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Version reporting of wearables in clinical trials

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We use this protocol and it's working

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Abstract

This study involved the extraction and analysis of version reporting information from completed and reported ClinicalTrials.gov entries for wrist-worn wearable intervention studies.

Guidelines

N/A

Materials

https://clinicaltrials.gov/

Safety warnings

N/A

Ethics statement

N/A

Before start

N/A

Search string

1 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

2
- 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

3
- 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

4 Study records, documents and linked publications were searched for wearable intervention details to determine:
- Manufacturer
- Family
- Model
- Software/firmware version numbers

Information inspected

5
- ClinicalTrials.gov study records
- Study Protocol and Statistical Analysis Plan documents

- Linked Publications

Preliminary analysis (first and last 10%)

6 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.

Protocol references

Khattak K.A., Woolley S. I. and Collins T., Wearables, Healthcare-Computer Interaction and the Internet of *Obscure* Medical Things, 37th International BCS Human-Computer Interaction Conference, Preston, 15-17 July 2024