Socio-economic and patient demographic challenges arising during the recruitment and enrolment process for a feasibility study exploring the implementation and acceptance of the INTELLIN® platform in patients with a previous history of diabetic foot ulcers

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Background

- Diabetic foot ulcers (DFUs) cause significant morbidity and mortality. The often difficult and prolonged healing of DFUs, alongside the subsequent health risks, result in reduced quality of life for patients and substantial costs for healthcare systems
- The INTELLIN® diabetes management platform is a novel mHealth application for the management of patients who have experienced a recently healed DFU, among other diabetes complications, with bespoke software that promotes engagement with DFU care and expedites the self-referral process

Aim

- To discuss the socio-economic and patient demographic challenges that arose during recruitment and enrolment in a feasibility study assessing the INTELLIN® platform, and how such challenges may impact future mHealth studies

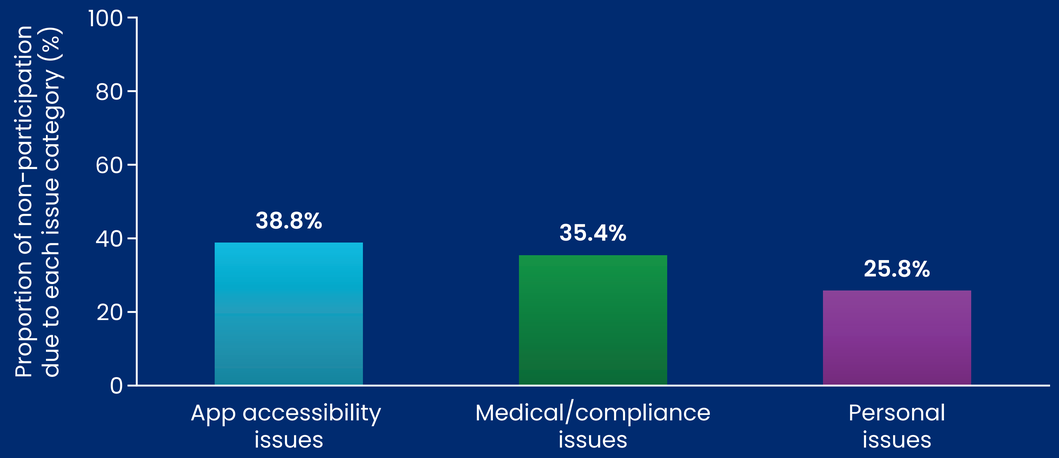
Methods

- Patients from the Salford Royal NHS Foundation Trust attended follow-up study visits at Weeks 1, 4, 16, 28, 40 and 52
- Patients completed a medical questionnaire to create their INTELLIN® profile
- Eligible patients were adults with T1/2DM and a history of a recent DFU, defined as being eligible for the National Diabetes Foot Care Audit and classified as healed for ≥4 weeks but no more than 12 weeks. Participants must also have owned a smartphone on study enrolment

Full study results and methodology can be found in DSFG Poster EP20 (Chadwick P, et al.)

Substantial barriers to enrolment encountered in an app feasibility study demonstrate the impact of socio-economics on mHealth in patients with diabetes

Figure 1: Reasons for patient non-participation in this study



Conclusions

- The substantial barriers to enrolment encountered in this feasibility study demonstrate the considerable impact of socio-economic factors on mHealth studies
- The diabetes demographic often includes older patients and those with comorbidities, which may also result in a high burden of technology accessibility issues. These may have been compounded by the relatively low-income demographic of the Salford ward
- Future studies should consider appropriate measures and additional support required for increased study accessibility

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

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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 (Table 1), 19 were enrolled and 15 entered the full analysis set; 2 patients completed the study
- App accessibility issues predominated (69/178; 38.8%), driven by a **lack of smartphone access** (58/178; 32.6%), **which was the most important barrier to enrolment**, with subsequent patient discussion highlighting concerns over use of mobile data packages and phone memory (Figure 1)
- **Cognitive impairment** (3/178 patients; 1.7%) and **eyesight problems** (5/178 patients; 2.8%) were also identified as barriers to smartphone use and enrolment
- **Medical/compliance issues** (63/178; 35.4%) and **personal reasons** for non-participation (46/178; 25.8%) were identified as additional major barriers

DFU, diabetic foot ulcer; FAS, full analysis set; SD, standard deviation; SINBAD, Site, Ischaemia, Neuropathy, Bacterial infection, And Depth; T1/2DM, type 1/2 diabetes mellitus.