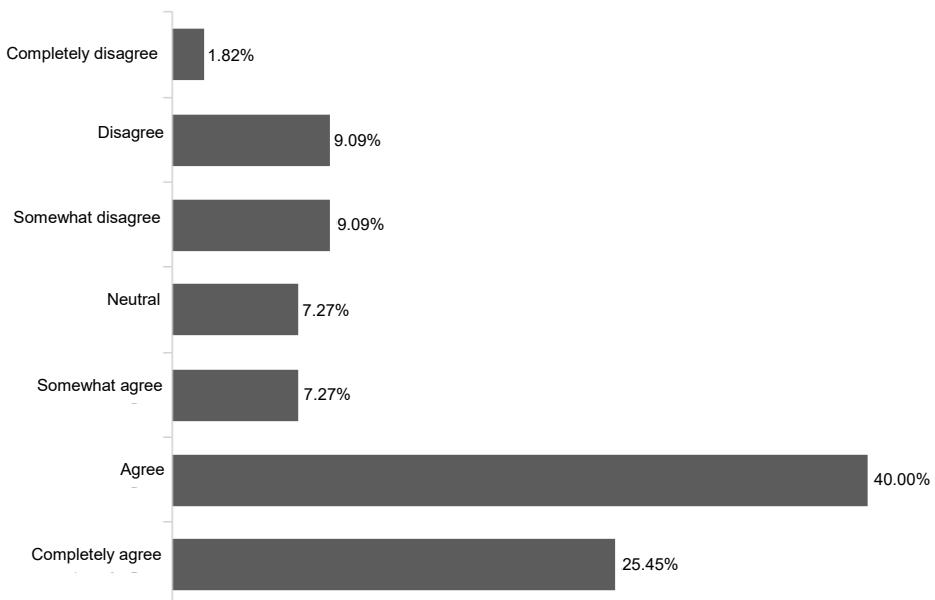
In addition, there seems to be consensus that a solid referral from the treating physician to the medical stocking supplier is necessary. However, we did not yet reach consensus on the content of the referral. Therefore, we ask you to assess the next (further refined) statement independently from statement 6.1.

**Statement 6.2 (major adaptation): The treating physician is responsible for determining the elastic compression stocking indication and the pressure class, and to include this information in the referral to the medical stocking supplier**

**Follow-up\***

**Statement 15: For patients with chronic venous disease, it is important to schedule a follow-up appointment with the treating physician after the elastic compression stocking is delivered (only for the first prescription)**

**Respons (n=55)**



**Summary of qualitative responses (n=22):**

- 65.45% of the respondents agreed or completely agreed with the statement of whom 50% of the medical stocking suppliers and 57.14% of treating physicians (only 12.5% of general practitioners agreed or completely agreed).
- Five respondents from different disciplines indicated that follow-up is not necessary if patients can recognize problems themselves (and inform their physician) or if there are no problems.
- Seven respondents from different disciplines stated that follow-up appointments are necessary to evaluate the effectiveness of treatment.
- One respondent (home care nurse) indicated that a follow-up appointment should be conducted by default since it is difficult to estimate if a patient can recognize problems, which poses the risk that patients do not use the elastic compression stockings appropriately.
- Some respondents from different disciplines (n=4) indicated that follow-up appointments are not necessary by default since it is too expensive to perform follow-up only to evaluate the use of elastic compression stockings. Furthermore, treating physicians are already fully booked and experience high working pressure. This care could be provided by the medical stocking supplier or skin therapist (n=5).

**Statement 15:** For patients with chronic venous disease, it is important to schedule a follow-up appointment with the treating physician within several weeks after delivery of the elastic compression stocking (only for the first prescription) to check the fitting, usage and self-reliance.

**New barrier statements round 3\***

The need to obtain prior permission from some insurance companies necessary for the implementation of more advanced assistive devices to receive coverage, and delivery times are a barrier for optimal implementation of these devices.

Thank you for filling out our survey. We will process all answers and keep you updated regarding the progress of the protocol.

\* All statements were provided with the following answer options and an open field text box.

Strongly disagree	Disagree	Somewhat disagree	Undecided	Somewhat agree	Agree	Strongly agree	Insufficiently informed
<input type="radio"/>							

## Appendix 5.3 Final statements and consensus levels per questionnaire round

Statement	Round 1		Round 2		Round 3	
	Count Agreement n (%)		Count Agreement n (%)		Count Agreement n (%)	
<b>General statements</b>						
1. Active involvement of the patient and (if relevant) their informal caregiver in the decision-making process improves the probability of independence in the treatment process	59	55 (93)	NA	NA	NA	NA
2. It is important to improve collaboration and dissemination of knowledge among health care professionals involved in elastic compression therapy	59	53 (90)	NA	NA	NA	NA
<b>Initial compression therapy</b>						
3. Both patients with deep venous thrombosis and chronic venous disease (with edema) need to receive initial compression therapy	50	38 (76)	NA	NA	NA	NA
4. The treating physician should structurally ask patients about their goals and wishes regarding self-reliance in the process and considers them in the selection of a specific type of initial compression therapy	58	45 (78)	NA	NA	NA	NA
5. The treating physician needs to provide general information regarding the options of using assistive devices to maintain self-reliance during the use of elastic compression stockings at the time of diagnosis (either written or oral)	57	33 (58)	57	43 (75)	NA	NA
6. The treating physician is responsible for determining the indication, the pressure class, and the type of ECS. This information should be included in the referral to the medical stocking supplier	55	35 (64)	51	33 (65)	See 6.1 and 6.2	NA
6.1. The treating physician is responsible for determining the indication, the pressure class and to determine if custom made or standard stockings are indicated.		N.A.		N.A.	51	21 (41)
6.2. The treating physician is responsible for determining the indication and pressure class of ECS. This information should be included in the referral to the medical stocking supplier.		N.A.		N.A.	53	42 (79)
7. For patients who do not need home care assistance, the medical stocking supplier needs to assess the presence of edema during the use of initial compression therapy before fitting the ECS*	56	16 (29)	57	44 (77)	NA	NA
8. If home care nurses are involved to apply and remove the initial compression therapy, they are responsible to assess whether the edema has disappeared in direct consultation with the medical stocking supplier. And to subsequently instruct the patient to contact the medical stocking supplier	54	41 (76)	NA	NA	NA	NA
<b>Onset of the elastic compression stocking and implementation of assistive devices</b>						
9. The medical stocking suppliers office should explicitly ask for the presence of edema during the first telephonic contact with the patient	53	40 (76)	NA	NA	NA	NA

Statement	Round 1		Round 2		Round 3	
	Count	Agreement n (%)	Count	Agreement n (%)	Count	Agreement n (%)
10. At the moment the elastic compression stocking is delivered, a physical follow-up appointment with the medical stocking supplier needs to take place to fit the stocking and discuss possibilities for self-reliance	57	52 (91)	NA	NA	NA	
11. The medical stocking supplier is primarily responsible for assessing the patient's ability to maintain self-reliance in using an assistive device	57	41 (72)	56	47 (84)	NA	
12. The medical stocking supplier needs to instruct and train the patient in using an assistive device. If it appears that the patient is not functioning self-reliant at this time, the medical stocking supplier needs to assess whether additional training is useful	57	42 (74)	56	45 (80)	NA	
13. It is the medical stocking suppliers (primary) responsibility to discuss the referral to the occupational therapist for additional training with patients who are not directly functioning self-reliant after instruction and training of an assistive device	56	43 (77)	NA	NA	NA	
14. The most suitable approach to select an assistive device is based on the estimated patient's physical characteristics and cognitive functioning; goals and wishes; and (if relevant) possibilities to involve the informal caregiver in the process	54	48 (89)	NA	NA	NA	
<b>Follow-up</b>						
15. For patients with chronic venous disease, it is important to schedule a follow-up appointment with the treating physician within several weeks after the elastic compression stocking is delivered (only for the first prescription) to check the fitting, adherence to therapy and self-reliance. The treating physician can delegate this care to another qualified health care professional.*	52	30 (58)	55	36 (66)	56	30 (54)
16. It is important to individualize deep venous thrombosis patients' treatment duration with elastic compression stockings based on a risk assessment using Villalta scores with a minimum treatment duration of six months	45	32 (71)	43	36 (84)	NA	
17. Patients with deep venous thrombosis need to have follow-up appointments with the treating physician until the treatment duration with elastic compression stockings is established (generally after 6 or 12 months)	53	43 (81)	NA	NA	NA	
18. If the treating physician changes from secondary to primary care during the treatment period, the treating physician should send a letter to the general practitioner which minimally includes the advised treatment duration	55	46 (84)	NA	NA	NA	
19. All patients should have annual physical follow-up appointments with the medical stocking supplier (as long as the treatment indication lasts) to check and (if necessary) re-measure the elastic compression stocking	55	46 (84)	NA	NA	NA	

Statement	Round 1		Round 2		Round 3	
	Count n (%)	Agreement	Count n (%)	Agreement	Count n (%)	Agreement
20. If the treating physician changes from secondary to primary care during the treatment period, the first treating physician should inform the patient, general practitioner, and home care organization (if involved)	57	43 (75)		NA		NA
21. When elastic compression therapy needs to be discontinued, the treating physician should inform the patient, the medical stocking supplier, and the home care organization (if involved)	57	46 (81)		NA		NA

\* These statements underwent major modifications throughout the questionnaire rounds as presented in Supplementary information 2.





# Chapter 6

Budget impact of three improvement topics for  
compression therapy for patients with deep venous  
thrombosis in the Netherlands

**EMBARGOED**

Schreurs RHP, Joore MA, De Brujin-Geraets DP, Ten Cate H, Ten Cate-Hoek AJ

*Submitted*

# Chapter 7

## Domein overstijgend ketenprotocol compressietherapie Voor de 1<sup>e</sup> en 2<sup>e</sup> lijnszorg

Schreurs R.H.P., Joore M, Ten Cate-Hoek A.J.,

**Mede beoordeeld door:**

Prof. Dr. E. Klok, Prof. Dr. M. Huisman (NIV/NVIVG)

Mevr. E. Ploeg & Mevr. D. Hoekstra (v&vn)

Kees Stuyt (Nederlandse vereniging compressiezorg)

Dhr. T. Potveer, Mevr. D. Spiering, Mevr. K. Kusters, Mevr. E. Hagedoren, Mevr. L. van de Ven-Stevens, Mevr. D. Wassink (Ergotherapie Nederland)

Mevr. Y. Roumen (Nederlandse Vereniging van Huidtherapeuten)

Dit protocol is onderdeel van een implementatieproject gefinancierd door ZonMw, grant nummer 84300095003. Dr. A.J. ten Cate-Hoek is arts-klinisch epidemioloog en projectleider, Prof. Dr. M.A. Joore is professor of Health Technology Assessment & Decision-Making en projectlid, drs. Schreurs is promovenda op dit project.

## Voorwoord

Compressietherapie is een veelvuldig voorgeschreven behandelmodaliteit in Nederland. Dit domein overstijgend ketenprotocol richt zich met name op patiënten met een acute diep veneuze trombose (DVT) en patiënten met chronische veneuze ziekte (CVZ) CEAP-stadium C3-C5 die conservatief behandeld worden. Voor deze laatste groep patiënten is compressietherapie de hoeksteen van de conservatieve behandeling. Voor het geven van compressietherapie werken meerdere zorgprofessionals met elkaar samenwerken om optimale zorg te bieden aan de patiënt. In de praktijk blijkt dat het aangaan van deze samenwerkingsverbanden complex is o.a. vanwege het aantal betrokken zorgverleners en onduidelijkheid over taken en verantwoordelijkheden. Daarnaast blijkt dat de benodigde kennis met betrekking tot essentiële onderdelen van compressietherapie vaak ontbreekt. Aanbevelingen uit lokale protocollen en richtlijnen variëren sterk van elkaar qua inhoud en uitgebreidheid. Vanwege deze complexiteit is het noodzakelijk een leidraad te geven hoe dit proces optimaal kan worden ingericht.

In het rapport “Verbetersignalement Diep veneuze trombose en longembolie” gepubliceerd door de commissie Zinnige Zorg (September 2021) werd aangegeven dat voor een optimale uitvoering van compressietherapie er moet worden voldaan aan de volgende kernvoorwaarden: voldoende kennis over compressie bij zorgprofessionals, er dienen goed onderbouwde en consistente richtlijnen te zijn, en er dient een controle traject te zijn ingericht voor compressietherapie.

Dit domein overstijgend ketenprotocol baseert zich op de huidige richtlijnen en beschrijft de optimale inrichting van compressietherapiezorg in de keten. Het protocol werd ontwikkeld in samenwerking met zorgprofessionals en velddeskundigen uit de zorgketen voor compressie. Ook werden patiënten met DVT en CVZ geconsulteerd en zijn hun ervaringen en behoeften meegenomen bij het opstellen van dit protocol. DVT- en CVZ-patiënten kunnen zowel in de tweede lijn (ziekenhuis) als in de eerste lijn (huisarts) behandeld worden. In de praktijk zien we dat de zorg voor patiënten met een DVT vaak (initieel) in de tweede lijn belegd is en dat patiënten met CVZ grotendeels door de huisarts behandeld worden. De beroepsgroepen die in Nederland compressiezorg verlenen bestaan uit de bandagist (oftewel compressietherapeut), de oedeem-fysiotherapeut en de huidtherapeut, in dit protocol worden zij gezamenlijk genoemd als compressiespecialist.

Dit protocol is ingedeeld in drie fasen:

1. Starten van compressietherapie
2. Verstrekken van de definitieve therapeutische elastische kous en selecteren van hulpmiddelen
3. Uitvoeren van follow-up (onderverdeeld in follow-up en behandelduur voor DVT-patiënten en follow-up voor CVZ-patiënten).

Daarnaast wordt beschreven 1. Wat kritische zorg- of beslismomenten zijn, 2. Wie in welke situatie verantwoordelijk is voor welke handeling en 3. Hoe afstemming van het beleid wordt bereikt door communicatie in de keten. Het startpunt van dit protocol is het moment dat een arts het onderliggend lijden van de patiënt heeft vastgesteld, en vervolgens de indicatie voor compressietherapie heeft gesteld, inclusief het uitsluiten van contra-indicaties (zie hulpkaart contra-indicaties, Bijlage 7.1).

Net zoals in de landelijke standaard antistolling (LSKA) onderscheiden we de volgende onderdelen in de zorg voorzien van een kleurcode:

- Kritische zorgmomenten/beslismomenten voor het verlenen van optimale zorg voor patiënten met compressietherapie (rood).
- Handelingen van de betrokken zorgverlener in genoemde situaties en verantwoordelijkheden hij/zij draagt (oranje).
- Communicatie en afstemming in de keten (groen). Alle handelingen en momenten van afstemming dienen gevolgd te worden om te komen tot veilige en optimale uitvoering van compressietherapie.

Dit protocol beschrijft de verschillende fases en beslissingen die genomen dienen te worden tijdens compressietherapie, en aanbevelingen over het geven van optimale zorg. Deze module richt zich op efficiënt samenwerken, bevorderen van therapietrouw en zelfstandigheid van de patiënt, en maximaal behandeleffect. Per hoofdstuk wordt de communicatie met de patiënt beschreven (in bulletpoints) gevolgd door de benodigde communicatie tussen zorgverleners (te vinden in de tabellen) In Bijlage 7.12 vindt u een samenvattend stroomschema van het protocol.

## 1. Starten compressietherapie

Vanaf het moment dat de indicatie voor compressietherapie is gesteld, zijn tijdens de initiële compressie fase twee beslissingen kritisch voor het verlenen van optimale zorg voor patiënten:

- 1.1: Selecteren van het optimale type initiële compressietherapie en bepalen door wie de compressietherapie wordt uitgevoerd
- 1.2: Selecteren van de optimale drukklasse van de therapeutische elastische kous (vervolg compressietherapie).

**Beslissing 1: selecteren van het optimale type initiële compressietherapie en bepalen door wie de compressietherapie wordt uitgevoerd.**

Mogelijk betrokken zorgverleners: hoofdbehandelaar (medisch specialist/huisarts), thuiszorg (evt. de huidtherapeut als hierover regionale afspraken bestaan).

### HOOFDBEHANDELAAR

**Communicatie met de patiënt:**

- Beoogd effect van de behandeling
- Tijdsbeloop (te starten met initiële compressie waarna overgang op definitieve therapeutische elastische kous voor bepaalde/onbepaalde duur)
- Motiveert tot therapietrouw
- Type compressietherapie en gezamenlijke besluitvorming
- Legt aanvullende conservatieve maatregelen uit (zie hulpkaart conservatieve maatregelen, Bijlage 7.2)
- Geeft instructie over gebruik compressiemiddel.

### Selecteren van het optimale type initiële compressietherapie en bepalen door wie de compressietherapie wordt uitgevoerd

#### Hoofdbehandelaar:

Gaat na of patiënt een hoog-risico heeft op complicaties van compressietherapie of complicaties van de onderliggende ziekte (zie '[Hulpkaart indicaties doorverwijzing naar dermatologie/vaatchirurgie](#)', [Bijlage 7.3](#))

Bepaalt in overleg met de patiënt het optimale type initiële compressie en start dit op\*. Hiervoor kan gebruik worden gemaakt van '[Hulpkaart initiële compressie](#), [Bijlage 7.4](#)'

Beoordeelt of inzet van thuiszorg noodzakelijk is en regelt dit. Bij verwijzing naar de thuiszorg dient explicet te worden aangegeven wie de hoofdbehandelaar is tijdens behandeling met compressietherapie

<b>Communicatie en afstemming:</b>		
<i>Bij zelfstandig gebruik initiële compressietherapie</i>		
<b>Door wie</b>	<b>Naar wie</b>	<b>Wat</b>
Hoofdbehandelaar	Verpleegkundige/ doktersassistent**	De hoofdbehandelaar draagt er zorg voor dat het gekozen type initiële compressie wordt geïnstructureerd en gedemonstreerd (in geval van standaard tijdelijke compressiekous (35 mmHg) of klittenbandzwachtels)***
<i>Bij thuiszorg voor gebruik initiële compressietherapie</i>		
<b>Door wie</b>	<b>Naar wie</b>	<b>Wat</b>
Hoofdbehandelaar	Thuiszorg	Informeert de thuiszorg over reden/indicatie en de vorm van initiële compressietherapie, de verwachte duur van behandeling en frequentie, eventuele bijzonderheden en contactgegevens van de hoofdbehandelaar
Hoofdbehandelaar	Openbare apotheek/ leverancier verbandmiddelen	De hoofdbehandelaar verstrekkt bij start conventioneel zwachtelen een recept. Zie voorbeeldrecept zwachtelmateriaal, Bijlage 7.5
Hoofdbehandelaar	Dermatoloog/vaatchirurg	Overlegt en verwijst op indicatie naar de dermatologie of vaatchirurgie (zie hulppkaart)

\* Voor DVT patiënten dient de initiële compressietherapie het liefst binnen 24 uur na diagnose gestart te worden. Voor CVZ patiënten dient de initiële compressietherapie zo snel mogelijk gestart te worden als onderdeel van de gehele behandeling;

\*\* Per setting dienen hiervoor de verantwoordelijkheden worden vastgelegd (dit kan verschillen per behandelsetting).

\*\*\* Overwogen kan worden om een glijzak in te zetten om de zelfstandigheid te bevorderen tijdens initiële compressie therapie. Deze kosten worden momenteel (voor gebruik tijdens initiële compressie) niet vergoed door de verzekeraar.

## THUISZORG/HUIDTHERAPEUT (indien hierover regionale afspraken bestaan)

### Communicatie met de patiënt:

- Verifieert het doel van inzet thuiszorg voor de initiële compressiefase
- Instrueert de patiënt direct contact op te laten nemen bij: toenemende pijnklachten, het afzakken of losgaan van de zwachtels, kortademigheid, blauwe verkleuring van de tenen, en koorts + roodheid van het been.

<b>Uitvoering initiële compressietherapie (voor patiënten die thuiszorg nodig hebben)</b>		
<b>Thuiszorg/huidtherapeut:</b>		
Plant zo spoedig mogelijk, en bij DVT-patiënten indien mogelijk binnen 24 uur en maximaal 48 uur na aanmelding, een intakeconsult		
Maakt een zorgplan voor de patiënt naar de richtlijnen van de organisatie, waarin tenminste is opgenomen: de hoofdbehandelaar, de indicatie, het doel van de behandeling en de verwachte duur en frequentie van de behandeling		
Voert de initiële compressietherapie uit inclusief het opnieuw aanbrengen van de zwachtel als deze voortijdig zijn afgezakt		
Bepaalt (in samenspraak met de compressiespecialist) of het oedeem verdwenen is en instrueert de patiënt om een afspraak te maken voor een aanmeetconsult bij de compressiespecialist		
<b>Communicatie en afstemming:</b>		
<i>Bij thuiszorg voor gebruik initiële compressietherapie</i>		
Door wie	Naar wie	Wat
Thuiszorg/huidtherapeut	Hoofdbehandelaar	Bij problemen (kortademigheid, blauwverkleuring van de tenen, toename van pijn en verdenking erysipelas), of indien het oedeem na 4 weken behandeling nog niet verdwenen is, neemt de thuiszorg contact op met de hoofdbehandelaar voor overleg
Thuiszorg	Compressiespecialist (evt. via patiënt)	Instrukteert de patiënt een afspraak te maken voor een aanmeetconsult bij de compressiespecialist als het oedeem verdwenen is

## Beslissing 2: selecteren van de meest optimale therapeutische elastische kous (vervolg compressietherapie)

Mogelijk betrokken zorgverleners: hoofdbehandelaar

### HOOFDBEHANDELAAR

Communicatie met de patiënt met als doel de patiënt voor te bereiden op de volgende fase van compressietherapie. Deze informatie kan ook gedelegeerd worden aan een verpleegkundige of doktersassistent afhankelijk van de lokale afspraken.

- Instrukteert zelfstandige zelfredzame patiënten hoe ze zelf het oedeem kunnen beoordelen inclusief contacteren compressiespecialist en contactgegevens. Dit geeft een indicatie van de aanwezigheid van oedeem maar bij voorkeur wordt dit nog geverifieerd door de behandelaar. Zie '*Hulpkaart beoordelen oedeem, Bijlage 7.6*'
- Instrukteert zelfstandige zelfredzame patiënten contact op te nemen met de hoofdbehandelaar indien het oedeem na 4 weken nog niet verdwenen is.
- Verstrekt (mondeling of schriftelijk) algemene informatie over het gebruik van hulpmiddelen Zie '*Hulpkaart selectie hulpmiddelen, Bijlage 7.7*'.
- Plant een follow-up afspraak

- Verstrekt contactgegevens van de hoofdbehandelaar.

<b>Selecteren van de optimale therapeutische elastische kous (vervolg compressietherapie)</b>		
Bepaalt op basis van wetenschappelijk bewijs en eventuele contra-indicaties de drukklasse van de definitieve therapeutische elastische kous. Hiervoor kan gebruik worden gemaakt van het 'Hulpkaart keuze therapeutische elastische kous, Bijlage 7.8'		
<b>Communicatie en afstemming</b>		
Door wie	Naar wie	Wat
Hoofdbehandelaar	Compressiespecialist (evt. via patiënt)	De hoofdbehandelaar instrueert de zelfstandige zelfredzame patiënt hoe te beoordelen of het oedeem verdwenen is en wanneer de patiënt contact op moet nemen met de compressiespecialist
Hoofdbehandelaar	Compressiespecialist (evt. via patiënt)	De hoofdbehandelaar verstrekt een recept (afhankelijk van de lokale afspraken) voor de definitieve therapeutische elastische kous (link naar voorbeeldrecept, Bijlage 7.9). Op deze verwijzing staat tenminste: de indicatie, het aantal kousen (links/rechts), de drukklasse kous, de lengte van de kous, relevante patiëntkenmerken, een indicatie voor het functioneringsniveau van de patiënt en doelen m.b.t. zelfstandigheid

## 2. Verstrekken definitieve therapeutische elastische kous en selectie hulpmiddelen

Tijdens deze fase is er een kritisch moment voor het verlenen van optimale zorg voor patiënten:

### **Beslissing 1: Selecteren van het optimale hulpmiddel om zelfstandigheid te bevorderen.**

Mogelijk betrokken zorgverleners: compressiespecialist, ergotherapeut, thuiszorg.

#### **COMPRESSIESPECIALIST**

**Communicatie met de patiënt tijdens inplannen aanmeetconsult (telefonisch):** actief navragen of de patiënt van mening is dat het oedeem verdwenen is

#### **Communicatie met de patiënt tijdens het fysieke aanmeetconsult:**

- Verifieert de informatie opgenomen in de verwijzing van de hoofdbehandelaar
- Instrueert voortzetten initiële compressietherapie tot de definitieve therapeutische elastische kous aanwezig is
- Geeft aanvullende informatie over hulpmiddelen inclusief de voor- en nadelen ervan, en stimuleert de patiënt mee te denken over eigen wensen/doelen/fysieke mogelijkheden. Zie 'Hulpkaart selectie hulpmiddelen, Bijlage 7.7'

- In geval van twijfel zelfstandig functioneren actief vragen naar mogelijkheid mantelzorg te betrekken

**Communicatie met de patiënt tijdens pasconsult:**

- Bespreekt geformuleerde doelen/wensen met de patiënt
- Instrueert de patiënt bij eventuele problemen bij gebruik compressietherapie (bijv. technische problemen met de therapeutische elastisch kous of problemen met aan-en uittrekken) en wanneer met wie contact op te nemen

**Aanmeten, leveren van de definitieve therapeutische elastische kous en beoordelen mogelijkheden voor zelfstandigheid in het aanbrengen en uittrekken van de therapeutische elastische kous**

**Tijdens inplannen aanmeetconsult bij zelfstandige patiënten**

Vraagt bij het telefonische contact actief naar de status van het oedeem en plant een aanmeetconsult

**Tijdens aanmeetconsult**

Controleert of het oedeem verdwenen is. Als er nog te veel oedeem aanwezig is wordt beleid vastgesteld en een nieuw aanmeetconsult gepland

Bepaalt het type therapeutische elastische kous (als er regionale/lokale afspraken zijn dat de compressiespecialist het type kous bepaalt)

Meet de voorgeschreven therapeutische elastische kous aan en plant een pasconsult in

**Tijdens pasconsult**

Laat de patiënt de definitieve therapeutische elastische kous passen

Beoordeelt (op basis van patiëntkarakteristieken, cognitief functioneren, wensen van de patiënt en mogelijkheden om een mantelzorger te betrekken) of de patiënt met eenmalige uitleg en demonstratie in staat is de therapeutische elastische kous zelf aan- en uit te trekken met- of zonder weerstand verlagend hulpmiddel (en instrueert dit)

Indien extra training met een hulpmiddel noodzakelijk is om zelfstandigheid te behouden/behalen verwijst de compressiespecialist, in overleg met de patiënt, door naar de ergotherapeut

Indien patiënt niet zelfstandig kan worden met een hulpmiddel verwijst de compressiespecialist de patiënt door naar de thuiszorg

Levert het hulpmiddel (evt. na tussenkomst van de ergotherapeut)

**Communicatie en afstemming**

Door wie	Naar wie	Wat
Compressiespecialist	Hoofdbehandelaar	De compressiespecialist contacteert de hoofdbehandelaar voor verstrekking van het hulpmiddelen recept, de bandagist/huidtherapeut kan hiermee het hulpmiddel declareren bij de zorgverzekeraar
Compressiespecialist	Hoofdbehandelaar	De compressiespecialist contacteert de hoofdbehandelaar bij onduidelijkheden in verwijzing of voor overleg klasse/type therapeutische elastische kous indien nodig
Compressiespecialist	Patiënt/mantelzorger	Actieve benadering mantelzorger bij verwachte problemen zelfstandigheid

<b><i>Patiënten die extra training nodig hebben om zelfstandig te worden</i></b>		
Bandagist/huidtherapeut	Ergotherapeut	Verwijzing (schriftelijk of mondeling) waarbij overdragen relevante patiëntinformatie: doelen, wensen, fysieke mogelijkheden, en hulpvraag met betrekking tot gebruik hulpmiddel

## ERGOTHERAPEUT

### Communicatie met de patiënt tijdens eerste consult:

- Verifieert de informatie opgenomen in de verwijzing door compressiespecialist of hoofdbehandelaar
- Bespreekt geformuleerde doelen/wensen met de patiënt
- Geeft aanvullende informatie over de verschillende typen hulpmiddelen inclusief voor- en nadelen. Hierbij kan gebruik worden gemaakt van de Bijlage 7.3: 'Hulpkaart selectie hulpmiddelen, Bijlage 7.7'
- Vraagt (in geval van twijfel over mogelijkheden tot zelfstandigheid) actief naar de sociale situatie en de mogelijkheid mantelzorg te betrekken.

### Communicatie met de patiënt tijdens het evaluatieconsult:

- Beoordeelt samen met de patiënt of de patiënt zelfstandig kan functioneren met gebruik van het hulpmiddel.

<b>Aanvullende training zelfstandig aan- en uittrekken van de therapeutische elastische kous en selectie hulpmiddel</b>
Plant op verzoek compressiespecialist/thuiszorg of hoofdbehandelaar een afspraak in voor intake met de patiënt
Onderzoekt en analyseert het functioneringsniveau van de cliënt en de mogelijkheden om de handeling van het aantrekken van de therapeutische elastische kous mogelijk te maken of te verbeteren (functionele diagnostiek)
Selecteert op basis van patiëntkarakteristieken, cognitief functioneren, fysieke mogelijkheden, wensen van de patiënt en mogelijkheden om een mantelzorger te betrekken een pakket van eisen op voor het hulpmiddel en beoordeelt of extra training door thuiszorg noodzakelijk is en voor welke geschatte tijdsperiode
Bepaalt op basis van klinische inschatting hoe lang de patiënt nodig heeft om het hulpmiddel zelfstandig te kunnen gebruiken en verstrekkt het hulpmiddel voor deze periode aan de patiënt indien mogelijk
Schakelt thuiszorg in voor extra oefening indien noodzakelijk
Plant een follow-up afspraak ter evaluatie van zelfstandigheid en behalen van wensen en doelen patiënt
<b><i>Bij geslaagde implementatie</i></b>
Regelt een hulpmiddelenrecept en schrijft een schriftelijke motivatie (zie voorbeeld schriftelijke verklaring, Bijlage 7.10) waarmee de compressiespecialist het hulpmiddel kan bestellen en leveren.

<b>Communicatie en afstemming</b>		
<b>Door wie</b>	<b>Naar wie</b>	<b>Wat</b>
Ergotherapeut	Verwijzer (compressiespecialist / thuiszorg of hoofdbehandelaar)	De ergotherapeut contacteert de verwijzer bij onduidelijkheden in verwijzing
<i>Patiënten waarvan de ergotherapeut inschat dat ze niet zelfstandig kunnen oefenen met een hulpmiddel</i>		
Ergotherapeut	Thuiszorg (indien nodig)	Communiceert opstarten training, gewenste trainingsfrequentie, en tijdsperiode tot evaluatie
Ergotherapeut	Thuiszorg (indien betrokken)	Communiceert na evaluatie bij de thuiszorg of patiënt zelfstandig is of dat thuiszorg moet worden voortgezet gedurende de gehele behandelperiode met de therapeutische elastische kous
Thuiszorg (indien betrokken)	Ergotherapeut	Neemt contact op met de ergotherapeut indien zich problemen voordoen tijdens begeleid oefenen met een hulpmiddel (bijv. omdat het de patiënt ondanks oefening niet zelfstandig lukt)
Ergotherapeut	Hoofdbehandelaar	De ergotherapeut contacteert de hoofdbehandelaar voor verstrekking van het hulpmiddelenrecept indien het hulpmiddel succesvol is geïmplementeerd en er nog geen recept aanwezig is
Ergotherapeut	Compressiespecialist	De ergotherapeut verstrekkt het hulpmiddelenrecept met een schriftelijke motivatie van de keuze van het hulpmiddel aan de compressiespecialist

## THUISZORG

### Communicatie met de patiënt tijdens eerste consult:

- Verifieert het doel van inzet thuiszorg.

<b>Aanvullende begeleid oefenen aan- en uittrekken van de therapeutische elastische kous</b>
Continueert op verzoek van de ergotherapeut de training zoals door de ergotherapeut is ingezet en geïnstrueerd
Plant zo spoedig mogelijk een intake consult en/of de start trainingstraject met het hulpmiddel (indien de patiënt al thuiszorg had)
Bij nieuwe patiënten: maakt een zorgplan voor de patiënt naar de richtlijnen van de thuiszorgorganisatie, waarin tenminste is opgenomen: de hoofdbehandelaar, de indicatie, het doel van de behandeling en de verwachte duur van de behandeling
Verleent zorg voor patiënten die niet zelfstandig kunnen zijn en biedt aanvullende oefening met een hulpmiddel. Evalueert aan het begin van dit proces of er toch mogelijkheden zijn voor zelfstandigheid

<b>Patiënten die extra training nodig hebben om zelfstandig te worden</b>		
Door wie	Naar wie	Wat
Thuiszorg	Ergotherapeut	Neemt contact op met de ergotherapeut indien zich problemen voordoen tijdens begeleid oefenen met een hulpmiddel (bijv. omdat vóór het evaluatiemoment al blijkt dat het de patiënt ondanks oefening niet lukt zelfstandig te worden met het hulpmiddel)

### 3. Follow-up en behandelduur bij DVT-patiënten

Tijdens de follow-up fase voor DVT-patiënten zijn er twee kritische momenten voor het verlenen van optimale zorg voor patiënten:

**Beslissing 1: Bepalen van de optimale behandelduur op basis van een klinische risicobeoordeling en zorgen voor adequate informatievoorziening m.b.t. verandering in klachtenpatroon na het afsluiten van standaard follow-up.**

**Beslissing 2: Zorgen voor borging van adequate (vervolg) verstrekking therapeutische compressie kous en wie de compressietherapie uitvoert.**

Mogelijk betrokken zorgverleners: hoofdbehandelaar, thuiszorg en compressiespecialist.  
**Voorwaarde:** er zijn lokale/regionale afspraken over de verantwoordelijkheid voor het uitvoeren van follow-up met betrekking tot de pasvorm van de therapeutische elastische kous. Dit kan bij de hoofdbehandelaar belegd zijn, of gedelegeerd zijn naar de compressiespecialist.

**Beslissing 1: Bepalen van de optimale, behandelduur op basis van een klinische risicobeoordeling.**

#### HOOFDBEHANDELAAR

Communicatie met de patiënt:

- Herhaalt informatie doel/reden van behandeling en mogelijke complicaties
- Verifieert therapietrouw
- Monitort progressie in het proces (Heeft de patiënt zijn definitieve therapeutische elastische kous? Zijn er hulpmiddelen geïmplementeerd?)
- Verifieert of wensen en doelen van patiënt behaald zijn bij gebruik van de therapeutische elastische kous

- Verstrekt informatie over geïndividualiseerde behandelduur en noodzakelijke follow-up inclusief de noodzaak de therapeutische elastische kous 's-ochtends niet aan te trekken tijdens de follow-up afspraken bij 3, 6 en 12 maanden
- Verstrekt contactgegevens en instrueert patiënt bij welke problemen contact op te nemen (bij wie, voor wat en hoe bereikbaar)
- Bij afsluiten van standaard follow-up instrueren van de patiënt om contact op te nemen met de huisarts bij: nieuw ontstane pijnklachten aan het been, het ontstaan van een wond, uitbreiding van varices en/of huidafwijkingen en koorts en roodheid van het been.

<b>Bepalen van optimale behandelduur op basis van klinische risicobeoordeling</b>		
Draagt zorg voor de noodzakelijke follow-up afspraken in het kader van een geïndividualiseerde behandelduur conform de richtlijn antitrombotisch beleid (NIV)		
Bepaalt bij iedere follow-up afspraak vanaf 3 maanden na diagnose de Villalta score en bepaald aan de hand van het 'hulpsel geïndividualiseerde behandelduur DVT, Bijlage 7.11' de geïndiceerde behandelduur		
<ul style="list-style-type: none"> <li>• Gebruikt eventueel de visuele uitleg: JTH_3294_sm_visualguide.pdf</li> <li>• Gebruikt eventueel de Villalta calculator: <a href="https://www.mdcalc.com/villalta-score-post-thrombotic-syndrome-pts">https://www.mdcalc.com/villalta-score-post-thrombotic-syndrome-pts</a></li> </ul>		
Evalueert of er tijdens behandeling contra-indicaties ontstaan voor het gebruik van compressietherapie en onderneemt zo nodig actie		
Controleert of de geleverde therapeutische elastische kous past, of deleert dit aan de compressiespecialist (indien hierover lokale of regionale afspraken bestaan)		
<b>Communicatie en afstemming</b>		
Door wie	Naar wie	Wat
Hoofdbehandelaar	Compressiespecialist	De hoofdbehandelaar informeert (evt. via de patiënt) de compressiespecialist ten tijde van staken van de compressietherapie ter voorkoming van jaarlijkse (automatische) oproepen aan de patiënt
Hoofdbehandelaar/patiënt	Thuiszorg (indien betrokken)	De hoofdbehandelaar informeert (evt. via de patiënt) de thuiszorg ten tijde van staken van de compressietherapie zodat deze zorg stopgezet kan worden
Hoofdbehandelaar (medisch specialist)	Huisarts	De medisch specialist informeert de huisarts schriftelijk bij ontslag of beleidswijzigingen. In de brief is tenminste opgenomen: de geadviseerde draagduur voor de therapeutische elastische kous en eventuele complicaties

**Beslissing 2: Zorgen voor borging van adequate (vervolg) verstrekking therapeutische compressie kous en wie de compressietherapie uitvoert.**

Mogelijk betrokken zorgverleners: thuiszorg (indien betrokken) en compressiespecialist

**THUISZORG (indien betrokken)**

**Communicatie met de patiënt:**

- Verkent of patiënt al geïnformeerd is over mogelijkheden om de therapeutische elastische kous zelfstandig te kunnen aan- en uittrekken en of deze wens er is.

<b>Organisatie en uitvoering van adequate follow-up</b>		
Verleent zorg aan patiënten die niet zelfstandig kunnen zijn. Aan het begin van dit proces evalueert de thuiszorg met de patiënt of er toch mogelijkheden en wensen zijn tot zelfstandigheid		
Bij nieuwe patiënten: maakt een zorgplan voor de patiënt naar de richtlijnen van de thuiszorgorganisatie, waarin tenminste is opgenomen: de hoofdbehandelaar, de indicatie, het doel van de behandeling en de verwachte duur van de behandeling		
<b>Communicatie en afstemming</b>		
Door wie	Naar wie	Wat
Thuiszorg	Ergotherapeut	Wanneer tijdens chronische zorg voor het aan- en uittrekken van de therapeutische elastische kous blijkt dat er toch mogelijkheden of wensen zijn om de therapeutische elastische kous zelfstandigheid te gebruiken schakelt de thuiszorgmedewerker de ergotherapeut in voor training van een hulpmiddel
Thuiszorg	Hoofdbehandelaar	Bij problemen/complicaties (toenemende pijnklachten, kortademigheid, ontstaan van wonden, koorts+roodheid van het been, blauwverkleuring van de tenen) neemt de thuiszorg contact op met de hoofdbehandelaar voor overleg

**COMPRESSIESPECIALIST**

**Communicatie met de patiënt:**

- Vraagt actief na welk advies de behandelend arts gegeven heeft over de draagduur van de therapeutische elastische kous
- Gaat na of er problemen zijn ontstaan in het kader van zelfstandigheid
- Overweegt indien noodzakelijk opnieuw het gebruik van een hulpmiddel conform de voorafgaande fase: ‘Verstrekken definitieve therapeutische elastische kous en selecteren hulpmiddelen’
- Verstrekt contactgegevens (indien nog niet bekend) en instrueert de patiënt contact op te nemen bij technische problemen.

<b>Zorgen voor borging van adequate (vervolg) verstrekking therapeutische elastische kous</b>		
Roeft de patiënt jaarlijks op voor een fysieke afspraak voor het aanmeten van een nieuwe therapeutische elastische kous zolang er een behandelindicatie bestaat en levert deze af		
Controleert of er problemen zijn met betrekking tot de zelfstandigheid bij het aan- en uittrekken van de elastische kous en verstrekt een hulpmiddel of schakelt hiervoor de ergotherapeut in (conform werkwijze selectie hulpmiddelen)		
Communicatie en afstemming		
Door wie	Naar wie	Wat
Compressiespecialist	Hoofdbehandelaar	De compressiespecialist contacteert de hoofdbehandelaar indien er vragen of problemen ontstaan, met name ook indien er onduidelijkheid bestaat m.b.t. de behandelduur*

\* Uit de uitgevoerde Functional Resonance Analysis Method bleek dat patiënten regelmatig oproepen kregen van de compressiespecialist terwijl de behandelindicatie al was afgelopen. In sommige gevallen zagen patiënten dit als een teken dat ze opnieuw met therapeutische elastische kousen moesten beginnen zonder dat de hoofdbehandelaar hiervan op te hoogte was.

#### 4. Follow-up voor CVZ-patiënten

Tijdens de follow-up fase voor CVZ-patiënten zijn er een aantal momenten kritisch voor het verlenen van optimale zorg voor patiënten:

**Beslissing 1: Organiseren en uitvoeren van adequate follow-up in het eerste jaar na diagnose en zorgen voor adequate informatievoorziening m.b.t. verandering in klachtenpatroon na het afsluiten van standaard follow-up.**

**Beslissing 2: Zorgen voor borging van adequate (vervolg) verstrekking therapeutische compressie kous en uitvoering.**

Mogelijk betrokken zorgverleners: hoofdbehandelaar/ compressiespecialist

**Beslissing 1: Organiseren en uitvoeren van adequate follow-up in het eerste jaar na diagnose en zorgen voor adequate informatievoorziening m.b.t. verandering in klachtenpatroon na het afsluiten van standaard follow-up.**

#### HOOFDBEANDELAAR/COMPRESSIESPECIALIST

**Voorwaarde:** er zijn lokale/regionale afspraken over de verantwoordelijkheid voor het uitvoeren van follow-up. Dit kan bij de hoofdbehandelaar belegd zijn, of gedelegeerd zijn aan de compressiespecialist. De primaire verantwoordelijkheid voor het regelen van adequate follow-up ligt bij de hoofdbehandelaar.

**Communicatie met de patiënt:**

- Herhaalt informatie doel/reden van behandeling en mogelijke complicaties
- Verifieert de therapietrouw en vraagt naar barrières bij therapie-ontrouw
- Verifieert of wensen en doelen van patiënt behaald zijn bij gebruik van de definitieve therapeutische elastische kous
- Monitort de progressie in het proces (Heeft de patiënt zijn definitieve therapeutische elastische kous? Zijn er hulpmiddelen geïmplementeerd?)
- Verstrekt contact gegevens in geval van problemen (bij wie, voor wat en hoe bereikbaar)
- Bij het afsluiten van reguliere follow-up instructie van de patiënt contact op te nemen met de huisarts bij: toenemende klachten, ontstaan van een wond, uitbreiding van varices en/of huidafwijkingen, kortademigheid, blauwverkleuring van de tenen, toenemende pijnklachten of koorts en roodheid van het been.

<b>Organisatie en uitvoering van adequate follow-up</b>		
Evalueert of er tijdens behandeling contra-indicaties ontstaan voor het gebruik van compressietherapie en onderneemt zo nodig actie		
Controleert therapietrouw en pasvorm van de therapeutische elastische kous		
<b>Communicatie en afstemming</b>		
Door wie	Naar wie	Wat
Hoofdbehandelaar	Compressiespecialist	Er dienen lokale/regionale afspraken te bestaan tussen de compressiespecialist en de hoofdbehandelaar over wie zorg draagt voor een follow-up afspraak
Compressiespecialist	Hoofdbehandelaar	Indien de compressiespecialist zorg draagt voor de follow-up afspraken en er ontstaan contra-indicaties voor het dragen van de therapeutische elastische kous, dan neemt de compressiespecialist contact op met de hoofdbehandelaar om het beleid vast te stellen
Hoofdbehandelaar (medisch specialist)	Huisarts	De medisch specialist informeert de huisarts schriftelijk indien controles worden afgesloten en de huisarts het hoofd behandelaarschap dient over te nemen. Deze brief omvat tenminste de behandelduur (meestal levenslang)

**Beslissing 2: Zorgen voor borging van adequate (vervolg) verstrekking therapeutische compressie kous en uitvoering.**

Mogelijk betrokken zorgverleners: thuiszorg (indien betrokken) en compressiespecialist.

## THUISZORG (indien betrokken)

### Communicatie met de patiënt:

- Verkent of patiënt al geïnformeerd is over mogelijkheden om de therapeutische elastische kous zelfstandig te kunnen aan- en uittrekken en of deze wens er is.

<b>Organisatie en uitvoering van adequate follow-up</b>		
Thuiszorgmedewerkers verlenen zorg voor patiënten die niet zelfstandig kunnen zijn. Aan het begin van dit proces evalueert de medewerker met de patiënt of er toch mogelijkheden en wensen zijn tot zelfstandigheid		
Bij nieuwe patiënten: maakt een zorgplan voor de patiënt naar de richtlijnen van de thuiszorgorganisatie, waarin tenminste is opgenomen: de hoofdbehandelaar, de indicatie, het doel van de behandeling en de verwachte duur van de behandeling		
Indien er nog een wens/mogelijkheid is om patiënt zelfstandig te laten worden bij het aan- en uittrekken van de therapeutische elastische kous zorgt de thuiszorgmedewerker voor verwijzing naar de ergotherapeut		
<b>Communicatie en afstemming</b>		
Door wie	Naar wie	Wat
Thuiszorg	Ergotherapeut	Wanneer tijdens chronische zorg voor het aan- en uittrekken van de therapeutische elastische kous blijkt dat er toch mogelijkheden voor zelfstandigheid zijn schakelt de thuiszorgmedewerker de ergotherapeut in voor training (na overleg met de patiënt). Er wordt 10 uur ergotherapie per kalenderjaar vergoed vanuit de basisverzekering.
Thuiszorg	Hoofdbehandelaar/compressiespecialist	Bij problemen/complicaties neemt de thuiszorg contact op met de hoofdbehandelaar of de compressiespecialist (bij technische problemen met de therapeutische elastische kous) voor overleg

## COMPRESSIESPECIALIST

### Communicatie met de patiënt:

- Gaat na of er problemen zijn ontstaan in het kader van zelfstandigheid:
- Indien noodzakelijk opnieuw het gebruik van een hulpmiddel overwegen conform de voorafgaande fase: ‘Verstrekken definitieve therapeutische elastische kous en selecteren hulpmiddelen’
- Verstrekt contact gegevens (indien nog niet bekend) en instrueert de patiënt contact op te nemen bij technische problemen met de kous en problemen in de zelfstandigheid

<b>Zorgen voor borging van adequate (vervolg) verstrekking therapeutische elastische kous</b>		
Roeft de patiënt jaarlijks op voor een fysieke afspraak voor het aanmeten van een nieuwe therapeutische elastische kous zolang er een behandelindicatie bestaat		
Meet de therapeutische elastische kous jaarlijks opnieuw aan en levert deze af		
Controleert jaarlijks of er problemen zijn met betrekking tot de zelfstandigheid bij het aan- en uittrekken van de elastische kous en verstrekt een hulpmiddel of schakelt hiervoor de ergotherapeut in (conform werkwijze selectie hulpmiddelen)		
Communicatie en afstemming		
Door wie	Naar wie	Wat
Compressiespecialist	Hoofdbehandelaar	De compressiespecialist contacteert de hoofdbehandelaar indien er vragen of problemen ontstaan

## Referenties

- Schreurs RHP, Joore MA, Ten Cate H, Ten Cate-Hoek AJ. Using the Functional Resonance Analysis Method to explore how elastic compression therapy is organised and could be improved from a multistakeholder perspective. *BMJ Open*. 2021;11(10):e048331.
- Rachel H.P. Schreurs, Manuela A. Joore, Daisy P. De Bruijn-Geraets, Hugo Ten Cate, Arina J. Ten Cate-Hoek. A realist evaluation to inform implementation strategies for the optimization of elastic compression therapy for deep venous thrombosis- and chronic venous disease patients. Submitted.
- Schreurs RHP, Joore MA, Ten Cate H, Ten Cate-Hoek AJ. Development of a consensus-based cross-domain protocol for the management of elastic compression stocking therapy in patients with deep venous thrombosis and chronic venous disease: a modified Delphi study. In progress.
- Ten Cate-Hoek AJ, Amin EE, Bouman AC, Meijer K, Tick LW, Middeldorp S, et al. Individualised versus standard duration of elastic compression therapy for prevention of post-thrombotic syndrome (IDEAL DVT): a multicentre, randomised, single-blind, allocation-concealed, non-inferiority trial. *Lancet Haematol*. 2018;5(1):e25-e33.
- Amin EE, Ten Cate-Hoek AJ, Bouman AC, Meijer K, Tick L, Middeldorp S, et al. Individually shortened duration versus standard duration of elastic compression therapy for prevention of post-thrombotic syndrome: a cost-effectiveness analysis. *Lancet Haematol*. 2018;5(11):e512-e9.
- Rabe E, Partsch H, Morrison N, Meissner MH, Mosti G, Lattimer C, et al. Risks and contraindications of medical compression treatment – A critical reappraisal. An international consensus statement. *Phlebology* 2020 Aug;35(7):447-460.
- Module Compressiehulpmiddelenzorg versie 1.0, november 2020
- <https://omring.nl/nieuws/doornraak-werkvloer-kracht-klittenbandzwachtels>
- Hulpmiddelenkompas: Handreiking bij het indiceren, typeren, selecteren, leveren en evalueren van hulpmiddelen; deel Therapeutische elastische kousen, eerste editie (pilot) van het College voor zorgverzekeringen 2002 – Amstelveen
- NIV (nederlandse internisten vereniging) richtlijn Antitrombotisch beleid 2015
- NHG-standaard diep veneuze trombose en longembolie versie 3.1 september 2017
- NHG-standaard varices
- Richtlijn veneuze pathologie/diepe veneuze ziekte; Federatie Medisch Specialisten op initiatief van de Nederlandse Vereniging voor Dermatologie en Veneorologie
- ESVS stroomdiagram
- Yeelai L, Rook B, Hansma I, Kruip M, van Rijn M J et al. Nut van compressietherapie na diep venvneuze trombose. *Ned Tijdschr Geneesk*. 2020;164:D3622

## Bijlage 7.1. Hulpkaart contra-indicaties compressietherapie

Contra-indicaties voor compressietherapie zijn\*:

- Perifeer arterieel vaatlijden (enkel-arm index < 0.6, enkeldruk < 60 mmHg, teendruk < 30 mmHg of transcutane zuurstofsaturatie < 20 mmHg)\*\*.
- Vermoeden van compressie van een bestaande epifasciale arteriële bypass
- Ernstig hartfalen (NYHA IV)
- Routinematige applicatie van compressie bij patiënten met NYHA III hartfalen zonder strikte indicatie en zonder hemodynamische monitoring
- Bekende allergie voor compressiematerialen
- Ernstige diabetische neuropathie met sensibiliteitsverlies of microangiopathie en het risico op huidnecrose

\* Rabe E, Partsch H, Morrison N, Meissner MH, Mosti G, Lattimer C, et al. Risks and contraindications of medical compression treatment – A critical reappraisal. An international consensus statement. *Phlebology* 2020 Aug;35(7):447-460.

\*\* De hoofdbehandelaar stelt de indicatie voor het al dan niet verrichten van aanvullend onderzoek naar het bestaan van perifeer arterieel vaatlijden

## Bijlage 7.2: Hulpkaart conservatieve maatregelen om het effect van de compressietherapie te ondersteunen

Conservatieve maatregelen:

- Been zoveel mogelijk hoog leggen zowel bij zitten als (in bed) liggen
- Regelmatig bewegen (gebruik kuitspier zorgt voor betere opname oedeem)
- Oefeningen in stoel (rondjes draaien met voeten en tenen naar u toetrekken en weer loslaten)

## Bijlage 7.3: Hulpkaart indicaties voor doorverwijzing dermatologie/vaatchirurgie

### In de acute fase:

#### Doorverwijzing naar de vaatchirurg:

- Patiënten met een acuut bedreigd been dienen direct te worden doorverwezen naar de vaatchirurg.

#### Doorverwijzing naar de dermatoloog:

- Patiënten met een afwijkende maatvoering : zeer hoge BMI, afwijkende vorm van het been
- Patiënten met een (relatieve) contra-indicatie voor compressietherapie (zie zakkaartje contra-indicaties compressietherapie)

#### Tijdens follow-up:

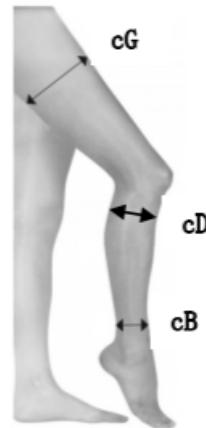
- Alle patiënten waarbij het oedeem na 4 weken (tijdens de eerste follow-up afspraak) niet voldoende is geresorbeerd waardoor nog geen definitieve therapeutische elastische kous kan worden aangemeten of indien er nog veel klachten van het been zijn.

## Bijlage 7.4a: Hulpkaart initiële compressie

### Diep veneuze trombose

#### Standaard tijdelijke compressiekous (35 mmHg)

Patiënten met een diep veneuze trombose dienen bij voorkeur te worden behandeld met een standaard tijdelijke compressiekous. Indien er sprake is van een uitgebreide DVT met betrokkenheid van de v. femoralis communis, of indien er praktische problemen zijn bij het aanmeten van de therapeutische elastische kous zoals bijv. een duidelijk omvangverschil tussen boven- en onderbeen of als er sprake is van ernstig overgewicht, wordt individueel bekeken wat de beste therapie is het been oedeem vrij te krijgen. Voor het aanmeten van de standaard (tijdelijke) compressiekous is een meetlint nodig, hiermee wordt de omvang van het been opgemeten op drie plaatsen (zie figuur 1): 1. Het dunste deel van het onderbeen vlak boven de enkel (cB), 2. 2 cm onder de knieplooi (cD) en 3. Het dijbeen (cG). Op basis hiervan kan met behulp van de instructie in de bijsluiter de maat bepaald worden. De standaard tijdelijke compressiekous geeft voor patiënten met diep veneuze trombose de beste mogelijkheden tot zelfstandigheid. De patiënt trekt de tijdelijke compressiekous 's-ochtends bij het opstaan aan en bij het naar bed gaan weer uit. Voor een betere grip bij het aan- en uittrekken kunnen rubberen huishoudhandschoenen gedragen worden. Eventueel kan ook een weerstand verlagend hulpmiddel worden aangeschaft via de thuiszorgwinkel, echter worden weerstand verlagende hulpmiddelen voor gebruik tijdens initiële compressie therapie meestal niet vergoed door de zorgverzekeraar.



### Compressief zwachtelen

Compressief zwachtelen wordt voorgeschreven bij patiënten met een diep veneuze trombose van de v. femoralis communis, een duidelijk omvangverschil tussen het boven- en onderbeen of anatomische afwijkingen. De manier van compressief zwachtelen dient te worden geïndividualiseerd. In Nederland wordt het meest gebruik gemaakt van korte rekzwachtels met een lage rustdruk en een hoge werkdruk (bij mobiliseren/oefenen). Deze zwachtels zijn dus bijv. geschikt voor mobiele patiënten. De korte rekzwachtels bestaan ook in zelfklevende vorm, deze zakken minder vaak of nauwelijks af en hoeven daardoor vaak minder vaak verwisseld te worden. Daarnaast kunnen meerlaagse zwachtelsystemen worden voorgeschreven, dit is een combinatie van (zelfklevende) zwachtels met korte en lange rek, die zorgen voor een middelhoge rustdruk. Deze zwachtels kunnen bijv. geschikt zijn voor minder mobiele/immobiele patiënten. Patiënten kunnen zwachtels niet zelf aanleggen en worden altijd tijdelijk afhankelijk van thuiszorg of poliklinische zorg. Vaak moeten zwachtels (afhankelijk van de mate van

oedeem) aan het begin van de therapie 2-4x per week opnieuw worden angelegd. De patiënt dient zwachtels dag en nacht te dragen.

## Bijlage 7.4b: Hulpkaart initiële compressie

### Chronische veneuze ziekte

#### **Compressief zwachtelen**

Compressief zwachtelen wordt voorgeschreven bij patiënten met chronische veneuze ziekte die oedeem hebben. De manier van compressief zwachtelen dient te worden geïndividualiseerd. In Nederland wordt het meest gebruik gemaakt van korte rekzwachtels met een lage rustdruk en een hoge werkdruk (bij mobiliseren/oefenen). Deze zwachtels zijn dus geschikt voor mobiele patiënten. Deze korte rekzwachtels bestaan ook in zelfklevende vorm, deze zakken nauwelijks af en hoeven daardoor minder vaak verwisseld te worden. Daarnaast kunnen meerlaagse zwachtelsystemen worden voorgeschreven, dit is een combinatie van (zelfklevende) zwachtels met korte en lange rek, die zorgen voor een middelhoge rustdruk. Deze zwachtelsystemen kunnen geschikt zijn voor minder mobiele/immobiele patiënten. Patiënten kunnen zwachtels niet zelf aanleggen en worden altijd tijdelijk afhankelijk van thuiszorg of poliklinische zorg. Vaak moeten zwachtels (afhankelijk van de mate van oedeem) aan het begin van de therapie 2-4x per week opnieuw worden angelegd. De patiënt dient zwachtels dag en nacht te dragen.

#### **Klittenbandzwachtels (adjustable compression device)**

Klittenbandzwachtels kunnen worden voorgeschreven bij patiënten met chronische veneuze ziekte. Het is een aanpasbaar zwachtelsysteem met klittenbandsluiting en kan worden gezien als alternatief voor het compressief zwachtelen. Er zijn enkele kleinere studies die aantonen dat klittenbandzwachtels tenminste even effectief zijn ten opzichte van compressief zwachtelen. Nog niet alle verzekeraars vergoeden klittenbandzwachtels in deze fase. Klittenbandzwachtels bevorderen de zelfstandigheid van patiënten ten opzichte van compressief zwachtelen. Klittenbandzwachtels dienen te worden aangemeten en gedemonstreerd en kunnen geleverd worden door de compressiespecialist. Steeds meer thuiszorgverpleegkundigen kunnen klittenbandzwachtels aanmeten. De meeste systemen bevatten een drukkaartje waarmee de patiënt zelf de geleverde druk kan meten en de zwachtel eventueel kan bijstellen. De patiënt trekt de klittenbandzwachtels 's-ochtends bij het opstaan aan en bij het naar bed gaan weer uit. Bij de keuze voor klittenbandzwachtels dienen de baten van de patiënt (bijv. het effect op zelfredzaamheid) op individuele basis te worden afgewogen t.o.v. de kosten.

## Bijlage 7.5: Voorbeeld lokaal standaardrecept hoog compressief zwachtelen met korte rek zwachtel

### Standaard materialen (voor zwachtelen één been)

Soort /naam artikel	Aantal	Vergoeding*	Standaard
Korte rek compressiezwachtel	2 stuks	Ja/nee	x
Kleefzwachtel met lengterek	1 stuk	Ja/nee	x
Kleefzwachtel met lengte- en breedterek	4 stuks	Ja/nee	x
Tape	2 stuks	Ja/nee	x
Synthetische watten	4 stuks	Ja/nee	x
Hechtpleisters	1 stuk	Ja/nee	x

### Ter fixatie indien gewenst (niet noodzakelijk voor de compressie)

Soort /naam artikel	Aantal	Vergoeding	Aankruisen indien gewenst
Elastisch buisverband	1 stuk	Ja/nee	
2-way stretch buisverband, keuze afhankelijk van beenomvang	1x 1m	Ja/nee	

Naam arts:

Contactnummer:

Handtekening:

\* In dit voorbeeld zijn merknamen vervangen door generieke namen. Check met de verzekeraar welke materialen voor de lokale situatie worden vergoed.

\* Materialen kunnen wisselend zijn afhankelijk van lokale afspraken. Voorwaarde voor levering, adequaat gebruik, en vergoeding is dat de materialen in overleg met de zorgverzekeraar, de thuiszorg, de apotheek en hoofdbehandelaars zijn samengesteld.

## Bijlage 7.6a: Hulpkaart beoordelen oedeem voor patiënten

### Bij trombosebeen

Uw arts heeft bij u een trombosebeen vastgesteld. Door het stolsel wordt de afvloed van vocht uit het been bemoeilijkt, hierdoor kan oedeem ontstaan. Oedeem is ophoping van vocht in één of beiden benen, terwijl het been normaalgesproken geen vocht bevat. Om de afvoer van het bloed te ondersteunen heeft u een tijdelijke kou of zwachtel gekregen. Dit zorgt ervoor dat het vocht wegtrekt, en er uiteindelijk een steunkous kan worden aangemeten.

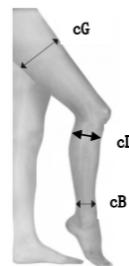
- U kunt oedeem zelf herkennen: als u uw vinger enige tijd (10 seconden) stevig in de huid drukt *aan de voorkant van uw scheenbeen* en dan uw vinger weghaalt, kunt u

een putje voelen als u zachtjes over uw huid wrijft. Bij veel oedeem kunt u het putje ook zien.

- Ook kunt u de dikte van het midden van het onderbeen opmeten met een meetlint en vergelijken met het andere onderbeen (indien dit geen oedeem bevat). Als de metingen ongeveer gelijk zijn, is het oedeem verdwenen.

Naast het gebruik van de tijdelijke standaard steunkous of zwachtel kunt u zelf een aantal acties ondernemen om het oedeem te doen afnemen zoals het been hoog leggen (boven harthoogte) zowel bij zitten als (in bed) liggen, regelmatig bewegen (gebruik kuitspier zorgt voor betere opname oedeem). Indien het niet mogelijk is te lopen, dan kunt u oefeningen zittend in de stoel doen (rondjes draaien met voeten en tenen naar u toetrekken en weer loslaten).

Het kan enige tijd duren voordat het been voldoende geslonken is, dit is sterk afhankelijk van hoeveel oedeem er aanwezig is. Gemiddeld is na 2-4 weken het vocht in het been verdwenen. Indien er geen oedeem meer aanwezig is, dan is het tijd om uw compressiespecialist (bandagist, huidtherapeut of oedeem-fysiotherapeut) te contacteren voor een aanmeetafspraak voor de op maat gemaakte steunkous. Indien er tijdens de behandeling sprake is van toenemende pijnklachten in de benen of voeten, blauwverkleuring van de tenen, benauwdheid, of roodheid van het been in combinatie met koorts dient u altijd direct contact op te nemen met de behandelaar die de tijdelijke steunkous of zwachtel voorgeschreven heeft. Ook als het vocht in het been na 4 weken nog niet verdwenen is dient u ook contact op te nemen met uw hoofdbehandelaar. U draagt de tijdelijke steunkous of u wordt gezwachteld totdat de uiteindelijke steunkous is geleverd.



Een onderbeen met oedeem, te herkennen aan putje na drukken. Bron: <https://www.huidarts.com/huidaandoeningen/open-been-ulcus-cruris/>

## Bijlage 7.6b: Hulpkaart beoordelen oedeem voor patiënten

### Bij chronische veneuze ziekte

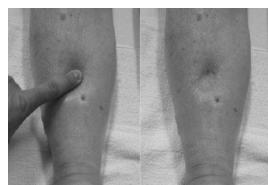
Uw arts heeft bij u oedeem vastgesteld als gevolg van spataderen. Oedeem is ophoping van vocht in één of beiden benen, terwijl het been normaalgesproken geen vocht bevat.

Dit vocht ontstaat doordat het vocht weer terugzakt naar de benen door verminderde werking van de kleppen in de bloedvaten. Om de kleppen en de afvoer van het bloed te ondersteunen heeft u een tijdelijke kous, zwachtel of klittenbandzwachtel gekregen. Deze zorgen ervoor dat het vocht wegtrekt, en er uiteindelijk een steunkous kan worden aangemeten.

- U kunt oedeem zelf herkennen: als u uw vinger enige tijd (10 seconden) stevig in de huid drukt *aan de voorkant van uw scheenbeen* en dan uw vinger weghaalt, kunt u een putje voelen als u zachtjes over uw huid wrijft. Bij veel oedeem kunt u het putje ook zien.

Naast het gebruik van de tijdelijke standaard steunkous, zwachtel of klittenbandzwachtel kunt u zelf een aantal acties ondernemen om het oedeem te doen afnemen: het been hoog leggen (boven harthoogte) zowel bij zitten als (in bed) liggen, regelmatig bewegen (gebruik kuitspier zorgt voor betere opname oedeem), indien u niet kunt lopen kunt u de oefeningen zittend in de stoel doen (rondjes draaien met voeten en tenen naar u toetrekken en weer loslaten).

Het kan enige tijd duren voordat het been voldoende geslonken is, dit is sterk afhankelijk van hoeveel oedeem er aanwezig is. Gemiddeld is na 2-4 weken het vocht in het been verdwenen. Indien er geen oedeem meer aanwezig is, dan is het tijd om uw compressiespecialist (bandagist, huidtherapeut of oedeem-fysiotherapeut) te contacteren voor een aanmeetafspraak voor de steunkous. Indien er tijdens de behandeling sprake is van toenemende pijnklachten in de benen of voeten, blauwverkleuring van de tenen, benauwdheid, of roodheid van het been in combinatie met koorts dient u altijd direct contact op te nemen met de behandelaar die de tijdelijke steunkous / zwachtel / klittenbandzwachtel voorgeschreven heeft. Ook als het vocht in het been na 4 weken nog niet verdwenen is dient u ook contact op te nemen met uw hoofdbehandelaar. U draagt de tijdelijke steunkous, zwachtel of klittenbandzwachtel door tot de uiteindelijke steunkous is geleverd.



Een onderbeen met oedeem, te herkennen aan putje na drukken.

Bron: <https://www.huidarts.com/huidaandoeningen/open-been-ulcus-cruris/>

## Bijlage 7.7: Hulpkaart selectie hulpmiddelen te gebruiken voor het aan- en of uittrekken van een therapeutische elastische kous voor het onderbeen

Er is in principe een indicatie voor het inzetten van een hulpmiddel indien een patiënt niet zelfstandig de therapeutische elastische kous kan aan- en/of uittrekken, dit past binnen de wensen/doelen van de patiënt, én de patiënt naar inschatting over voldoende fysieke en cognitieve mogelijkheden beschikt zelfstandig te worden met een hulpmiddel (evt. met extra training).

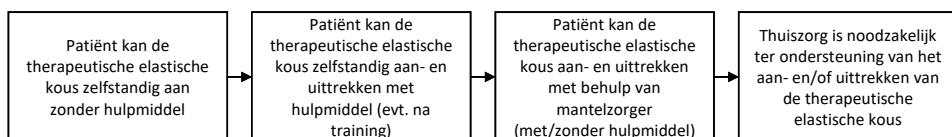
### Meest voorkomende indicaties inzet hulpmiddel voor therapeutische elastische kousen:

- Niet kunnen vooroverbuken en reiken tot de tenen
- Evenwichtsstoornis, waardoor niet voorover kunnen bukken
- Zwaarlijvigheid/obesitas en/of zwangerschap
- Verminderde arm en/of handfunctie of eenhandigheid
- Conditionele beperkingen (de krachtsinspanning is te belastend)
- Afwijkende vorm van voet of been, bijv. situaties waarbij het smalle enkelgedeelte van de kous over de bredere wreef verplaatst moet worden
- Te weinig kracht in de armen
- Cognitieve beperkingen

### Indicaties voor vergoeding:

- In principe is een hulpmiddel alleen geïndiceerd wanneer:
  1. De patiënt de therapeutische elastische kous niet zelfstandig kan aan- of uittrekken met behulp van het standaard bij de kous geleverde voetje (let op: dit is geen glijzak).
  2. Het hulpmiddel de zelfstandigheid van de patiënt (eventueel met hulp van diens mantelzorger) bevordert.

Voorwaarde: de patiënt mag geen thuiszorg hebben voor de zorg met betrekking tot de therapeutische elastische kous.



- Behalve voor een glijzak dient er voor elk hulpmiddel een hulpmiddelen recept van de hoofdbehandelaar beschikbaar te zijn met hierop het geïndiceerde hulpmiddel én een schriftelijke motivatie dat patiënt door gebruik van het hulpmiddel zelfstandig kan functioneren (zonder thuiszorg).
  - Verzekeraars vergoeden deze hulpmiddelen op basis van het "stepped care" principe, dat betekent dat in principe het eenvoudigste, minst belastende aan-

en uittrekhulpmiddel wordt geselecteerd dat lijkt te voldoen aan de eisen om te komen tot het beoogd functioneren (zoals opgesteld in overleg met de patiënt en tevens rekening houdend met cognitief functioneren, wensen en doelen van de patiënt, en indien aanwezig het betrekken van een mantelzorger). Als dit soort aan- en uittrekhulpmiddel, inclusief de eventueel daarbij behorende zorg, niet het gewenste resultaat oplevert (of dit naar verwachting niet zal opleveren), wordt gekozen voor meer geavanceerde aan- en uittrekhulpmiddel. Oplopend van eenvoudig hulpmiddel naar geavanceerd kan een onderverdeling worden gemaakt in 3 groepen hulpmiddelen:

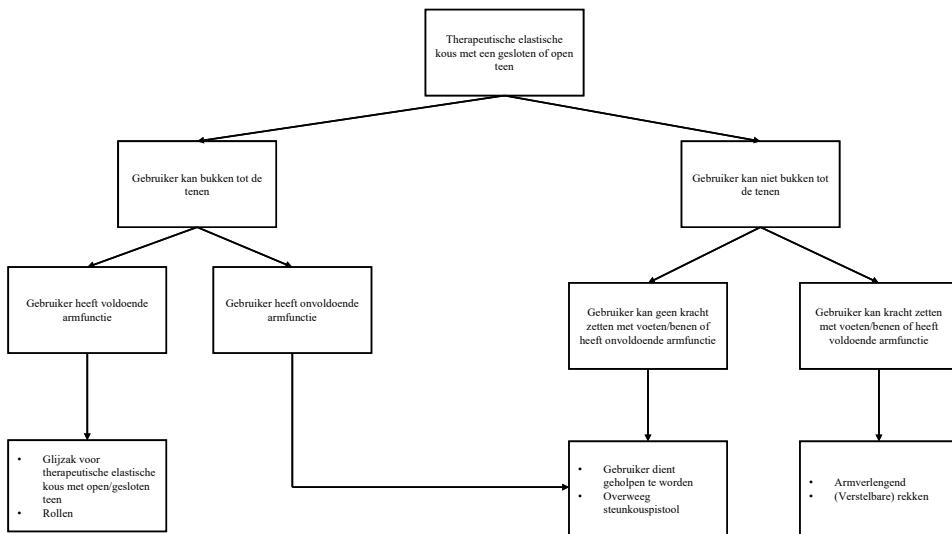
- Groep 1: weerstand verlagende hulpmiddelen,
- Groep 2: arm verlengende hulpmiddelen of rekjes,
- Groep 3: therapeutische elastische kous pistool.

**Vergoeding:**

- Voor alle verzekeringen geldt dat voor het inzetten van het steunkouspistool voorafgaande toestemming van de verzekeraar noodzakelijk is alvorens het geleverd mag worden.
- Het vervangen van weerstand verlagende hulpmiddelen (glijzakken) wordt globaal genomen éénmaal per 1-2 jaar vergoed afhankelijk van de zorgverzekeraar.
- Vervangen van geavanceerde hulpmiddelen wordt globaal genomen éénmaal per 5 jaar vergoed afhankelijk van de zorgverzekeraar.

### Stroomdiagram

Als blauwdruk voor het selecteren van een geschikt hulpmiddel op basis van een aantal fysieke mogelijkheden is onderstaand stroomdiagram een voorbeeld. Echter moet vooropgesteld worden dat het voorschrijven van compressie hulpmiddelen patiëntgericht moet zijn en dat hierin niet alleen fysieke mogelijkheden moeten worden meegenomen:



NB Rollen maken ook onderdeel uit van hetarsenaal aan hulpmiddelen. Echter hebben deze hulpmiddelen nog geen formele plaats binnen het stepped care principe. Experts op dit gebied geven aan dat de rollen ofwel binnen de eerste groep hulpmiddelen zouden moeten vallen ofwel een tussengroep zouden moeten zijn tussen groep 1 en 2. De contra-indicatie van een rol bij DVT-patiënten zoals vermeld in de bijsluiter geldt niet voor de inzet van rollen bij gebruik van de definitieve therapeutische elastische kous.

## Informatie hulpmiddelen

Categorie I: weerstand verlagend (glizak)	Wanneer inzetten	Links
	<p>Als het aan-en uittrekken stroef gaat.</p> <p>Voor therapeutische elastische kousen met een gesloten teen of een open teen</p>	<p><b>Instructiefilm:</b>  <a href="https://goedgebruik.nl/filmpjes-van-alle-technieken/3steunkousen-aan-en-uitrekken/32-steunkous-met-open-teenstuk-aantrekken">https://goedgebruik.nl/filmpjes-van-alle-technieken/3steunkousen-aan-en-uitrekken/32-steunkous-met-open-teenstuk-aantrekken</a></p> <p><a href="https://goedgebruik.nl/filmpjes-van-alle-technieken/3steunkousen-aan-en-uitrekken/31-steunkousen-met-gesloten-teenstuk-aantrekken">https://goedgebruik.nl/filmpjes-van-alle-technieken/3steunkousen-aan-en-uitrekken/31-steunkousen-met-gesloten-teenstuk-aantrekken</a></p> <p><a href="https://goedgebruik.nl/filmpjes-van-alle-technieken/3steunkousen-aan-en-uitrekken/33-steunkous-uittrekken">https://goedgebruik.nl/filmpjes-van-alle-technieken/3steunkousen-aan-en-uitrekken/33-steunkous-uittrekken</a></p> <p>Schriftelijke instructie:  <a href="https://goedgebruik.nl/download-file/V3EQXD0Q6g">https://goedgebruik.nl/download-file/V3EQXD0Q6g</a></p> <p><a href="https://goedgebruik.nl/download-file/lg3xYKjQVm">https://goedgebruik.nl/download-file/lg3xYKjQVm</a></p> <p><a href="https://goedgebruik.nl/download-file/GJOLGRVQ7K">https://goedgebruik.nl/download-file/GJOLGRVQ7K</a></p>
Tussencategorie: Rollen	Wanneer inzetten	Links
	<p>Voor therapeutische elastische kous met zowel een open als gesloten teen.</p> <p>Bij weinig grip / de therapeutische elastische kous niet goed kunnen vastpakken.</p> <p>Het mechanisme werkt op basis van rollen en duwen in plaats van trekken.</p>	<p><b>Instructiefilm + schriftelijke instructie</b>  <b>PDF te downloaden via:</b>  <a href="https://goedgebruik.nl/filmpjes-van-alle-technieken/3steunkousen-aan-en-uitrekken/34-steunkousen-aan-en-uitrekken-met-hulpmiddel-doff-n-donner-dnd">https://goedgebruik.nl/filmpjes-van-alle-technieken/3steunkousen-aan-en-uitrekken/34-steunkousen-aan-en-uitrekken-met-hulpmiddel-doff-n-donner-dnd</a></p> <p><a href="https://goedgebruik.nl/download-file/pq6xwpNbOw">https://goedgebruik.nl/download-file/pq6xwpNbOw</a></p>

Categorie II: rekjes en armverlengend	Wanneer inzetten	Links
	<p>Als de patiënt niet goed (meer) kan bukken en reiken.</p> <p>Patiënten met beperkte kracht in de handen.</p> <p>Voor therapeutische elastische kous met zowel een open als gesloten teen.</p> <p>Zowel geschikt als aan- en als uittrekhulp.</p>	<p><b>Instructiefilm:</b>  <a href="https://goedgebruik.nl/filmpjes-van-alle-technieken/3steunkousen-aan-en-uitrekken/312-zelf-steunkous-open-teen-aantrekken-met-handyfix">https://goedgebruik.nl/filmpjes-van-alle-technieken/3steunkousen-aan-en-uitrekken/312-zelf-steunkous-open-teen-aantrekken-met-handyfix</a></p> <p><a href="https://goedgebruik.nl/filmpjes-van-alle-technieken/3steunkousen-aan-en-uitrekken/313-zelf-steunkous-open-teen-uitrekken-met-handyfix">https://goedgebruik.nl/filmpjes-van-alle-technieken/3steunkousen-aan-en-uitrekken/313-zelf-steunkous-open-teen-uitrekken-met-handyfix</a></p> <p><a href="https://goedgebruik.nl/filmpjes-van-alle-technieken/3steunkousen-aan-en-uitrekken/314-zelf-steunkous-gesloten-teen-aantrekken-met-handyfix">https://goedgebruik.nl/filmpjes-van-alle-technieken/3steunkousen-aan-en-uitrekken/314-zelf-steunkous-gesloten-teen-aantrekken-met-handyfix</a></p> <p><b>Schriftelijke instructie:</b>  <a href="https://nl.handylegs.com/wp-content/uploads/2020/08/2019-02-Actueel-HandyFix-NL_HandleidingUitneembaar_PaarsWikkelvouw_2019_LR.pdf">https://nl.handylegs.com/wp-content/uploads/2020/08/2019-02-Actueel-HandyFix-NL_HandleidingUitneembaar_PaarsWikkelvouw_2019_LR.pdf</a></p>
	<p>Als de patiënt niet goed (meer) kan bukken en reiken.</p> <p>Patiënten met beperkte kracht in de handen.</p> <p>Voor therapeutische elastische kous met zowel een open als gesloten teen.</p> <p>Zowel geschikt als aan- en als uittrekhulp.</p>	<p><b>Instructiefilm:</b>  <a href="https://goedgebruik.nl/filmpjes-van-alle-technieken/3steunkousen-aan-en-uitrekken/35-zelf-steunkous-open-en-gesloten-teen-aantrekken-met-handylegs">https://goedgebruik.nl/filmpjes-van-alle-technieken/3steunkousen-aan-en-uitrekken/35-zelf-steunkous-open-en-gesloten-teen-aantrekken-met-handylegs</a></p> <p><a href="https://goedgebruik.nl/filmpjes-van-alle-technieken/3steunkousen-aan-en-uitrekken/36-zelf-steunkous-open-en-gesloten-teen-uitrekken-met-handylegs">https://goedgebruik.nl/filmpjes-van-alle-technieken/3steunkousen-aan-en-uitrekken/36-zelf-steunkous-open-en-gesloten-teen-uitrekken-met-handylegs</a></p>
	<p>Als de patiënt niet goed (meer) kan bukken en reiken.</p> <p>Patiënten met beperkte kracht in de handen.</p> <p>Voor therapeutische elastische kous met zowel een open als gesloten teen.</p> <p>Zowel geschikt als aan- en als uittrekhulp.</p>	<p>Visuele handleiding:  <a href="https://www.youtube.com/watch?v=bY_GCFThTJY">https://www.youtube.com/watch?v=bY_GCFThTJY</a></p>

	<p>Als de patiënt niet goed (meer) kan bukken en reiken.</p> <p>Patiënten met beperkte kracht in de handen.</p> <p>Voor therapeutische elastische kous met zowel een open als gesloten teen.</p> <p>Zowel geschikt als aan- en als uittrekhulp.</p>	<p>Instructiefilm en schriftelijke instructie: <a href="https://www.steunkousgemak.nl/instructies-steve-plus-aantrekhulp-steunkous-aantrekken">https://www.steunkousgemak.nl/instructies-steve-plus-aantrekhulp-steunkous-aantrekken</a></p>
Categorie III: steunkouspistool	Wanneer inzetten	Link youtube
	<p>Als de patiënt niet goed (meer) kan bukken en reiken en weinig kracht in de armen heeft.</p> <p>Voor therapeutische elastische kous met zowel een open als gesloten teen.</p> <p>Zowel geschikt als aan- en als uittrekhulp.</p> <p>Het bedrijf dat deze middelen levert kan aan huis van de patiënt instructie en demonstratie komen geven.</p>	<p>Instructiefilm: <a href="https://www.youtube.com/watch?v=D66jekR4-KA">https://www.youtube.com/watch?v=D66jekR4-KA</a></p> <p>Schriftelijke instructie: <a href="http://www.memeso.nl/wp-content/uploads/2015/01/Gebruiksaanwijzing-EC-therapeutische-elastische-kouspistool-Personal-v2.22-ECMD.pdf">http://www.memeso.nl/wp-content/uploads/2015/01/Gebruiksaanwijzing-EC-therapeutische-elastische-kouspistool-Personal-v2.22-ECMD.pdf</a></p>

## Bijlage 7.8: Hulpkaart keuze therapeutische elastische kous

### Patiënten met diep veneuze trombose

Patiënten met diep veneuze trombose dienen een klasse 3 therapeutische elastische kous tot kniehoogte te krijgen met graduele compressie (druk 34-46 mmHg op enkelniveau). Tenzij (relatieve) contra-indicaties bestaan voor deze druk (zie Bijlage 7.1). De drukklasse van de therapeutische elastische kous dient niet automatisch naar beneden te worden bijgesteld als blijkt dat de patiënt de kous niet zelfstandig kan aan- of uittrekken. In dit geval dient gekeken te worden naar de inzet van hulpmiddelen zoals eerder in dit protocol besproken. Voor de behandeling van DVT is een kous tot de knie in de regel voldoende.

### Patiënten met chronische veneuze insufficiëntie

Patiënten met chronische veneuze insufficiëntie en een C5 classificatie (tekenen van veneuze insufficiëntie en een genezen veneus ulcus, op basis van de CEAP) krijgen bij voorkeur een klasse 3 therapeutische elastische kous. In geval van een sterke oedeemneiging is ook een hoge stiffness wenselijk. CVZ-patiënten met CEAP-classificatie C3 en C4 die conservatief behandeld worden wordt een klasse 2 (druk 23-32 mmHg op enkelniveau) of klasse 3 (druk 34-46 mmHg op enkelniveau) therapeutische elastische kous voorgeschreven.

Voor achtergrondinformatie over de verschillende karakteristieken van de therapeutische elastische kous (bijv. druk en type) zie:

<https://www.wcs.nl/wp-content/uploads/Therapeutisch-elastische-kousen.pdf>

De werkzaamheid van therapeutische elastische kousen is afhankelijk van de druk die ze uitoefenen op het been, in het bijzonder op de enkel, en daarnaast de mate waarin de therapeutische elastische kous weerstand biedt tegen de mate van vervorming. Dit laatste wordt de weerstandscoëfficiënt of stiffness genoemd en kan klinisch vertaald worden als het oedeem preventief effect. Vlakbrei kousen hebben in de regel een hogere DSI (dynamic stiffness index), een hogere stiffness staat voor een betere effectiviteit qua oedeem preventie<sup>1</sup>.

In de lijst van Bernink vindt u de een lijst van Therapeutische Elastische Kousen die zijn getoetst en voldoen aan de eisen van Bernink (<https://lijstvanbernik.nl/register/>).

<sup>1</sup> Van der Wegen-Franken CPM, Mulder P, Tank B, Neumann HAM. Variation in the dynamic stiffness index of different types of medical elastic compression stockings. Phlebology 2008; 23: 77-84.

## Bijlage 7.9: Voorbeeldrecept definitieve therapeutische elastische kous

Datum:

Naam patient:

Adres:

PC/Woonplaats:

Telefoonnummer:

Verzekerd bij:

Polisnummer:

Geboortedatum:

BSN nr.:

Diagnose

- DVT (diep veneuze trombose) L / R / beiderzijds
- CVZ (chronisch veneuze ziekte) L / R / beiderzijds
- Varices L / R / beiderzijds
- Anders, namelijk.....

Aantal: .... stuks

Klasse: 2        3        (4)

Bijzonderheden:

- AD (kniehoogte)
- AG (dijhoogte)
- Vlakbrei therapeutische elastische kous (op maat gemaakt)
- Rondbrei therapeutische elastische kous (confectiekous)
- Anders, namelijk.....

Relevante patiëntkenmerken (zoals van belang zijnde co-morbiditeit en evt. doelen en wensen patiënt m.b.t. zelfstandigheid):  
.....  
.....

Indicatie functioneringsniveau:

- Patiënt kan waarschijnlijk zelfstandig functioneren zonder aan- en uittrekhulpmiddel
- Patiënt kan waarschijnlijk zelfstandig functioneren na korte uitleg van een aan- en uittrekhulpmiddel
- Patiënt kan waarschijnlijk zelfstandig functioneren na training van een hulpmiddel door de ergotherapeut
- Patiënt kan waarschijnlijk zelfstandig functioneren met een hulpmiddel en hulp van de beschikbare mantelzorger
- Patiënt kan niet zelfstandig functioneren en heeft thuiszorg nodig

Handtekening en stempel arts:

## Bijlage 7.10: Voorbeeld schriftelijke motivatie aan- en uittrekhulpmiddel

De schriftelijke motivatie bestaat tenminste uit de volgende punten:

- Dat de patiënt niet in een instelling woont waarbij het aan- en uittrekken van de therapeutische elastische kous deel uitmaakt van de te leveren zorg
- Welke lichamelijke beperkingen er zijn waardoor de patiënt geen eenvoudiger/goedkoper hulpmiddel kan gebruiken en dus is aangewezen op inzet van het voorgestelde hulpmiddel
- Of de patiënt eerder een duurzaam aan- of aantrek hulpmiddel heeft gehad (hulpmiddelen uit de categorieën boven glijzakken zie hulpkaartje selectie hulpmiddelen) en in welk jaar (over het algemeen vergoeden verzekeraars 1x per 5 jaar een duurzaam hulpmiddel)
- Dat de patiënt of diens mantelzorger het hulpmiddel adequaat kan gebruiken na instructie /training
- Dat de verzekerde geen thuiszorg ontvang voor het aan- en uittrekken van de therapeutische elastische kous of dat deze zorg door implementatie van het hulpmiddel kan worden stopgezet/vermindert

### Aanvraagformulier (voorbeeld)

Soort hulpmiddel:

.....Maat:.....

Woont de cliënt in een zorginstelling waarbij het aan- en uittrekken van de therapeutische elastische kous deel uitmaakt van de te leveren zorg?

Ja/nee. Indien ja: patiënt komt niet in aanmerking voor vergoeding van een duurzaam hulpmiddel.

Welk lichamelijke beperking is er die dit aan- en/of uittrekhulpmiddel nodig maakt:

.....

Specificeer eventueel welke typen hulpmiddelen eerder zijn uitgeprobeerd die niet hebben geleid tot zelfstandigheid bij de patiënt (evt. met hulp van diens mantelzorger):

.....

Indien patiënt eerder een duurzaam hulpmiddel heeft gebruikt, in welk jaar was dit?

.....

Heeft verzekerde en/of diens mantelzorger met het aangevraagde hulpmiddel voldoende geoefend en kan verzekerde nu zelfstandig, of met behulp van mantelzorg, de TEK aan-/uittrekken?

Ja

Nee

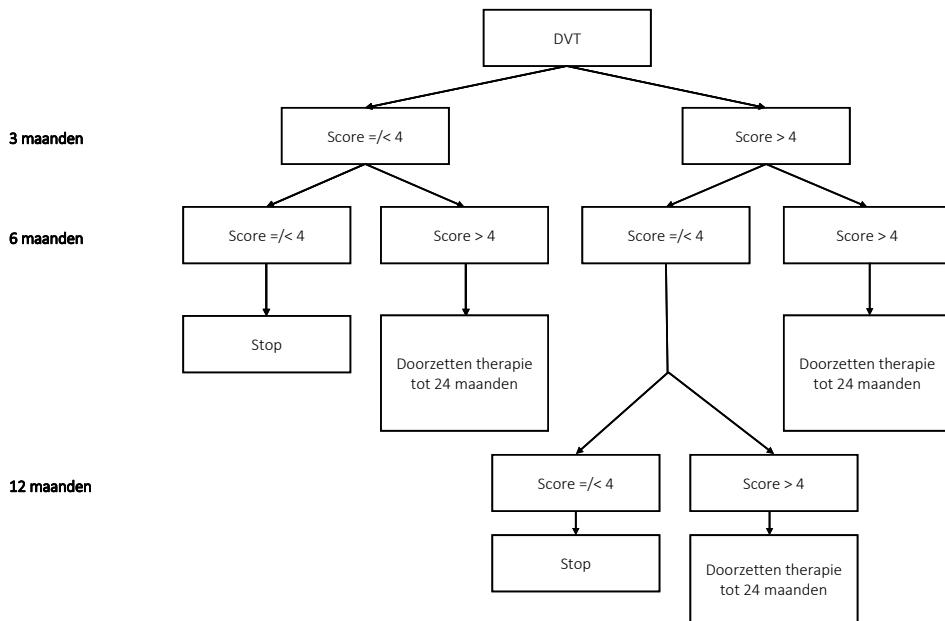
Gegevens verzekerde:

Naam	:	.....
Geboortedatum	:	.....
BSN nummer	:	.....
Verzekerd bij	:	.....
Verzekeringsnummer	:	.....
Handtekening	:	.....

*In te vullen door behandelaar*

Naam behandelaar: .....	Datum .....
-------------------------	-------------

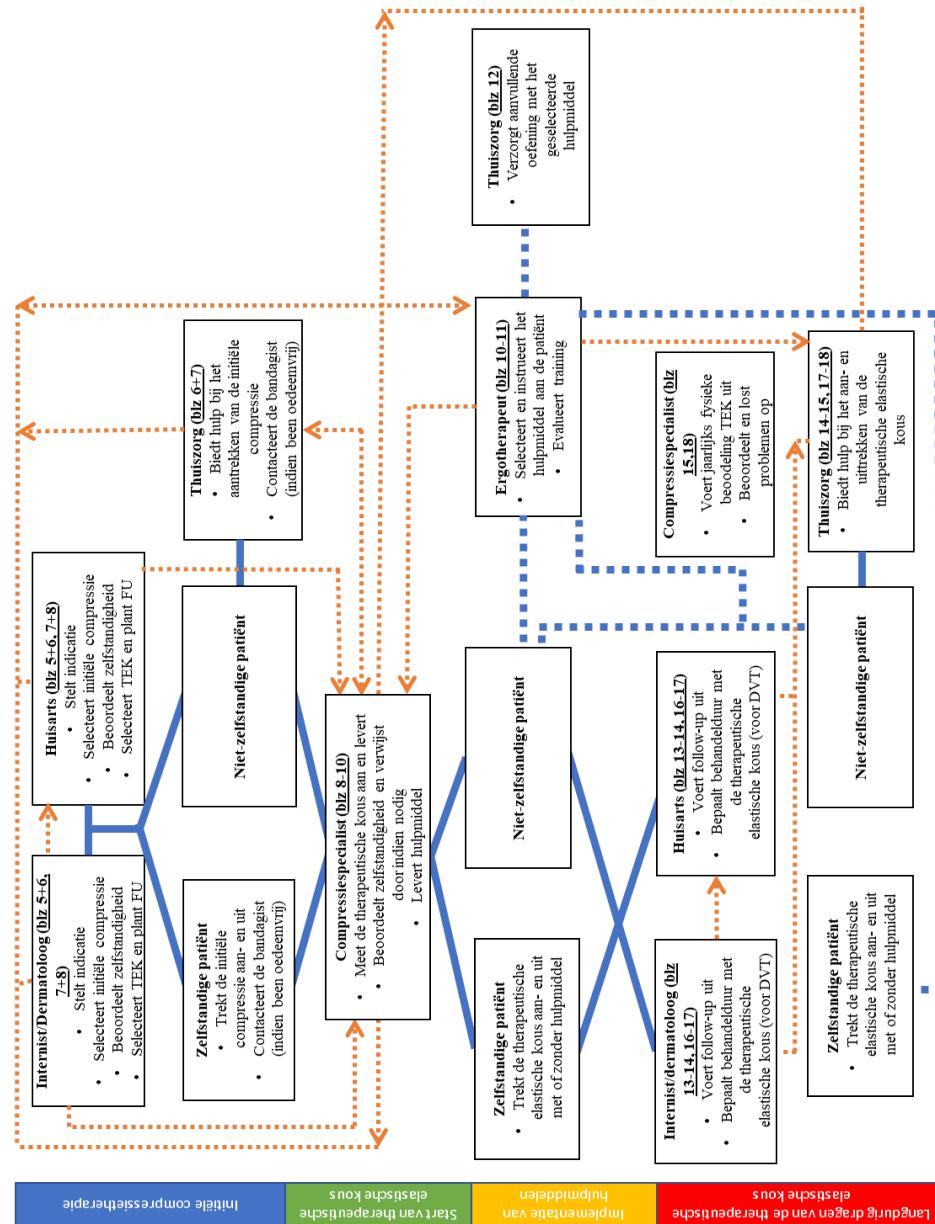
## Bijlage 7.11: Hulpkaart geïndividualiseerde behandelduur DVT



### Villalta score

	Geen	Mild	Matig	Ernstig
<i>Symptomen</i>				
Pijn	0	1	2	3
Krampen	0	1	2	3
Zwaar gevoel	0	1	2	3
Paresthesie	0	1	2	3
Pruritis	0	1	2	3
<i>Klinische tekenen</i>				
Pretibiaal oedeem	0	1	2	3
Induratie	0	1	2	3
Hyperpigmentatie	0	1	2	3
Roodheid	0	1	2	3
Veneuze ectasieën	0	1	2	3
Pijnlijke kuit bij compressie	0	1	2	3
Veneus ulcer	-			+

## Bijlage 7.12: Samenvattend stroomschema





# Chapter 8

Implementation of a cross-domain protocol for the optimization of compression therapy guided by the model of diffusion of innovation

**EMBARGOED**

Schreurs RHP, Joore MA, De Bruijn-Geraets DP, Ten Cate H, Ten Cate-Hoek AJ

*Submitted*

# Chapter 9

Summary and general discussion



Compression therapy of the leg is a commonly prescribed treatment modality worldwide. The therapy is indicated to reduce leg complaints in the acute phase of deep venous thrombosis (DVT)<sup>1-3</sup> and to prevent the post-thrombotic syndrome.<sup>4</sup> For chronic venous disease (CVD) patients, compression therapy has been associated with improved venous symptomatology, reduced edema and skin changes, and prevention of ulcer recurrence.<sup>5</sup>

This thesis aims to develop a national cross-domain protocol compression therapy that guides healthcare professionals in optimizing compression therapy for patients with DVT and CVD (C3-C5). This chapter summarizes and discusses the main findings of the studies that were performed.

## Summary of main findings

In **chapter 2**, we provided an overview of current evidence regarding the usefulness of compression therapy in the management of venous disease, and we highlighted the role of individualized elastic compression stocking (ECS) therapy for DVT patients, which was previously found to be non-inferior to a standard duration of two years.<sup>6</sup> However, evidence from clinical trials is limited in its practical applicability as these trials do not assess the structure of current ECS therapy in various health care systems. To ultimately improve compression care, it was necessary to gain detailed insight into the structure and actual variability of organization of compression therapy in daily practice.

To this end, we conducted a Functional Resonance Analysis Method (FRAM) study as presented in **chapter 3**. For this analysis, we performed thirty interviews in two regions in the Netherlands (region Limburg and region North-Holland) with health care professionals from various disciplines (n=25) and patients (n=5). These two regions were chosen because of their differences in geographical location as well as their organization of care. Based on the information provided in the interviews, we created two FRAM models to visualize the process and to identify the variability of the functions, their effect on outcomes, and interdependencies between different functions. Finally, we arranged two stakeholder meetings in which we discussed the findings and identified six improvement themes: improving dissemination of knowledge of the entire process among health care professionals; optimizing and standardizing initial compression therapy; optimizing timing to contact the medical stocking supplier (when edema has receded); improving the implementation of assistive devices, which enhances patients' chances to remain self-reliant; harmonizing follow-up duration for CVD patients, and personalizing follow-up and treatment duration in DVT patients. Additionally, four time-consecutive phases were empirically identified: 1. Initial compression therapy, 2. Implementation of assistive devices, 3. The onset of long-term ECS therapy, and 4. Long-term ECS therapy.

In **chapter 4** we further refined the improvement themes as identified in the FRAM study by identifying what works (or does not work), for whom, and under which circumstances. For this purpose, we conducted a Realist Evaluation. For this evaluation we expanded the interviews as performed in the FRAM with additional questions to identify important outcomes in the organization of compression therapy and the main contextual factors and mechanisms resulting in either desirable or undesirable outcomes. Shared links and consistent patterns between context, mechanisms, and outcomes across the data were identified to generate the CMOcs (context-mechanism-outcome configurations).<sup>7</sup> In addition, we administered online surveys among a larger sample of health care professionals (occupational therapists, general practitioners, and home care nurses, response rate 74% (n=114)) to provide quantitative insight into the occurrence of undesirable and desirable outcomes. Based on the CMOcs we ultimately identified five targets for improvement strategies: 1. Increase all health care professionals' knowledge of compression therapy, 2. Provide unambiguous recommendations in guidelines and protocols, 3. Increase patient involvement (and if applicable informal caregivers) in the decision-making process, 4. Provide access to resources (time, trained staff, and clear reimbursement agreements), and 5. Promote interdisciplinary consultation.

In **chapter 5**, we performed a modified Delphi analysis to evolve the targets for improvement as identified in **chapters 3 and 4** into national recommendations as a base for a cross-domain protocol. Three questionnaire rounds were distributed among a panel of 56 national health care professionals and seven patients. The panel was asked to score statements regarding interdisciplinary collaboration, roles and responsibilities, and treatment decisions in compression therapy to reach consensus on critical issues of compression care as identified in **chapters 3 and 4**. We achieved full consensus on 19 out of 21 statements. No agreement was reached on the need for a follow-up appointment for CVD patients and on who should be responsible for determining the ECS type (custom-made or standard). Furthermore, panelists were asked to score barriers for implementation of optimal ECS therapy which were identified in the qualitative information of the prior rounds. The treating physicians' lack of knowledge, reimbursement constraints for assistive devices and training time, administrative burdens, and a lack of expertise regarding applying multilayer compression bandages were identified as barriers to implement optimal compression care. The consensus statements were used as a fundament for the recommendations in the general cross-domain protocol as presented in chapter 7.

In **chapter 6**, we conducted a budget impact analysis. First, we gained insight into the per-patient and population resource use and the costs of current care pathways for compression therapy in DVT-patients in the Netherlands. Second, we evaluated the potential impact of the three main improvement targets as identified in the modified Delphi analysis (**chapter 5**). These targets were selected based on their expected clinical

implications for patient outcomes and costs and included: providing initial compression therapy to all DVT patients with the preference for temporary compression hosiery, early and accessible consultation of the occupational therapists to train patients on how to use assistive devices to preserve autonomy and increase adherence, and implementation of an individualized treatment duration with formal leg assessments based on Villalta scores.

We found that the per-patient costs per episode associated with the current pathways were €1046 (NH-A pathway), €947 (NH-B pathway), and €1,256 (Limburg pathway). The improvements increased workload for occupational therapists, general practitioners, and internists (the latter only for NH) and decreased workload for home care personnel in all regions. In some regions implementing the new protocol will directly lead to cost savings. Other regions will be confronted with an initial increase in population costs followed by cost savings after three years of implementation, depending on how compression therapy is currently organised.

The annual population costs (assuming nationwide implementation) of the three improvement targets combined ranged from €1,0 million (mln) (Limburg pathway) saved to €6,4 mln (NH-B pathway) increased costs for the first year after implementation. After three years, this was between €4,7 mln (Limburg pathway) saved and €0,6 mln (NH-B pathway) increased costs. Finally, we identified that the number of patients referred to the occupational therapist and the successful implementation rate of an assistive device during training by the occupational therapist mainly impacted the number of patients that ultimately received long-term home care assistance. Moreover, for patients requiring home care assistance during long-term ECS therapy, the time needed for assistance decreased from 130 to 92 hours for the NH pathway, and from 115 to 108 hours for the Limburg pathway. Long-term home care assistance was identified as the main driver of total costs.

In **chapter 7** we presented the cross-domain protocol which provides practical guidance on optimizing the organization of compression therapy in daily practice. It includes guidance on how health care professionals should act regarding critical care moments, describes their roles and responsibilities, and presents how professionals from different professional groups should communicate and collaborate to optimize outcomes.

In **chapter 8** we reflected on the proposed barriers and facilitators of the protocol's implementation and developed an implementation model theoretically guided by the diffusion of innovation model.<sup>8</sup> Our model includes ongoing engagement of stakeholders and national health care professionals' organizations during implementation, recruiting local stakeholders to form (local) interdisciplinary teams, sharing individual benefits of the protocol, discussing financial constraint and reimbursement issues with insurance

companies, and pilot testing and continuously information on implementation rates and outcomes to health care professionals.

In conclusion, this thesis shows there is considerable variation in how compression therapy is managed in current practice for patients with DVT and CVD in the Netherlands. It provides a detailed insight into the main variability in the organisation of compression therapy, important barriers for implementation of optimal compression therapy, and improvement targets to optimize compression therapy (**chapters 3, 4, and 5**). Additionally, insight was gained into the cost implications of compression therapy in current practice and the budget impact of the main improvements in different care pathways for patients with DVT (**chapter 6**). Based on the combined findings of the chapters combined, a general cross-domain protocol was developed. The protocol provides practical guidance on optimal interdisciplinary collaboration, roles and responsibilities, and treatment decisions in compression therapy (**chapter 7**). Finally, an implementation model was developed to direct the implementation of the cross domain protocol into daily practice (**chapter 8**).

## General discussion

### Methodological considerations and implications for research

The major strength of this thesis is that we used a mixed method design. In complex healthcare systems such as compression care, an in-depth understanding of current care pathways including interactions and functioning is essential before improvement interventions can be successfully designed and implemented.<sup>9</sup> Mixed methods are a powerful tool during these early stages of intervention development and implementation, especially when targeting a diversity of contextual settings.<sup>10-12</sup> Recent perspectives on implementation science argue that in complex healthcare systems the design of improvement interventions risks being flawed if there is limited focus beforehand to gain a deep insight into how the system under study actually functions when things go right and wrong.<sup>13-16</sup> In this thesis we combined qualitative methods (a FRAM and a Realist Evaluation), quantitative methods (a budget impact analysis and surveys) and methods that integrated both methods (the modified Delphi analysis) to ultimately develop our cross-domain protocol ('the intervention'). This type of mixed methods is well suited to address the increasing complexity of public health problems and their solutions.<sup>12</sup> The qualitative designs allowed us to obtain a detailed insight into how the clinical pathways are organized in daily practice and how they could be improved. This revealed many influential factors that could not have been specified a priori or measured quantitatively.

First, we used the FRAM to explore it as a basis to identify targets for improvement and to explore its use in the early stages of the development of an intervention optimizing compression therapy. Although literature increasingly recognizes the need to standardize by function rather than form<sup>17</sup>, to our knowledge, the FRAM has only been used to guide future intervention development twice.<sup>18,19</sup> Second, we used a Realist Evaluation to obtain a deeper insight into contextual factors and mechanisms resulting in desirable and undesirable outcomes. Realist evaluation is increasingly conducted to address complex problems in health policy and to determine and evaluate improvement strategies.<sup>20,21</sup> The method is especially suitable for this purpose, as more traditional evaluation efforts that focus on aggregate effectiveness represent an oversimplification of both the environment and the interventions themselves.<sup>22</sup> These traditional methods primarily focus on outcomes instead of how these outcomes are achieved.<sup>23,24</sup> In contrast, Realist Evaluation acknowledges the complexity of a system by identifying how outcomes are achieved, how complex causal pathways work or do not work, and how these pathways can advance the best circumstances for increasing improvement strategies' impact.<sup>23,25,26</sup> Afterward, we used quantitative methods (for example the surveys) to put the qualitative findings into perspective and to provide insight into the cost consequences of the main improvements.

In the next stage of intervention development, we used a Modified Delphi analysis to develop consensual guidance on how to optimally organize compression therapy. Evidence from meta-analysis and randomized controlled trials is considered of highest quality to inform professional guidance.<sup>27</sup> Gaining expert consensus, as the primary focus of a Delphi analysis, is regarded as the lowest grade of evidence.<sup>28</sup> However, there are no clinical trials or large observational studies regarding the optimal organization of compression therapy. Therefore, expert consensus was most feasible for our research goal and allowed us to translate local findings to national consensus recommendations.

Finally, a budget impact analysis was used to assess the main improvements' impact on resource use and budget. The methods we consecutively used to develop our cross-domain protocol represent a novel contribution to the field of implementation science. To our opinion, the use of these consecutive methods has the potential to empower implementation rates since it acknowledges early and widespread involvement of stakeholders from all disciplines and ensures the development of protocols based on the implementation context. Earlier studies also found these factors as important facilitators to implementation.<sup>25,29-31</sup>

The main limitation of this thesis concerns the quantification of our results, especially the global representations of patient volumes involved in the main care pathways, and the associated costs. Due to a lack of both literature and registration of the number of patients involved in the different pathways, we depended on involved health care professionals' estimations. Unfortunately, the current registration systems for delivered

care and reimbursement lack the possibility to extract this kind of detailed data as health care professionals usually declare ‘service packages’ such as ‘diagnose-behandel-combinaties’ (DBCs) or cluster packages (for medical stocking suppliers and home care organizations). In these packages, several services are included and it remains unclear which care individual patients receive exactly. For example, it was not possible to identify the number of patients needing home care assistance for compression therapy as home care organizations’ registration often only indicate a global care demand instead of specific care requirements. Hence, if a patient needs care for activities for daily living (ADL), this could include applying and removing the ECS without specific registration. For future research, we suggest that estimated input parameters should be validated with patient-level data to increase the robustness of the results. Furthermore, to gain better insight into the patient volumes and resource use associated with compression therapy and outcomes of care, we suggest an interdisciplinary information and declaration system with a broader scope. In this system, all health care professionals register delivered care and products for the entire patient journey.

The implementation model described in **chapter 8** can be used to guide the actual implementation of the protocol in daily practice. The main elements to be targeted are: financial constraints and reimbursement issues to improve the systems readiness for innovation, ongoing engagement of the involved stakeholders and local key actors in the implementation process, stimulating the formation of local and national interdisciplinary teams for ongoing monitoring, sharing strategies and dissemination of implementation outcomes.

### Recommendations and implications for clinical practice

The next step is implementation of the cross-domain protocol in daily practice. The protocol is the starting point to guide regional work arrangements and collaborations to optimize compression therapy. The proposed implementation strategy as presented in **chapter 8** will facilitate implementation into daily practice. We recommend to adjust the health care professionals guidelines according to the recommendations included in the protocol and make the protocol accessible for all health care professionals involved. Furthermore, the national professional associations should be approached to play an active role in the diffusion process of the protocol (for example by including a link and information in their newsletter). In addition, insurance companies should remove the financial barriers and reimbursement constraints in consultation with health care providers. During this consultation, special attention should be paid to the financial constraint for medical stocking suppliers and the reimbursement of assistive devices for training purposes. Furthermore, the protocol emphasizes patient involvement in the decision making process. It is important to find ways to facilitate patients taking this role and taking control of their own health care process as much as possible. Finally, keeping health care professionals updated regarding the effects of the intervention on patient outcomes is likely to keep them engaged.

## References

1. Amin EE, Joore MA, Ten Cate H, Meijer K, Tick LW, Middeldorp S, et al. Clinical and economic impact of compression in the acute phase of deep vein thrombosis. *J Thromb Haemost.* 2018 Jun 1.
2. Partsch H, Blättler W. Compression and walking versus bed rest in the treatment of proximal deep venous thrombosis with low molecular weight heparin. *J Vasc Surg.* 2000;32(5):861-9.
3. Roumen-Klappe EM, den Heijer M, van Rossum J, Wollersheim H, van der Vleuten C, Thien T, et al. Multilayer compression bandaging in the acute phase of deep-vein thrombosis has no effect on the development of the post-thrombotic syndrome. *J Thromb Thrombolysis.* 2009;27(4):400-5.
4. Appelen D, van Loo E, Prins MH, Neumann MH, Kolbach DN. Compression therapy for prevention of post-thrombotic syndrome. *Cochrane Database Syst Rev.* 2017;9(9):CD004174.
5. Nelson EA, Bell-Syer SE. Compression for preventing recurrence of venous ulcers. *Cochrane Database Syst Rev.* 2014;2014(9):CD002303.
6. Ten Cate-Hoek AJ, Amin EE, Bouman AC, Meijer K, Tick LW, Middeldorp S, et al. Individualised versus standard duration of elastic compression therapy for prevention of post-thrombotic syndrome (IDEAL DVT): a multicentre, randomised, single-blind, allocation-concealed, non-inferiority trial. *Lancet Haematol.* 2018;5(1):e25-e33.
7. Pawson R, Tilley N. *Realist evaluation.* London: SAGE. 1997.
8. Greenhalgh T, Robert G, Macfarlane F, Bate P, Kyriakidou O. Diffusion of innovations in service organizations: systematic review and recommendations. *Milbank Q.* 2004;82(4):581-629.
9. McNab D, Freestone J, Black C, Carson-Stevens A, Bowie P. Participatory design of an improvement intervention for the primary care management of possible sepsis using the Functional Resonance Analysis Method. *BMC Med.* 2018;16(1):174.
10. Lindacher V, Curbach J, Warrelmann B, Brandstetter S, Loss J. Evaluation of Empowerment in Health Promotion Interventions: A Systematic Review. *Eval Health Prof.* 2018;41(3):351-92.
11. Southam-Gerow MA, Dorsey S. Qualitative and mixed methods research in dissemination and implementation science: introduction to the special issue. *J Clin Child Adolesc Psychol.* 2014;43(6):845-50.
12. Palinkas LA, Mendon SJ, Hamilton AB. Innovations in Mixed Methods Evaluations. *Annu Rev Public Health.* 2019;40:423-42.
13. Craig P, Dieppe P, Macintyre S, Michie S, Nazareth I, Petticrew M. Developing and evaluating complex interventions: the new Medical Research Council guidance. *Int J Nurs Stud.* 2013;50(5):587-92.
14. Campbell NC, Murray E, Darbyshire J, Emery J, Farmer A, Griffiths F, et al. Designing and evaluating complex interventions to improve health care. *BMJ.* 2007;334(7591):455-9.
15. Kaplan HC, Brady PW, Dritz MC, Hooper DK, Linam WM, Froehle CM, et al. The influence of context on quality improvement success in health care: a systematic review of the literature. *Milbank Q.* 2010;88(4):500-59.
16. Marshall M, de Silva D, Cruickshank L, Shand J, Wei L, Anderson J. What we know about designing an effective improvement intervention (but too often fail to put into practice). *BMJ Qual Saf.* 2017;26(7):578-82.
17. Hawe P. Lessons from complex interventions to improve health. *Annu Rev Public Health.* 2015;36:307-23.
18. O'Hara JK, Baxter R, Hardicre N. 'Handing over to the patient': A FRAM analysis of transitional care combining multiple stakeholder perspectives. *Appl Ergon.* 2020;85:103060.
19. Ross A, Sherriff A, Kidd J, Gnich W, Anderson J, Deas L, et al. A systems approach using the functional resonance analysis method to support fluoride varnish application for children attending general dental practice. *Appl Ergon.* 2018;68:294-303.
20. Dossou JP, Van Belle S, Marchal B. Applying the Realist Evaluation Approach to the Complex Process of Policy Implementation-The Case of the User Fee Exemption Policy for Cesarean Section in Benin. *Front Public Health.* 2021;9:553980.
21. Salter KL, Kothari A. Using realist evaluation to open the black box of knowledge translation: a state-of-the-art review. *Implement Sci.* 2014;9:115.
22. Kernick D. Wanted--new methodologies for health service research. Is complexity theory the answer? *Fam Pract.* 2006;23(3):385-90.

23. Hewitt G, Sims S, Harris R. The realist approach to evaluation research: an introduction. *Int J Ther Rehabil.* 2012;19(5):250-9.
24. Pawson R, Tilley N. Realist Evaluation. 2004. Available from: [https://www.communitymatters.com.au/RE\\_chapter.pdf](https://www.communitymatters.com.au/RE_chapter.pdf).
25. Rycroft-Malone J, Fontenla M, Bick D, Seers K. A realistic evaluation: the case of protocol-based care. *Implement Sci.* 2010;5:38.
26. Ridde V, Guichard A. Perception of each mechanism favorable to the reduction of social and health inequalities in France. *Glob Health Promot.* 2011;18(3):47-60.
27. Greenhalgh T, Howick J, Maskrey N. Evidence based medicine: a movement in crisis? *BMJ.* 2014;348:g3725.
28. Burns PB, Rohrich RJ, Chung KC. The levels of evidence and their role in evidence-based medicine. *Plast Reconstr Surg.* 2011;128(1):305-10.
29. Rogers L, De Brún A, Birken SA, Davies C, McAuliffe E. Context counts: a qualitative study exploring the interplay between context and implementation success. *J Health Organ Manag.* 2021 Mar 9;ahead-of-print(ahead-of-print):802-824.
30. Rycroft-Malone J, Fontenla M, Seers K, Bick D. Protocol-based care: the standardisation of decision-making? *J Clin Nurs.* 2009;18(10):1490-500.
31. Paina L, Namazzi G, Tetui M, Mayora C, Kananura RM, Kiwanuka SN, et al. Applying the model of diffusion of innovations to understand facilitators for the implementation of maternal and neonatal health programmes in rural Uganda. *Global Health.* 2019;15(1):38.





# Addendum

Nederlandse samenvatting



## Nederlandse samenvatting

Compressietherapie wordt wereldwijd zeer frequent voorgeschreven. Voor patiënten met diep veneuze trombose (DVT) verbetert het klachten van het been in de acute fase en op de langere termijn verkleint compressietherapie de kans op het ontstaan van het post-thrombotisch syndroom. Ook voor patiënten met chronische veneuze ziekte (CVZ) vormt compressietherapie de hoeksteen van de conservatieve behandeling. Het verbetert voor deze patiënten klachten van de benen, vermindert oedeem, en verkleint de kans op het ontstaan en recidiveren van veneuze ulcera.

Het doel van dit proefschrift is het optimaliseren van compressietherapie voor patiënten met DVT en CVZ (stadium C3-C5) door middel van het ontwikkelen van een domein-overstijgend protocol met aanbevelingen over het optimaal inrichten van samenwerking en organisatie binnen de zorgketen. De belangrijkste bevindingen zullen in dit hoofdstuk worden samengevat.

**Hoofdstuk 1** behelst de algemene inleiding. In **hoofdstuk 2** geven we een onderbouwing van de meerwaarde van compressietherapie bij veneuze ziekten. Daarbij benadrukken we de rol van het individualiseren van de behandelduur met therapeutische elastische kousen voor patiënten met diep veneuze trombose aangezien eerder onderzoek (de IDEAL-DVT trial) aantoonde dat dit niet slechter is dan een standaard behandelduur van twee jaar. Het is echter zo dat resultaten van dergelijke onderzoeken vaak niet of moeizaam geïmplementeerd worden omdat dergelijke onderzoeken meestal geen rekening houden met de structuur van de bestaande zorgketen. Om compressiezorg te optimaliseren is het daarom nodig om inzicht te krijgen in de variabiliteit van de organisatie van compressietherapie in de dagelijkse praktijk.

Om deze vragen te beantwoorden, maken we in **hoofdstuk 3** van dit proefschrift gebruik van een Functional Resonance Analysis Method (FRAM). De basis voor de FRAM zijn 25 interviews met zorgprofessionals vanuit verschillende betrokken disciplines en vijf interviews met patiënten. Professionals en patiënten kwamen uit twee verschillende regio's: Limburg en Noord-Holland (NH). Deze regios werden gekozen omdat ze geografisch ver van elkaar gescheiden zijn en doordat ze verschillen in organisatie van zorg. Op basis van de interviews werden twee FRAM modellen ontworpen die het zorgproces van compressietherapie, de variabiliteit in functies inclusief het effect op uitkomsten, en afhankelijkheden tussen verschillende zorgprofessionals visualiseren. Na validatie van deze modellen in twee bijeenkomsten met de voornaamste lokale stakeholders werden 6 verbeterthema's geïdentificeerd: 1. Verbeteren van kennis over het gehele proces tussen betrokken zorgprofessionals, 2. Optimaliseren en standaardiseren van initiële compressietherapie, 3. Optimaliseren van de timing om de bandagist te contacteren indien oedeem is verdwenen, 4. Verbeteren van de selectie en implementatie van hulpmiddelen, 5. Harmoniseren van de follow-up duur voor

patiënten met CVZ, en 6. Personaliseren van follow-up en behandelduur voor patiënten met DVT. Tevens werden er 4 behandelfases geïdentificeerd in het proces: 1. Initiële compressietherapie, 2. Start van behandeling met therapeutische elastische kousen, 3. Selectie en implementatie van hulpmiddelen en 4. De onderhoudsfase met therapeutische elastische kousen.

In **hoofdstuk 4** hebben we de verbeterthema's zoals geïdentificeerd in **hoofdstuk 3** verder verfijnd door te identificeren wat werkt (of niet werkt), voor wie, en onder welke omstandigheden. Hiervoor hebben we gebruik gemaakt van een Realistische Evaluatie. Voor deze evaluatie hebben we de interviews zoals beschreven in **hoofdstuk 3** verder uitgebreid met vragen die meer inzicht gaven in belangrijke uitkomsten en hoe deze uitkomsten tot stand zijn gekomen. Door analyse van veel voorkomende antwoorden werden 'context-mechanisme-outcome configuraties' (CMOcs) geïdentificeerd. Deze CMOcs maakten inzichtelijk welke contextfactoren en reacties van zorgprofessionals en patiënten leiden tot bepaalde (zowel optimale als suboptimale) uitkomsten. Daarnaast hebben we enquête gehouden binnen een grote groep zorgprofessionals (ergotherapeuten, huisartsen en thuiszorgmedewerkers (n=114, respons 74%)) om meer kwantitatief inzicht te krijgen in het voorkomen van optimale en suboptimale uitkomsten. We hebben uiteindelijk vijf specifieke aangrijppingspunten voor verbeterstrategieën geïdentificeerd: 1. Verbeteren van kennis van compressie therapie voor zorgprofessionals, 2. Opstellen van duidelijke aanbevelingen in richtlijnen en protocollen, 3. Het meer betrekken van patiënten (en indien nodig de mantelzorger) in het besluitvormingsproces, 4. Beschikbaar stellen van voldoende tijd, getraind personeel en duidelijke vergoedingscriteria voor hulpmiddelen, en 5. Het stimuleren van interdisciplinaire samenwerking.

In **hoofdstuk 5** hebben we een gemodificeerde Delphi analyse uitgevoerd om de diffusiestap te maken van lokale verbetermogelijkheden naar landelijke aanbevelingen voor het domein overstijgende protocol. In deze analyse werden in drie rondes stellingen beoordeeld door een panel van 56 zorgprofessionals (huisartsen, internisten, dermatologen, compressiespecialisten, ergotherapeuten en thuiszorgmedewerkers) en zeven patiënten. Deze stellingen waren gebaseerd op de bevindingen uit **hoofdstuk 2 en 3** en hadden betrekking op interdisciplinaire samenwerking, rollen en verantwoordelijkheden, en kritische behandelbeslissingen in compressietherapie. In deze analyse werd voor 19 van de 21 stellingen volledige consensus behaald. Er werd geen consensus bereikt over het standaardiseren van een follow-up afspraak voor patiënten met CVZ en over de verantwoordelijk voor het voorschrijven van het type kous (maatwerk of confectie). Het gebrek aan kennis bij behandelend artsen, vergoedingsproblemen voor aan- en uittrekhulpmiddelen en trainingstijd, de administratielastiek, en een tekort aan kennis over meerlaags compressief zwachtelen werden geïdentificeerd als barrières om optimale zorg te kunnen bieden. De stellingen waarover consensus werd behaald

worden gebruikt als fundament voor de aanbevelingen in het domeinoverstijgende protocol (**hoofdstuk 7**).

**Hoofdstuk 6** beschrijft een budget impact analyse uitgevoerd voor patiënten met DVT. Ten eerste geven we inzicht in de patiëntgebonden en populatiegebonden kosten en middelen van de huidige zorgpaden binnen de compressietherapie. Ten tweede berekenen we de potentiële budget impact en effect op middelen van de drie belangrijkste verbeterthema's geïdentificeerd in **hoofdstuk 5**. Deze verbeterthema's werden gekozen op basis van de verwachte klinische impact op patiëntuitkomsten en hun kostenimplicatie. De drie thema's waren: het verstrekken van initiële compressie therapie aan alle patiënten met een voorkeur voor een standaard tijdelijke compressiekous, laagdrempelig betrekken van de ergotherapeut om een hulpmiddel te selecteren en de patiënt te trainen deze te gebruiken bij het aan- en uittrekken van de therapeutische elastische kous, en tevens het implementeren van een geïndividualiseerde behandelduur met formele beoordelingen van het been (de Villalta-score).

De patiëntgebonden kosten van de huidige zorgpaden voor compressie therapie per episode waren €1046 (zorgpad NH-A), €947 (zorgpad NH-B) en €1256 (zorgpad Limburg). De verbeterthema's verhoogden de werkdruk voor ergotherapeuten, huisartsen en internisten (de laatste alleen in NH) en verminderden de werkdruk voor de thuiszorg in alle regio's. Op nationaal niveau zal de implementatie van het domeinoverstijgende protocol in sommige regio's direct leiden tot kostenbesparingen. In andere regio's zullen de populatiekosten in eerste instantie oplopen gevolgd door besparingen drie jaar na implementatie. Dit is met name afhankelijk van de huidige organisatie van zorg.

De jaarlijkse populatiekosten (uitgaande van nationale implementatie) van de drie verbeterthema's gecombineerd wisselden tussen een besparing van één miljoen (zorgpad Limburg) en een investering van 6.4 miljoen (zorgpad NH-B) in het eerste jaar na implementatie. Na 3 jaar zal dit variëren tussen een besparing van 4.7 miljoen (zorgpad Limburg) en een investering van 0.6 miljoen (zorgpad NH-B). Het aantal patiënten dat werd doorverwezen naar de ergotherapeut, en de succeskans van implementatie van een hulpmiddel door de ergotherapeut waren de grootste factoren die bepaalden hoeveel patiënten uiteindelijk werden doorverwezen naar de chronische thuiszorg. Chronische thuiszorg werd geïdentificeerd als de grootste kostenpost binnen het proces.

In **hoofdstuk 7** presenteren we het domeinoverstijgende protocol. Dit protocol geeft praktische aanbevelingen over het optimaliseren van de organisatie van compressietherapie in de dagelijkse praktijk. Daarbij geeft het aanbevelingen over behandelbeslissingen op kritische moment in de zorg, rollen en verantwoordelijkheden

van de verschillende zorgprofessionals, en het vormgeven van optimale samenwerking tussen verschillende professionals in het proces om optimale uitkomsten te realiseren voor de patiënt.

**Hoofdstuk 8** reflecteert op de veronderstelde barrières en ondersteunende factoren om het protocol te implementeren. Op basis van deze reflecties werd een implementatie model ontwikkeld aan de hand van het ‘diffusie van innovatie’ model van Greenhalgh et al. Ons model toont dat het belangrijk is om stakeholders betrokken te houden tijdens het implementatieproces, om lokale stakeholders te werven om (lokale) interdisciplinaire teams te vormen, om financiële barrières en vergoedingsproblemen op te lossen in samenwerking tussen verzekерingsmaatschappijen en zorgprofessionals, en om zorgprofessionals gedurende implementatie voortdurend te voorzien van informatie over de voortgang van implementatie en effecten op patiëntuitkomsten.

Dit proefschrift toont aan dat er veel variatie is in hoe compressietherapie wordt geleverd aan patiënten met DVT en CVZ. Het geeft inzicht in de voornaamste variaties, verbetermogelijkheden en barrières voor het leveren van optimale compressie zorg (**hoofdstuk 3, 4 en 5**). Daarnaast geven we inzicht in de kosten van de huidige zorgpaden voor compressietherapie en de impact van de belangrijkste verbeterthema’s op deze kosten voor patiënten met DVT (**hoofdstuk 6**). Op basis van de verkregen inzichten presenteert **hoofdstuk 7** het uiteindelijke domein-overstijgende protocol. Dit is een praktische handleiding waarin duidelijke aanbevelingen staan betreffende: interdisciplinaire samenwerking, de rollen en verantwoordelijkheden van de verschillende zorgverleners en de patiënt in het proces, en het nemen van belangrijke behandelbeslissingen. Uiteindelijk is er een implementatie model ontwikkelt om implementatie van het domeinoverstijgende protocol in de dagelijkse praktijk te ondersteunen (**hoofdstuk 8**).

De volgende stap is de daadwerkelijke implementatie van het domeinoverstijgende protocol in de dagelijkse praktijk. Het protocol is het startpunt om regionale werkafspraken en samenwerkingen op te zetten en te intensiveren om compressie therapie te optimaliseren. De implementatiestrategie zoals beschreven in **hoofdstuk 8** zal deze implementatie ondersteunen. Voor een optimale implementatie is het verder van belang dat richtlijnen voor zorgprofessionals de aanbevelingen uit het protocol opnemen, en dat het protocol laagdrempelig beschikbaar is voor alle zorgprofessionals in het proces. Wetenschappelijke verenigingen kunnen een belangrijke rol spelen in de diffusie van het protocol (bijv. door een link en informatie op te nemen in hun nieuwsbrieven en hun websites). Daarnaast zullen verzekeringsmaatschappijen de financiële barrières en vergoedingsproblemen moeten oplossen in overleg met zorgprofessionals. Met name dient er discussie te zijn over de financiële beperkingen die compressiespecialisten ervaren en vergoedingsproblemen bij het verschaffen van hulpmiddelen voor trainingsdoeleinden. Als laatste is het belangrijk om

zorgprofessionals tijdens het implementatieproces te blijven voorzien van informatie over de effecten van de interventie betreffende patiëntuitkomsten.



# Addendum

Impact paragraph



## Impact paragraph

The present thesis aimed to develop a national cross-domain protocol compression therapy that guides healthcare professionals in optimizing compression therapy for patients with deep venous thrombosis (DVT) and chronic venous disease (CVD) without active venous leg ulcers.

### Societal relevance

#### *Patients, caregivers, and healthcare professionals*

The results of the current thesis directly impact compression therapy provided by involved healthcare professionals (general practitioners, internists, dermatologists, occupational therapists, medical stocking suppliers, and home care nurses) to patients in different phases of the process. First, the cross-domain protocol guides communication and collaboration among healthcare professionals and between the healthcare professional and the patient. In this way, it supports patients' (or informal caregivers') involvement in the decision-making process, which is supposed to be positively correlated with adherence to therapy, autonomy, and improved coordination of care.

Second, the cross-domain protocol provides recommendations to increase patients' self-reliance during initial compression therapy, the implementation of assistive devices, and long-term elastic compression stocking (ECS) therapy. Earlier, a discrete choice experiment involving 300 DVT patients showed that maintaining self-reliance in using the ECS was one of the major preferences for patients. This experiment indicated that patients accepted an increase in the risk of post-thrombotic syndrome of 29% if they could put on the ECS themselves<sup>1</sup>. Based on this study, we expect an increase in adherence to therapy, improved effectiveness of therapy, and a decrease in home care demands by maximally supporting patients' self-reliance. As home care nurses spend most of their time on providing assistance related to compression therapy, we suspect the latter to contribute to the system's future sustainability and deployment of home care.

Finally, the protocol creates awareness among healthcare professionals and provides recommendations for a tailored treatment duration for DVT patients based on the assessment of Villalta scores. This tailored strategy will result in a shortened ECS treatment duration for approximately 66% of patients that currently are treated for a prolonged period without additional benefits<sup>2</sup>.

#### *Health care insurance companies*

This thesis provides a detailed insight into the costs associated with compression therapy for DVT during the four consecutive phases. We showed that prescribing initial

compression therapy with a preference for a temporary compression hosiery, early consultation of occupational therapists to train patients on how to use assistive devices, and a tailored ECS treatment duration resulted in cost savings within three years after implementation for regions North-Holland location A and Limburg. With this strategy, we also expect a decrease in patients who develop the post-thrombotic syndrome and related costs.

#### *Scientific and economic relevance*

The thesis contributes to the sparse literature on compression therapy by showing what needs to be in place to optimize the organization of compression therapy and it highlights important targets to improve the system. We used a Functional Resonance Analysis Method (FRAM) and a realist evaluation to gain a deep insight into the realities of daily practice, including facilitators and barriers. This insight was used to create statements to improve compression therapy, which was presented to stakeholders from all disciplines and patients to gain a broad consensus of what 'optimal organization of compression care' means before the actual cross-domain protocol was developed. Afterwards, we showed that the three main improvement targets resulted in cost savings for most regions within three years after implementation. These insights were then combined to create the cross-domain protocol, which was assessed and refined by national stakeholders from the different health care professionals associations. We suggest this approach could also be relevant to researchers in other fields.

#### *Dissemination of knowledge and products*

Efforts have been made to share the findings made in this dissemination with the broader audience of health care professionals, patients, and researchers concerned with compression therapy. As described before, local and national stakeholders from all health care professional groups and patients were closely involved in all stages of this research project. During the development of the protocol, we maintained accessible contacts with different national associations for discussion and feedback (i.e. the Dutch federation of occupational therapists (Ergotherapie Nederland), the Dutch association for compression care (NVCZ), the Dutch association for general practitioners (NHG), the Dutch internists association (NIV), the association for dermatology and venereology (NVDV) and the Dutch association for formal caregivers and nurses (V&VN)).

These contacts introduced us to consecutive contacts; for example, we were approached by the project group 'Zinnige Zorg' from the Dutch health care institution. This project group was concerned with creating a report to improve care for patients with DVT and pulmonary embolism. By sharing results and providing mutual input for our projects, we disseminated our results to the Dutch health care institution. In the future, we intend to make the protocol easily approachable for all healthcare

professionals involved. For now, further implementation of the current protocol is designated to the professional associations and stakeholders as described in chapter 8.

To date, three articles are published in open-access, peer-reviewed journals (BMJ Open, Plos One and Frontiers in Cardiovascular Medicine), one chapter is published as a book chapter (chapter ‘compression’ by Minerva Medica Publisher available via Research Gate on request), two chapters have been submitted to international journals, and the cross-protocol is ready to be implemented. The dissertation as a whole is available through Maastricht University. Further to this, research performed as part of this thesis has been presented as three posters at the ISTH (International Society on Thrombosis and Haemostasis) congress (2021 and 2022). At a national level, we presented our results during three webinars to a group of medical stocking suppliers and skin therapists (n=60).

## References

1. Bouman AC, Ten Cate-Hoek AJ, Dirksen CD, Joore MA. Eliciting patients' preferences for elastic compression stocking therapy after deep vein thrombosis: potential for improving compliance. *J Thromb Haemost.* 2016;14(3):510-7.
2. Ten Cate-Hoek AJ, Amin EE, Bouman AC, Meijer K, Tick LW, Middeldorp S, Mostard GJM, Ten Wolde M, van den Heiligenberg SM, van Wissen S, van de Poel MH, Villalta S, Serne EH, Otten HM, Klappe EH, Bistervels IM, Lauw MN, Piersma-Wichers M, Prandoni P, Joore MA, et al. Individualised versus standard duration of elastic compression therapy for prevention of post-thrombotic syndrome (IDEAL DVT): a multicentre, randomised, single-blind, allocation-concealed, non-inferiority trial. *Lancet Haematol.* 2018;5(1):e25-e33.





# Addendum

List of publication



## List of publications

### This thesis

Rabe E, Pannier F, Milic J D, Da Matta E S, **Schreurs RHP**, Ten Cate A J. Indications for compression according to venous disease. The role of compression in Deep vein thrombosis, post thrombotic syndrome prevention and treatment. In: Mosti G and Patsch H, editors. Compression. Minerva Medica Publisher 2022.

**Schreurs RHP**, Joore MA, Ten Cate H, Ten Cate-Hoek AJ. Using the Functional Resonance Analysis Method to explore how elastic compression therapy is organised and could be improved from a multistakeholder perspective. BMJ Open. 2021;11(10):e048331.

**Schreurs RHP**, Joore MA, De Bruijn-Geraets DP, Ten Cate H, Ten Cate-Hoek AJ. A realist evaluation to identify targets to improve the organization of compression therapy for deep venous thrombosis- and chronic venous disease patients. PLoS One. 2022;17(8):e0272566.

**Schreurs RHP**, Joore MA, Ten Cate H, Ten Cate-Hoek AJ. Development of a Consensus-Based Cross-Domain Protocol for the Management of Elastic Compression Stocking Therapy in Patients With Deep Venous Thrombosis and Chronic Venous Disease: A Modified Delphi Study. Front Cardiovasc Med. 2022;9:891364.

**Schreurs RHP**, Joore MA, Ten Cate H, Ten Cate-Hoek AJ. Budget impact of three improvement topics for compression therapy for patients with deep venous thrombosis in the Netherlands. Under review.

**Schreurs RHP**, Joore MA, Ten Cate H, Ten Cate-Hoek AJ. Implementation of a cross-domain protocol for the optimization of compression therapy guided by the model of diffusion of innovation. Submitted.

### Other publications

Melman S, **Schreurs RHP**, Dirksen CD, Kwee A, Nijhuis JG, Smeets NAC, Scheepers HCJ, Hermens RPMG. Identification of barriers and facilitators for optimal cesarean section care: perspective of professionals. BMC Pregnancy Childbirth. 2017;17(1):230.

Bosman MCJ, **Schreurs RHP**, Nieuwenhuizen L, Bakkeren DL, Jacobs JFM. Broad Bands Observed in Serum Electrophoresis Should Not Be Taken *Lightly*. Clin Chem. 2019; 65(5):618-621.

Addendum

Alisma J, van Saase JLCM, Nanayakkara PWB, Schouten WEMI, Baten A, Bauer MP, Holleman F, Ligtenberg JJM, Stassen PM, Kaasjager KAH, Haak HR, Bosch FH, Schuit SCE; **FAMOUS Study Group\***. The Power of Flash Mob Research: Conducting a Nationwide Observational Clinical Study on Capillary Refill Time in a Single Day. Chest. 2017;151(5):1106-1113.





# Addendum

About the author



## About the author

Rachel Schreurs was born in Horn, The Netherlands, in 1989. After completing pre-university education at Sint Ursula in Horn, she studied Medicine at the Faculty of Health, Medicine, and Life Sciences at Maastricht University from 2007 onwards. In 2014 she started her clinical training in internal medicine at the Maxima Medical Centre and the Maastricht University Medical Centre (MUMC+). In the last years of her training, she specialized in endocrinology. During her study and internship, Rachel developed a special interest in management. She followed various management courses and fulfilled several board positions (e.g. as a board member of the Dutch Junior Internists association). This special interest involved her in the current research presented in this thesis. She finished her registration as an internist-endocrinologist on January 9<sup>th</sup> and she will start working as an endocrinologist at Zuyderland MC in February.



# Addendum

Acknowledgement



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