Wearable technologies for health research: A scoping review

Sophie Huhn, Miriam Axt, Hanns-Christian Gunga, Martina A. Maggioni, Stephen Munga, David Obor, Ali Sié, Valentin Boudo, Aditi Bunker, Rainer Sauerborn, Till Bärnighausen, Sandra Barteit

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Abstract

Background: Wearable devices hold great promise particularly for data generation for cutting-edge health research, and demand has risen dramatically in recent times. However, there is a shortage in aggregated insights for how wearables have been used in health research.

Objective: We aim to broadly overview and categorize the current research conducted with consumer-grade wearable devices.

Methods: We performed a scoping review to understand the uses of consumer-grade wearables for health research from a population-health perspective using PRISMA-Scoping Review framework. We found a total of 7 499 articles in four medical databases (PubMed, Ovid, Web of Science and CINAHL). Studies were eligible if they used non-invasive wearables; i) worn on the wrist, arm, hip and chest, ii) measured vital signs, and iii) analyse collected data quantitatively. We excluded studies not using wearables for outcome assessment and those that used prototypes, devices that cost >500€ or obtrusive smart clothing.

Results: We found 179 studies involving 10 835 733 participants. Most studies were observational (n=128, 72%), conducted in 2020 (n=56, 31%) and in North America (n=94, 53%), and 93% (10 104 217) of participants featured in global health studies. Typical wearable measures comprised fitness trackers (n=86, 46%) and accelerometer wearables (measures movement) (n=49, 26%) that counted steps (n=95, 53%), heart rate (n=55, 31%), as well as sleep duration (n=51, 28%). Rarely used devices typically measured blood pressure (n=4, 2%), skin temperature (n=3, 2%), oximetry (n=3, 2%), or respiratory rate (n=2, 1%). The most popular wearables were; i) worn on the wrist (n=138, 73%), ii) cost <200€ (n=120, 63%), and iii) used accelerometery (n=145, 83%). Reviewing aims and approaches of all 179 studies revealed six prominent uses for wearables, comprising: i) correlations - wearable and other physiological data (n=40, 22%), ii) method evaluations (with subgroups) (n=40, 22%), iii) population-based research (n=31, 17%), iv) experimental outcome assessment (n=30, 17%), v) prognostic, forecasting (n=28, 16%), and vi) explorative analysis of big datasets (n=10, 6%). The most frequent strengths of consumer-grade wearables were validation, accuracy and clinical certification (n=104, 58%).

Conclusions: The potential and application of consumer-grade wearables used in research increased in the last years. Although most studies perceived wearables as advantageous for research, some studies experienced shortcomings like inaccuracy or technical issues. There is a lack of research conducted of wearable devices in low-resource contexts. Fuelled by the COVID-19 pandemic, we see a shift to more large-sized, online studies where wearables were used to increase knowledge of the developing pandemic, including forecasting models and effects of the pandemic on different populations regarding age, nationality and morbidity. Big data extracted from wearables may potentially transform understanding of populations, health trends and forecasts, as some studies in this field adumbrate. Wearables – although often piloted in the studies – also showed an increasingly diverse field of application and included also rare and possibly underrepresented populations.

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Abstract

Background: Wearable devices hold great promise particularly for data generation for cutting-edge health research, and demand has risen dramatically in recent years. However, there is a shortage in aggregated insights for how wearables have been used in health research.

Objective: We aim to broadly overview and categorize the current research conducted with affordable wearable devices for health research.

Methods: We performed a scoping review to understand the uses of affordable, consumer-grade wearables for health research from a population-health perspective using PRISMA-Scoping Review framework. We found a total of 7 499 articles in four medical databases (PubMed, Ovid, Web of Science and CINAHL). Studies were eligible if they used non-invasive wearables; *i)* worn on the wrist, arm, hip and chest, *ii)* measured vital signs, and *iii)* analysed collected data quantitatively. We excluded studies not using wearables for outcome assessment and prototype studies, devices that cost >500€ or obtrusive smart clothing.

Results: In total, we included 179 studies covering 10 835 733 participants. Most studies were observational (n=128, 72%), conducted in 2020 (n=56, 31%) and in North America (n=94, 53%), and 93% (10 104 217) of participants were part of global health studies. The most popular wearables were fitness trackers (n=86, 46%) and accelerometer wearables which primarily measure movement (n=49, 26%). Typical measurements were steps (n=95, 53%), heart rate (n=55, 31%), and sleep duration (n=51, 28%). Other devices measured blood pressure (n=3, 2%), skin temperature (n=3, 2%), oximetry (n=3, 2%), or respiratory rate (n=2, 1%). The most popular wearables were; *i)* worn on the wrist (n=138, 73%), *ii)* cost <200€ (n=120, 63%), and *iii)* used accelerometery (n=145, 83%). Reviewing aims and approaches of all 179 studies revealed six prominent uses for wearables, comprising: *i)* correlations - wearable and other physiological data (n=40, 22%), *ii)* method evaluations (with subgroups) (n=40, 22%), *iii)* population-based research (n=31, 17%), *iv)* experimental outcome assessment (n=30, 17%), *v)* prognostic, forecasting (n=28, 16%), and *vi)* explorative analysis of big datasets (n=10, 6%). The most frequent strengths of affordable wearables were validation, accuracy and clinical certification (n=104, 58%).

Conclusion: The potential and usage of wearable devices in research increased in the past few years, although mostly as part of pilot studies. Wearables also showed an increasingly diverse field of application like COVID-19 prediction, fertility tracking, heat-related illness, drug effects, and psychological interventions; and included also underrepresented populations like individuals with rare diseases. Although most studies perceived wearables as advantageous for research, some studies experienced shortcomings like inaccuracy or technical issues. There is a lack of research conducted of wearable devices in low-resource contexts. Fuelled by the COVID-19 pandemic, we see a shift to more large-sized, online studies where wearables increased insights of the developing pandemic, including forecasting models and effects of the pandemic on different populations regarding age, nationality and morbidity. Some studies indicated that big data extracted from wearables may potentially transform understanding of populations, health trends and forecasts.

Introduction

Wearable devices hold great promise particularly for data generation for cutting-edge health research, and demand has risen considerably in the last few years [1–3].
Non-invasive, consumer-grade wearables (hereafter “wearables”) may provide manifold advantages for health research: generally, they are generally unobtrusive, less expensive than gold standard research devices [4], comfortable to wear [5] and affordable for consumers [6]. In recent years, quality and accuracy of wearables has improved [7,8], resulting in more clinically approved certifications [9]. Wearables can measure long-term data in the naturalistic environment of study participants, allowing for ecological momentary assessments [10,11]. Therefore, wearables are valuable developments, particularly for generating data for health research in large study populations, i.e. Global Health or epidemiological studies, or in low-income contexts [6,9,12].
One example of a large study is the so-called “Datenspende”-study by the Robert Koch Institute (RKI), the German research institute for disease control and prevention, which aims to tackle the COVID-19 (corona virus disease) pandemic with anonymous data donations acquired through wearables [13]. Based on Radin et al.’s work [14], researchers used wearable data to calculate the regional probability of COVID-19 outbreaks incorporating data on pulse, physical activity (PA) and sleep, as well as weather data. Using a large sample size exceeding half a million participants, they forecasted numbers of COVID-19 infections for the proceeding four days. The Apple Heart Study [15] is another example that was a breakthrough for showing that wearable devices may detect atrial fibrillation and fostered a discussion of potentials and limitations with regards to health care providers, researches, media, and economy [16,17].

Beyond these two examples, wearables are applied in diverse fields of health including: acoustic, gastrointestinal sensors for ileus prediction [18], ultra-violet sun exposure [19], heat-related illness measurements [20], electrolyte monitoring e.g. for cystic fibrosis or training management [21,22], early warning of atrial fibrillation with a wearable ring [23], generation of electrocardiograms (ECG) [15], measuring cardiopulmonary resuscitation quality [24], measuring continuous non-invasive blood glucose [25], as well as smart inhalers and activity trackers for asthma monitoring [26].

Numerous reviews and studies have investigated validation and accuracy, particularly of specific affordable wearables comparing these to gold-standard measurements [21] or comparing evidence in a meta-analysis [8]. Many studies focused on novel technologies, presenting prototypes or investigating feasibility and acceptance of a wearable in a specific setting [3,27]. Similarly, reviews on the application and potential of wearables were focused on *i)* specific wearable devices or specific wearable measurements, e.g. only smartwatches [4] or only sleep measurements [28], or *ii)* applications of specific medical fields and interventions, e.g. only for diagnosis and treatment in cardiological conditions [29], or wearables as an intervention to promote physical activity (PA) in oncology patients [30]. Amongst these publications, we identified a lack of aggregated insight for wearable use in health research and respective strengths and shortcomings. With this scoping review, we aim to overview and categorize the current research conducted with wearable devices.

Methods

We conducted a scoping review to explore applications of affordable wearables worn on wrists, arms, chests or waists, which constitute characteristic locations [31]. We focused on the following aspects: *i)* demographics, *ii)* wearable device and measured vital signs, *iii)* wearable data and its analysis, *iv)* reported shortcomings and strengths of wearables and *v)* study aims, results and types of wearable usage. We present our findings in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses reporting standard and extension for scoping reviews (PRISMA-ScR) [32], the methodological framework of Arksey and O'Malley [33], and Peters [34]. A scoping review seemed most appropriate given the broad nature of this subject and range of potential implementations in the setting of health research.

Eligibility criteria

We sought to define and characterise the state of affordable wearables for health research. Eligible publications were peer-reviewed, published in English and published after 2013 (after wearables became widely commercially available [1–3]), and had a full-text version available (in instances no full-text was available, authors were contacted three times with a waiting period of 7 days between each contact before exclusion).

Our review scopes the current information available on affordable, non-invasive wearables which are *i)* worn on the wrist-, arm- and chest, *ii)* measure vital signs and *iii)* analyse the generated wearable data for outcome assessment. Validation studies or qualitative studies were excluded. We focus only on devices below 500€/device (i) to allow affordability of larger studies, for example, where wearable devices need to be provided to study participants via the study, and also (ii) to ensure that wearables are available commercially available and (iii) intended for consumers. For transparency, devices unavailable for consumers or not consumer-grade per se are highlighted with asterisks (*). As the definition of vital signs is not distinct [35], we included the following vital signs [9,36,37]: heart rate (HR), heart rate variability (HRV), electrocardiogram (ECG) or heart rhythm analysis (detection of arrhythmias), blood pressure, blood oxygen, respiratory rate, body temperature, sleep, electrodermal activity, electromyogram, physical activity (see Table 1).

Table 1. Inclusion and exclusion criteria

Inclusion criteria	Exclusion criteria
Publications	
- full text available - English language - peer- reviewed articles - published 2013-2020	- studies not analysing wearable generated data for (health) outcome assessment: studies focusing on *i)* accuracy, validation, improvement (algorithms, software), *ii)* patents, *iii)* smart clothing, *iv)* obtrusive wearables (i.e., the device comprises obstructive parts or wires, etc.), *v)* behaviour change intervention studies (i.e. where the wearable is provided as promotion for more physical activity (PA) only and not for health outcome assessment), *vi)* qualitative studies, *vii)* or studies with research objectives and outcomes not related to health or a medical condition
Wearable device	
- commercially available wearable, price below 500€/device [a] - wearable worn on: arm, wrist, chest, waist	- wearable not commercially available (e.g., prototype, discontinued) - invasive, obtrusive device (comprising obstructive parts or wires, etc.) - prosthesis, smart clothing (sensors in clothing)
Outcomes	
- measuring and analysing one or more vital sign	- not measuring vital sign, i.e., gait, posture, motion recognition analysis (e.g., gesture recognition for sign language)
- range of vital signs as defined in this review: heart rate (HR), heart rate variability (HRV),	- studies with research objectives and outcomes not related to health or a medical condition

electrocardiogram (ECG) or heart rhythm analysis (detection and classification of atrial fibrillation, extrasystoles, and other arrhythmic events), blood pressure, blood oxygen, respiratory rate, body temperature, sleep (time, deepness, etc.), electrodermal activity, electromyogram (emg), physical activity (PA: steps, distance covered, intensity, energy expenditure, etc.; PA included as basic measurements of wearables); or very similar / related parameters). See: [9,36,37]	

[a] Only hardware prices were considered. Software, subscriptions, or similar which might be necessary for device usage are not included. All prices were captured in the timeframe of this study and therefore are only to be considered as approximations as they might not be applicable.

Information sources and search

We used PubMed, Ovid, Web of Science (WoS) and CINAHL to search peer-reviewed literature using a search string based on the following three concepts including synonyms and medical subject headings (MeSH terms): *i)* wearables (synonyms, top 15 vendors with most market shares [38–40] or frequently used in research [41,42]), *ii)* physical wear location of wearables (torso, arm, wrist) and *iii)* measurement of vital signs (for full search string see Multimedia Appendix 1). We hand-searched the reference lists of relevant articles.
We imported identified articles into the literature reference management system Zotero [43] and then into the systematic review management platform Covidence [44]. Literature was screened by two independent reviewers. Any disagreements were resolved by discussion between the two reviewers (SH, MA) and a third researcher (SB).

Quality Assessment

To overview the quality of included studies and their various study designs (credibility), we considered the Medical Education Research Study Quality Instrument (MERSQI) [45] score as adequate (see Multimedia Appendix 2).

Data synthesis

We conducted data synthesis in accordance with Arksey and O'Malley [33], comprising the analytical framework, analysis on the extent and nature of studies, and thematic analysis. We categorized the findings by: title, author, year, country of study, objectives of study, study population, sample size, methods, intervention type, outcomes, key findings related to the scoping review question [34]. We extracted mutually exclusive groups including: wearable manufacturer, in-built sensors, scope of measurements (vital signs), shortcomings and strengths of wearables mentioned by authors, employed methods for data analysis, and medical fields.

Results

Our initial search yielded 7 499 hits (PubMed: 2 514; Ovid: 1 905; WoS: 1 440; CINAHL: 1 640) and we identified 121 publications by hand search. Of 7 620 total publications, we screened 4 525 non-duplicates for title and abstract, leading to assessment of 660 full-texts. After full-text screening, we included 179 studies in our review [14,15,20,46–221] (Figure 1).

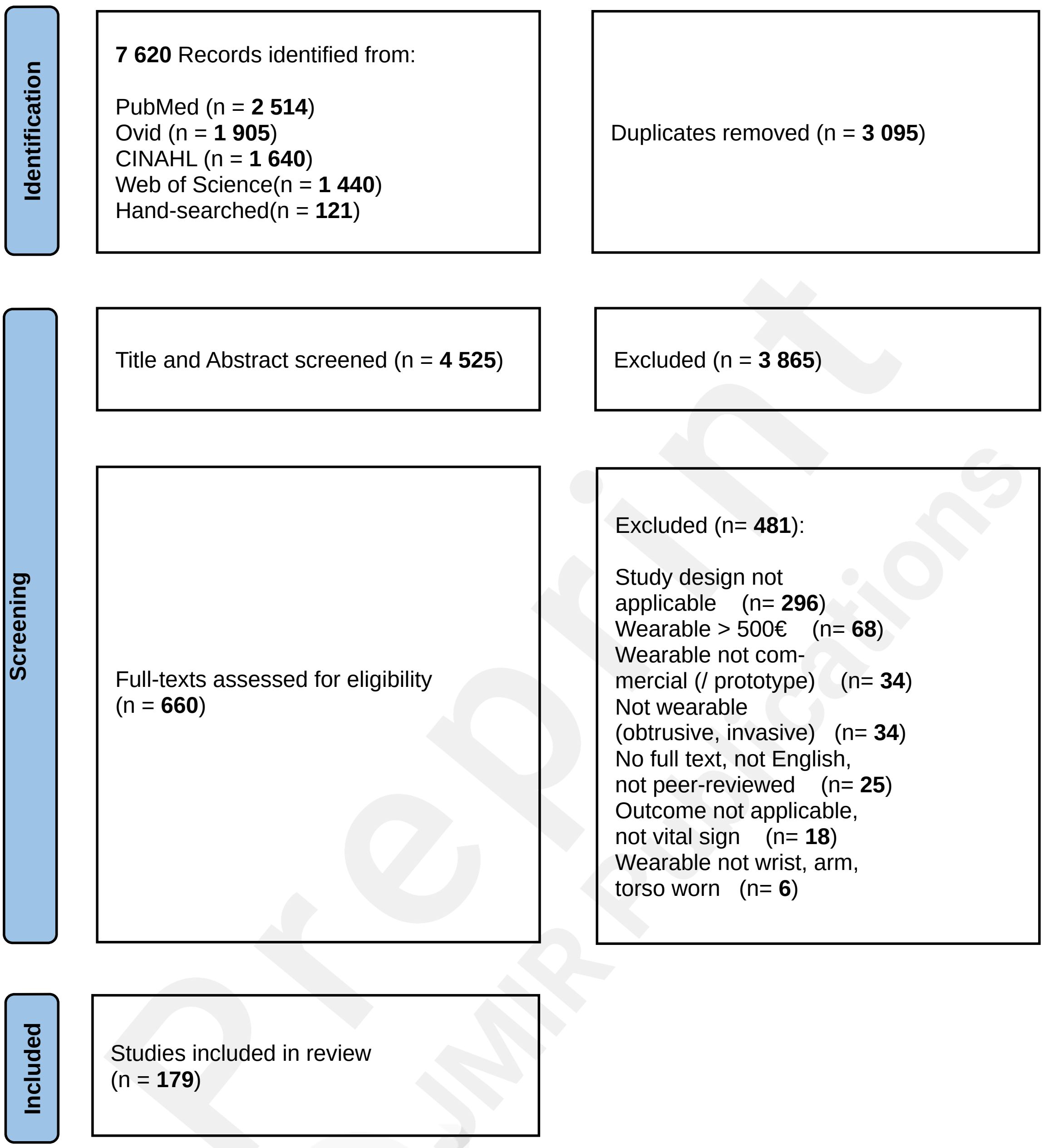

Figure 1: PRISMA flow diagram [222]

Study characteristics

Demographics

Between 2013 to 2020, we observed an increase in the number of studies and study participants (Figure 2, Table 2). The year 2019 featured the largest sample size and studies were predominantly conducted in North America (Figure 3). The largest study we identified was conducted in 2019 in North America and included over eight million participants [155], the second largest was a European study comprising 742 000 participants [164]. Without the aforementioned, largest study, Europe and

Asia would lead in participant numbers and we would see a continuous increase in participants from 2013 to 2020.

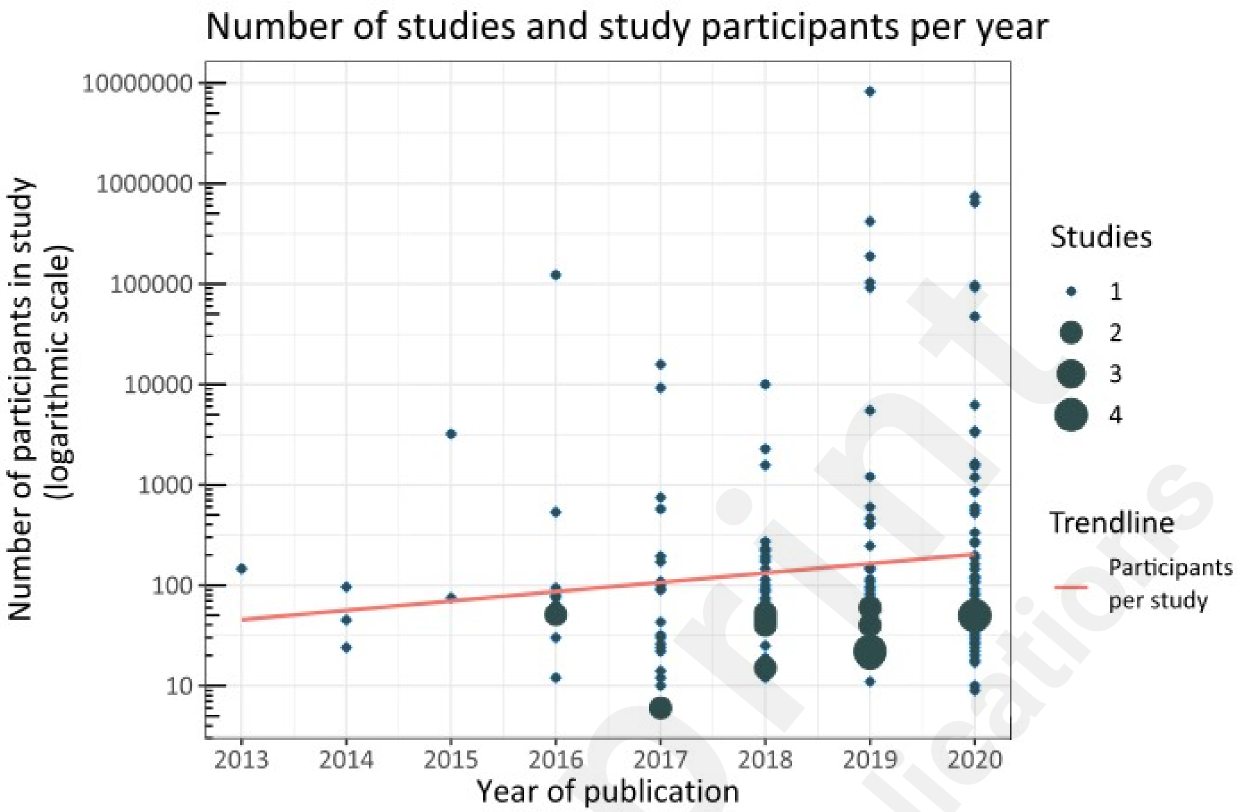

Figure 2. Number of studies and study participants (logarithmic scale) per year of study publication. The sizes of the circles visualize the overlapping and number of studies within the year.

Table 2. Characteristics of studies

Study characteristics	No. of studies (%)	No. of participants (%)
Total	**179 (100%)**	**10 835 733 (100%)**
Year of publication		
2013	1 (1%)	146 (0%)
2014	3 (2%)	165 (0%)
2015	2 (1%)	3 284 (0%)
2016	14 (8%)	124 060 (1%)
2017	21 (12%)	27 377 (0%)
2018	34 (19%)	16 700 (0%)
2019	48 (27%)	9 016 909 (83%)
2020	56 (31%)	1 647 092 (15%)
Continents		
North America	94 (53%)	8 916 888 (82%)
Europe	50 (28%)	991 357 (9%)
Asia	24 (13%)	925 768 (9%)
Australia	8 (4%)	1 198 (0%)
South America	3 (2%)	522 (0%)

Study objectives		
Correlations and influencing factors of study population and outcome data [a]	70 (39%)	394 296 (4%)
Population and/or patient characterisation [b]	54 (30%)	8 315 559 (77%)
Evaluation of method/intervention	47 (26%)	2 124 328 (20%)
Prognostic evaluation [c]	8 (4%)	1 550 (0%)
Study design		
Cross sectional study	66 (37%)	9 780 808 (90%)
Cohort study	62 (35%)	628 641 (6%)
Non-randomised experimental study	14 (8%)	724 (0%)
Randomised-controlled trial	11 (8%)	2 332 (0%)
Method evaluation	8 (4%)	314 247 (3%)
Other	7 (4%)	108 462 (1%)
Case control study	7 (4%)	348 (0%)
Mixed-methods, Feasibility study	4 (2%)	171 (0%)
Medical field of study		
Multidisciplinary, General Medicine	43 (24%)	107 148 (1%)
Neurology, Psychiatry	29 (16%)	2 630 (0%)
Cardiology, Fitness, Sports Medicine	28 (16%)	557 120 (5%)
Global Health, Epidemiology, Prevention	19 (11%)	10 104 217 (93%)
Gynaecology, Paediatrics	18 (10%)	5 575 (0%)
Orthopaedics, Surgery	16 (9%)	2 749 (0%)
Pulmonology	13 (7%)	1 326 (0%)
Other	13 (7%)	54 968 (1%)

[a] Studies aimed to find associations, correlations or influencing factors within their study population, study outcomes and generated data.
[b] Studies aimed to observe and characterize observed their study population and, or patients.
[c] Studies aimed to evaluate patient-reported outcomes, health care practices, diagnostics and screenings, etc.

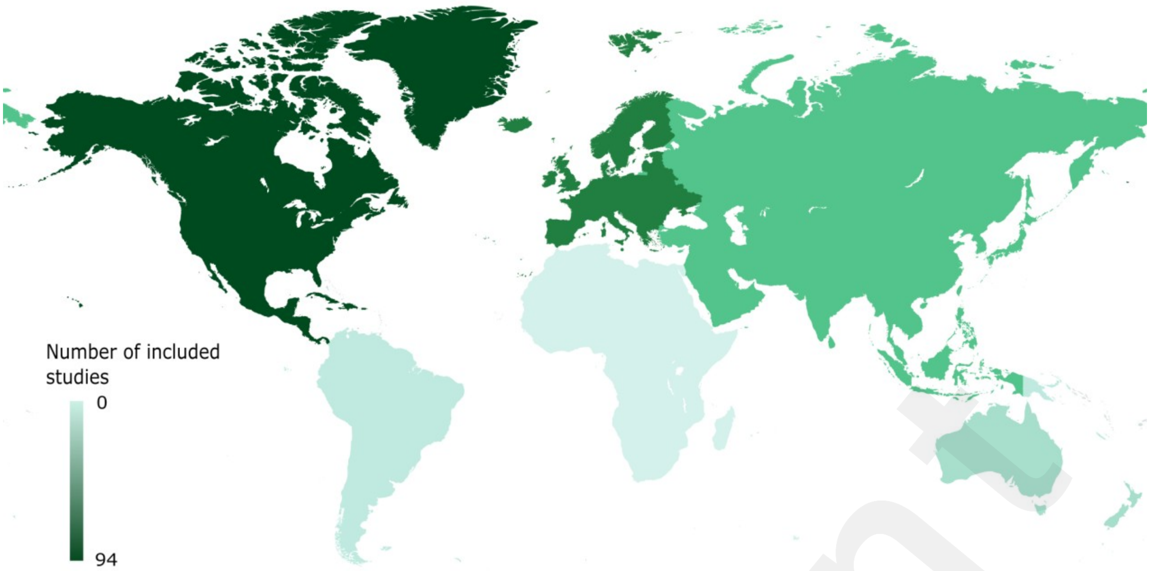

Figure 3. Included studies per continent. The colours of the continents visualize the number of included studies published on the respective continent. Created with: Mapchart.com

Study types and fields

Most studies (n=128, 72%) employed observational study designs like cross-sectional (n=66, 37%) and cohort studies (n=62, 35%), comprising a total of 9 780 808 participants (90%) and 628 641 participants (6%) respectively. Most frequently, studies (n=70, 39%) aimed to find associations, correlations or influencing factors within their study population, study outcomes and generated data. Slightly less than a third of the studies (n=54, 30%) aimed to characterize and observe their study population.

Most studies were conducted in the field of Multidisciplinary and General Medicine (n=43, 24%), Cardiology, Fitness, Sports Medicine (n=29, 16%), as well as Neurology, Psychology, and Psychiatry (n=28, 16%) (Figure 4). The fields of Global Health, Prevention, and Epidemiology featured the largest sample size with a total of 10 104 127 participants (93%).

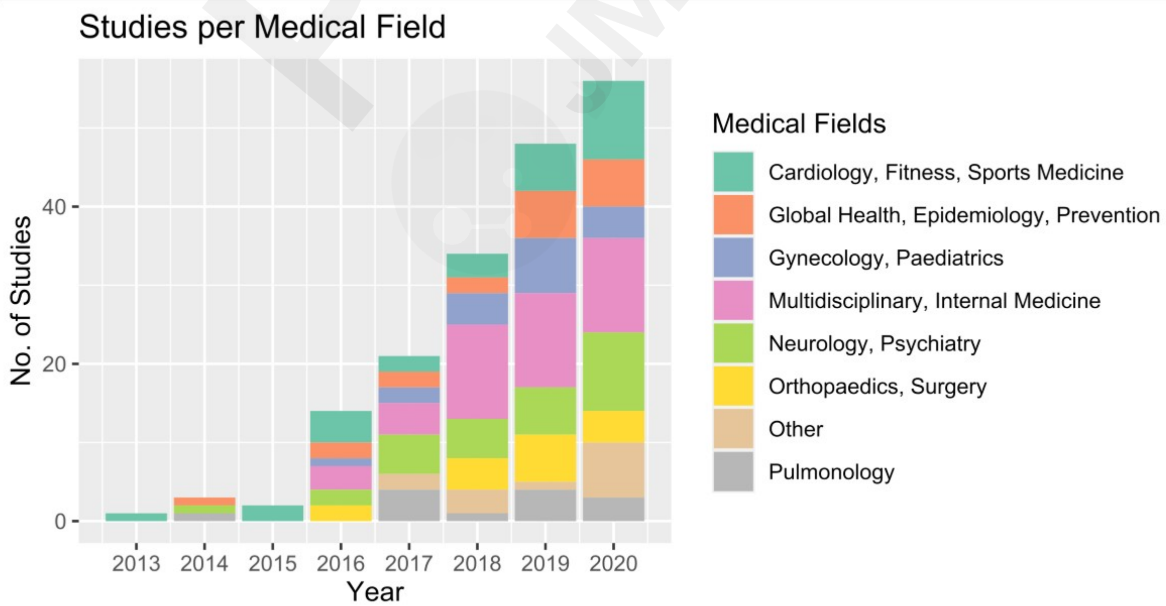

Figure 4. Studies per medical field.

Wearable characteristics

The company with most wearable devices in the included studies was Fitbit (n=97, 51%), covering a total of 8 361 035 participants (74%). Fitbit is followed by the companies ActiGraph* (n=19, 10%), Polar Electro (n=9, 5%) and Withings (n=8, 4%). In number of study participants, Huawei and Withings comprised a total of 832 036 participants (7%) and 794 174 participants (7%), respectively (Table 3).

Table 3. Characteristics of wearable devices.

Wearable characteristics	No. of studies (%)	No. of participants (%)
Total	**189 (100%)**	**11 244 872 (100%)**
Wearable companies employed in studies		
Fitbit	97 (51%)	8 361 035 (74%)
ActiGraph*	19 (10%)	2 571 (0%)
Polar Electro	9 (5%)	6 970 (0%)
Withings	8 (4%)	794 174 (7%)
iRhythm	6 (3%)	128 641 (1%)
Xiaomi	5 (3%)	176 (0%)
Axivity*	4 (2%)	291 871 (3%)
Garmin	4 (2%)	308 (0%)
Apple	4 (2%)	420 826 (4%)
Activinsights*	3 (2%)	1 971 (0%)
Samsung	2 (1%)	120 (0%)
Ava AG	2 (1%)	285 (0%)
Huawei	2 (1%)	832 036 (7%)
Whoop	2 (1%)	305 (0%)
Omron	2 (1%)	159 (0%)
Other companies (wearable only included in one study)	20 (11%)	423 424 (4%)
Wearable models / devices per study		
1	156 (87%)	486 684 (4%)
2	11 (6%)	420 007 (4%)
3	3 (2%)	838 266 (8%)
More than 3 or not applicable [a]	9 (5%)	9 090 776 (84%)
Wearable device types		
Fitness tracker	86 (46%)	22 823 (0%)
Accelerometer (wrist, torso, hip worn)	49 (26%)	299 251 (3%)
ECG chest patch/strap	21 (11%)	530 332 (5%)
Smartwatch	12 (6%)	1 259 605 (11%)
Diverse wearable devices - secondary data via wearable data platform	11 (6%)	9 122 758 (81%)
Distinct vital sign trackers (e.g., oximetry ring, temperature wristband tracker, blood pressure	10 (5%)	10 103 (0%)

armband) [b]		
Physical location of wearable		
wrist	138 (73%)	10 702 843 (95%)
hip	25 (13%)	2 257 (0%)
chest	21 (11%)	550 332 (5%)
arm	3 (2%)	9 392 (0%)
finger	2 (1%)	48 (0%)
Utilized in-built sensor in wearables [c]		
Accelerometer	146 (82%)	1 157 069 (11%)
Photoplethysmography	59 (33%)	9 622 147 (89%)
Electrode/s (i.e. ECG)	21 (12%)	550 500 (5%)
Gyroscope	6 (3%)	1 585 (0%)
Thermometer	4 (2%)	842 (0%)
Blood pressure sensor	3 (2%)	9 397 (0%)
Wearable costs		
< 200€	120 (63%)	340 460 (3%)
200€ - 350€	41 (22%)	18 256 (0%)
> 350€	13 (7%)	551 128 (5%)
Not applicable [d]	15 (8%)	10 355 028 (92%)
Analysis, Statistical tests [e]:		
Regression	62 (35%)	1 021 032 (9%)
t-test	41 (23%)	8 309 202 (77%)
Correlation (Pearson, Spearman, etc.)	40 (22%)	11 044 (0%)
Wilcoxon u-test, Mann-Whitney U, other non-parametric	23 (13%)	7 180 (0%)
Chi-square, Fisher-Yates-test	15 (8%)	433 785 (4%)
Mixed methods model, other statistical models	14 (8%)	57 938 (1%)
Artificial Intelligence (data mining, cluster, machine learning, etc.)	11 (6%)	835 967 (8%)
ANOVA	11 (6%)	810 (0%)
Descriptive	8 (4%)	423 093 (4%)
Prognostic analysis (Kaplan Meier, permutation test, etc.)	3 (2%)	420 928 (4%)

[a] Studies collected data with multiple wearable devices (that belonged to the study participants) or studies used secondary data provided by online wearable platforms, mobile applications, or wearable companies.

[b] Distinct vital sign trackers are specialised on a specific vital sign, e.g., oximetry ring, temperature wristband tracker, blood pressure armband. They differ in measured vital sign and worn location compared to the other wearable device types.

[c] "Utilized in-built sensors in wearables" sums up to more than the total of wearables, as sometimes more than one in-built sensor was used.

[d] Providing wearable hardware pricing was not transparent as some studies used data provided by diverse participant-owned wearables or wearable hardware costs were part of a subscription or a membership fee, i.e., Whoop strap of Whoop.

[e] "Analysis, Statistical tests" sums up to more than the total of included studies, as some studies applied more than one type of analysis or statistical test.

The majority of studies (n=156, 87%) used one wearable model. Most study participants, however, (n=9 090 776, 84%) were part of large-scale population-based studies whereby data was mostly collected with multiple wearable devices that belonged to the study participants.
Some large-scale population-based studies (n=11, 6%) relied on secondary data that were collected with mobile applications [89], online wearable platforms [155] or provided through the wearable company [191]. Thus, the device type could not be specified (assigned to category "Diverse wearable devices - secondary data via wearable data platform"). A total of 15 out of 24 studies (63%) which used secondary data were conducted in 2020, five studies (21%) in 2019.
Fitness trackers (n=86, 46%) and accelerometers (measuring body movement acceleration [37]) worn on wrist, torso and hip (n=49, 26%) were most frequent. Other wearable device types comprised ECG chest straps and patches (n=21, 11%), smartwatches (n=12, 6%), and distinct vital sign trackers (n=10, 5%) like oximetry rings or blood pressure armbands (Table 3).
Most wearables were worn on the wrist (n=138, 73%), followed by the location hip (n=25, 13%) and chest (n=21, 11%). Only few wearables were worn on the arm (n=3, 2%) and finger (n=2, 1%) (Figure 5).

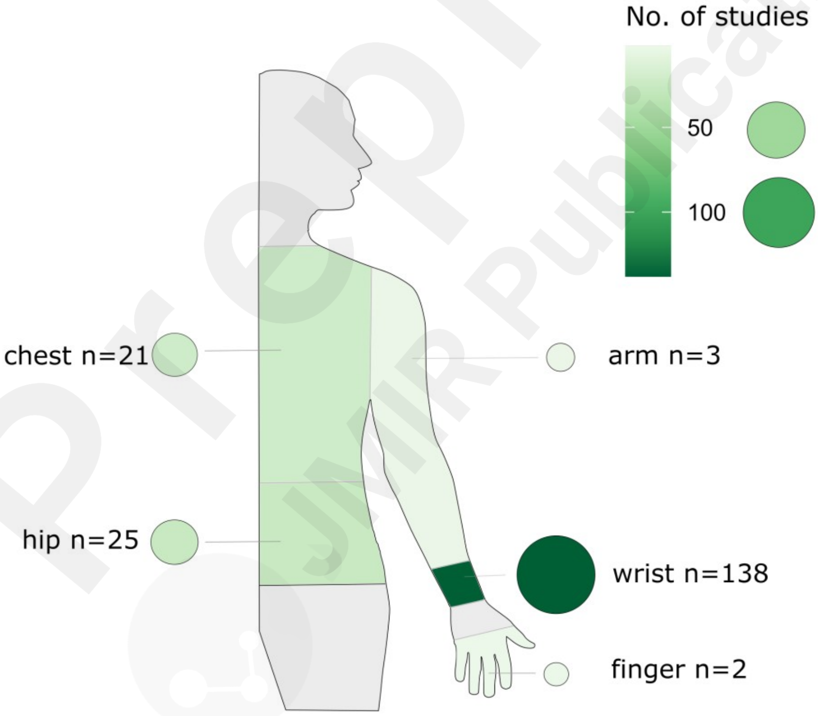

Figure 5. Wear locations of wearables and their frequencies: The colour and size of the circles assigned to the body location visualize the frequency of wearables worn on the respective location.

The majority of research employed the wearable built-in sensors of: *i)* accelerometers (n=146, 82%) which measure acceleration on a 3- or 1-axis [37] and *ii)* photoplethysmography (PPG, n=59, 33%) an "optical technique that […] detects blood volume changes in the microvascular bed of tissue" [223]. Other built-in sensors were: electrodes for ECG measurements (n=21, 12%), gyroscopes (n=6, 3%) which determine how different portions of the body rotate [37], thermometers (n=4, 2%) measuring skin temperature, and blood pressure sensors (n=3, 2%).
Most studies investigated steps (n=95, 53%), heart rate (n=55, 31%) and sleep time (n=51, 28%). We

classified measured vital signs in three categories, whereby PA measures were most frequent (n=228, 127%) (see Multimedia Appendix 3):

i) Physical activity (PA) measures: steps, intensity (e.g., time spent in moderate to vigorous PA (MVPA)), energy expenditure (e.g., kilocalories, metabolic equivalent), axial or raw movement data, distance (covered), and others (like stairs taken, elevation, sedentary time)

ii) Cardiac measures: comprises HR, HRV, and ECG (or other direct heart rhythm analysis, like atrial fibrillation (AF) detection)

iii) Other measures: including blood or pulse pressure, body temperature, blood oxygen and respiratory rate

Most studies (n=120, 63%) used wearables that cost less than 200€. In some studies (n=15, 8%), wearable prices were not transparent as data was provided through a variety of participant-owned wearables [89] or used wearable hardware was part of a subscription or a membership fee, i.e., Whoop strap of Whoop [180].

Regression analysis (n=62, 35%) and t-tests (n=42, 23%) were the most commonly used statistical methods to analyse wearable data. Other methods comprised non-parametric tests such as correlations, Wilcoxon U-test, Kaplan-Meier-survival analysis and chi-square tests. Variance analysis (ANOVA), and significance tests such as permutation were also employed. Further data analyses was conducted in a data-driven manner [224] with artificial intelligence, such as k-means [178] or unsupervised cluster analysis [174], recursive feature elimination technique [172], rotation random forests classifier [132] and supervised machine learning algorithms using logistic regression, decision tree, and random forest [217].

Categorisation of wearable application in the studies

We categorized included studies based on their study objective, the role of the wearable and the collected wearable data within the study in the following six categories (overlaps are possible as separation is artificial). In the following, categories are presented in order of their frequency (see Figure 6 and Multimedia Appendix 4 for article references and examples):

(i) Correlations – wearable and other physiological data (n=40, 22%)
Studies examined the correlation of a wearable derived measure with clinical-, patient reported and other health related outcomes to find new associations and correlations. The data generated by the wearable were correlated to data from mostly physiological or patient-reported outcomes.

(ii) Population-based research (n=31, 17%)
Wearables produced insights into a specific population through monitoring (observational and cross-sectional) of vital signs like steps, HR, etc. Oftentimes, these were cross-sectional studies (n=17) where the wearable measurement was the sole outcome. Resulting data provided novel insights and characteristics of populations.

(iii) Outcome assessment (n=30, 17%)
In these studies, wearables generated the outcome measurement and monitored the dependent variable in an (quasi-) experimental setting or intervention, in mostly randomised controlled trials and quasi experimental designs.

(iv) Prognosis, forecasting, risk stratification (n=28, 16%)
Data generated with wearables were integrated in risk calculations (risk for a certain event or outcome), prognostic models or cut-points. Wearable data constituted inputs for models to

estimate risks.

(v) Explorative analysis of big datasets (n=10, 6%)
These studies exploratively analysed big data [224], generated by wearables and accessible via applications, commercial platforms, eCohorts or companies themselves, to find trends and generate new hypotheses.

(vi) Method evaluation (n=40, 22%)
Studies evaluated and compared methods and tools (like screenings for diseases, general practices, questionnaires or other patient reported outcomes) with the help of wearables. The wearable might be the gold-standard device or probed itself.

a. **Feasibility** (n=12, 7%)
The feasibility of using wearables for disease screenings, and to improve on existing methods, practices, etc. is focused, mostly accompanied by a qualitative component.

b. **Diagnostics, screening** (n=6, 3%)
Studies in this category evaluated details of diagnostics and disease screening outcomes, (cost-) effectiveness, utility, screening length, etc.; or are compared to standard measurement methods.

c. **Disease monitoring** (n=8, 4%)
Wearables supported the monitoring of an already diagnosed condition or a patient at risk (of deterioration).

d. **Others** (n=14, 8%)
Studies evaluated methods, with no other, particular subgroup being appropriate.

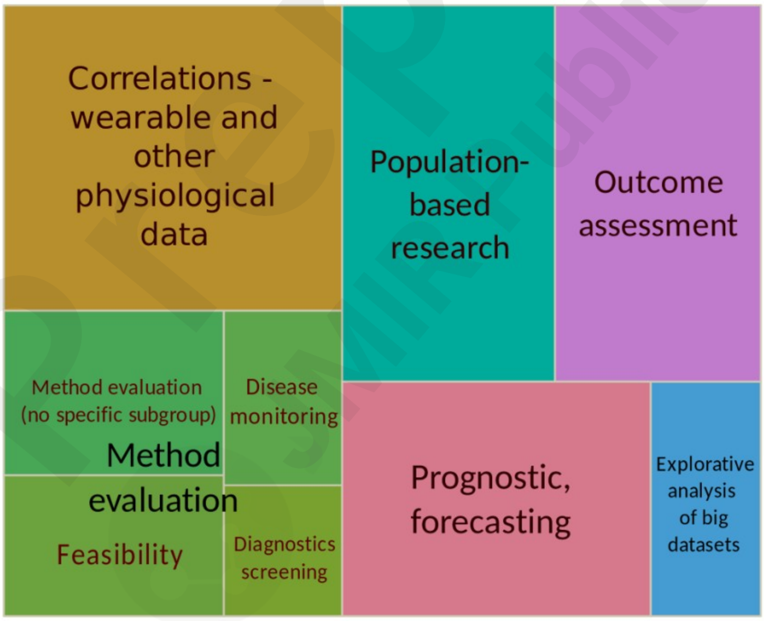

Figure 6. Categorisation of wearable applications, showing proportions of the six categories (with four subcategories). The size of depicted categories (in different colours) corresponds to the number of studies.

Strengths and shortcomings of wearables

Overall, studies mentioned more strengths than shortcomings. A few studies (n=16, 9%) mentioned no strengths of wearables, while 55% (n=99) mentioned no shortcomings.
Most often, authors (n=104, 58%) emphasised the accuracy and reliability, positive results of peer-

reviewed validation studies (own and of others), or clinically approved certifications (e.g., the Food and Drug Administration (FDA) clearance in the United States, or CE mark of the European Union) (Figure 7).

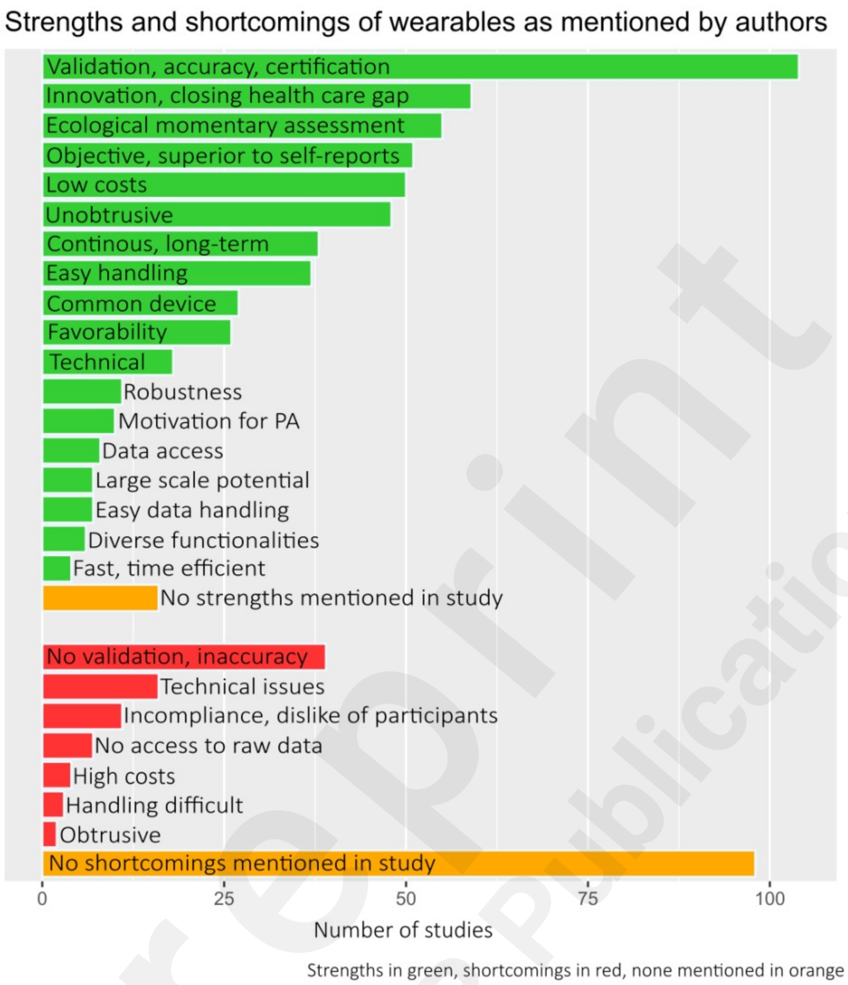

Figure 7. Chart of reported strengths and weaknesses of wearables as mentioned by authors.

Often, studies (n=59, 33%) identified the wearable as innovative, i.e. as a cutting edge tool and method [105] with the wearable device potentially closing a gap in or improving health care and research. For example, one study described how wireless wearables and data synching could improve the quality of care [71]: "The data can be sent from the wearable to the physician's office, avoiding the need for office visits, ultimately making possible preventive medicine and improving quality of care." Low et al. [131] concluded that "Fitbit devices may provide opportunities to improve postoperative clinical care with minimal burden to patients or clinical providers." Tomitani et al. [201] reflected how wrist-worn blood pressure wearables could "significantly improve blood pressure control." As per Shilaih et al. [186], wrist-worn wearables might ameliorate fertility awareness research and care.
A number of studies (n=55, 31%) acknowledged the ability of wearables to measure in the naturalistic environment of the participants, so called "ecological momentary assessment" [10,11,225].

Multiple studies (n=51, 28%) described the wearables as objective and superior to self-reported outcomes as they were more accurate, reliable, and easier to generate. Often, authors valued low(er) costs of wearables (n=50, 28%). Others appreciated wearables being unobtrusive or non-invasive (n=48, 27%) and enabling continuous, long-term measurements (n=38, 21%). Furthermore, the handling (n=37, 21%) of hardware and software was often found user-friendly, as well as the prevalence of wearables in the population (n=27, 15%), decreasing stigma and easing participant recruitment. Some studies (n=26, 15%) reported that participants accepted and liked the wearables, resulting in high participant compliance (wearing and using the wearable). Some authors (n=18, 10%) perceived technical wearable characteristics as positive, e.g., good sampling rate of measurements, long battery life, big memory space, raw data availability, data security, compatibility with other devices like smartphones, and availability of application programming interfaces (APIs).

Few studies (n=11, 6%) described the wearable as robust and not easy to break. Authors (n=10, 6%) valued the wearable-induced behaviour change as a co-benefit, i.e., motivating study participants to more PA and increasing health awareness.

A few studies (n=8, 4%) mentioned data accessibility, via APIs, apps and online platforms and a few other studies (n=7, 4%) potential of large-scale wearable studies, or the easy data handling. A minority (n=6, 3%) underlined the variety of functionalities and vital sign measurements as positive aspects, and four studies (2%) perceived the wearables as fast or time-efficient in data generation.

The majority of shortcomings (n=39, 22%) were related to the inaccuracy of the wearable or the absence of validation or clinically approved certification. Studies (n=16, 9%) also mentioned technical issues like a low sampling rate of measurements, no wear time recognition, or missing data. Other technical issues comprised, for example, synchronisation, charging and device setup [93] or data cleaning [139]. Rare experienced shortcomings were: participants' noncompliance or dislike towards the wearable (n=11, 6%), no access to raw data or company's algorithms (n=4, 2%), difficulties in handling the wearable (n=3, 2%), and wearables perceived as obtrusive in daily life (n=2, 1%).

Discussion

Study characteristics

Overall, we have identified a positive trend in wearable studies, underlining the growing interest for wearables in health research, in line with other reviews [3,225–227]. Our results show a strong interest of researchers and study participants in this technology, but we also identified cautionary behaviour towards using wearables. The vast majority of studies were undertaken in North America, about twice as many as in Europe, which is consistent with previous literature [226]. One North American study, conducted in 2019 with over eight million participants [155], dominated the image of the distribution of participants. Reasons for the American-European gap might be multifaceted. One factor may be the differences in political and administrative frameworks, e.g., comparing CE and FDA processes which may result in slower certification processes for wearables and new technologies in general [31]. Another factor may be cultural mentality resulting in faster adoption of new technology in the US, as North Americans own proportionally more fitness trackers in comparison to Europeans [228,229].

Some factors discussed in other research were not or only briefly mentioned in the included studies [6,29,31], but should also be reflected, especially technical and legal aspects, such as data security [225], data synching and export. For example, the Germany-based study of Koehler et al. [116] was one of few that detailed on data security and transfer of home-based telemonitoring data to the clinic. Data security and privacy are severely governed by the European Union's General Data Protection Regulation (GDPR), which is according to their website the "toughest privacy and security law in the world" [230]. Administrative limitations and challenges presumably obscure the benefits of wearable research in Europe. A possible solution regarding data security and usability might be data trusts [231] as alternative to large platforms.

The majority of medical fields represented in the included studies showed similarities with other reviews [225], e.g., studies often focusing on cardiology, sports medicine, and neurology. However, we found a multitude of studies from multidisciplinary fields as well as the field of Global Health Global Health indicating a likely adoption and expansion of wearables in other medical fields. That underlines the potential for wearables in health research beyond a mere trend or hype, as wearables may provide new possibilities for a broad spectrum of health research, such as for infectious disease prediction, like COVID-19, or fertility awareness, amongst many others.

Wearable characteristics

Similar to other reviews, most devices were wrist-worn fitness trackers and accelerometers, and most of them by the company Fitbit, measuring PA, HR and sleep [3,27,31,225,226]. These vital signs and device types seem to become the standard in wearable research [3,27,31,225,226]. Included studies also emphasised the growing wearable usage [149,197,199], which is also reflected in commercially available devices [38–40]. Currently, further wearable devices emerge measuring, for example, oximetry, blood pressure, skin temperature or respiratory rate.

Categorisation of wearable application in the studies

In general, included studies covered a great scope of health applications like fertility tracking, monitoring of body characteristics like weight or diseases like Alzheimer, diabetes mellitus, and AF, diabetes mellitus, and AF, as well as associations of coffee intake, sleep, and PA, or blood pressure and steps. We have noted an increase of smaller studies that also included rare populations and conditions, like fibromyalgia or the rare genetic Pompe disease, indicating that wearables may be valuable for insights of patients with rare conditions. Using affordable, consumer-grade wearables for rare disease assessment and monitoring might eventually be less expensive than specifically developed devices, and easier to use for patients. As a result, currently underrepresented populations may be better researched through wearables [232], i.e., different ethnic groups, nationalities, individuals with disabilities or (rare) conditions, etc. Future studies could look into the participation of underrepresented groups in wearable research in greater depth, particularly in studies analysing wearable user data.

Global Health and low-resource contexts

Included studies are predominantly from high-income countries, constituting a gap of wearable studies in low-resource contexts. The AliveCor device showed to be feasible in Kenya to help detect AF [233], also for early diagnosis. Literature underlines a potential for wearable-based research in low-resource settings to generate data and improve health care [9], based on their low-cost and ease of use (data acquisition, hardware and software handling) [234]. Xu et al. emphasized that physiological monitoring with wearables hold "promise for substantial improvements in neonatal outcomes" in low- and middle-resource countries [235]. Wearables could generate a solid data base for Global Health research, particularly for morbidity measurements [236], large-scale studies, and modelling and descriptive studies. Also topics like climate change-induced impacts focusing on extreme weather events as an outcome and impact on health [237] may be approached. For example, one included studies [20] measured farm workers physiological response to climate conditions with wearables to investigate heat-related illness in a high-income setting. Lam et al. [238] investigated thermal adaptation and comfort of participants originated from various climate regions. Fitness tracker measured HR was integrated with other weather and human-based measurements and predicted the thermal sensation of non-local participants, amongst others. Similar studies could be administered in low-resource regions.

Strengths and shortcomings of wearables

A few studies experienced issues or shortcomings such as inaccuracies in measurements and technical issues. Nevertheless, most authors were satisfied with wearables as strengths were mentioned more frequently than shortcomings. Novelty and innovation seemed to outweigh shortcomings for most authors. Most mentioned positive wearable characteristics were: validity and accuracy, technical reliability, innovation, and unobtrusiveness. Only few authors mentioned data access through APIs or cloud platforms as a strength. However, the practical value of wearables is heavily reliant on the mode and reliability of data access. Depending on the company, there may be different data access policies in place, whereby it may not be possible to access the raw data of the wearable. Most authors have not considered wearable data access. However, data access and availability of wearable devices is an important aspect which researchers need to be aware of before using a potential study device. Another aspect is open access to the wearables' raw data or source codes - as companies might change the source code and implement algorithms without the obligation to announce or detail changes which might lead to bias and inconsistency of data [225]. For example, Thjis et al. [197] mentioned consequences of Fitbit's non-disclosed algorithms for their data analysis and standardisation. Moreover, lack of standardisation and replicability of wearable raw data and analysis [28] is hindering comparability between studies.

Most studies mentioned and discussed validation, accuracy and certification of employed wearables as part of good research practice approaches. However, the mentioning of validation or accuracy did not necessarily imply that the wearables had been certified (FDA, CE) or validated in peer-reviewed research. Nevertheless, authors also reported the used wearable as accurate enough even with existing inaccuracies [14,145,199]. Authors seemed to tolerate smaller inaccuracies and validation drawbacks - especially of established consumer-grade wearables - if usability was of high importance like, for example, in large-scale studies.

Large-scale, big datasets for wearable research

We noted an increase in large-scale wearable studies in recent years, which is consistent with previous literature [226]. During the COVID-19 pandemic in particular, we have seen an increase in studies using secondary data. Studies aimed to generate insights with regards to the developing pandemic, focusing on forecasting models and effects on different populations. Overall, wearable-generated big datasets might decrease biased data because measurements are objectively taken in the natural environment of numerous and diverse individuals. Although data analytical skills are needed for handling big datasets, their analysis might be extremely valuable for health research in generating new evidence [31,226].

Limitations

Firstly, not all studies using wearables might have been identified by our search. We included only wearables of companies in the search who had the highest market shares. Therefore, wearables of smaller or new companies might be missing in this review. In addition, we only included studies published in English which may have excluded evidence from other regions which may not publish in English. Though this review provides a wide scope of wearable research, the list of included studies is by no means exhaustive.

Also, wearable costs are only approximations and could be imprecise: *i)* companies follow different sales and distribution models, e.g., membership, rental, and subscription, *ii)* we only incorporated wearable (hardware) prices, excluding costs for software, maintenance, and other charges like subscription fees which may even exceed wearable hardware costs, *iii)* sales prices are subject to fluctuation. We also had to exclude many studies as wearables were discontinued. The fluctuant and unstable market, therefore, might also be a factor in decisions regarding the use of wearables [28]. Although interesting and promising, some wearables and similar devices were beyond the scope of this article but might also be valuable for health research. We have provided a wide overview of wearable devices, but nevertheless, the included studies do not show the full range of possible wearables and measured vital signs [9,37].

Besides, we are reporting opinions of included studies with regards to shortcomings and strengths of wearables. These insights might be helpful, but nevertheless are not objective measures. Moreover, our introduced categories for studies and aims in using wearables might overlap, as a separation and categorisation is artificial.

Conclusion

We see a growing uptake of wearables in health research and a trend to employ wearables for large-scale, population-based studies. Wearables, which were often piloted in included studies, were used in diverse health fields including COVID-19 prediction, fertility awareness, geriatrics, AF detection, and evaluation of methods, drug effects, psychological interventions or patient-reported outcomes. Measurement of steps, PA, HR, and sleep may be considered as standard wearable measurements. Nevertheless, wearables are becoming more diverse in their measurements and appearance. Therefore, wearable-induced research may include currently underrepresented populations like elderly, disabled participants, participants with rare chronic or genetic diseases, participants from low socio-economic backgrounds, etc.

For many researchers, novelty and innovation seem to outweigh shortcomings such as measurement inaccuracies. Overall, included studies shared key characteristics that wearables should meet: validity, technical reliability (including data access solutions), innovation, and unobtrusiveness.

We have identified a lack of wearable research in low-resource settings. We assume reasons for the gap may be a lack of funding and doubts about the wearables' usefulness. However, wearable devices may be used to generate data in such settings that may otherwise be difficult and expensive to get. Therefore, wearable devices may be valuable for health research in a global context. During the COVID-19-pandemic in particular, large-sized wearable studies were used to generate insights of the developing pandemic and may potentially lead to novel insights in population-health trends and forecasts. Future research is needed to determine the utility of wearable devices for underrepresented populations, as well as the feasibility and usefulness of health research in low-resource contexts.

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Contributors

SH, SB and MA conceived of and designed the review. SH drafted the manuscript with the help of SB and MA. All authors contributed to the critical revision of the draft, and approved the final version of the manuscript.

Conflict of interest

The authors declared that no competing interests exist.

Ethics approval

Not applicable.

Data availability

Not applicable.

Abbreviations

* – (research-grade) wearable devices unavailable for consumers or not consumer-grade per se
API – application programming interface
Apps – commercial software applications
CE – Communauté Européenne
ECG – electrocardiogram
FDA – Food and drug administration (USA)
HR – heart rate
HRV – heart rate variability
MPVA – moderate-to-vigorous physical activity (intensity)
PA – physical activity
PPG – Photoplethysmography
WOS –Web of Science

Multimedia Appendix 1: Details on search and search strings
Multimedia Appendix 2: MERSQI scores of included studies
Multimedia Appendix 3: Vital signs measured by studies
Multimedia Appendix 4: Categorisation of wearable application in the studies - Article references and examples
Multimedia Appendix 5: Preferred Reporting Items for Systematic reviews and Meta-Analyses extension for Scoping Reviews (PRISMA-ScR) Checklist

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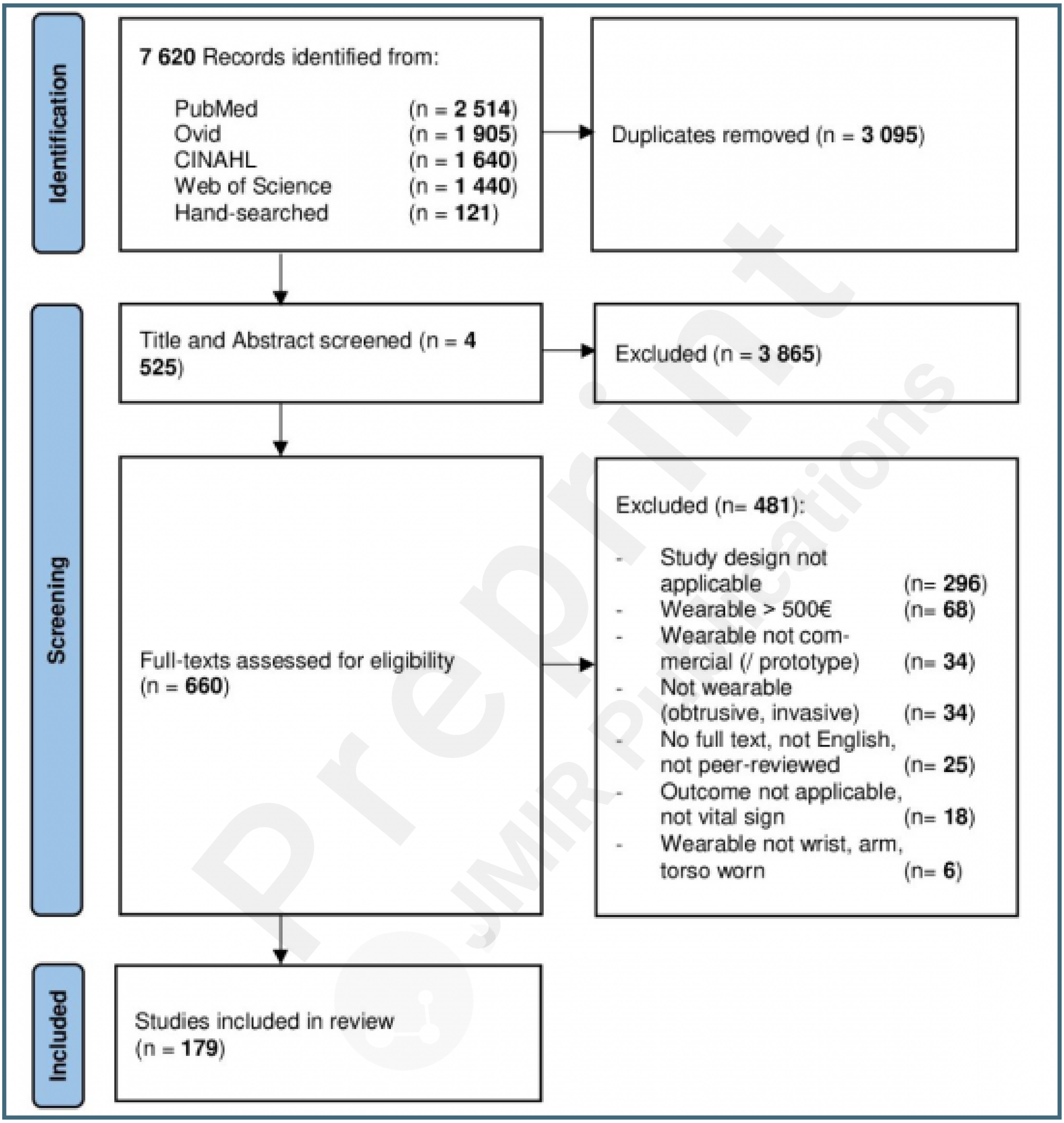
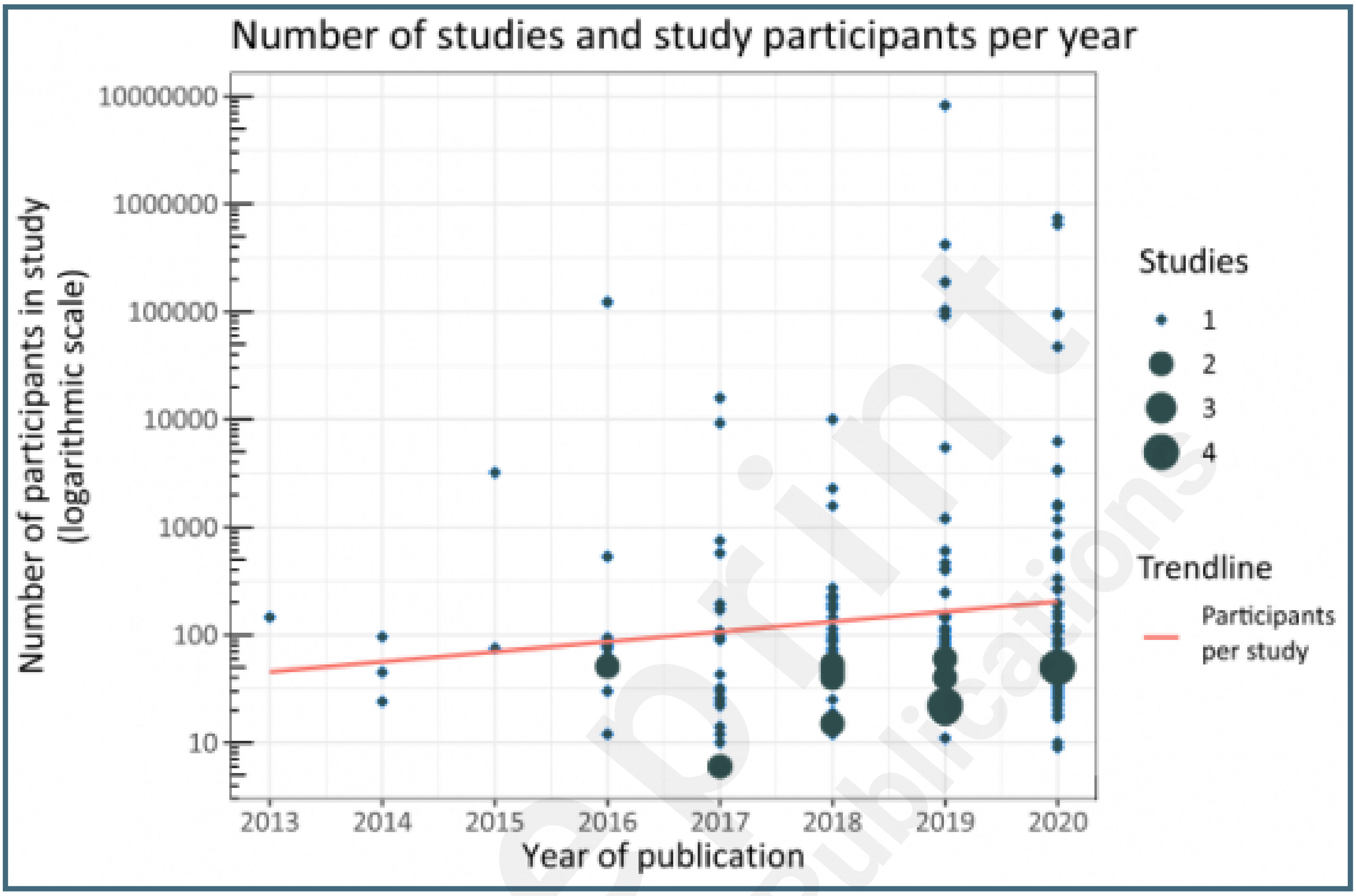
Supplementary Files

Figures

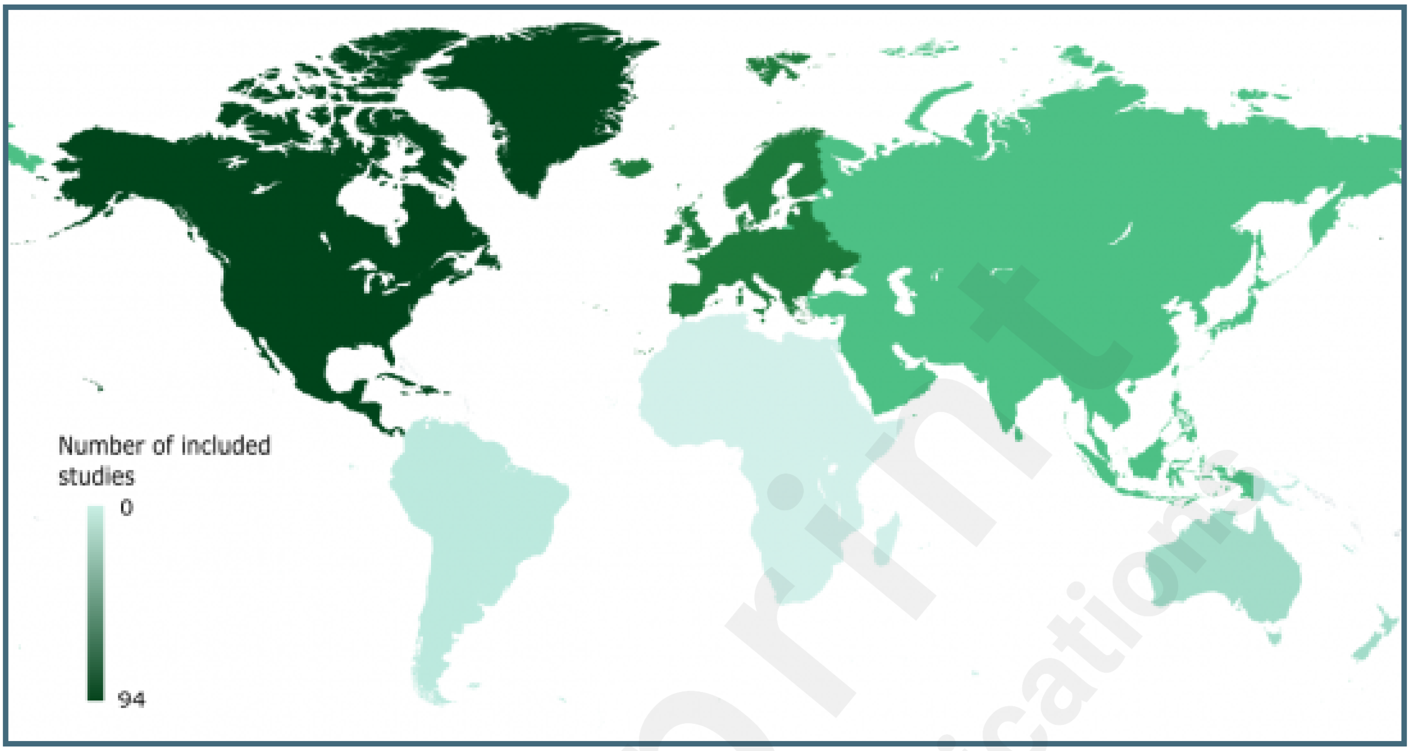
PRISMA flow diagram [222].



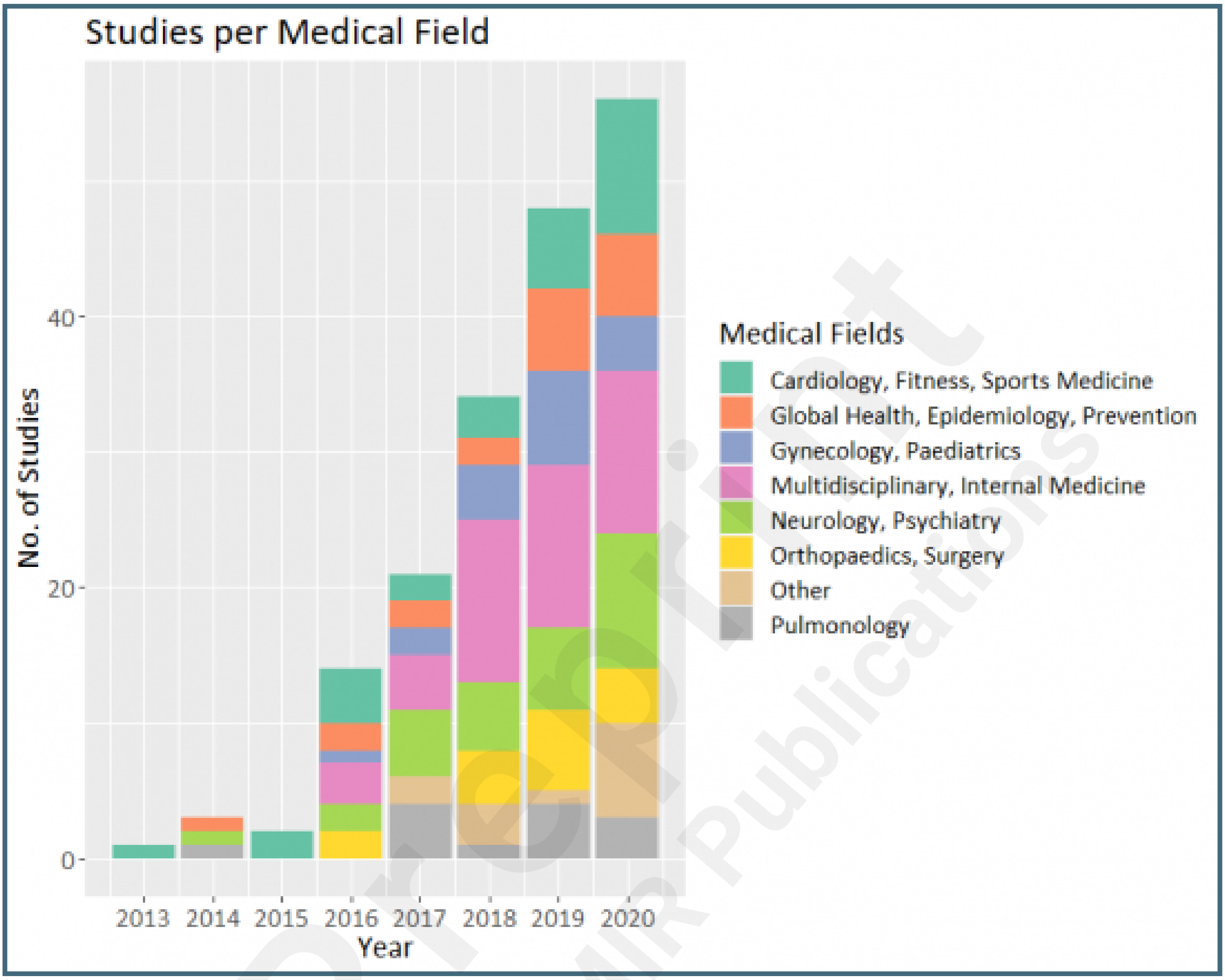
Number of studies and study participants (logarithmic scale) per year of study publication. The sizes of the circles visualize the overlapping and number of studies within the year.



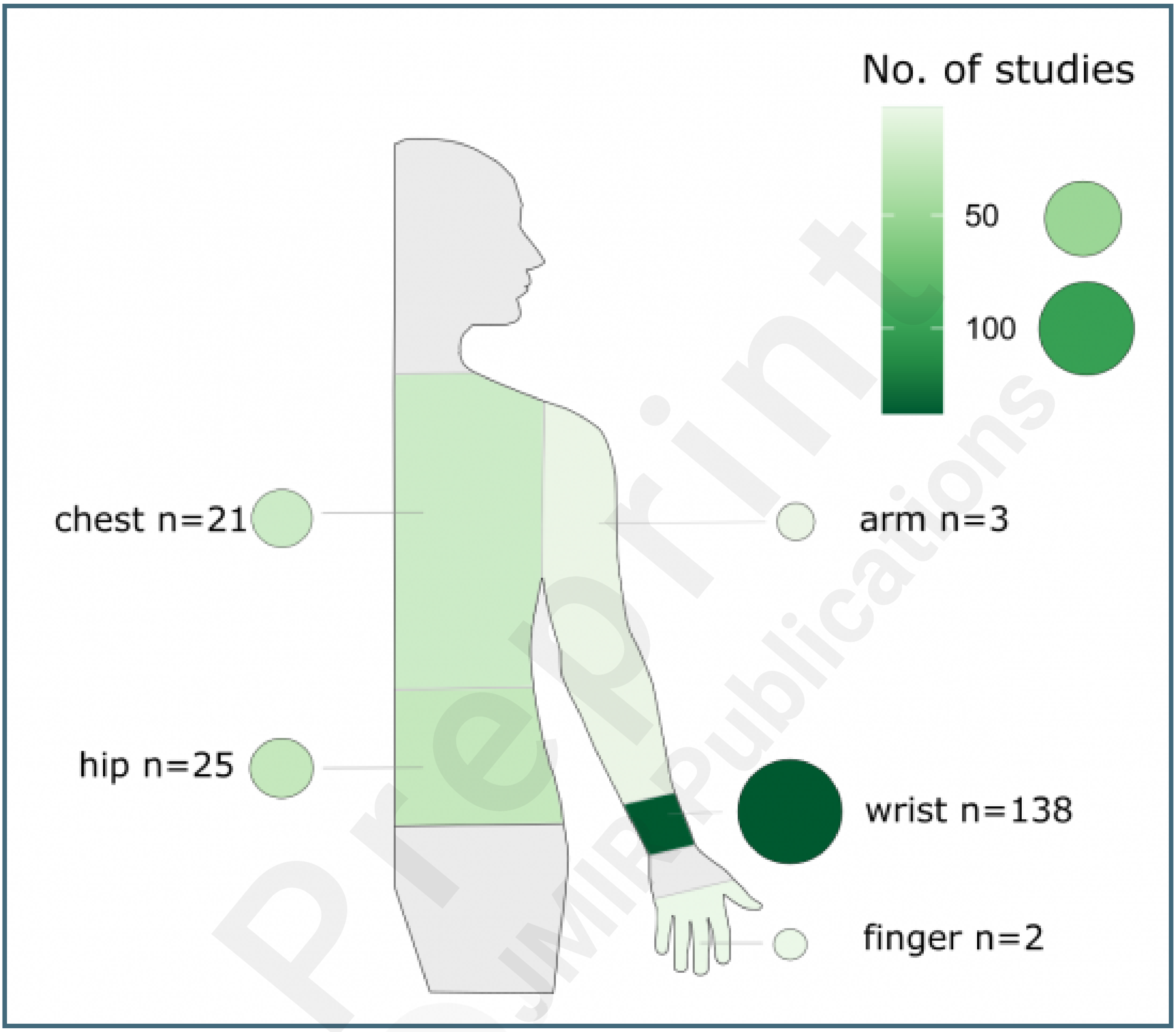
Included studies per continent. The colours of the continents visualize the number of included studies published on the respective continent. Created with: Mapchart.com.



Studies per Medical Field.



Wear locations of wearables and their frequencies: The colour and size of the circles assigned to the body location visualize the frequency of wearables worn on the respective location.



Categorisation of wearable applications, showing proportions of the six categories (with four subcategories). The size of depicted categories (in different colours) corresponds to the number of studies.

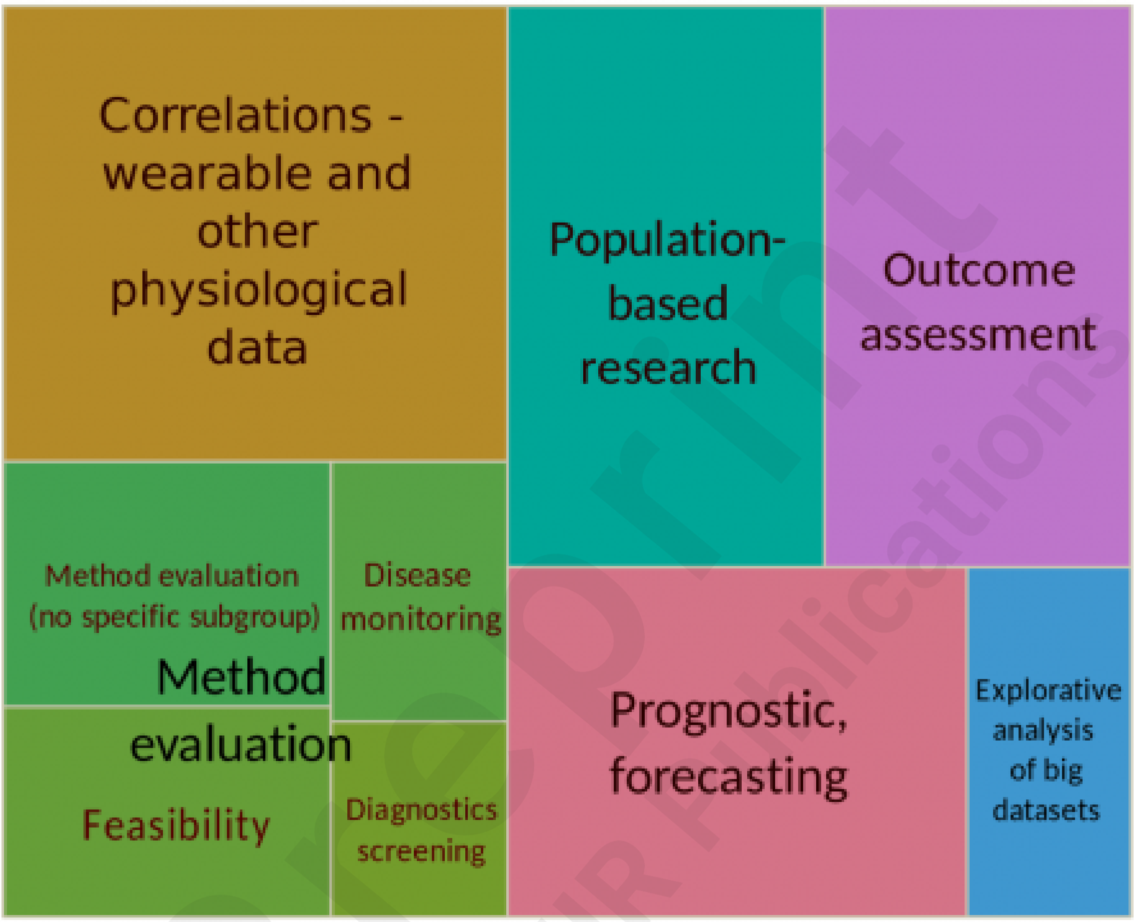
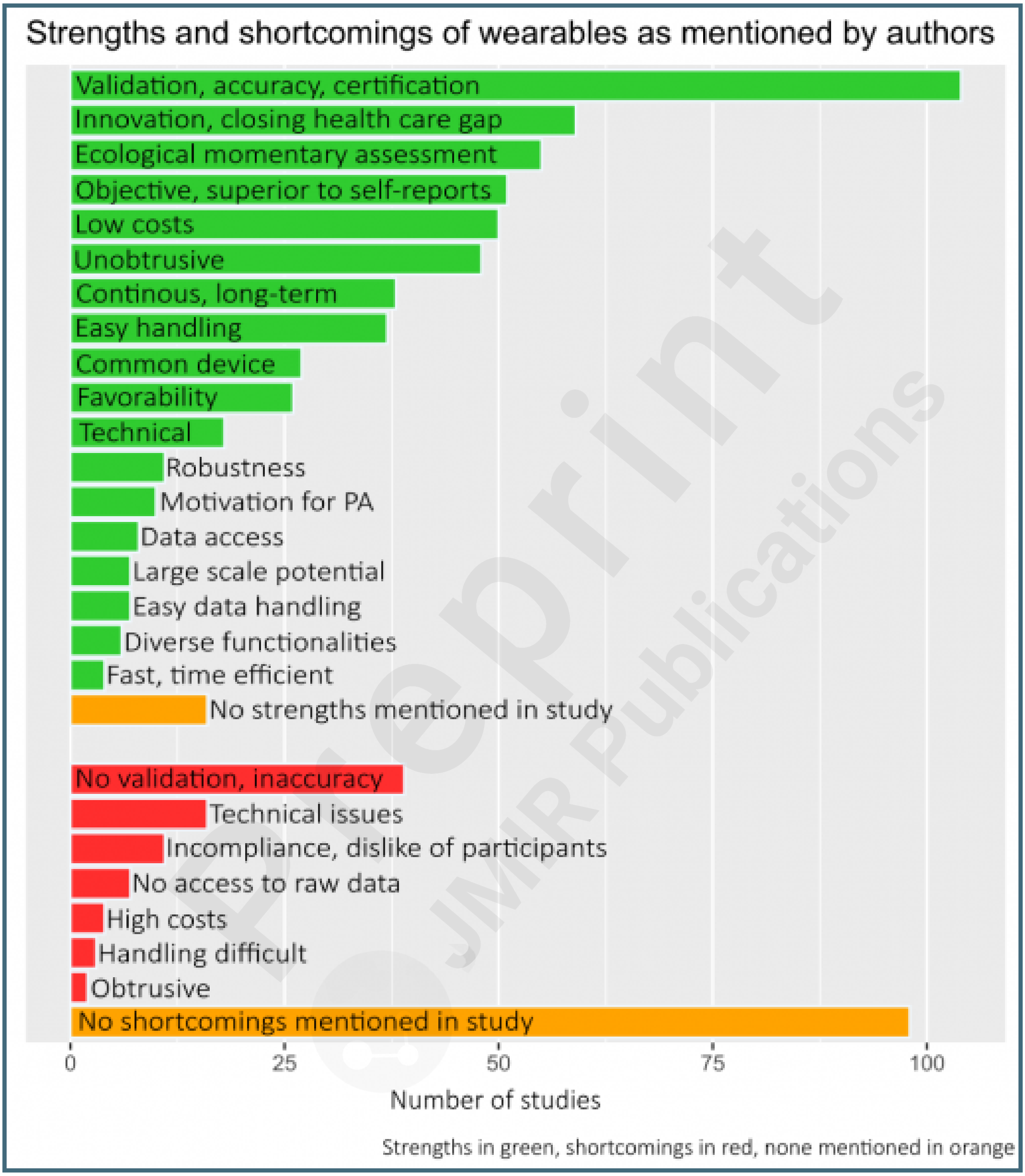


Chart of strengths and weaknesses of wearables as mentioned by authors.



Multimedia Appendixes

Revised manuscript with tracked changes.
URL: http://asset.jmir.pub/assets/1ae1b41cf763a7183aa07a09b4567f2c.docx

Responses to reviewers.
URL: http://asset.jmir.pub/assets/ae8bfbf52e9d9c52941c62e86f6c264b.docx

Details on search and search strings.
URL: http://asset.jmir.pub/assets/772b48fd18a6f545211933f664b5612e.docx

MERSQI scores of included studies.
URL: http://asset.jmir.pub/assets/5beca80c565ba310c249b53a1cbe8c42.docx

Vital signs measured by studies.
URL: http://asset.jmir.pub/assets/3d8de5a4905076f88aea8d58baf5199f.docx

Categorisation of wearable application in the studies - Article references and examples.
URL: http://asset.jmir.pub/assets/a02ac405994d72dc13398dbdd034a12d.docx

Preferred Reporting Items for Systematic reviews and Meta-Analyses extension for Scoping Reviews (PRISMA-ScR) Checklist.
URL: http://asset.jmir.pub/assets/c10c24a1e39a81375db4d99957422e188.docx

TOC/Feature image for homepages

TOC placeholder.