

TITLE: Development and Feasibility of a Multidisciplinary Education Program on Adherence to Treatment in Persons With Venous Leg Ulcers in Western Switzerland: a Pilot Study.

ABSTRACT

Aims: The aim of this study is to;

- a) develop an evidence-based multidisciplinary educational intervention for patients with a venous leg ulcer.
- b) conduct a pilot-study to assess the feasibility of the intervention in the clinical setting.

Design: A two-stage study design was used;

- a) an interprofessional expert committee designed an educational intervention including support materials.
- b) a pilot randomised controlled trial was conducted to assess the feasibility of the intervention in one wound-care outpatient clinic in Western Switzerland.

Methods: An interprofessional expert committee identified evidence for effective interventions improving venous leg ulcer patients wound healing and recurrences rate and designed the educational intervention and support materials. Subsequently venous leg ulcer patients were randomly assigned to receive the multidisciplinary education or standard care from March to July 2018. The objective was to evaluate the feasibility and adequacy of the nurse-led intervention in the clinical setting. The primary analysis was based on the effectiveness of the recruitment strategy, as well as on the performance of the specific tools selected for comparing adherence to therapy in the two groups. The intervention being an educational program, blinding either for the participants or for the staff performing the intervention was obviously not possible.

Results: The intervention, including support material was developed and twelve venous leg ulcer patients were recruited (control group n=6; intervention group n=6). Recruitment expectations were fully met and participation rate was 75%. The nurse-led intervention was satisfactory for both the participants and the caregivers. The performance of the Venous Leg Ulcer Self Efficacy Tool for measuring adherence to therapy and the Mini Nutritional Assessment and Frequent Food Questionnaire for the assessment of the nutritional intake were satisfactory. However, Fitbit smartwatch for measuring activity was not a suitable device in this study-population.

Conclusion: The implementation of the designed multidisciplinary educational program seems to be feasible. The pilot-study identified weaknesses in the study protocol.

Impact: Findings of the pilot study informed the improvement of the design of the main-study.

Key words:

Nursing, venous leg ulcer, multidisciplinary, education, feasibility

Main paper

Introduction

Venous leg ulcers (VLU) are a health problem accompanying most patients for life. The occurrence ranges between 0.8 and 2.2 per 1000 people/year (Berenguer Perez, Lopez-Casanova, Sarabia Lavin, Gonzalez de la Torre, & Verdu-Soriano, 2019). Their healing rates are long with a recurrence rate of 70% and a 60% risk of becoming chronic (Frykberg & Banks, 2015).

The therapeutic VLU management approach targets the management of risk factors and protective factors associated with wound healing and recurrence prevention. Best practice wound care suggests approaches including compression therapy, leg elevation, specific ankle-exercises and a protein rich diet (Franks et al., 2016). To offer these approaches an multidisciplinary team of health care professionals from the domains of nursing, physiotherapy and nutrition is required. Approximately 70% of VLU patients have a knowledge deficit in regards to therapeutic measures and have difficulties with adherence to treatment protocols (Finlayson, Edwards, & Courtney, 2011). Therefore, it is of utmost importance that the treatment team provides effective patient education and support during the learning phase. However, there are no published studies describing and evaluating the impact of multidisciplinary educational interventions on adherence to the treatment plan and wound-size reduction in VLU patients. We therefore firstly

developed an evidence-based interprofessional educational intervention and secondly conducted a pilot-study to assess the feasibility of the intervention in the clinical setting.

Development of the intervention

DESIGN

Development of an educational intervention by a multiprofessional committee of experts to compile evidence about VLU best practice care and interventions improving VLU wound healing and recurrences rate. Professionals in nursing, physiotherapy and nutrition were chosen to design the intervention for their specific knowledge and expertise about wound management/compression, physical activity/exercise and optimal diet, respectively.

METHODS

A literature review was conducted in order to identify the most effective interventions to promote wound healing and prevent recurrences of VLUs. Systematic reviews and relevant RCTs (randomized controlled trial) were retained on the base of the methodological quality of their design, validity, and applicability to VLU patient-care.

RESULTS

The most effective interventions were;

- a) knowledge about etiology and pathophysiology of VLU's.
- b) adherence to wearing compression stockings/hosiery's.
- c) doing exercises in the region of the lower extremities.
- d) carrying out physical activity.
- e) leg elevation, and
- f) following a protein-rich diet.

These were included into a structured intervention program for delivery during a wound-care consultation. The multiprofessional expert committee decided that the education program covering the identified interventions will be delivered by a wound care specialist nurse during three thirty minutes sessions. Written education-material (brochure) was developed to support the education session. The development process was guided by Farrell-Miller & Gentry (1989).

Testing of the intervention

DESIGN

To assess the feasibility of the intervention in the clinical setting we carried out an eight-week pilot study. This was a single-centered randomized controlled study with four measurement points in one outpatient clinic in Western Switzerland.

METHOD

Persons were eligible to participate in the pilot study if they had an existing diagnosed open VLU, an ankle brachial pressure index (ABPI) between 0.6 and 1.3, were 18 years of age or older and spoke French, random sequence was produced using RAND function in MS Excel, randomization into groups was concealed. Participants in the control group (CG) received standard wound care in the outpatient clinic as prescribed by the physician. Participants in the intervention group (IG) received standard care plus the previously developed intervention. Each groups own study nurse collected the data. Feasibility was assessed in two ways. Firstly using participation rate as an indicator of the acceptability of the study design/instruments and secondly, by analyzing the collected data for tendencies. The following instruments were used: the Swiss French version of the Venous Leg Ulcer Self-Efficacy Tool (VeLUSET) to

measure adherence to therapy, FitBit for measuring movement, Mini Nutritional Assessment (MNA), and the Frequent Food Questionnaire (FFQ) for nutrition. Trained study nurses collected data.

RESULTS

From March to July 2018 a convenience sample of sixteen patients were eligible for inclusion in the study. Four declined due to holiday absence (n=3) and “no time” to participate (n=1) resulting in a participation rate of 75%. All participants were Caucasian. The mean age of the study-population was 74.5 years (SD±16.81). Six were female (see table 1). The adherence to therapy (VeLUSET) scores at baseline were IG: M=247.7, SD ±55.90; CG M=224.2, SD ±11.69 and at the end of the study IG: M=264.5, SD ±22.94; CG M=224.5, SD ±49.78. The collection of movement-data (Fitbit) was difficult because patients did not adhere to instructions. They reprogrammed the device and downloaded data to their own smart-phones. The MNA results indicate that no participant was malnourished. The nutritional status for one participant in the CG changed from “normal” to “at risk” whereas in the IG two participants improved from “at risk” to “normal”. The FFQ results demonstrate that at baseline 83% of all participants’ protein-intake was below the recommended level of 1.25 to 1.5 g/kg/d. The protein-take of one participant decreased below the recommended level. The protein-intake of all others did not change.

CONCLUSION

An evidence-based interprofessional education program and education-material was developed and a pilot-study was conducted. Recruitment procedure worked as expected in terms of access to participants and participation rate as well as data completion. Baseline VeLUSET-scores were similar to the ones reported by Probst et al. (2019). The recruitment strategy will be retained for the main study being a multi-centre trial. Assessment of the movement (Fitbit) was ineffective and will be replaced with

a wrist-worn accelerometer that cannot be manipulated by the participants. Data collection with the MNA was satisfactory and will be retained as an assessment-tool for the main study. The estimation of the protein intake using the FFQ was probably too low as participants had difficulties to report their intake. For the main study, the education material will provide more details of the protein content of different food items.

IMPACT:

Data from this pilot-study will help to design the intervention and adjust the study protocol for a larger study.

Conflict of Interest statement

This study was funded with an unrestricted grant of the Ebnet foundation, Switzerland

Ethical approval: was obtained from the Ethical Committee (CCER-2018-00195).

Trial registration: ClinicalTrials.gov, [NCT03454698](https://clinicaltrials.gov/ct2/show/study/NCT03454698) . Registered on 6 March 2018.

The protocol can be found under: **Probst, S., Allet, L., Depeyre, J., Colin, S. & Buehrer Skinner (2019).** A targeted interprofessional education intervention to address therapeutic adherence of venous leg ulcer persons (TIEIVLU): study protocol for a randomized controlled trial *Trials*, 20(1). 243.

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References

- Berenguer Perez, M., Lopez-Casanova, P., Sarabia Lavin, R., Gonzalez de la Torre, H., & Verdu-Soriano, J. (2019). Epidemiology of venous leg ulcers in primary health care: Incidence and prevalence in a health centre-A time series study (2010-2014). *Int Wound J*, *16*(1), 256-265. doi:10.1111/iwj.13026
- Farrell-Miller, P., & Gentry, P. (1989). How effective are your patient education materials? Guidelines for developing and evaluating written educational materials. *Diabetes Educ*, *15*(5), 418-422. doi:10.1177/014572178901500505
- Finlayson, K., Edwards, H., & Courtney, M. (2011). Relationships between preventive activities, psychosocial factors and recurrence of venous leg ulcers: a prospective study. *J Adv Nurs*, *67*(10), 2180-2190. doi:10.1111/j.1365-2648.2011.05653.x
- Franks, P. J., Barker, J., Collier, M., Gethin, G., Haesler, E., Jawien, A., . . . Weller, C. (2016). Management of Patients With Venous Leg Ulcers: Challenges and Current Best Practice. *J Wound Care*, *25* Suppl 6, S1-S67. doi:10.12968/jowc.2016.25.Sup6.S1
- Frykberg, R. G., & Banks, J. (2015). Challenges in the Treatment of Chronic Wounds. *Adv Wound Care (New Rochelle)*, *4*(9), 560-582. doi:10.1089/wound.2015.0635
- Probst, S., Turcotte, M., & Buehrer Skinner, M. (2019). Internal consistency and reliability of the Swiss-French translation of the venous leg ulcer self efficacy tool (VeLUSSET). *BMJ Open*, *9*(12), e031529. doi:10.1136/bmjopen-2019-031529