Step-counters for clinical use in mHealth at the time of the COVID-19 pandemic: the recovery of pre-smartphone experience

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Received: 09 June 2021; Accepted: 07 September 2021; Published: 25 December 2021. doi: 10.21037/jphe-21-49 View this article at: https://dx.doi.org/10.21037/jphe-21-49

Motion activity in the pandemic era

COVID-19 imposed severe house restrictions during the lock down. In all the nations, physical activity was limited during the acute phases of the pandemic. It is evident that this limitation, cannot avoid to have an impact on the health of individuals. It is in fact evident that moderate physical activity such as walking and running at a slow pace have a great physiological benefit in the cardiorespiratory system, in cardiology, in the treatment of diabetes (helping to minimize insulin or hypoglycemic therapy) and in respiratory diseases (such as the BPCO) and in mental health (1-4). This physical activity could improve various health parameters: the reduction of the body mass index (BMI), the BMI which is the ratio between weight and square of the height of an individual with whom indicates the ideal weight; the containment of bad cholesterol, or low-density lipoproteins (LDL); the decrease in fasting blood sugar and again the improvement of depressive symptoms in the elderly or of the joint motility of the hip. Being able to guarantee a minimum of physical activity was fundamental. In some cases, it was necessary to try to maintain this degree of physical activity by not exceeding, by legislative impositions, a distance of 100/150 m from home and perhaps (and this is good) conducting a dog because the law in this case allowed a degree greater than flexibility. Pedometers and physical activity monitoring systems in general for wellness and fitness could be a valid help in estimating physical activity.

Before the advent of the smartphone (5), wearable devices also dedicated to these activities had to be designed ad hoc. Today there are many commercial solutions capable to monitor the physical activity. These solutions are often integrated with smartwatches and/or smartphones, such as for example Fitbit, Apple Watch, or Garmin.

The use of wearable devices for monitoring physical activity has a lot of potential.

From a simple PubMed search with the key (wearable [Title]) AND (activity monitor [Title]), (available at https://pubmed.ncbi.nlm.nih.gov/?term=%28wearable%5BTitle%5D%29+AND+%28activity+monitor%5BTitle%5D%29& sort=date&size=200).

We get 11 papers on 8/25/2021.

From the seven most recent works (6-12), the potential of these devices emerges as regards the following aspects:

- (I) Home monitoring of cancer patients;
- (II) Monitoring and encouragement of the physical activity of the elderly;
- (III) Home monitoring of subjects with vascular problems and/or in recovery after fractures;
- (IV) Incentive towards physical activity;
- (V) Potential in long-term monitoring.

This highlights the potential of these devices, in general, during the COVID-19 pandemic and in fragile subjects (in which in many cases the stay at home is imposed by the disease).

The limits of the commercial pedometers on the subjects with disability

For subjects with motor disabilities the problem is further accentuated, in fact commercial pedometers, for example in Parkinson's disease and stroke, do not enjoy great reliability in clinical use and are not subject to errors. In some studies, we had seen the limitations of general-purpose pedometers (for all subjects based for example on accelerometers) in subjects with disabilities and we had dedicated ourselves

Page 2 of 5

to the development of pedometers for clinical use. Commercial pedometers mainly based on accelerometers showed limits in performance (13) and in several motion disabilities such as the Parkinson's disease (14) in the past. This is due to general limits in performances, positioning errors, and (in the case of disabilities) motion activities (for example tremors) confounding the sensors. Accelerometers have reached at the starting of the 2000 a plateau in terms of performance improvement. Today step counters use the accelerometers inside to the smartphone creating further problems on the effectiveness of the measure changing due to the positioning of the device during the monitoring.

The positioning of the accelerometer in the segment to be monitored is a very important aspect (15). In fact, it is important that the accelerometer axis sensitive to acceleration is perfectly aligned with the segment to be monitored. A slight misalignment causes error.

It is evident that using a smartphone this precaution cannot be respected. It is therefore necessary to use solutions based on wearable devices that connect to it, for example with Bluetooth (BT), but (I) which are external so that they can be positioned exactly; (II) use sensors different from accelerometers.

Solutions from the past for the fragile subjects

Two different step-counters have been proposed by these authors and tested in performance for the clinical use in several motion disabilities before the smartphone age/boom (16,17). The first device, described in Giansanti *et al.* (16) was successfully tested in clinical applications focused on the Parkinson's disease. The second device, described in Giansanti *et al.* (17) was successfully tested in patients with stroke. Both the two devices (16,17) have been compared to an accelerometric device (15), showing high performance and acceptance

During the COVID-19 pandemic subjects with disabilities were strongly penalized, two or more times if you like, compared to people without disabilities. In fact, in addition to the closures, there have been closures of canters for motion rehabilitation, lack of continuity of care and other problems that have made this period even more difficult for them and increased their degree of fragility.

Why do not recovery the old solutions?

We have thought to fragile subject with motion disabilities and we considered that could be useful to recover the inheritance of these solutions (16,17); update the obsolete components of these technologies; create a kit of stepcounters compatible with the mobile health (mHealth) technology to be used separately and to perform a primary acceptance analysis in the field. This needs a long feasibility study comprehending certification of the technology and suitable trials in this difficult period. In consideration of the objectives of the Special Issue, we believe it is useful to repropose these two pedometers in brief as a starting point for future work also useful to other researchers with some reflections to share.

Two examples of clinical step-counter from the past

The codivilla-spring (COSP)

As it is well known the COSP is one of the most-used aids in motion disabilities. Because it is cumbersome, gastrocnemius expansion measurement is not useful while ambulating with the COSP, worn. A COSP with sensors is proposed for telemonitoring and telerehabilitation in order to track the step count. A full description of a previous version of the COSP not integrated into mHealth and validation has been described in (17). For the sake of clarity, we report a brief description of this re-engineered version of the sensorized COSP (SECOSP). The system is based on force sensing resistors (FSRs) affixed to the plantar area of a commercial COSP, and a wearable unit with the conditioning electronics and a microprocessor μP PIC 16F877 (Microchip, Chandler, AZ, USA). While the subject is ambulating, the FSRs detect the pressure of the foottip and the heel. This information is used by the PIC to continuously add up the step count based on an algorithm. The power supply is four NI-MH rechargeable batteries with 3.6 V and capacity I = 160 mA \times h (Extracell, NY, USA). Figure 1 shows the FSRs affixation. Figure 2 shows the COSP after sensors are added.

Step counters monitoring the gastrocnemius

Commercial pedometers fail to furnish suitable performances in subjects with a motion disability (caused by their more complex model of gait). Furthermore, in most cases commercial pedometers are not easily linkable to a telemedicine system designed for tele-rehabilitation.

A full description of the gastrocnemius measurement unit (GEMU) with a detailed illustration of its validation is

Journal of Public Health and Emergency, 2021

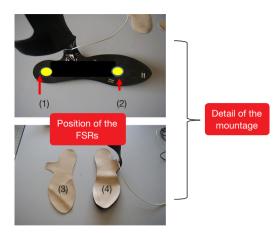


Figure 1 The FSRs affixation. FSRs, force sensing resistors.



Figure 2 The assembled device (SECOSP). SECOSP, sensorized codivilla-spring.

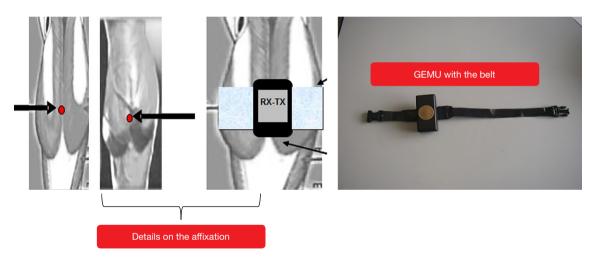


Figure 3 The assembled device (GEMU). GEMU, gastrocnemius measurement unit.

available in (16). For the sake of clarity, the re-engineered system is briefly described here. The GEMU, consists on a wearable device sensor with a belt (*Figure 3*) to monitor the force exerted by the gastrocnemius muscle against the device sensor during muscular expansion. At the fixation point, we refer to the horizontal plane at the vertex of the junction of the two bodies of the gastrocnemius. The wearable system is based on an FSR and a microcontroller PIC μ P PIC 16F877 (Microchip, Chandler, AZ, USA). The μ P is programmed to facilitate step counting. Once a variation of pressure is detected by the FSR, the step count is incremented by a trigger mechanism based on a threshold (50% of the supervised maximal signal excursion mediated on three consecutive steps). The power is supplied by three Extracell NI-MH rechargeable batteries (Extracell, NY, USA) that provide 3.6 V and a capacity I = $160 \text{ mA} \times \text{h}$.

Reflections for the scholars

Wearable devices in healthcare underwent a radical change after 2008 (5) when the smartphone with its potential became popular. Thanks to the introduction of this device, it was possible to initiate a process of integrating wearable sensor technologies and allow for the widespread diffusion of digital health in mHealth. Wearable tools that once had to be developed with ad hoc transmission devices now enjoy the opportunity to be hosted by the smartphone.

As for the step count, the smartphone has accelerometric sensors inside that allow you to monitor movement and therefore the step count through specific apps.

Page 4 of 5

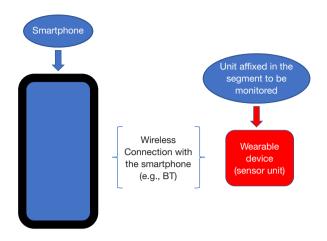


Figure 4 Model of intervention for the wearable monitoring. BT, Bluetooth.

However, as it is easy to guess, problems that have emerged in the past such as the positioning of the device for an accurate measurement re-emerge (16,17): different is the smartphone, you keep it in a shirt or pant pocket or on the support devices on the shoulder (18).

For this reason, in consideration of the potential usefulness of pedometers for fragile subjects in the pandemic period of COVID-19 and subsequently we believe it is useful to recover the experience with pedometers designed in the past for the clinical use including those proposed above and integrate them into mHealth.

These devices were developed focusing on specific technological and sensoristic issues for optimal monitoring of parameters. They were also thought to be positioned in a certain body segment and/or for a certain pathology.

The two aforementioned devices respect precisely this approach. In the evolution towards smartphone technology, this approach will be maintained according to the scheme in *Figure 4*. Solutions based on BT can for example be used for this purpose.

Acknowledgments

Funding: None.

Footnote

Provenance and Peer Review: This article was commissioned by the editorial office, *Journal of Public Health and Emergency* for the series "Telemedicine in COVID-19 Pandemic". The article has undergone external peer review. *Conflicts of Interest:* The authors have completed the ICMJE uniform disclosure form (available at https://dx.doi. org/10.21037/jphe-21-49). The series "Telemedicine in COVID-19 Pandemic" was commissioned by the editorial office without any funding or sponsorship. DG served as the unpaid Guest Editor of the series and serves as an unpaid editorial board member of *Journal of Public Health and Emergency*. The authors have no other conflicts of interest to declare.

Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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Journal of Public Health and Emergency, 2021

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doi: 10.21037/jphe-21-49

Cite this article as: Simeoni R, Maccioni G, Giansanti D. Step-counters for clinical use in mHealth at the time of the COVID-19 pandemic: the recovery of pre-smartphone experience. J Public Health Emerg 2021;5:40.

Support Care Cancer 2021. [Epub ahead of print]. doi: 10.1007/s00520-021-06234-5.

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