Impact of utilising a novel mHealth application on clinical outcomes in the management of people with diabetes who have experienced a recently healed foot ulceration: an evaluation of the INTELLIN® platform

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Scan to view supplementary data, including full reasons underlying enrolment failure

Background

- Diabetic foot ulcers (DFUs) cause significant morbidity and mortality. Fast and appropriate referral to a specialist clinic after symptom onset has been shown to reduce the risk of patients developing severe DFUs and improves outcomes
- The INTELLIN® platform provides support and health education for patients with a recently healed DFU, with the aim of improving ulcer self-detection and to prompt individuals to take timely action in case of recurrence

Aims

- To determine the acceptability, suitability and usability of the INTELLIN® platform as assessed by patients and the clinical team
- To assess the proportion of patients who self-refer for recurrence of DFU over a 12-month period, compared with the current average of approximately 40%[1]

Methods

- Adult patients with T1/2DM and a history of a recent DFU, defined as being eligible for the NDFA and classified as healed for ≥4 weeks but no more than 12 weeks, who attended the Salford Royal NHS Foundation Trust were eligible to enter the study
- At study enrolment, participants were smartphone users; participants completed a medical questionnaire to create an INTELLIN® profile
- Follow-up visits were scheduled at Weeks 1, 4, 16, 28, 40 and 52. Patients and clinic staff assessed usability on a 5-point scale at Weeks 1, 16 and 52. Time until reulceration was measured through Week 52. The proportion of patients who self-referred for recurrence was also assessed

An assessment of the socioeconomic and demographic challenges encountered in this study are in DSFG Poster EP21 (Haycocks S, et al.)

Results

Table 1: Baseline characteristics

Baseline characteristic	Patients in the FAS (n=15)
Diabetes mellitus	
T1DM, n (%)	3 (20)
T2DM, n (%)	12 (80)
Mean time from diabetes diagnosis, years (SD)	17.9 (10.1)
Most recent DFU prior to study entry	
Mean time since healing of last DFU, days (SD)	45.9 (23.9)
Mean (SD) SINBAD score of last DFU	2.1 (1.0)
Cases where last DFU was severe, n (%)	4 (27)
Patients receiving insulin, n (%)	6 (40)
Mean basal insulin dose per day, units (SD)	16.9 (20.1)
Mean bolus insulin dose per day, units (SD)	5.7 (10.0)
Number of patients overdue their annual 8 care processes, n (%)	2 (13.3)

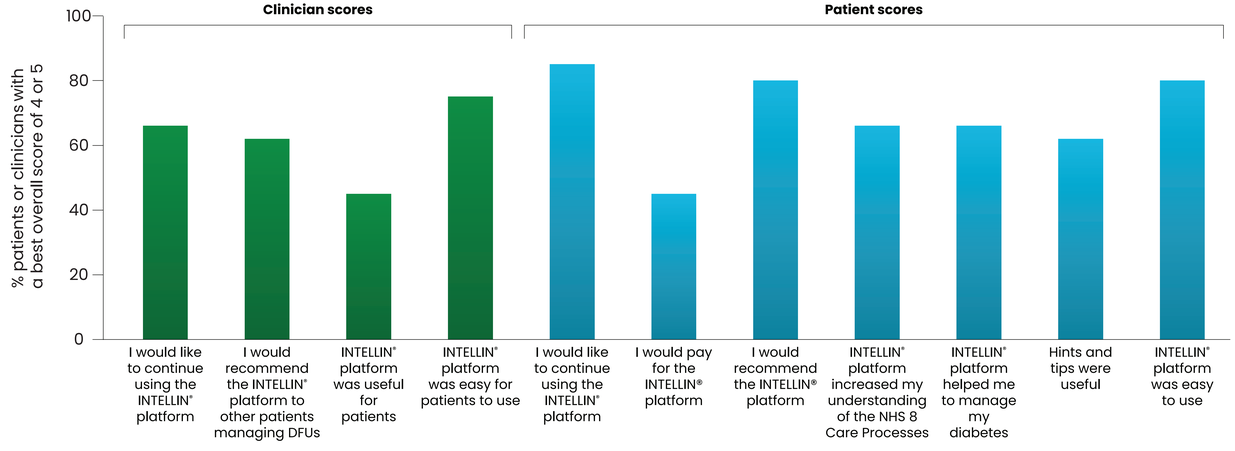
- 197 patients were assessed for eligibility and 15 entered the full analysis set (FAS) (Table 1). Through Week 52, **8/15 FAS patients experienced a recurrence**, with a mean (SD) SINBAD score of 2.1 (1.0) and a mean duration of 2.6 days. **Mean time from last DFU to recurrence during follow-up was 273.0 days (95% CI 74.0, 484.0). No patients self-referred**
- In the qualitative assessment, 12/15 patients and 11/15 staff rated the platform 4–5/5 for ease of use overall, and 13/15 patients and 10/15 staff gave a rating of 4–5/5 for likelihood of continuing the platform after the study overall[a] (Figure 1)
- In this model, the INTELLIN® platform only required a relative reduction in DFU recurrence of 5% compared with standard of care (SoC) to attain an ICER of £20 000 per QALY

Conclusions

- **Despite the small sample size, initial qualitative data show high INTELLIN® platform acceptability and usability for patients and clinicians, with high likelihood of recommendation for future use**
- **There were no instances of self-referral reported, though this finding is likely to be due to pre-booked prospective visits and patient familiarity with the appointment service**
- **The number of ulcer-free days reported is high compared to previous reports. Future studies may explore the potential for increased time to reulceration vs published data**
- **Wider adoption of the INTELLIN® platform has the potential to provide significant healthcare cost savings**

Figure 1: Proportion of best overall scores of 4 or 5 on the INTELLIN® 5-point rating scale

Strongly agree (5) to strongly disagree (1) for each question – clinician (green; n=15) and patient (blue; n=15) full analysis sets



[a]As not every study participant scored at each visit, the best overall score across visits was taken for each patient or staff member.

Reference: 1. Armstrong DG, et al. N Engl J Med 2017;376(24):2367–2375.

DFU, diabetic foot ulcer; FAS, full analysis set; HEOR, health economics & outcomes research; SD, standard deviation; SINBAD, Site, Ischaemia, Neuropathy, Bacterial infection, And Depth; SoC, standard of care; T1/2DM, type 1/2 diabetes mellitus.