Efficacy and safety of the Patient Empowerment through Predictive Personalised Decision Support (PEPPER) system: an open-label randomised controlled trial

Parizad Avari[1]*, Yenny Leal[2]*, Marzena Wos[2], Narvada Jugnee[1], Maria Thomas[1], Quim Massana[3], Beatriz Lopez[3], Lucian Nita[4], Clare Martin[5], Pau Herrero[6], Nick Oliver[1], José Manuel Fernández-Real[2], Monika Reddy[1], Mercè Fernández-Balsells[2]

***Authors contributed equally**

[1]Division of Diabetes, Endocrinology and Metabolism, Faculty of Medicine, Imperial College London, UK
[2]Institut d'Investigació Biomèdica de Girona Dr Josep Trueta, Spain
[3]Enginyeria Elèctrica, Electrònica i Automática, Universitat de Girona, Spain
[4] Department of Research & Development, Romsoft SRL, Romania
[5]School of Engineering, Computing and Mathematics, Oxford Brookes University, Oxford, UK
[6]Department of Electrical and Electronic Engineering, Imperial College London, London UK

Background and Aims

- PEPPER (Patient Empowerment through Predictive PERsonalised decision support) is an EU-funded H2020 project that provides personalised insulin bolus advice for people with Type 1 diabetes (T1D).
- The PEPPER system includes an artificial intelligence (AI) powered insulin dose recommender and a safety system comprised of predictive glucose alarms, low-glucose suspend for insulin pump users and personalised carbohydrate recommendations [1].
- PEPPER offers a dual architecture to cater for both insulin injections and insulin pump treatments.
- Users wear a real-time continuous glucose monitor and an activity monitor that communicates to the handheld device.
- Here, we evaluate the safety, feasibility and usability of the PEPPER system compared to a standard bolus calculator.

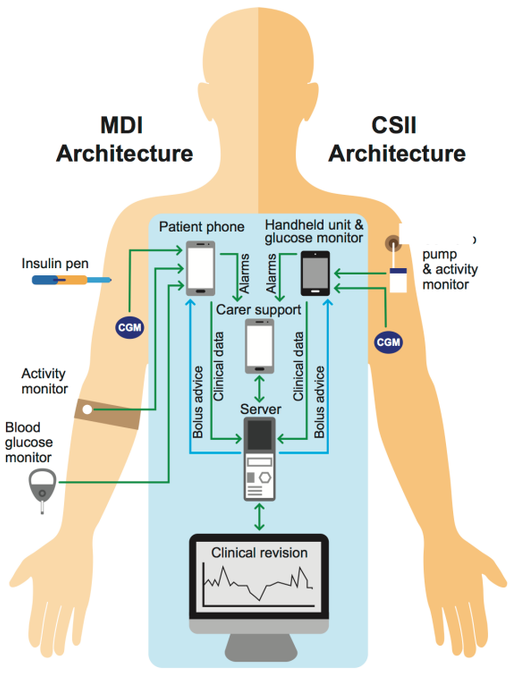

Figure 1: PEPPER Architecture and clinical platform

Methods

- Randomized controlled cross-over study.
- After a 4-week run-in, participants were randomized to PEPPER/Control or Control/PEPPER in a 1:1 ratio for 12-weeks.
- Participants then crossed over after a 3-week wash-out period.
- The primary endpoint is percentage time in range (70 –180mg/dL) between the two groups.

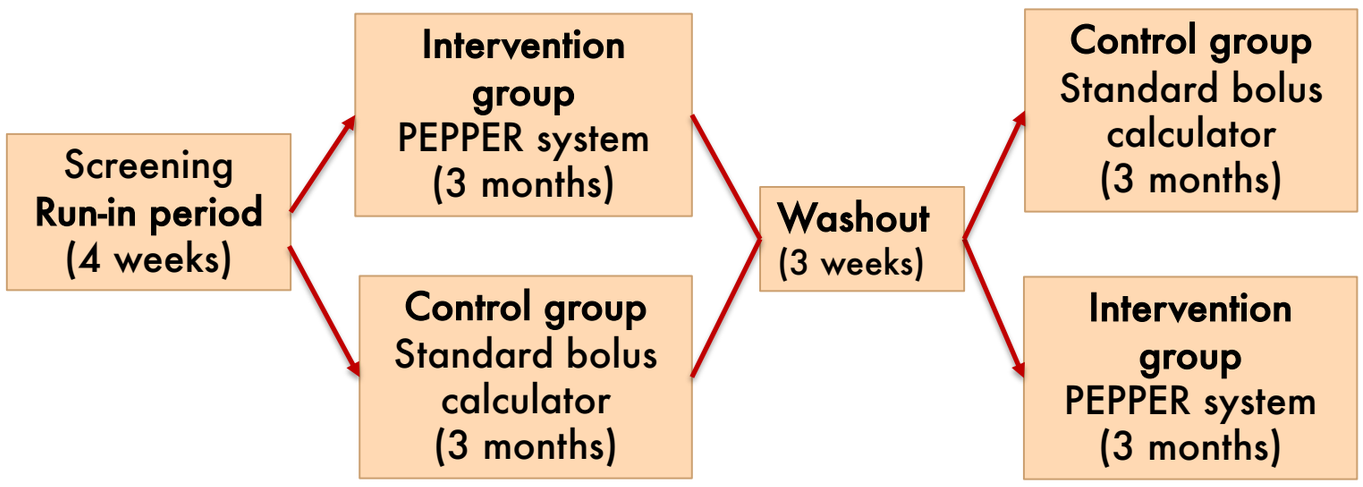

Figure 2: PEPPER Phase 3 Clinical Study design

Results

- 58 participants were recruited at two clinical sites; Imperial College London in the UK and the Institut d'Investigació Biomèdica de Girona in Spain.
- 44 participants were included in the final analysis.
- Of 19 pump users (43%), the study had to be terminated early in 10 participants due to cessation of Cellnovo (pump manufacturer and study partner). Data has been included for analysis as these participants completed either intervention phase (Control or PEPPER) and was compared to the baseline run-in period.

Demographics (n=44)	Median (IQR)
Gender (male:female)	23:21
Pump:MDI	19:25
Age (years)	42 (37 – 51)
Duration of diabetes (years)	19 (11 – 26)
HbA1c (mmol/mol)	60 (58 - 66)

Table 1: Baseline Demographics

Time in Glycaemic range	Baseline (n=44)	Control (n=39)	PEPPER (n=39)	p-value
%TIR (70-180mg/dL)	55.3 (45.7 - 67.0)	1.3 (-6.0 to 7.6)	4.2 (-5.2 to 10.9)	0.44
%TIR (70-140mg/dL)	31.5 (25.0 - 43.4)	-0.2 (-7.0 to 6.2)	2.1 (-6.6 to 7.9)	0.64
%T <70mg/dL	3.0 (1.7 - 5.7)	-0.3 (-1.7 to 0.9)	-0.9 (-2.3 to 0.3)	0.22
%T <54mg/dL	1.1 (0.4- 2.0)	-0.1 (-0.9 to 0.3)	-0.2 (-1.1 to 0.1)	0.35
%T >180mg/dL	42.3 (27.8 - 48.8)	-1.6 (-7.6 to 6.9)	-3.9 (-10.0 to 6.5)	0.66

Table 2: Difference in percentage times in glycaemic ranges compared to baseline (run-In period)

Conclusion

- The PEPPER Personalised Decision Support system is safe and feasible for use in people with Type 1 diabetes.
- A trend suggesting improvement in time in range was observed between PEPPER and the control group.
- These results are preliminary and further analysis is to be conducted on secondary outcomes, including glycaemic variability, quality of life, and safety system outcomes.

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