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Wearables, Healthcare-Computer Interaction and the Internet of *Obscure* Medical Things

Khalid Ahmad Khattak
Keele University
Staffordshire, UK
k.a.khattak@keele.ac.uk

Sandra I. Woolley
Keele University
Staffordshire, UK
s.i.woolley@keele.ac.uk

Tim Collins
Manchester Metropolitan University
Manchester, UK
t.collins@mmu.ac.uk

In recent years, wearable computers, in the form of wrist-worn trackers and smartwatches, have transitioned apace from the well-being market into the set of 'Internet of Medical Things' (IoMTs) used in clinical research and healthcare. Despite concerted efforts invested in improved clinical research practices and, more generally, in improved reporting and repeatability in research, failings in the reporting practices of IoMTs and other health technologies mean that fundamental materials information is too frequently obscure. This paper contributes novel insights from work in progress that is systematically analysing the specificity of wearable wrist-worn IoMT interventions reported in completed and reported clinical trials. Results compiled for the earliest and most recent 10% of completed trials recorded in the international ClinialTrials.gov repository demonstrates substantial failings in reporting practices and a complete absence of version reporting. To better understand and improve on current practice and failings, we propose that *Healthcare*-Computer Interaction (as a sub-genre of Human-Computer Interaction) is deserving of further attention.

Clinical Trials, Wearables, Internet of Medical Things (IoMT), Version Reporting

1. INTRODUCTION

Popular consumer-grade wearable trackers and smartwatches, though not medical devices (Fitbit 2023; Garmin 2023), have been transitioning from well-being markets into corporate wellness (Giddens et al, 2017), health research (Khattak, 2020), health insurance, (Krüger and Ni Bhroin, 2020) and healthcare (Colvonen, 2021).

These consumer-grade wearables substantially add to the number of clinical trials using medical-grade devices and, indeed, some consumer- and research-grade devices have received medical certifications, e.g. Apple Watch atrial fibrillation sensing (FDA, 2018) and Empatica Embrace (Epilepsy Foundation, 2019).

Typically, the consumer-grade wearables are wrist-worn, and provide tracked estimates of steps, activities and sleep, that are often accompanied by heart rate estimates together with other tracked or inferred values such as calories burned etc. Supported by appealing, intuitive and persuasive goal-setting apps and dashboards, these devices undoubtably incentivise many individuals toward personal or shared goals (Woolley, 2023). There are, however, concerns about the sensing accuracy and inequity of the devices. For example, in a commentary positing ways in which wearables might improve health equity, Walter et al, (2024) observed that *"… the trajectory of medical wearables to promote health equity is not inevitable… For example, photoplethysmography (PPG)-derived heart rate and oxygen saturation… which is notoriously inaccurate in patients with darker skin".*

There are also concerns about the ease of access to system level information, and in the reporting of wearable device system level information in the academic and clinical trial documentation (Collins et al. 2019), particularly given the iterative updating nature of device models (Khattak and Woolley, 2023) and the physically distinct nature of the models themselves, exemplified in Figure 1 which illustrates different models of the Garmin Vivosmart 'family' of wrist-worn trackers.

Figure 1. *The Garmin Vivosmart family of physically distinct models: (i) Vivosmart, (ii) Vivosmart HR, (iii) Vivosmart 3, (iv) Vivosmart 4, (v) Vivosmart 5*

More generally, software reporting and code availability (and therefore research repeatability) has been demonstrated to be poor in academic literature, even in software engineering (Collberg, 2015). However, a comprehensive and systematic appraisal of wearable intervention reporting in clinical trials has not previously been reported. The motivation for this research, and the contribution of this study, is the preliminary analysis of the specificity of wearable intervention reporting in clinical trials.

2. BACKGROUND

Publicly available international clinical trials registries include the World Health Organisation's International Clinical Trials Registry Platform (WHO ICTRP), the EU Clinical Trials Register, and the U.S. National Institutes of Health ClinicalTrials.gov register. Though it may not fully represent global clinical trials the ClinicalTrials.gov database (ClinicalTrials.gov, 2023a) of over 500,000 trial records from 200 countries[1], is the largest of the repositories and, as such, researchers and health professionals rely on the published results to make evidence-informed decisions (Stergiopoulos et al, 2019). Ultimately, the repository usefulness relies on the research community submitting accurate and informative data, but Zarin et al., (2011) reported that 61% of records lacked specificity in describing metrics used in planned analyses.

Wu et al. (2016) assessed the readability of ClinicalTrials.gov record descriptions using five scoring algorithms. The evaluation was conducted in comparison with MedlinePlus Health Topics articles and clinical notes retrieved from an Electronic Health Record (EHR) system. Their results indicated that the trial descriptions on ClinicalTrials.gov were *"…the most difficult corpus, on average requiring 18 years of education in order to proficiently read and comprehend"*. The authors recommended that significant work was warranted to improve readability and thereby achieve the goals of the database in facilitating information dissemination and subject recruitment.

Butcher et al. (2022) highlighted that clinicians, patients, and policymakers rely on published trial results to help make evidence-informed decisions. The authors emphasised that, to critically evaluate and use trial results, readers require complete and transparent information regarding what was planned, what was done, and what was found. Their recommendation was for specific and harmonised guidance regarding what information should be reported in clinical trials, to reduce deficient reporting practices that obscure issues with outcome selection, assessment, and analysis.

3. METHODOLOGY

The ClinicalTrials.gov database was used to search for trial "Interventions/treatment" fields matching the search string:

> "tracker OR fitbit OR fit bit OR wearable OR smartwatch OR smart watch OR Apple watch"

The results were assessed according to inclusion and exclusion criteria (below) and findings from inspections of the wearable intervention material information.

Inclusion criteria:

- Results first reported prior to 1st May 2024
- Interventions using non-specialised, non-prototypical wrist-worn wearable devices.

ClinicalTrials.gov filters:

- Status: completed
- Study: with results
- Participant age: 18+
- Study type: Interventional clinical trial

Exclusion criteria:

- Trials exclusively recruiting minors
- Trials using specialised or laboratory prototype devices
- Trials using devices designed primarily for wrist use but not worn on wrist

Information sought:

Study records, documents and linked publications were searched for wearable intervention details to determine:

- Manufacturer
- Family
- Model
- Software/firmware version numbers

Information inspected:

- ClinicalTrials.gov study records
- Study Protocol and Statistical Analysis Plan documents
- Linked Publications

[1] https://clinicaltrials.gov/about-site/about-ctg (accessed 12th July 2024)

Two researchers independently applied the inclusion and exclusion criteria and a third researcher assessed instances where there were differences or uncertainties, and a consensus agreed.

The resulting trials were listed chronologically by "Results first reported". In order to test and refine the inclusion and exclusion criteria, a sample of the earliest completed 10% and most recently completed 10% of studies was analysed. Selecting the earliest and latest of the wearable intervention trials also provided an opportunity to identify changes in reporting practice over time.

4. RESULTS

Figure 2 illustrates how results for ClinicalTrials.gov searches for clinical trials with wearable interventions have dramatically increased in recent years.

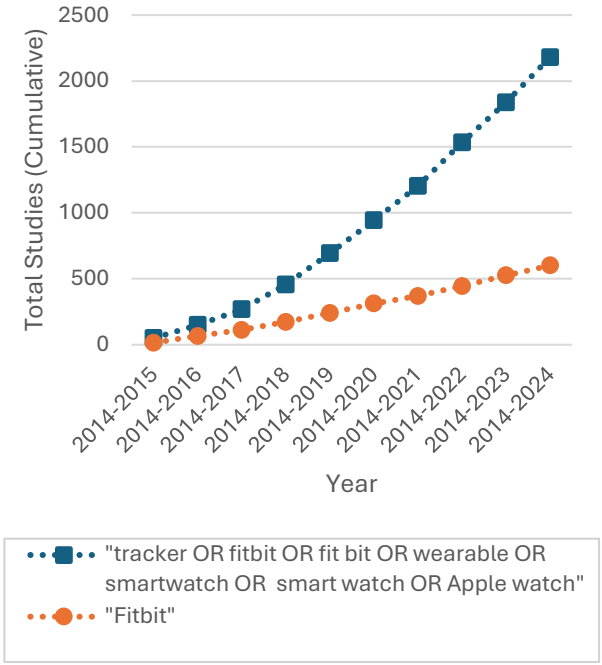

Figure 2: *Intervention field search results*

As shown in Figure 3, 106 clinical trials (of the original 2,179 search string results) matched the inclusion and exclusion criteria. For the preliminary analysis, the earliest and latest 10% of these trial results ($N_s = 2 \times 11 = 22$) were then selected.

The $N_s = 22$ trials included studies with between five and 6,135 participants, totalling 7,912 participants of whom 6,562 (83%) completed. Several of these trials focused on activity promotion, for example, amongst individuals with knee osteoarthritis (ClinicalTrials.gov, 2019) and multiple sclerosis (ClinicalTrials.gov, 2021), and amongst veterans (ClinicalTrials.gov, 2020) and caregivers (ClinicalTrials.gov, 2023b), and two trials focused on the monitoring of sleep and insomnia (ClinicalTrials.gov, 2017; ClinicalTrials.gov, 2024).

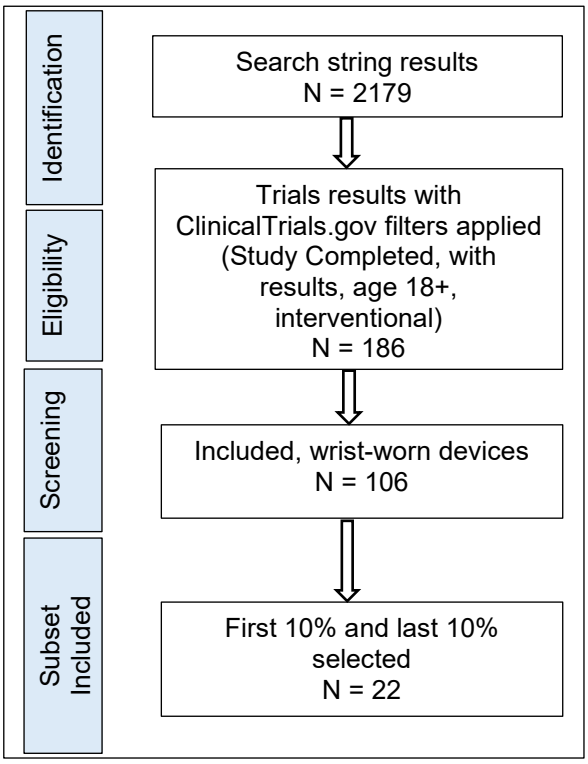

Figure 3: *Systematic clinical trials search flow chart*

Of the 22 trials, 19 trials were located in the USA, two in Canada and one in Israel. Ten of the 22 trial reports included links to one or more research publications.

Summarised results for the wearable reporting information are provided in Table 1. As shown, the $N_s = 22$ selected trials referred to a total of 23 wrist-worn wearable devices ($D = 23$) (because one trial used both an Apple Watch and a Fitbit Versa) from five manufacturers: Fitbit, Apple, Garmin FitBug, and Amiigo. All three trials that used Apple Watch interventions were in the most recent 10% sample of included trials.

Six trials referred *only* to manufacturer name (i.e., did not provide model information). In all six cases the manufacturer was "Fitbit".

Wearable intervention information location

The details of the wearable interventions themselves were reported in various locations across the trial literature, as illustrated in the Figure 4 Venn diagram showing materials information distribution across: i) the 'Trial Record' main text, ii) the 'Protocol Document' ('Study Protocol and Statistical Analysis Plan' documents under 'More Information' > 'Drug and device information, study

documents, and helpful links') and iii) the linked publications.

Table 1: *Summary of wearable intervention reporting information in N_s = 22 trials*

Category	Specified in Trials (N_s = 22)	Wearable Devices (D = 23)
Manufacturer	22	Fitbit (17) Apple (3) Garmin (1) FitBug (1) Amiigo (1)
Family	16	Fitbit Flex (3) Fitbit Inspire (3) Fitbit Charge (2) Fitbit Zip (1) Fitbit Versa (1) Apple Watch (3) Garmin Vivofit (1) FitBug Orb (1) Amiigo Wristband (1)
Model	16	Fitbit Flex (3) Fitbit Inspire (1) Fitbit Inspire 2 (2) Fitbit Charge 2 (2) Fitbit Zip (1) Fitbit Versa (1) Apple Watch S6 (2) Garmin Vivofit 4 (1) FitBug Orb (1) Amiigo Wristband (1)
Software Version	0	-

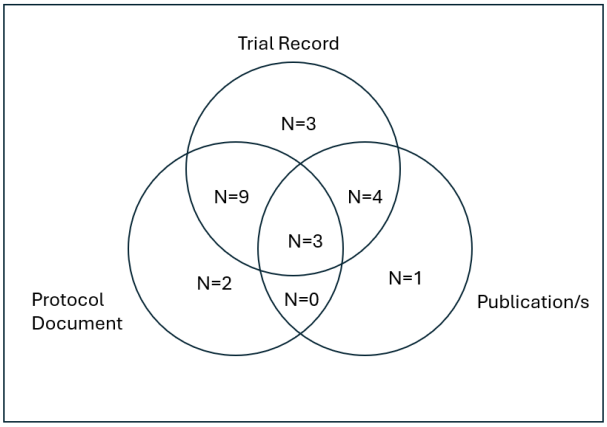

Figure 4: *Location of wearable intervention information in N_S = 22 ClinicalTrials.gov trial documentation*

5. DISCUSSION

In some trial instances, the challenge of finding tangible wearable device specifics was such that it was difficult to determine whether trials did or did not meet the inclusion criteria.

A further challenge to information confidence was the unfortunate ambiguity between references to a device family and to its original 'base' versions. For example, like other new models of devices, the *original* Garmin 'Vivosmart' wrist-worn wearable had no tangible model reference identifier. Subsequent Vivosmart models were identified as Vivosmart HR, Vivosmart 2, Vivosmart 3, etc. It is, therefore, difficult, if not impossible, to distinguish between 'Vivosmart' references to the *original* model and more *obscure* references to the Vivosmart model range.

There were some ambiguities about the location of worn devices. The now-discontinued Fitbit Zip was, by default, a clip-on device (and, therefore, a device that did not meet the on-wrist inclusion criteria) but it *could* be worn on the wrist with the use of a 3rd party wristband. Trials using the Fitbit Zip were therefore excluded with the exception of one trial where documentation specifically referred to the Fitbit Zip worn on the wrist.

In terms of a geographical bias, although a North American focus was anticipated for the ClinicalTrials.gov repository, it was somewhat unexpected that there would be no European trials and only one trial outside North America.

The complete lack of version reporting for the wearable interventions contrasted somewhat with the explicit inclusion of version information for statistical software used in data analyses in three of the trials.

6. CONCLUSIONS AND FURTHER RESEARCH

Significant findings of this preliminary systematic clinical trials review results were that i) <u>*none*</u> of the 20% sample (N_S = 22) of completed and reported wearable intervention trials reported version information for the wearable interventions in the ClinicalTrials.gov studies records, accompanying protocol documents nor linked publications, and ii) six of the 22 students (27%) reported only manufacturer name and <u>*no*</u> model information. Additionally, there was no significant change in the reporting over time from the earliest to latest completed studies.

Ideally, in human-computer interaction research there would be some clarity regarding which humans and which computers. Of course, original (pre-) clinical trial documents cannot be expected to report all specifics of prospective materials, however, post-study reports and publications would ideally contain tangible intervention material details.

In further research the systematic review of the complete set of trials will be analysed.

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