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Health Wearables for Early Detection of Frailty Syndrome in Older Adults in Mexico: An Informed, Structured Process for the Selection of a Suitable Device

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Abstract

This paper presents an informed, structured process to the selection of health wearables in the context of mobile health projects, though it may be applied to other wearable devices in different contexts. In particular, this process was applied to the selection of a consumer heatlh wearable for physical activity tracking based on step count within the context of an actual mobile health project that aims to address the early detection of frailty syndrome in the geriatric population in Mexico. The process started with the identification of user needs, followed by their translation to technical specifications defined in terms of metrics (quantifiable features). These metrics were defined using ideal and marginally acceptable values based on national regulations and constraints imposed by the specific context. The devices available in the market were screened and rated against these technical specifications using weighted rating scales that recognise the relative importance of certain specifications. Finally, the selected device was submitted to a preliminary verification test for accuracy. Additional work is required to validate the device for its use under real-life conditions.

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1. Introduction

Population aging is an important demographic process that will shape societies of the 21st century[1]. Mexico is not exempt of this trend: with an increasing life expectancy at birth and a decreasing total fertility, the country will experience a significant change in its demographic composition in the years to come[2, 3]. This shift will imply new public health challenges for the country, which will require new healthcare models and services.

Among the health issues that derive from the process of ageing, human frailty is one the more pressing. Frailty syndrome is a condition characterized by a diminished homeostatic reserve and less tolerance of the subject to stress situations in old age (e.g. acute illness, surgery, falls and fractures)[4]. Frailty increases patient vulnerability, limited mobility and risk of fractures. Table 1 summarizes the criteria proposed in 4, 5 and 6 *vis-à-vis* the diagnosis of frailty syndrome; namely, weight loss, exhaustion, walking speed, physical activity level and falls occurrence. The early detection of the frail patient based on these criteria would allow to timely provide him/her with appropriate interventions in order to reverse this state[7].

Table 1. Frailty syndrome diagnosis

Criteria	Definition	Parameters
Weight loss	Unintentional weight loss [4]	Weight loss $\geq$ 3 kg in the last year
Exhaustion	Tiredness feeling [4]	"What I did required me a great effort"
Walking speed	Walking speed for 4 meters [4]	Female: < than 0.6 m/s Male: < than 0.8 m/s
Weakness	Grip strength [6]	Female: < 18 Kg Male: < 30 Kg
Physical activity level	Weekly physical activity [4], [5]	Female: < 270 kcal/week Male: < 383 kcal/week (excluding Basal Metabolic Rate in both cases)
Falls occurrence	Recurrent falls [4]	Falls > 1 per year

The use of wearable devices, in conjunction with other technologies and methods (e.g. mobile devices, big data, and machine learning) is a promising area of research and development towards the deployment of new healthcare models to tackle public health issues. However, there is concern about the variability of the measurements of wearable devices. Because devices are not considered to clinical use, the health sector regulation does not apply. Manufacturers shirk their responsibility by adding a label saying that their use does not have clinical or diagnostic purposes. Accordingly, the authors are working on a project to develop tools for the early detection of frailty among Mexican geriatric population. The project aims to define, measure, and assess frailty in order to trigger suitable interventions in a timely manner[8]. Another problem that has been identified in wearable devices is that the measurements that they provide are designed and calibrated for young and adult people with physical activity, but not for older people with mobility problems or limitations in their movements.

In a previous report[8], a working definition of frailty was presented (Table 1). In this paper, the application of an informed, structured decision-making process to the selection of a suitable device to quantify the level of physical activity (e.g. through the measurement of steps) within the specific context of the abovementioned project is presented. The focus was made on this criterion given that the other criteria can be determined in the doctor's office during follow-up consultations.

2. Methods

Fig 1 depicts the process followed in the selection of a suitable device to quantify the level of physical activity in Mexican elderly population. It was adapted from the process proposed in [9]. Originally, the process is meant to be used for product design and development. However, some of the activities and tools were deemed by the authors as useful and relevant for the selection of health wearables in the context of mobile health projects. In the following subsections, the stages of the process are briefly explained.

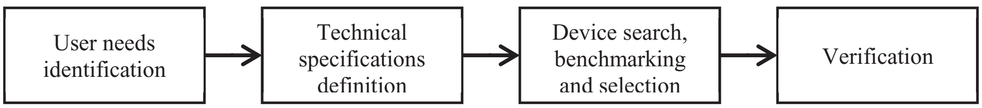

Fig. 1. An informed, structured process for health wearables selection in the context of mobile health

2.1. User needs identification

In this paper, the word *need* refers to any attribute of a "candidate" device that is required or desired by the users. These needs can be physical characteristics, technical requirements or usability features, among other categories. Identifying user needs is in itself a process whose aims are to define and prioritise the requirements that will maximise the adoption of the selected device. Hence, the following activities were carried out: firstly, users (also referred to as "stakeholders") were identified. Secondly, a list of raw needs (both required and desired) was elaborated with all the stakeholders and the specific context in mind. Finally, the relative importance of the needs was established. The output of this stage was a list of written statements expressing the users' needs with a relative importance score for each.

These activities were conducted by a multi-disciplinary group of researchers and clinicians with expertise in fields such as biomedical engineering (BME), information and communications technologies (ICTs), computer science, geriatrics and social work.

2.2. Technical specifications definition

User needs are written statements typically expressed in subjective terms (e.g. "the device must be portable"). Hence, the needs elicited in the previous stage were translated to target technical specifications. Each technical specification was expressed as a *metric* (e.g. weight) and its *ideal and marginally acceptable values* (e.g. ideal value ≤ 150g; marginal acceptable value = 150g). The use of appropriate units is a critical issue. Moreover, a need can produce more than one technical specification (e.g. the portability of a wearable device can be linked to both its weight and size). The output of this stage was a list of target technical specifications against which the specifications of the selected device were later compared to verify for compliance.

This activity was carried out by a group of four BME students and the output was validated and amended by two of the authors (GSR and RBB). The ideal and marginally acceptable values were defined based on the technical specifications found online for a few potential physical activity trackers and other surrogate devices (e.g. smartphones).

2.3. Device search, benchmarking and selection

In order to identify "candidate" devices, a search for the terms "fitness wearables" and "physical activity trackers" was conducted by one of the authors (RBB) using the Google Search engine in August 2015. The results were reviewed and those devices allowing to measure the level of physical activity were considered as "candidates", including only pedometers and fitness bands. Smart watches and devices monitoring physiological variables (e.g. heart rate) were excluded from later stages given their high price for a low-resources setting.

Subsequently, a benchmarking of those devices was conducted following these steps:

1. The general description and technical specifications for each "candidate" device were gathered through the manufacturers' and/or national distributors' websites.
2. A rating scale was defined for each *metric* using higher rates for more desirable values. For continuous variables (e.g. weight) the scale was defined in term of ranges (e.g. the rating scale for the metric "weight" might look like this: 4 if weight ≤ 50g; 3 if 50 < weight ≤ 100g; 2 if 100 < weight ≤ 150g, and, 1 if weight > 150g). As for categorical variables (e.g. connectivity), the higher rates were assigned to preferred categories (e.g. for "connectivity", the rating scale might be: 4 for Bluetooth; 3 for WiFi; 2 for USB; 1 for other protocols).
3. A weight, w_i, was assigned to each metric, m_i, based on the relative importance of the needs from which they were derived.
4. A selection matrix was prepared with the list of "candidate" devices in the first column and the metrics on the top row.
5. Each device was rated for each metric using the scales defined in step 2.
6. A total score was computed for each device. The total score for each device is the sum of the weighted scores:

$$S_j = \sum_{i=1}^{n} r_{ij} w_i$$

where
r_{ij}: raw rating of the device j for the ith metric
w_i: weighting for the ith metric
n: number of metrics
S_j: total score for device j

7. Devices were ranked according to their total score

The top ranked device was selected for a final stage of validation and testing.

2.4. Verification

The technical specifications of the selected device were compared with the target technical specifications defined in subsection 2.2 to verify the latter were met. Additionally, three healthy adults participated in some trials conducted in September 2015 with the purpose to make a preliminary verification of the accuracy of the device (given that this metric was not included in the selection matrix). The trials consisted of three tasks:

1. Subject walking 100 metres in straight line
2. Subject walking 100 metres in curved line
3. Subject walking the number of steps needed to complete 100 metres in a randomly chosen trajectory. The actual number of steps was determined from task 1.

The subjects were asked to wear sport clothes and trainers during the three tasks, which were done on a semi-professional running track. A three to five-minute break between tasks was given to subjects between tasks.

During the tasks, subjects wore the device selected in the previous stage (subsection 2.3) and an additional device randomly selected from the list for comparison purposes. For each task/subject the number of steps measured with both devices was recorded and lately used to compute the accuracy for each of them.

3. Results

3.1. User needs

The users were identified as: geriatric patients and their families, first contact physicians, and geriatricians. A team of senior BME students observed different individuals from each stakeholder group, as well as the interaction among the stakeholders' groups within a clinical facility setting. Following these observations, the user needs presented in Table 2 were drafted in conjunction with researchers and clinicians. The first four needs were deemed the most important by the stakeholders.

Table 2. User needs

No.	Need	No.	Need
1	Good amount of available device memory	8	Ergonomic
2	Affordable to low-income population	9	Intuitive
3	Long battery duration	10	Easy transportation
4	Accurate measurements	11	Compact
5	Compatible with operating systems of main portable communication devices	12	Waterproof
6	Approved by main regulatory organizations	13	Minimum amount of wires
7	Safe for patients		

3.2. Technical specifications

Table 3 shows the target technical specifications as translated from stakeholders needs. The greater the quantity of asterisks, the greater the importance of that need in relation to other needs. According to the need criteria showed in Table 3, some specifications are related to ergonomics and comfort, to guarantee that the selected device accomplishes the respective human factors according to the age range of the intended users.

Ideal values associated to metrics 1-4 were defined taking into account recommendations from the Colegio Nacional de Ergonomía de México (National College of Ergonomy of Mexico) described in the technical norm with reference number NT-CNEM-001, as well as the size and weight of a standard watch.

Table 3. Target technical specifications

No	Need	Metric	Importance	Units	Marginal value	Ideal value
1	8,10,11	Total mass	****	[g]	150	<150
2	8,10,11	Total width	***	[mm]	50	<50
3	8,10,11	Total height	***	[mm]	50	<50
4	8,10,11	Total length	***	[mm]	20	<20
5	2,3	Amount of wires required	****	quantity	1	0
6	9	Time elapsed in "connect-disconnect"	***	[s]	5	<5
7	8	Number of rounded corners	****	quantity	4	0
8	9	Time spent learning how to use it	***	days		
9	2	Price	****	MXP$	MXP$1,800	< MXP$1,800
10	5	Number of communication ports	**	quantity	1	3
11	12	Amount of time device remains waterproof	*	[s]	30	60
12	5	Number of compatible Operating Systems	***	quantity	2	3
13	6, 7	Number of regulatory organizations that approve the device	****	quantity	2	>2
14	4	Percentage error in measurements	*****	percentage	<=10%	<=5%
15	4	Measurements standard deviation	*****	number	----	-----
16	3	Battery duration	****	months	3	6
17	1	Storage capacity	****	[Kbytes]	1000	5000

The maximum price of the device mentioned in metric 10 was defined considering the national income of elderly population, reported by the *Instituto Nacional de Estadistica y Geografia* in Mexico (National Institute of Statistics and Geography). Similar considerations were taken into account to define the rest of the metrics and values.

3.3. Benchmark and device selection

A summary with the general characteristics and technical specifications of the pre-selected is presented in Table 4. The comparison criteria were distilled from the most important needs in Table 2. Although availability in the Mexican market was not identified by the stakeholders as a need, it was crucial for the research team and was also included as a criterion in terms of the product supplier. Moreover, Table 5 shows the rating scales developed and used to rate "candidate" devices. Finally, Table 6 shows the result of the application of those rating scales to the pre-selected devices.

Table 4. Summary of general characteristics and technical specifications of pre-selected devices

Device	Price (MXP$)	Measurements	Storage capacity (days)	Battery duration	Communication	Supplier	Compatibility
Misfit Flash	500	Steps, distance, calories, sleep quality	NA	6 months	Bluetooth	NA	iOS/Android
LG Lifeband	2,475	Steps, distance, calories, sleep quality, pace, velocity, height	NA	Up to 5 days	Bluetooth	Amazon	iOS/Android
Striiv Play	1,155	Steps, distance, calories, height	Up to 60	Up to 7 days	Bluetooth	Amazon	iOS
Jawbone UP	860	Steps, distance, calories, food intake	Up to 7	Up to 10 days	Audio Jack	Amazon	iOS/Android
Fitbit Zip	850-1,500	Steps, distance, calorie	Up to 23	Up to 6 months	Bluetooth	Mercado Libre	iOS/Android
Xfit Band	790	Steps, distance, calories, sleep quality	NA	Up to 5 days	Bluetooth	Store	iOS/Android

Table 6 lead the authors to conclude that the device that best satisfies the stakeholders' needs is the Fitbit Zip band. A similar process was followed to select a physical activity tracking app which was later used solely for benchmark purposes. The selected app was Pacer (Pacer Health, Inc).

Table 5. Rating scales

Parameter	1	2	3	4	5
Price (MXP$)	Over 1500	Between 1500 and 1200	Between 1200 and 1000	Between 1000 and 800	Below 800
Measurements	Steps	Steps and distance	Steps, distance, calories	Steps, distance, calories, extras	
Storage capacity	NA	One week	Two Weeks	Three weeks	Over 1 month
Battery duration	Below 1 week	Between 1 and 2 Weeks	Between 2 and 4 Weeks	Between 1 month and 5 months	Over 6 months
Communication	Wired	Wireless	-	-	-
Supplier	Import	Amazon	Mercado Libre	Department stores	
Compatibility	iOS	Android	iOS/Android	-	-

Table 6. Comparison between fitness bands, based on the importance of their characteristics.

Device	Price (Weight: 2)	Measurements (Weight: 1)	Memory (Weight: 3)	Battery Duration (Weight: 2)	Communication (Weight: 1)	Supplier (Weight: 1)	Compatibility (Weight: 1)	Total score
Misfit Flash	10	5	3	10	2	1	3	34
LG Lifeband	2	5	3	2	2	2	3	19
Striiv Play	6	5	15	4	2	2	1	35
Jawbone UP	8	5	6	4	1	2	3	29
Fitbit Zip	8	4	12	10	2	3	3	42
Xfit Band	10	5	3	2	2	5	3	30

3.4. *Verification*

The comparison between the selected devices was performed according to the test protocol described in section 2.4. In addition to the Fitbit, the Xfit band was also used merely to test the protocol on more than one device.

The three subjects that tested the devices were the same age. Subjects' weight and height were introduced to the devices as input parameters. Table 7 shows that the Fitbit has a relative error below 1.1% for the three subjects for counting steps and below 0.5% for walked distance estimation. The Fitbit had a better performance than the Xfit and a performance comparable to the Pacer app.

Table 7. Results of walking trials

	Measured steps	Actual steps	Error (%)	Measured distance (km)	Actual distance (km)	Error (%)
Subject 1						
Fitbit	141	140	0.71	0.1	0.1	~0
Xfit	105	140	25.00	0.07	0.1	0.3
Pacer	140	140	0.00	0.11	0.1	0.1
Subject 2						
Fitbit	145	145	0.00	0.11	0.1	0.1
Xfit	116	145	20	0.07	0.1	0.3
Pacer	144	145	0.69	0.1	0.1	~0
Subject 3						
Fitbit	182	184	1.09	0.14	0.1	0.4
Xfit	37	184	79.89	0.01	0.1	0.9
Pacer	171	184	7.07	0.1	0.1	~0

4. Discussion

The rise of consumer health wearables available in the market and the fact that they fall out of the scope of medical devices regulations imply necessarily an evaluation process for wearable technologies *vis-à-vis* their use in new healthcare delivery initiatives, as the one referred in this work for the early detection of frailty syndrome.

Consequently, a structured process for the selection of wearable devices to quantify the level of physical activity of older adults in Mexico was adapted from a process originally conceived for the design and development of new products. The needs of different users were identified and they were translated into technical specifications. The list of specifications was weighted according to the importance given by users. Moreover, technical specifications were written as metrics in terms of ideal and marginal values, which were defined taking into account suitable recommendations from some Mexican norms and organizations, as well as the features of similar devices (e.g. size and weight of a standard watch). The maximum price of the device was defined considering the national income of elderly population, reported by the Instituto Nacional de Estadistica y Geografia in Mexico (National Institute of Statistics and Geography). Similar considerations were taken into account to define the rest of the metrics and values. However, these metric values could be changed according to the context of the problem and the selected population.

This process allowed to identify a suitable device to quantify daily physical activity by means of step count. The device chosen fullfills the needs expressed by potential users regarding portability, usability, affordability, and availability in the Mexican market, as well as general technical specifications such as memory size and battery lifetime. As for accuracy, the results from the trials presented in this paper should not be considered conclusive due to the sample size and the duration of the taks. These trials were conducted with a preliminary verification of the device accuracy; a complete validation of the device needs to be conducted as part of the future work.

Too, additional work in regulatory agencies for a rigorous normative on wearable technologies in order to help medical diagnostics is necessary

5. Conclusions and future work

In this paper, the adaptation of a process first described by Ulrich and Eppinger (9) was presented for the selection of a suitable health wearable to accurately quantify the level of physical activity of older adults. By following this process, the authors aimed to maximise the adoption of the device *vis-à-vis* its use in a mobile health project conducted in Mexico. The device chosen fullfills the needs expressed by potential users regarding portability, usability, affordability, and availability in the Mexican market, as well as general technical specifications such as memory size and battery lifetime.

Nevertheless, further work is needed in order to validate the accuracy of the device in real use conditions (i.e. older adults carrying out theur daily life activities for longer periods), both in terms of number of steps and calories 'burnt' measured by the device. Accordingly, a study addressing these questions is being designed by the authors.

Additionally, the use of wearables could be an alternative for improve the diagnosis of frailty syndrome with the supervision on real time about the quality of gait and the detection of falls. The evaluation of wearable technology is the first step for the development of advanced applications with this kind of devices. The measure of the number of steps with a correct time register allows to do falls prediction or accurate measure of step characteristics and energy consumption for physical activity monitoring and falls detection and prediction. The use of wearable technologies is a promise for measuring the evolution of frailty syndrome in its initial steps, allowing a best medical intervention before a dramatic event.

Finally, the framework and process presented in this paper can be used for other wearable devices.

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