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***It is on my skin,  
on my soul, and on my life***

Development of a disease-specific quality  
of life instrument for adult patients with acute  
cutaneous leishmaniasis in Iran

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It is on my skin, on my soul, and on my life. Development of a disease-specific quality of life instrument for adult patients with acute cutaneous leishmaniasis in Iran.

**Abstract**

**Background:** Cutaneous leishmaniasis (CL), is the most common form of a group of diseases known as leishmaniases. They are caused by obligatory intracellular protozoa from the genus *Leishmania* and transmitted by sandflies. Over 350 million people are at risk of getting leishmaniasis and 1,000,000 to 1,200,000 individual get CL each year, the majority of them are living in developing countries. CL may affect a patient's physical and mental health, and social relations impairing his/her quality of life (QoL).

**Aim:** The aim of this thesis was to develop a disease-specific instrument for measuring QoL in adult patients suffering from the acute form of CL in Iran according to a needs-based approach.

**Methods:** This thesis used a mixed-method approach and was based on two quantitative studies and one qualitative study. The first study was a systematic review on the randomized controlled clinical trials (RCTs) conducted on acute CL in the Old World. The second one was a qualitative content analysis study conducted through interviews with patients with CL in Iran. The third study was a psychometric evaluation of an instrument that was developed according to the results of the second study. For making a QoL instrument with fundamental measurement properties, the Rasch method was used.

**Results:** The findings of the first paper demonstrated that the majority of the 50 reviewed RCTs were of poor quality of conduct and report. An important finding was that none of those studies included a patient-reported outcome in their primary, secondary, or even tertiary outcome assessments. To obtain the patients' lived experience and perspectives on their disease, 12 individual in-depth interviews were conducted with patients with CL. Four themes were developed: "Fearing an agonizing disease" reflects patients' experiences of disease development resulting in sadness and depression, "struggling to cope" and "taking on the blame" both illustrate how patients experience living with the disease, which included both felt and enacted stigma as major social concerns. "Longing for being seen and heard" refers to patients' experiences with healthcare as well as their expectations and demands from communities and healthcare system to be involved in closing the knowledge and awareness gap. The third study was conducted as a survey on 107 patients with acute CL answering 50 questions with four response categories focusing different aspects of QoL, named "P-CL-QoL", an acronym for Preliminary Cutaneous Leishmaniasis Quality of Life instrument. The Rasch fitness criteria for the original 50-item questionnaire indicated that it was not optimal for fundamental measurement of the QoL in CL patients. Two more Rasch models were developed by merging the last two response categories and making a 3-point Likert scale, and the three last response categories, making a dichotomized "Yes" and "No" response choices to each item. The final 34-item instrument with dichotomous responses showed improved measurement properties including very good targeting and item-separation index, internal consistency (Chronbach's  $\alpha=0.94$ ), and a log-likelihood Chi square=2242.50 (degree of freedom=2640, and  $P=1.000$ ) indicating excellent fitting to the Rasch model. This version was named Cutaneous Leishmaniasis Quality of Life instrument (CL-QoL). According our findings, the mean ( $\pm$ standard deviation) of raw scores and 0-34 scaled measures of the participants were 15.9 ( $\pm 9.2$ ) and 16.8 ( $\pm 6.9$ ), respectively. The impact of CL on the QoL of the patients was none to minimal in 17.0 %, mild in 25.0 %, moderate in 31.8 %, high in 12.5 %, and very high in 13.7 % of the participants. QoL impairment was not related to the sex and age of the individuals, geographic location where CL was caught, duration of the disease, and its severity ( $P>0.05$ ).

**Conclusion:** This thesis demonstrated that there is a lack of patients' reported outcomes in clinical trials on CL, and that mental and social dimensions of CL are complex and adversely affect patients' lives by causing psychological burden and limiting their social interactions. The health authorities have to plan programs to increase the disease awareness in communities and among healthcare professionals to prevent the existing stigma and improve patients' social condition and medical care. While we could suggest a disease-specific QoL measurement instrument through our third study, we acknowledge that the developed instrument may not be optimal and has to be validated in other populations, preferably using the Rasch method.

**Keywords:** cutaneous leishmaniasis, fundamental measurement, needs-based approach, neglected tropical disease, probabilistic model, quality of life, qualitative content analysis, the Rasch model

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