Prioritising lower-extremity lymphoedema outcomes: a focus group study among dermal therapists in the Netherlands

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Core outcome set, Dermal therapist, Lower-extremity lymphoedema, Patient-reported outcome

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Background: Lower-extremity lymphoedema (LEL) impairs quality of life and highlights the need for effective management. The absence of standardised outcome registries limits evaluation of dermal therapists' care. The International Classification of Functioning, Disability and Health (ICF) Core Outcome Set (COS) for LEL provides a framework, but stakeholder perspectives are needed to optimise its use. **Aims:** To explore how dermal therapists prioritise outcomes within the COS for LEL and how these are assessed in practice. **Methods**: Fifteen dermal therapists took part in three online focus groups, identifying outcomes important to patients and clinicians and describing assessment methods. Data were analysed using the COS as a framework and thematic analysis (Braun and Clarke, 2006). **Results:** Patient-reported outcomes (PROs) focused on activities of daily living, participation and emotional wellbeing, and were assessed subjectively, whereas clinician-reported outcomes (ClinROs) centred on limb structure, skin and subcutaneous tissue. Limb volume was typically measured circumferentially, while other tissue characteristics were assessed through clinical examination. **Conclusion:** PROs emphasised activities and participation, while ClinROs focused on body structures. Findings highlight the need for systematic integration of PROMs and standardisation of ClinRO procedures.

Lower-extremity lymphoedema (LEL) is a chronic condition associated with significant morbidity, including skin complications and reduced quality of life (QoL) (Földi et al, 2012; Grada and Phillips, 2017). While much lymphoedema research focuses on breast cancer–related upper limb lymphoedema (BCRL) (Dessources et al, 2020), LEL is more prevalent and often associated with more severe physical and psychosocial impact (Dean et al, 2020; Grada and Phillips, 2017; MacLaren, 2001; Noh et al, 2015). It commonly follows cancer treatment but may also result from venous disease, infection, trauma or congenital lymphatic dysfunction (Beesley et al, 2007; Bunke et al, 2009; Dessources et al, 2020; International Society of Lymphology, 2020; Okeke, 2004; Yost et al, 2014). Without appropriate management, LEL can lead to irreversible tissue changes and recurrent infections (Dean et al, 2020; Kayiran et al, 2017; Oh, 2015).

Standardising LEL care

In the Netherlands, care for patients at risk and/or with lymphoedema is provided by various healthcare professionals, including general practitioners, physiotherapists, nurses, and compression therapists. Dermal therapists and lymphoedema physiotherapists provide lymphoedema therapy, essential for reducing swelling and managing this chronic condition (Nederlandse Vereniging voor Dermatologie en Venereologie [NVDV], 2023). Dermal therapists are specialised healthcare professionals involved in oedema management and skin care in lymphoedema patients. They contribute to swelling reduction and the prevention and management of lymphoedema-related skin complications, including infection and impaired skin integrity.

However, the quality of care by dermal therapists cannot currently be measured due to the lack of standardised outcome registries (Tjin et al, 2020). Standardised outcome measures are crucial for patient-centred care and for evaluating treatment effectiveness (Elf et al, 2017), and they should align with measures used by other related (para) medical disciplines (Tjin et al, 2020). A Core Outcome Set (COS) supports this process, embracing value-based healthcare and emphasising outcomes that matter to patients (Porter, 2010).

The existing COS for LEL – based on the International Classification of Functioning, Disability and Health (ICF) – was developed with input from professionals and patients. Its practical use is limited and mainly restricted to research contexts. A limitation is the underrepresentation of dermal therapists compared to physiotherapists and medical specialists (Viehoff et al, 2015). Including all key stakeholders is essential and given their vital role (Kirkham and Williamson, 2022), the perspective of dermal therapists is needed to optimise the COS.

The primary aim of this study was to explore how dermal therapists with experience in lymphoedema therapy prioritise outcomes within the existing COS for LEL, in relation to the evaluation of treatment strategies. The secondary aim was to explore how they measure these prioritised outcomes in clinical practice.

Methods

Study design and researchers' characteristics

This study employed a generic qualitative research design with a descriptive focus. Online focus groups were conducted with dermal therapists to explore beliefs and opinions on evaluating LEL. This facilitated idea generation and encouraged participants to share and reflect on their own and others' experiences. (Morgan, 1996; Ellis and Hart, 2023). J.B. led the sessions, a dermal therapist with 4 years' experience in lymphoedema care, while undertaking concurrent master's-level academic training. T.H., a senior researcher and principal lecturer in dermal therapy, moderated the sessions and has 10 years' experience in COS development and outcome registry research.

According to Dutch regulations, this study did not fall within the scope of the Medical Research Involving Human Subjects Act (WMO) and, therefore, did not require formal ethical approval. Participation was voluntary and all participants provided written informed consent.

Study sample and setting

Dermal therapists providing care for primary or secondary LEL in the Netherlands were purposively sampled. Participants were practising dermal therapists with a bachelor's in dermal therapy from one of the two Dutch universities of applied sciences offering this programme. The sample aimed for homogeneity with variation in age, work experience, region, and setting (Grønkjær et al, 1970). Participants were recruited through the professional association, alumni networks, and JB's professional contacts. Participants indicated availability and received an information letter and consent form.

Data collection

Three online focus groups were held via Microsoft Teams (February and March 2024), each lasting 90–120 minutes. JB led discussions and TH moderated. A semi-structured topic guide was developed to facilitate discussion (*Appendix A*). The researchers asked open-ended questions about which outcomes were important to the participants and patients, and how these outcomes were measured. Google Jamboard was used to visualise responses. The third group built on earlier sessions to confirm and deepen understanding. The researchers discussed each focus group after each session.

Data analysis

Sessions were transcribed verbatim and imported into NVivo 14 for thematic analysis (Braun and Clarke, 2006). Deductive coding was based on ICF codes from the COS LEL, with new ICF or non-ICF codes added for units that did not fit existing codes. Open and axial codes addressed secondary aims. Coding was led by J.B. with T.H. reviewing the coded transcripts after each session. Through regular discussion, adjustments were made to the assignment of text segments to the relevant ICF categories and all decisions were documented in a logbook.

Trustworthiness

The interview guide was refined with feedback from a dermal therapist experienced in lymphoedema therapy to improve participants' understanding of the questions. After each session, participants reviewed a summary (member check) and could suggest changes. The study adhered to the Standards for Reporting Qualitative Research (O'Brien et al, 2014).

Sample characteristics and overview of prioritised outcomes

There were 15 participants across three focus groups (n=5, 6 and 4; *Table 1*). The majority worked in primary care, with three in multidisciplinary settings. Participants typically treated both primary and secondary LEL, and most practised in the southern and western regions of the Netherlands.

Participants prioritised both outcomes that corresponded with the existing COS-LEL and outcomes not currently included (ICF and non-ICF). They also described contextual factors relevant to the interpretation of outcomes, such as self-management, acceptance, family support, lifestyle, age, coping style, health literacy, financial circumstances and living situation. *Appendix B* illustrates prioritised ICF outcomes (excluding non-ICF outcomes).

Outcomes corresponding to the COS LEL

Activities and participation

Participants consistently emphasised the importance of evaluating patients' ability to engage in daily activities and participate in society. Improvements in walking – either ease or distance – were frequently regarded as meaningful. Activities of daily living (ADLs), such as cycling, driving, grocery shopping or being able to wear shoes again, were also described as central to recovery. Social participation, including returning to work or engaging socially, was repeatedly valued.

"Participating in society, recognition and a bit of appreciation, societal appreciation which often correlates with working – whether paid or volunteer work – yes, is essential. There's a huge societal appreciation attached to that, and I notice that it's very important for people." – Group 3, participant 2

"For example, one I visit at home. Yes, she finds it important that she can just go outside again at some point. Yes, that she can socialise with people again." – Group 2, participant 6

Physical aspects and body image

Participants reported that skin characteristics – including colour, condition, skin defects, veins and hyperkeratosis – were integral to evaluating progress.

"And skin changes in general… The less oedema, the fewer skin changes … the appearance of the legs also improves." – Group 1, participant 2

Reduction of lymphoedema, changes in limb size and improved anatomical shape were also highly valued when evaluating treatment. Several participants noted that complete absence of lymphoedema was not essential to patients, though physical appearance and the ability to wear clothes or shoes again because of the oedema therapy, often mattered greatly.

Emotional and sleep functions

Emotional functions – such as increased happiness or reduced shame – were recognised as both outcomes and influential factors.

One participant highlighted that emotional responses can directly influence the effectiveness of oedema therapy. Sleep functions were considered by one participant both as an outcome that could be used to evaluate the effectiveness of lymphoedema therapy and as a contextual

Table 1: Demographic information of participants (n=15)	
Characteristics of participants	
Age (years), mean; range	37; 22–64
Work experience (years), mean; range	11; 0.5–32
Women Men	15 0
Work setting	
Primary care, n	14
Tertiary care, n	1
Work region in the Netherlands	
North	2
East	2
South	5
West	6
Population of patients	
Secondary LEL	4
Primary and secondary LEL	11

Table 2: Measuring methods related to outcomes	
Outcomes	Measuring methods
Structure of lower extremity	Circumferential measurement (CM) using tape measure (intervals: 4, 5 or 10 cm, or fixed points for compression garments); limb volume calculation; photography; inspection and palpation
Structure of areas of skin	Tissue dielectric constant, photography, pitting oedema test, Stemmer's sign, and inspection and palpation
Structure of areas of subcutaneous tissue	Inspection and palpation
Sensation of pain	Visual analogue scale
Different PROs related to body functions, activities and participation	Lymphoedema Functioning, Disability and Health Questionnaire for Lower Limb Lymphoedema (Lymph-ICF-LL); Distress Thermometer (DT); Multidimensional Fatigue Index; Work and Wellbeing Inventory

factor influencing its management, as illustrated by the following quote:

"Due to lymphoedema, you can experience problems with your sleep, such as falling asleep, staying asleep and waking up feeling rested. However, this can also maintain your lymphoedema. So, these are two separate issues." – Group 3, participant 2

Pain

Some participants highlighted discomfort or pain as relevant to the evaluation of lymphoedema, although they acknowledged that pain is not a direct symptom but remains an important issue to address.

New outcomes

ICF-linked outcomes

Participants introduced additional ICF-linked outcomes not currently included in the COS-LEL. These included performing sports or hobbies (e.g. gardening, walking) and maintaining informal social relationships. Loss of participation due to reduced mobility or discomfort was noted as having broader social consequences.

"The natural loss of body functions, loss of your hobbies because of the lymphoedema, because you can no longer perform them, loss of surroundings, loss of friends, because you no longer can keep up." – Group 3, participant 2

Family participation was also identified as meaningful by one participant and was linked to the ability to manage ADLs.

Non-ICF outcomes

Non-ICF outcomes included QoL, wellbeing and patient-specific goals. Participants highlighted the importance of personalised goals, which varied across patients and did not always align with standardised classifications. In their professional evaluation of oedema, participants also assessed tissue consistency characteristics, such as pitting and non-pitting oedema, induration, fat deposition and fibrosis. Changes in tissue, especially in cases of fibrosis, consistency were considered indicators of improvement.

"The consistency of the tissue does a lot for patients… a young male patient with a truly fibrotic thigh … those thighs can be really intense." – Group 1, participant 2

A heavy limb sensation, often experienced alongside pain and fatigue, was frequently described as a burden influencing emotional wellbeing and participation.

"If you're in a younger patient group … heavy feeling … fatigue, pain … can't keep up with friends… may be accompanied by loneliness or sadness." – Group 3, participant 1

Non-prioritised outcomes

Ninety-one of the 111 ICF outcomes in the COS-LEL were unmentioned or considered irrelevant (see *Appendix B*). These included cardiovascular or immunological structures/functions, skin sensory functions and repair functions, and several movement-related functions (e.g. joint mobility, muscle power). Participants generally viewed movement-related functions as beyond their scope, more suited to physiotherapists. Furthermore, many unmentioned outcomes were related to specific physical activities (e.g. changing and maintaining body positions, climbing, running).

Measurement of outcomes

Participants varied widely in how they

measured outcomes. Most methods focused on body structures (ClinROs). Circumferential measurements (CMs) were most common, though segment lengths varied (4, 5 or 10 cm) and compression-garments reference points were sometimes used to save time. Some participants assessed limb volume. Tissue Dielectric Constant (TDC) was used by a few participants to assess moisture levels of the skin, though many found it time-consuming and difficult to interpret.

Only a minority used patient-reported outcome measures (PROMs). Instead, most participants evaluated patient-reported outcomes (PROs) informally through interviews and conversations. *Table 2* summarises measurement methods linked to specific outcomes.

Discussion

Summary of key findings

This is the first study on outcome measurement practices among dermal therapists treating LEL. Participants prioritised a broad range of PROs and ClinROs. PROs mainly concerned ADLs, participation and emotional wellbeing, whereas ClinROs focused on limb structure, skin and subcutaneous tissue, despite dermal therapists predominantly relying on ClinROs and using standardised PROMs infrequently in daily practice. The many non-prioritised outcomes reflect the COS-LEL's broad perspective on functional issues in patients with LEL (Viehoff et al, 2015).

Comparison to existing literature

Our findings are consistent with previous literature, as studies by Zhang et al., (2022) and Stolldorf et al, (2016) show that lymphoedema-related swelling and associated symptoms substantially affect physical activity, ability to do hobbies, emotional well-being, and body image, although issues related to sexual attractiveness were primarily reported in the context of genital lymphoedema in our study. Further COS-LEL development should examine whether they also apply more broadly within LEL. Findings also align with a recently developed COS for BCRL, which prioritised similar outcomes such as volume, tissue consistency, pain, patient-reported QoL and mobility (Doubblestein et al, 2024).

Sleep disturbances have been identified as an important factor in BCRL, affecting fatigue, emotional well-being, and overall quality of life (Mete Civelek et al, 2022). However, the impact of LEL on sleep remains unclear. One study suggested that individuals with LEL did not differ significantly in sleep quality from those without lymphoedema (Abakay et al, 2023), highlighting the need for further investigation into this outcome in LEL populations.

Pain was frequently discussed in the focus groups and is a common reported symptom in LEL literature (Bowman et al, 2020; Stolldorf et al, 2016). In addition, a qualitative study described that patients with LEL experience higher levels of pain, fatigue and functional limitation compared to those with lymphoedema in other locations (Río-González et al, 2021). Pain may also result from surgical procedures or other underlying causes. Guidelines suggest assessing different causes of pain, including sensitisation, nociceptive, neuropathic or nociplastic origins (Nijs et al, 2023; NVDV, 2023; Tiwari, 2003). A clearer understanding of pain in people with LEL – considering variation in underlying causes, such as primary versus secondary lymphoedema, cancer type, and treatment-related factors (e.g. operation or radiotherapy) – is needed to optimise the COS-LEL. Newly identified outcomes highlight limitations of the current ICF-based COS-LEL, as several relevant aspects are insufficiently captured. Although personal factors remain poorly defined within the ICF (Heerkens et al, 2018; Karhula et al, 2021; Mitra and Shakespeare, 2019), patient-specific goal setting may help address these gaps (Stevens et al, 2017, 2018).

Our findings reveal a discrepancy between the importance dermal therapists attribute to PROs and their limited use of standardised PROMs in daily practice, despite literature supporting the use of PROMs (e.g. Lymph-ICF-LL) (Devoogdt et al, 2014) for evaluating lymphoedema treatment. Instead, participants mainly relied on ClinROs, with circumferential measurement as the most applied technique, their reliability depends on adherence to standardised protocols (Russo et al, 2021), which vary in practice. Similarly, TDC measurements, although promising as a sensitive measure of localised changes (Markarian et al, 2024), was perceived as challenging. This highlights the need for further standardisation and training.

Strengths and limitations

A key strength of this study is the use of focus groups to address gaps in the existing COS-LEL, enabling in-depth exploration of clinical perspectives (Williamson et al, 2017). The iterative design enhanced data refinement, and the findings were reviewed by both a lymphoedema expert and an LEL patient, increasing the credibility of the results. Limitations include the absence of participants from secondary care and reduced non-verbal interaction due to the online format. However, as most dermal therapists work in primary care, the sample is likely representative. Although coding was conducted by a single researcher, ongoing peer discussion and use of a conceptual framework support the trustworthiness of the findings.

Conclusion

Dermal therapists prioritised a wide range of outcomes consistent with the COS-LEL and introduced additional ICF and non-ICF outcomes. While PROs related to activities and participation were highly valued, outcome measurement in practice focused largely on ClinROs. The findings underline the need to integrate recommended PROMs more systematically and to standardise ClinRO procedures. Collaboration with occupational therapists may better address participation-related outcomes. The electronic patient record (EPD) should also support structured outcome measurement protocols. The results contribute to gaps in previous COS-LEL research and offer input for a future Delphi study. This next phase should include patients with various LEL types and healthcare professionals such as physiotherapists and occupational therapists.

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Scan the QR code to access the Appendix.