## Outpatient nurse managed counseling program for patients with diabetic foot ulceration

## Abstract:

Background: In Switzerland about 578'840 people suffer from Diabetes Mellitus (DM), representing approximately 7.42% of the population. One of the most severe complications of DM is the diabetic foot. The prevalence in patients with DM is as high as 25%. The recurrence rate of developing a diabetes ulcer in the first year varies between 7% and 34%. After three years the incidence rate is as high as 62% and increases to 70% after five years. The risk of amputation is at 3% (first year), 10% (three years) respectively 12% (five years). In 80 to 85% of all cases amputation was due to foot ulceration. Patient education as an integral part of treatment has been emphasized to decrease diabetic complications and amputation rates. Guidelines state that instruction on foot care and self-monitoring are crucial. A RCT pilot study between October 2011 and March 2012 has been conducted in Switzerland to test feasibility of a nurse-led patient education and counseling program and to investigate whether the intervention will increase self-efficacy of patients. Eighteen patients could be enrolled and the results showed that self-efficacy from baseline to week increased significantly in the intervention group (n=7, M=9.86, SD±8.2) and decreased in the control group (n=11, M=.40,  $SD\pm8.8$ , t(15)=2.24, p=.041, r=0.3). Despite the needs of this high risk population and the good effect on self-efficacy of patients, little evidence exists about effective nursing education programs to decrease amputation or re-amputation rates. Existing results are controversial. Therefore, further research in this high-risk population of patients with diabetes food is needed.

**Aim:** The purpose of the study is to evaluate the effectiveness of a nurse led intervention for high risk patients with diabetic foot ulceration and/or amputation.

Primary outcomes are 1) reduction of recurrence rates and time to adverse event (time till ulceration recurrence, new ulcerations, amputation or re-amputation) and 2) reduction of hospital readmissions for foot related complication (one year survival probability: failure = readmission for ulceration recurrence, new ulcerations, amputation or re-amputation). Selected covariates (self-efficacy, self-management, quality of life, social support and depression) will be included to estimate predictors for foot related complications and hospital readmissions.

**Method:** A randomized control trial (RCT) will be conducted with 100 patients with DM from a wound care outpatient-clinic in Zurich (Uniklinik Balgrist) in collaboration with the Zurich University of Applied Sciences, Winterthur over the enrolment period of 15 months. The intervention consists of an outpatient nurse-led individualized patient education and counseling program applied by eight face to face sessions at participants' homes and two telephone follow-ups by the intervention nurse.

**Benefit:** The project will combine the ambulatory wound treatment with a complementary intervention of specialized home care nurses (Advanced Practice Nurses). The results will inform health care authorities about the necessity and possibility to include the program as a special service in the existing system of home care (Spitex) in Switzerland.