The use of MEMS technology to monitor medication adherence in the Tina Trial: a double-blind randomised placebo-controlled trial of mirtazapine for methamphetamine use disorder.

Palmer L[1], Keygan J[1], Degan T[1], Saunders L[1], Morrison C[2], Wrobel A[2], Thomas T[3], Hatton E[3], Turner A[2], Dean O[2], Kelly P[3], Sinclair B[4], Reid D[4], Cordaro F[4], Hayllar J[5], Christmass M[6], Berk M[2], Hill H[7], Lundin R[7], Arunogiri S[8], Colledge-Frisby S[1,9], Dore G[10], Shoptaw S[11], Goodman-Meza D[12], Clare P[12], Koeijers J[1], Farrell M[1], Degenhardt L[1], McKetin R[1].

The Difference is Research

Background

Accurately measuring and monitoring medication adherence in clinical trials is critical to their success [1]. Poor medication adherence is particularly problematic in pharmacotherapy trials for stimulant use. Currently there is no consensus on how best to monitor trial medication adherence [2]. Self-report diaries are commonly used but rely on participant recall and place a high burden on trial participants. Electronic monitoring systems have come to the fore as a potentially more accurate and convenient way of monitoring medication adherence [3].

We have adopted a Medication Event Monitoring System (MEMS) to monitor medication adherence in the Tina Trial, a Phase 3 clinical trial to determine the safety and efficacy of take-home mirtazapine for methamphetamine use disorder (ACTRN12622000235707).

Aim

We describe how MEMS is used in the Tina Trial to monitor medication adherence and we provide examples of data output from the MEMS system.

Figure 1. Medication bottles in the Tina Trial.

Methods

Trial medication bottles are each fitted with a MEMS® SmartCap® (AARDEX Group) which captures data on the date and time of each bottle opening (Figure 1).

An adherent dose is defined as at least one bottle opening within a 24-hour period (from 3 am each day).

At each assessment, medication adherence data can be taken from the MEMS® SmartCap® using a MEMS reader or a near field communication enabled device (Figures 2 and 3).

Data is displayed on a dashboard that shows overall medication adherence as well as a calendar display (Figures 4 and 5). This data is used to discuss medication adherence with the participant and counsel them on strategies to improve adherence.

The MEMS® SmartCap® also has a Liquid Crystal Display showing participants how many times the bottle has been opened each day, so participants can see if they have already taken their dose for that day (Figure 1).

Figure 2. Activation of the MEMS SmartCap® using the MEMS Reader and the adherence dashboard on the MEMS software.

Results

The MEMS® SmartCap® technology has been helpful in monitoring medication adherence in the Tina Trial. Showing participants the calendar and data plots has helped to identify and discuss lapses in medication adherence.

Advantages of this system include the provision of summary adherence data that can be easily captured with minimal participant burden. Participants also find the novelty of the technology engaging.

Limitations of the system include the cost, the need for a PC to access the full data dashboard (with a limited view of adherence data on mobile devices), and the reliance of the technology on the bottle with the MEMS® Smartcaps® being returned.

Implications

MEMS technology provides useful insights into medication adherence in the Tina Trial. This technology may be particularly useful to promote trial engagement in more regional and remote areas (in conjunction with other digital health technologies, such as telehealth), because it can provide a means of remotely monitoring medication adherence.

Additionally, the use of electronic monitoring systems to track adherence of clinical trial participants, further promotes take-home medications in clinical trials.

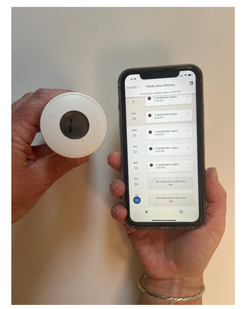

Figure 3. Uploading adherence data from the MEMS Smartcap® using a Smartphone with Near Field Communication

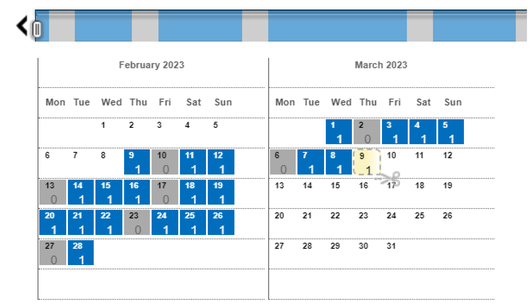

Figure 4. A 'calendar' view of medication adherence.

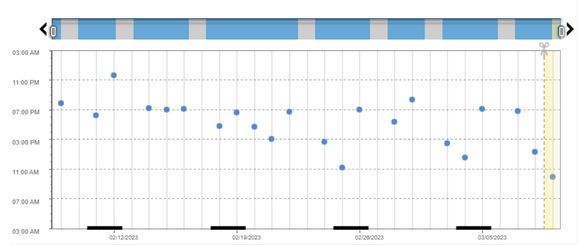

Figure 5. A 'chronology' view of medication adherence.

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[1] National Drug and Alcohol Research Centre, University of New South Wales, Sydney, [2] IMPACT Trials, School of Medicine, Deakin University, Geelong, [3] School of Psychology, University of Wollongong, Wollongong, [4] Illawarra Drug and Alcohol Service, Illawarra Shoalhaven Local Health District, NSW Health, Wollongong [5] Biala, Metro North Health, Brisbane [6]Next Step Community Alcohol and Drug Service, East Perth [7]Drug and Alcohol Services, Barwon Health, Geelong [8] Alfred Psychiatry Research Centre, Central Clinical School, Monash University, Melbourne [9] National Drug Research Institute, Curtin University, Perth, [10] Kirby Institute, UNSW, Sydney [11] Department of Family Medicine, UCLA, Los Angeles [12]Division of Infectious Diseases, David Geffen School of Medicine, UCLA, Los Angeles [13] Prevention Research Collaboration, The University of Sydney, Sydney