

Self-monitoring of Urine Specific Gravity using Study Smartphone Applications Promotes Adherence to High Water therapy and facilitates remote data capture in the DRINK Randomised Trial

Dr Ragada El-damanawi^{1,2}, Ms Tess Harris³, Mrs Laura B Mader⁴, Dr Richard Sandford⁵, Professor Ian B Wilkinson^{1,2}, Professor Fiona E Karet Frankl⁵, Dr Thomas F Hiemstra^{1,2}

¹Cambridge Clinical Trials Unit, Cambridge, United Kingdom, ²Division of Experimental Medicine and Immunotherapeutics, University of Cambridge, Cambridge, United Kingdom, ³PKD Charity, London, United Kingdom, ⁴Patient Led Research Hub, Cambridge, United Kingdom, ⁵Division of Renal Medicine and Departments of Medical Genetics, University of Cambridge, Cambridge, United Kingdom

Introduction and aims

High water (HW) intake inhibits vasopressin release, a key promoter of cyst growth and disease progression in Autosomal Dominant Polycystic Kidney Disease (ADPKD). Maintaining HW intake requires patient motivation and commitment to self-management. We evaluated the role of smartphone applications to facilitate adherence in a randomised feasibility trial of HW intake.

Methods

We developed and deployed a cross-platform smartphone application to allow home monitoring and remote submission of urine specific gravity (uSG) data in a randomised feasibility trial of HW versus ad libitum (AW) water intake in patients with ADPKD (NCT02933268). Participants were required to target uSG ≤ 1.010 (HW) or >1.010 (AW). Fluid intake instructions were embedded in the app, which also provided graphical data display. Data submitted via the app were transferred in real time to a central administration portal. Use of the app was encouraged but optional.

Results

The trial app was used by 81% (34/42) of trial participants (HW n=16, AW n=18). Baseline characteristics were similar between treatment arms amongst app users (female 53% vs 56% $p=0.75$, White British 81% vs 83% $p=0.82$, mean age 47 ± 11 vs 43 ± 11 years $p=0.38$, in the HW and AW groups respectively). Plasma osmolality was 290 ± 9 (HW) vs 289 ± 7 (AW) mOsm/kg ($p=0.68$) with a corresponding median uSG 1.010 IQR 1.010-1.015 (HW) and 1.010 IQR 1.010-1.015 (AW), $p=0.52$. Over the 8 week follow up period, HW patients used the app to submit uSG data 92% (165/179) of the time compared to 91% (199/219) in the AW group, $p=0.38$. Target uSG was achieved 83% of the time in the AW group and 77% in the HW group, $p=0.67$. Patients reported high levels of satisfaction with their experience of using the app.

Conclusions

Smartphone technology resulted in high levels of adherence to the study intervention, reliable remote data collection and attainment of target USG with separation between treatment arms. Incorporation of this methodology into future trials is feasible, improves patient experience, facilitates adherence and enhances research efficiency.