Foot care prevention programme to evaluate diabetic foot risk reduction in high risk diabetic patients

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Background

- 25% of diabetic patients will suffer Diabetic Foot Ulcers (IDF 2017)
- Annual prevalence is 4 to 10%
- 40% of previous healed ulcers patients develop another one in a year time
- DFU is associated with reduced life expectancy
- Treatment is expensive
- In low & middle income countries few attention is paid to prevention



In my city something needs to be done

Why?

- Because education reduces DFU
 incidence
- Lack of specific plans in our place causes late medical evaluation
- And to implement local prevention strategies we need our local trials



Evaluate feasibility and efficacy of an educational intensive care programme versus standard care for DFU prevention in high risk diabetic outpatients from Hospital Centenario (public heath care system)

Patients

- Inclusion criteria
 - ✓ Diabetic patients > 40 years with more than 10 years of diagnosis and previous healed ulcer
- Exclusion criteria
 - ✓ Revascularization requirement
 - ✓ Cognitive impairment

Methods

- Experimental study with two interventions, standard and intensive care depending on which day they attend hospital (Wednesday or Friday)
- Groups of treatment:
 - Standard care group will receive standard information and education according to current guidelines, podiatrist evaluation, traumatologist consultation if needed, foot care written information + semestral follow up
 - Intensive care group will receive standard care group education and semestral follow up +
 - ✓ education through interactive programme at visit 1, in groups of 5/7 patients. 60' long

✓ Information via social media monthly (simple, relevant, consistent, repeated)

 Baseline demography & clinical data: Age, gender, age of diabetes diagnosis, years of education, tobacco comsuption, physical activity, micro & macrovascular complications, other comorbilities, physical examination, BMI, vital signs, treatment, rutine laboratory values, EQ5 (initial and final), foot exam (sensitivy by monofilament, presence of deformations, ankle braquial index measurement)

Methods and outcomes

- 164 patients will be included to achieve 20% DFU reduction DFU in standard care group and 40% DFU reduction in intensive care group with stadistical power of 80% and alfa error 0.05 with 2 years follow up
- Ulcer recurrence expected risk is to 40% according to bibliography
- Endpoints:
 - ✓ Primary endpoints: ulcer recurrence
 - ✓ Secondary endpoints: quality of life measured by EQ5

