

Letter to Editor

Acceptability and feasibility of a sensor-instrumented 'SmartSocks' wearable prototype to detect agitation in people with dementia

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Agitation is one of the most common neuropsychiatric syndromes affecting people with dementia [1]. Central to robust clinical research and effective management is the development of more objective measurement methods, with wearable technology emerging as a promising approach [2–4]. Many studies have reported good tolerability for wrist-worn devices, but there have also been reports to the contrary. To address this, SmartSocks (Milbotix Ltd; <https://milbotix.com/>) have been developed. This novel wearable device looks and feels like a normal pair of socks with a sensor box attached at the ankle that measures physiological parameters (heart rate, temperature, electrodermal activity, and movement) via photoplethysmography; an infrared thermopile; a capacitive touch sensor; a six-axis inertial measurement unit measuring linear acceleration and angular velocity; and copper yarn woven into the sock fabric. These data are then fed through an algorithm that is trained to detect agitation. On detection, an alert is then sent from the sensor to a tablet or mobile device used by care staff, who can then respond accordingly.

This study reports the first trial of this technology in care homes, with the principal aims being feasibility, acceptability and concurrent validity against the Cohen-Mansfield Agitation Inventory (CMAI). The full protocol has been previously published, and code (<https://github.com/creesebyron/SmartSocks>) and data (10.17633/rd.brunel.30127036) are available which will allow researchers to fully reproduce the findings presented here [5].

We recruited and followed up ten people with dementia – against a target of 30 – across three care homes between February and June 2025 per the Research Ethics Committee-approved protocol. While we did not recruit to target due to manufacturing delays, a sample size of ten is comparable to many (though not all) prior wearable studies and the recruitment rate was reasonable for this type of study [2]. Here, we present a brief description of the results of the pre-planned analysis relating to the aims that we could address with the reduced sample size.

The clinical and demographic characteristics of participants were in line with expectations for this population (history of falls in 4/10; clinically significant agitation present in around 1/3 of participants). Mean age was 83 (SD: 11) and all participants had moderately-severe to severe dementia, with severe or very severe frailty.

The hardware itself was well tolerated among the ten participants, and comfortable (all completed the per-protocol follow up for four weeks). In focus groups, staff reported no tolerability or comfort problems and did not feel that using the SmartSocks interfered with their routine duties. However, they also reported functionality problems with the alert system (false positives and false negatives). We believe this is due to technical issues in data transmission, which are not uncommon in early prototype research and should be viewed in this context; a systematic review cited wireless connectivity, battery life and human error as common in studies of wrist, ankle and phone wearables [2]. On examination of recorded hours of transmission, we found that data were recorded on only 60 % of possible days despite there being no reports of wearer compliance issues from staff (Fig. 1). Moreover, there was no correlation between SmartSock alerts and CMAI, in contrast to previous research in other wearables [6,7]. The CMAI is well validated, and our findings that younger age was associated with more severe agitation and that there were no major sex differences are consistent with prior research (data not shown but available), suggesting ratings were reliable [8,9]. However, agitation was only measured at three time points using the CMAI, which, while consistent with the 2-week reference period for this measure, may not provide the ideal frequency to validate SmartSock data due to recall biases and staff changes. More frequent questionnaire-based measures could be considered but must be balanced against staff time burden. Another approach could be single-day researcher-led observations using tools such as the observational CMAI (CMAI-O), though these would be impractical to do on a daily basis [10].

This research forms part of an evidence-based development pipeline and has yielded several insights, which have led to improvements in the product. From a technological perspective, Wi-Fi connectivity may have contributed to transmission issues. Non-Wi-Fi communications are now being introduced to improve reliability in care homes, using mesh networking for local coverage. Battery life is also being extended from ten hours to two days through power optimisations.

In this four-week feasibility and acceptability study, we found the SmartSocks prototype to be well tolerated among people with dementia, with no challenges to recruitment once kits were available.

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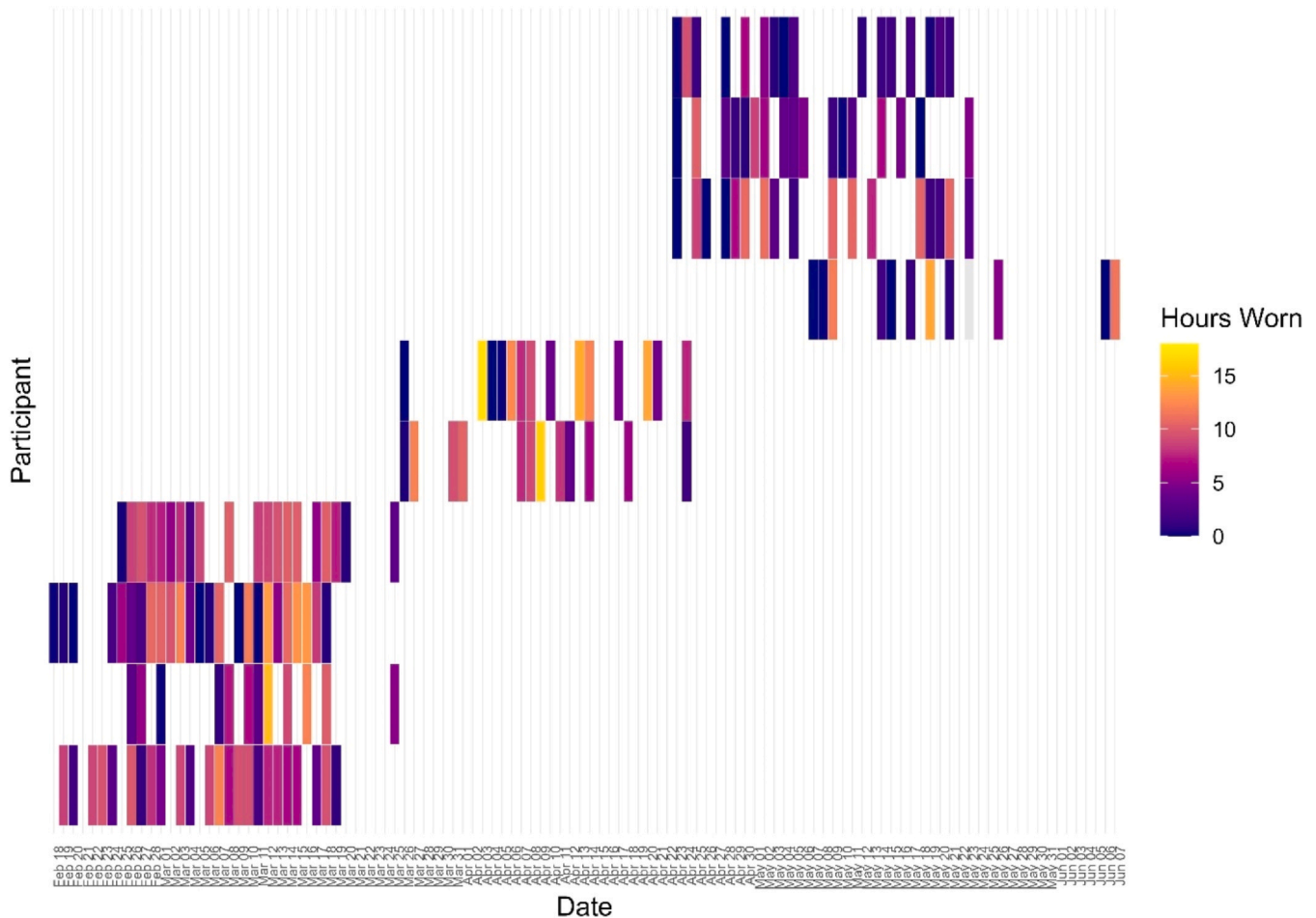


Fig. 1. Daily data transmission time in hours for each participant. Only non-zero days are coloured. Blanks represent days where no transmission was recorded. Each row represents data for one participant.

While data transmission issues limited analysis, the hardware was acceptable and warrants further studies examining the objective measurement of agitation using SmartSocks.

CRediT authorship contribution statement

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The sponsor of the study was Brunel University of London. Neither the sponsor nor funder had a role in study design, writing the protocol or other study documentation. Milbotix provided input into the study design only with respect to logistical aspects of the SmartSocks (e.g., the number of pairs to be provided and the inclusion criteria relating to medical contraindications); all other elements were decided by the academic research team. Neither, the sponsor, the funder nor Milbotix will have any role in the data analysis. Milbotix Ltd inputted into sections of the discussion pertaining to the technical learning from the SmartSocks but did not have a role in what data was presented. Neither the sponsor nor funder had any role in the study design, interpretation, manuscript writing or dissemination of results. All decisions regarding the study (including publication of results) will be made by the academic research team.

Data availability

Code used in the data preparation and analysis is available at <https://github.com/creesebyron/SmartSocks>. Consent was not obtained for open posting of data. Data are embargoed on Brunel University of London's research data repository, Figshare ([10.17633/rd.brunel.30127036](https://doi.org/10.17633/rd.brunel.30127036)) and accessible via request. Access will be granted once users have consented to the data sharing agreement.

Declaration of Competing Interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: Byron Creese reports financial support was provided by Milbotix Ltd. Zahinoor Ismail reports financial support was provided by Eisai Inc. Zahinoor Ismail reports financial support was provided by Eli Lilly and Company. Zahinoor Ismail reports financial support was provided by Lundbeck. Zahinoor Ismail reports financial support was provided by Novo Nordisk Inc. Zahinoor Ismail reports financial support was provided by Otsuka Pharmaceutical Co Ltd. Zeke Steer reports a relationship with Milbotix Ltd that includes: board membership and employment. Prabha Venkatesh reports a relationship with Milbotix Ltd that includes: employment. Zeke Steer has patent #GB2629048B issued to Dr Zeke Steer. Prabha Venkatesh has patent #GB2629048B pending to Prabha Venkatesh. None If there are other authors, they declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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