Feasibility of Wearable-Based Remote Monitoring in Patients During Intensive Treatment for Aggressive Hematologic Malignancies

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PURPOSE Intensive treatment protocols for aggressive hematologic malignancies harbor a high risk of serious clinical complications, such as infections. Current techniques of monitoring vital signs to detect such complications are cumbersome and often fail to diagnose them early. Continuous monitoring of vital signs and physical activity by means of an upper arm medical wearable allowing 24/7 streaming of such parameters may be a promising alternative.

METHODS This single-arm, single-center observational trial evaluated symptom-related patient-reported outcomes and feasibility of a wearable-based remote patient monitoring. All wearable data were reviewed retrospectively and were not available to the patient or clinical staff. A total of 79 patients (54 inpatients and 25 outpatients) participated and received standard-of-care treatment for a hematologic malignancy. In addition, the wearable was continuously worn and self-managed by the patient to record multiple parameters such as heart rate, oxygen saturation, and physical activity.

RESULTS Fifty-one patients (94.4%) in the inpatient cohort and 16 (64.0%) in the outpatient cohort reported gastrointestinal symptoms (diarrhea, nausea, and emesis), pain, dyspnea, or shivering in at least one visit. With the wearable, vital signs and physical activity were recorded for a total of 1,304.8 days. Recordings accounted for 78.0% (63.0-88.5; median [interquartile range]) of the potential recording time for the inpatient cohort and 84.6% (76.3-90.2) for the outpatient cohort. Adherence to the wearable was comparable in both cohorts, but decreased moderately over time during the trial.

CONCLUSION A high adherence to the wearable was observed in patients on intensive treatment protocols for a hematologic malignancy who experience high symptom burden. Remote patient monitoring of vital signs and physical activity was demonstrated to be feasible and of primarily sufficient quality.

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INTRODUCTION

Therapy of hematologic malignancies has progressed rapidly over the past few decades because of the diversification of treatment concepts, such as blood stem-cell transplantation, monoclonal antibody, and chimeric antigen receptor T-cell therapy. However, such treatment protocols harbor a high risk of serious clinical complications, such as infections, systemic immune reactions, and arrhythmias. These complications also include side effects from administered medications (eg, symptom exacerbation and cytokine release syndrome). In fact, nearly every patient on these treatment protocols experiences at least one complication requiring follow-up treatment. Early diagnosis and specific treatment of serious clinical complications are known to reduce associated morbidity and mortality. Depending on the treatment protocol, the expected toxicity and the individual risk stratification determine the allocation of patients as inpatients or outpatients. Presumably, the proportion of outpatient treatment protocols will increase because of the limited capacities of specialized wards, increased costs, and shortage of oncology nurses. Outpatients usually experience limited monitoring for serious clinical complications and determine autonomously when to contact their health care professional. Optimization of remote patient monitoring (RPM) in this population may be helpful. Currently, development of digital measures for this specific population is becoming available so that deployment may be accomplished. In recent years, medical wearables have been changing the way we collect and analyze patient data. These wearables enable continuous and noninvasive
monitoring of vital signs and physical activity in various recreational and medical settings.\textsuperscript{6,7}

Collection and interpretation of data from wearables requires multidisciplinary teams and precise consideration of the context to derive meaningful information.\textsuperscript{8} RPM of various vital signs by such devices combined with advanced analytical tools may enable (early) detection of clinical events.\textsuperscript{9}

The aim of this trial was to assess the symptom burden in patients with a hematologic malignancy during intensive treatment protocols and the feasibility of continuous vital sign and physical activity monitoring by an upper arm medical wearable in both inpatient and outpatient settings.

**METHODS**

This was an open-label, single-arm, and single-center observational trial including patients with a hematologic malignancy who were planned for an intensive treatment (chemotherapy alone or in combination with hematopoietic stem-cell transplantation). The trial was approved by the Ethical Committee of the University Hospital Duesseldorf, Germany, and was registered in the German Clinical Trials Register (DRKS00014782). Recruitment occurred at the Department of Hematology, Oncology, and Clinical Immunology of the University Hospital Duesseldorf, Germany, between November 2018 and January 2020. Consecutive patients were screened for their eligibility and provided their consent to participate in the trial. Inclusion criteria were age $\geq$ 18 years and an indication for a treatment protocol with expected hematotoxicity according to Common Terminology Criteria (v4.0) $\geq$ 3 alone or in combination with blood stem-cell transplantation. Exclusion criteria were medical or mental conditions impairing the ability to continuously wear the device (eg, language barriers, arm tattoos, and skin diseases) and implants, which might impair recordings.

Patients who were admitted for their treatment on a specialized ward were allocated to the inpatient cohort (IC) and those intended for ambulatory treatment were assigned to the outpatient cohort (OC) irrespective of possible hospital admittance during the course of the trial (Fig 1). The RPM period started before chemotherapy, and continuous RPM was enabled using the wearable. For patients in the IC, the RPM period ended either with discharge from the hospital or after 50 days. For OC patients, the RPM period ended earliest after hematologic reconstitution combined with the decision by the treating physician that the patient is no longer vulnerable to complications or after 30 days, whichever occurred first.

At the baseline visit, two identical wearables were assigned to each patient and one was handed directly out to the patients. The commercially available wearable (Everion, Biovotion AG, Zürich, Switzerland) is a Conformité Européenne-marked medium-risk device (class IIa) according to the Directive 93/42/EEC (firmware used was for clinical investigation only). This wearable is attached to the upper arm with an elastic band tailored to the arm circumference of the patient. A standardized armband size table was provided by the manufacturer and individually adjusted if needed. Different sensors for noninvasive monitoring of vital signs and physical activity (eg, photoplethysmography, temperature probe, and accelerometry) are implemented. The wearable stores recorded data with a resolution of one data set per second. The battery of the wearable had to be recharged daily for 90 minutes. Parameters, such as heart rate, temperature, respiratory rate, and physical activity, and if applicable respective quality indices are calculated using proprietary algorithms of the manufacturer implemented in the firmware (Table 1).

To align with EU General Data Protection Regulations, the collected data were stored locally. Therefore, data on the
Device were downloaded via a stationary Bluetooth interface. The frequency of downloads was driven by the maximum internal data storage capacity of the wearable. Therefore, patients were seen at trial visits at least every third day and assigned devices were swapped at each visit to allow for continuous RPM despite downloading times. At baseline visit, the investigator instructed the patients in the self-managed use of the wearable (eg, charging procedure and attaching). In addition, a safety briefing session was carried out to reduce the risk of adverse device effects (eg, regular relocation of the wearable to prevent pressure lesions).

In addition, demographics, medical history, and concomitant medication were recorded on paper-based case report forms (Data Supplement). At each follow-up visit, a clinical examination and safety assessment were performed, evaluating discomfort, stress, pain, and adverse effects induced by the wearable. Patients provided feedback about device and symptom-related patient-reported outcomes (PROs) at all subsequent visits. For symptom-related PROs, four somatic aspects were assessed longitudinally. Equivalent to the Edmonton Symptom Assessment Scale, intensity of reported symptoms was rated by the patients on a numeric scale from 0 (no symptoms) to 1 (mild) to 5 (moderate) to 10 (severe) in the time periods since the last visit.

As a standard of care, patients in the IC were visited at least three times daily by nursing staff for vital sign measurement (blood pressure, heart rate, body temperature, and respiratory rate). In addition, a physician visited at least once per day and assessed symptoms and clinical parameters. For patients in the OC, visits were routinely scheduled three times a week and the same measurements were collected as in the IC. If abnormal parameters were noted, the frequency of visits was increased or patients were admitted. Clinical staff on-site had limited participation in the trial conduct and only reminded the patients to reattach the wearable when they observe nonadherence. No clinical activity was triggered by wearable-based RPM, that is, there was no alert given of abnormal readings to patients or clinical staff.

For assessment of the primary outcomes, feasibility and safety of the wearable, adherence, and adverse device effects were documented and analyzed. Potential recording time was defined as time patients participated in the trial. Recording time, defined as the time when data were recorded independent of quality, was calculated as a proportion of potential recording time to ascertain adherence and use of wearable. For reliability assessment, an interpretable time, defined as the proportion of potential recording time with data sets that can reliably be interpreted using the provided quality indices, was calculated equivalently. Results were reported as median (interquartile range [IQR]). Data recorded with the wearable are presented for each day, and additional data are given per trial visit. The confidence interval was set to 95% for all statistical analyses. Nonparametric distributed continuous variables were tested.
### TABLE 1. Vital Signs and Activity Parameters Provided by the Medical Wearable According to the Instruction for Use Provided by the Manufacturer

| Parameter                        | Unit                      | Quality Index | Description of Parameters Provided by the Manufacturer                                                                 |
|----------------------------------|---------------------------|---------------|-----------------------------------------------------------------------------------------------------------------------|
| Heart rate                       | 30-240 beats per minute   | X             | Pulse per minute on the basis of the PPG signal                                                                        |
| Oxygen saturation                | 65%-100%                  | X             | Oxygen saturation level in the blood on the basis of the spectrophotometric (red/infrared) measurement                |
| Perfusion index                  | 0-255, arbitrary          | X             | Percentage change of blood volume in local tissue resulting from a single heart beat (PPG signal)                     |
| Activity classification          | Categorical, eg. resting and walking flat | X      | Estimate of activity on the basis of accelerometer measurements                                                       |
| Activity                         | 0-255, arbitrary          |                | Measurement on the basis of the accelerometer in x-, y-, and z-axes                                                   |
| Steps                            | 0-65,535 per day          |                | Estimate on the basis of accelerometer measurements                                                                   |
| Blood pressure wave              | 0-5.1, arbitrary          |                | Measurement of the shape and rhythmicity of the pulse wave (PPG signal)                                              |
| Heart rate variability           | 0-255 ms                  | X             | Established metric: RMSSD of pulse waves (PPG signal)                                                                |
| Respiration rate                 | 6-30 per minute           | X             | No. of breaths per minute (PPG signal)                                                                               |
| Energy expenditure               | 0-65,535 kcal per day     | X             | Accelerometer-based measurement of physical activity to estimate energy expenditure to complete all regular bodily functions |
| Temperature                      | 0-60°C                    |                | Surface temperature of the skin (temperature probe)                                                                  |
| Interbeat interval               | 1-4,095 ms                |                | The time difference between consecutive pulse waves (PPG signal)                                                     |
| Electrodermal activity           | 0-21.8 kOhm               | X             | Measurement of surface electronic resistance (electrode)                                                             |

Abbreviations: PPG, photoplethysmography; RMSSD, root mean square of successive differences.

Patients in the IC recorded data for 84.6% (76.3-90.2) of potential recording time. An analysis of the daily average recording time showed a decline over the course of the trial in both groups (Fig 2). There was no significant difference in daily average recording time whether recordings were obtained on a weekday or weekend (weekday 86.0%, weekend 84.4%, \( P = .59 \)). No wearable data were available for 121 (calendar) days (8.3%) for patients in the IC and 18 (4.7%) days in the OC. Five patients from the OC were admitted to the hospital because of serious clinical complications during the RPM period. These individuals were hospitalized for a mean of 5.8 days, and average recording time per day was not significantly different compared with recordings obtained in the outpatient setting (during hospitalization 82.0%, outpatient setting 81.2%, \( P = .34 \)).

Nineteen patients (35.0%) in the IC and 3 (12.0%) in the OC dropped out of the trial. The median time to dropout was 16 days (11.5-31.5 days) in the IC and 8 days (7.5-12.0 days) in the OC. The most frequent reason reported by six of these 22 patients (27.2%) for trial discontinuation was discomfort. Five other patients (22.7%) reported that parallel medical procedures, for example, continuous blood pressure measurements, were stressful. Four patients (18.1%) reported emotional stress as a reason for dropout. Three patients (13.6%) reported technical issues, that is, daily charging procedure of the wearable was regarded as too cumbersome. The remaining dropouts provided no reason.

As the wearable recorded a set of different parameters, the duration of interpretable time varied. In relation to recording time, the parameter with the most interpretable time was energy expenditure (Table 4). This was followed by heart rate activity classification, perfusion index, and oxygen saturation.

Using Kruskal-Wallis test, PROs were correlated (Spearman’s correlation) with the recorded data by the wearable.

For the analysis, standard software tools were used (MATLAB R2018b; MathWorks, Natick, MA and SPSS; IBM, Armonk, NY).

**RESULTS**

In the IC, 54 of 67 (80.6%) of the screened patients were included, and in the OC, 25 of 35 (71.4%; Data Supplement) were included. Of the 23 patients not included in both cohorts, seven did not meet inclusion criteria and 16 declined to participate. Demographic data, hematologic malignancies, comorbidities, and concomitant medication of the included patients are summarized in Table 2. In the IC, the 100-day mortality rate was 1.9% and the intensive care unit or intermediate care admission rate was 5.6%. In the OC, no death or intensive care unit or intermediate care admission occurred within 100 days. However, the 100-day (unplanned) hospitalization rate in OC was 36.0%.

Patients in the IC participated in this trial for a cumulative total of 1,434.9 days (Table 3), and the median participation time of a patient was 25.7 (IQR 17.6-33.3) days. The total participation time of the patients in the OC was 385.1 days, and the median was 15.1 (12.7-17.1) days.

Patients in the IC participated in a total of 483 visits, with a median of 9 (7-11) visits per patient. Patients in the OC participated in 6 (5-7) visits, resulting in a total of 162 visits. During all trial visits, no (serious) adverse device effects were reported.

In patients in the IC, wearable recordings accounted for 78.0% (63.0-88.5) of potential recording time, whereas patients in the OC recorded data for 84.6% (76.3-90.2) of potential recording time. An analysis of the daily average recording time showed a decline over the course of the trial in both groups (Fig 2). There was no significant difference in daily average recording time whether recordings were obtained on a weekday or weekend (weekday 86.0%, weekend 84.4%, \( P = .59 \)). No wearable data were available for 121 (calendar) days (8.3%) for patients in the IC and 18 (4.7%) days in the OC. Five patients from the IC were admitted to the hospital because of serious clinical complications during the RPM period. These individuals were hospitalized for a mean of 5.8 days, and average recording time per day was not significantly different compared with recordings obtained in the outpatient setting (during hospitalization 82.0%, outpatient setting 81.2%, \( P = .34 \)).

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rate, respiration rate, and then interbeat intervals. The interpretable time for oxygen saturation was lowest in both cohorts.

Patients in the OC tend to have a lower symptom burden than those in the IC. Fifty-one patients (94.4%) in the IC and 16 (64.0%) in the OC reported that they experienced a gastrointestinal symptom (diarrhea, nausea, and emesis), pain, dyspnea, or shivering at least once (Data Supplement). In both cohorts, gastrointestinal symptoms (GI symptoms) were the most frequently reported symptoms (IC 180/OC 20), followed by pain (IC/OC: 88/11), shivering (IC/OC: 39/7), and dyspnea (IC/OC: 25/5). For patients in the IC and for those in the OC, 65.4% and 81.3% of symptom-related PROs were reported in association with patient’s respective neutropenic phase, respectively. Symptom rating on a numeric scale for intensity revealed that for the patients in the IC, pain was the most intense symptom, followed by GI symptoms, shivering, and dyspnea. Correlation of recording time per day with the intensity of PROs showed a negative correlation with dyspnea only ($r = -0.56, P = .03$). There were no significant correlations between recording time and other PROs (Data Supplement).

Plausibility of the recorded parameter data was checked by plotting the heart rate and activity over the course of the trial (Data Supplement). The heart rates of both cohorts showed a parallel course in the beginning of trial participation with a pronounced decrease in heart rate at day three after the start of the intensive treatment. Subsequently, the heart rate increased in patients in both cohorts to a level well above 80 bpm. The patients in the IC showed a steady

| TABLE 2. Baseline Characteristics of the Patients in the IC and OC |
|---------------------------------------------------------------|
| **Patient Characteristic** | **IC (n = 54), No. (%)** | **OC (n = 25), No. (%)** | **Total, No. (%)** |
|---------------------------|--------------------------|--------------------------|-------------------|
| Male                      | 30 (55.6)                | 14 (56.0)                | 44 (55.7)         |
| Female                    | 24 (44.4)                | 11 (44.0)                | 35 (44.3)         |
| Age, median (IQR), years  | 56 (49-62)               | 54 (50-62)               | 55 (50-62)        |
| BMI, kg/m²                 | 25.0 (21.7-28.5)         | 24.9 (23.3-27.1)         | 25.0 (22.1-28.0)  |
| Hematologic malignancy    |                          |                          |                   |
| Acute leukemias (ALL and AML) | 21 (38.9)               | 12 (48.0)                | 33 (41.8)         |
| MDS and MPN (PMF and CML) | 20 (40.7)                | 0 (0.0)                  | 21 (26.6)         |
| Others (CLL, HL, NHL, myeloma and germ cell) | 13 (20.4) | 13 (52.0) | 25 (31.6) |
| Comorbidities             |                          |                          |                   |
| Arterial hypertension     | 13 (24.1)                | 14 (56.0)                | 27 (34.2)         |
| Diabetes mellitus (type 1 and 2) | 2 (3.7)               | 0 (0.0)                  | 2 (2.5)           |
| Macrovascular event (eg, stroke) | 1 (1.9)              | 1 (4.0)                  | 2 (2.5)           |
| Heart failure with a reduced ejection fraction | 0 (0.0) | 0 (0.0) | 0 (0.0) |
| Arrhythmias               | 2 (3.7)                  | 2 (8.0)                  | 4 (5.0)           |
| Concomitant medication    |                          |                          |                   |
| Antiplatelet drugs        | 3 (5.6)                  | 7 (28.0)                 | 10 (12.7)         |
| Beta blocker              | 5 (9.3)                  | 5 (20.0)                 | 10 (12.7)         |
| Calcium channel blocker   | 5 (9.3)                  | 11 (44.0)                | 16 (20.0)         |
| Renin-angiotensin system inhibitors | 9 (16.7) | 7 (28.0) | 16 (20.0) |
| Other antihypertensives   | 4 (7.4)                  | 0 (0.0)                  | 4 (5.0)           |

**Table 3.** Days of Trial Participation and Visits Performed by the Patients in the IC and OC

| Trial Participation/Procedures | IC (n = 54) | OC (n = 25) |
|-------------------------------|------------|------------|
|                              | Cumulative | Per Patient, Median (IQR) | Cumulative | Per Patient, Median (IQR) |
| Days                          | 1,434.9    | 25.7 (17.6-33.3)           | 385.1      | 15.1 (12.7-17.1)          |
| Days (excluded estimated wearable charging time) | 1,345.2 | 24.1 (16.5-31.2) | 361.0 | 14.1 (11.9-16.0) |
| Days recording time of the wearable | 1,004.2 | 19.1 (13.5-22.4) | 300.6 | 13.1 (9.5-14.2) |
| Visits                        | 483        | 9 (7-11)               | 162        | 5 (5-7)                  |

**Abbreviations:** ALL, acute lymphocytic leukemia; AML, acute myeloid leukemia; BMI, body mass index; CLL, chronic lymphocytic leukemia; CML, chronic myeloid leukemia; HL, Hodgkin lymphoma; IC, inpatient cohort; IQR, interquartile range; MDS, myelodysplastic syndrome; MPN, myeloproliferative neoplasms; NHL, non-Hodgkin lymphoma; OC, outpatient cohort; PMF, primary myelofibrosis.
increase in heart rate until day 35. In the OC, the heart rate of the patients declined below baseline levels in the last days of their trial participation.

By contrast, patients’ physical activity in both cohorts showed a diverging course during the trial with a lower physical activity level of the patients in the IC in comparison with that in the OC. The higher physical activity level of the patients in the OC remained approximately constant.

**DISCUSSION**

Despite the fact that patients on intensive treatment protocols for hematologic malignancies experience high symptom burden, our trial shows that they are willing and able to carry a wearable for RPM for a large proportion of the potential recording time and that most data gathered by a device will be interpretable. Recording time with the wearable was higher for patients in the OC, which at the same time, showed a lower symptom burden, compared with those treated in an inpatient setting because of a higher symptom burden. That the recording time was higher for patients in the OC than in the IC may reflect that frequent monitoring is already part of standard care, with the wearable being only an add-on. Patients showed a good acceptance (on the basis of the high inclusion to screening ratio) for a RPM approach, despite the lack of immediate individual benefit.

**TABLE 4.** Duration of Recordings by the Wearable for Different Parameters on the Basis of the Quality Index Provided by the Wearable

| Parameter                          | IC                   | OC                   |
|------------------------------------|----------------------|----------------------|
| Total Hours                        | % of Potential Recording Time | % of Recording Time |
| Heart rate, /minute                | 23,476.4             | 77.3 (62.0-87.2)     | 98.8 (96.4-99.6) |
| Oxygen saturation, %               | 7,884.8              | 21.1 (14.6-33.7)     | 30.5 (19.9-39.9) |
| Heart rate variability, RMSSD in ms | 19,810.3             | 62.6 (44.3-73.8)     | 82.6 (69.9-90.7) |
| Respiration rate, /minute          | 23,320.0             | 75.5 (60.4-86.3)     | 96.7 (95.2-97.7) |
| Energy expenditure, kCal/day       | 24,100.0             | 78.0 (63.0-88.5)     | 100.0 (99.9-100.0) |
| Interbeat interval, ms             | 15,195.2             | 48.8 (38.8-54.6)     | 80.1 (71.2-86.3) |

NOTE. Percentage of interpretable time is provided in relation to potential recording time (time that patients were in the trial) and recording time (% of time is given as median [interquartile range]).

Abbreviations: IC, inpatient cohort; OC, outpatient cohort; RMSSD, root mean square of successive differences between normal heartbeats.

FIG 2. Daily average recording time with the wearable. Data are given for the patients in the IC in blue (left y-axis) and in red for the OC (left y-axis; error bars indicate the standard error). The number of patients included in the IC is given as blue bars (right y-axis) and in the OC as red bars (also right y-axis). Wearable data were recorded not only at the trial visits but also every day (x-axis). IC, inpatient cohort; OC, outpatient cohort. Wearables enable remote therapy monitoring of patients with hematologic malignancies with high adherence.
The literature reports heterogeneity in definitions of adherence rates and criteria. For example, Dreher et al evaluated a wearable to record comparable parameters over a period of 9 months and used > 10 hours of use/day as a marker for adherence. Adherence was low with a mean ratio of 44.5%. The application of this approach to our trial showed the adherence of 83.0% for the patients in the IC and of 89.6% in the OC, albeit not over a duration of nine months. However, a longitudinal analysis of the daily recording time as a marker for adherence reveals a decrease over time in both cohorts. The high frequency of trial visits might have positively contributed to the adherence. Tonino et al report a comparable dropout rate investigating an equivalent population. Individual median trial participation was twice as long in this trial.

It is worth mentioning that the wearable used in this trial is not a lifestyle device (no display, fitness tracker, etc) like those used in some other trials. Instead, it was selected on the basis of the multiple sensors (ie, vital signs and physical activity) and the high amount of measured data points, that is, high signal resolution. Since the device is worn at the upper arm, it has a low interference with movements and therapy. Furthermore, the device is user-friendly and reduces the possibility of user operating errors. Data quality of the recorded parameters (defined as interpretable time) differed among the individual parameters as indicated by the respective indices provided by the proprietary algorithms implemented in the wearable. Although heart rate, heart rate variability, energy expenditure, and respiration rate had a sufficient interpretable time in both cohorts, oxygen saturation had an insufficient availability with only 25.0%-30.5% of the recorded time. The impaired measurement quality of oxygen saturation may be due to the light scattering approach used by this arm-worn device in contrast to the light transmission measurements at the fingertips/earlobes more frequently used in inpatient care.

Frequency and intensity of symptoms assessed by PROs were lower in patients in the OC in comparison with those in the IC. The highest rates of distress and PROs were reported by the patients—as to be expected—in a timely manner with low neutrophilic counts (Data Supplement). In other trials, a high symptom burden was associated with changes in heart rate and activity. A trend in this direction was observed in our trial as well. However, this did not reach significance in either cohort. Nevertheless, a correlation was observed between dyspnea and heart rate. In the PRO assessment, the focus was on somatic symptoms, and in principle, psychologic aspects, such as fatigue and depression, should also be assessed.

The daily charging time of approximately 90 minutes represents an important technical limitation with relevant measurement gaps and a clear burden for the patients. The internal data storage capacity of the wearable required a high trial visit frequency for data downloading. This, however, would play a subordinate role in implementation of a secure web-based service, compliant with EU General Data Protection Regulations. The upper arm appears to be a safe location for wearable attachment in this population. To improve adherence, wearables should be even smaller and more convenient in terms of charging procedures.

The sample size evaluated in this trial is limited. To our knowledge, this is the largest trial using a RPM solution in patients treated for malignancies. The screening procedure might have induced some bias, and patients with technical affinity more likely agreed to participate in this trial.

The data analysis in this trial is based on data preprocessed by the wearable, and one has to rely on proprietary algorithms. Therefore, it would be more desirable to use a wearable that provides the raw data and to deploy open-source algorithms. Furthermore, some symptoms used for the PRO assessment were chosen on the basis of expert opinion and no validation was performed beforehand. The aim was a pragmatic and concise symptom assessment that would not excessively interfere with the patient’s daily activities.

Implementation of RPM in clinical oncology offers an option of continuous surveillance of patients. This may improve detection of complications throughout the clinical course of the disease and could thereby optimize the timing of interventions. Ideally, the recorded data would be automatically analyzed to provide immediate actionable information.

In conclusion, patients on intensive treatment protocols for a hematologic malignancy experience a high symptom burden. Even so, they are willing and able to carry a wearable. This trial provides evidence that this digital-based approach of continuous monitoring of vital signs and physical activity with a medical wearable is feasible, generally well tolerated, and reliable for most measured parameters.

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CLINICAL TRIAL INFORMATION
The trial was registered in the German clinical trials register (DRKS00014782).

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AUTHORS’ DISCLOSURES OF POTENTIAL CONFLICTS OF INTEREST
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Open Payments is a public database containing information reported by companies about payments made to US-licensed physicians (Open Payments).

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