Remotely captured daily mobility pattern in age-related sarcopenia. A pilot clinical study.

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Introduction.

Physical Frailty&Sarcopenia, PF&S, (Del Signore, Roubenoff, 2017) represents an underestimated health risk among older adults leading to increased morbidity (including falls/injurious falls) and mobility disability. In physically frail older adults mobility should be carefully assessed in order to prevent further deterioration. Connected actimetry allows to gather relevant information about mobility patterns of the older person without interfering with everyday activity - an innovative application of the Internet of Things (IOT) to Clinical Trials.

Objectives.

The key objective of this study was to record remotely the pattern of physical activity, e.g. a sedentary life style and to test its relationship with the patient reported difficulty in physical function, assessed by a Patient-Reported-Outcome (PRO) and with an established functional tests, the gait speed at the 400-metre walking test(400mWT).

Original 1-week observation results are discussed with respect to medium-term (≥ 90 days continuous recording) collected in a different cohort from the "DECI" study, recruiting patients suffering from Mild Cognitive Impairment (MCI) or Mild Dementia (MD) in 4 different countries.

Methods.

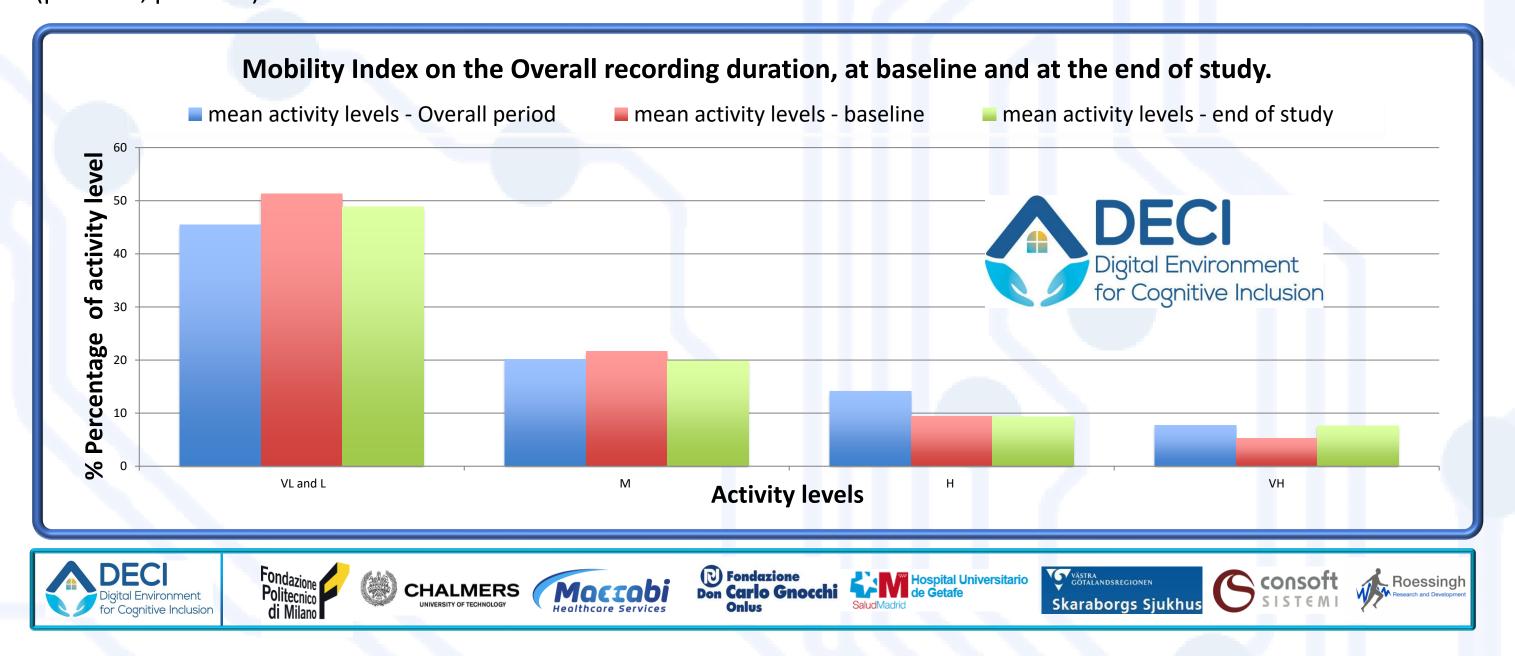
Twenty-five community-dwelling older adults (71±6 years; 60% women) worn continuously ADAMO for a week. The mobility index (MI) is a parameter explaining the daily grade of performed physical activity, as: Very Low (VLM), Low (LM), Medium (MM), High (HM), and Very High (VHM). Mobility. Walking ability and physical frailty were estimated using the 400 m walking test and the Tilburg Frailty Indicator (TFI), respectively.

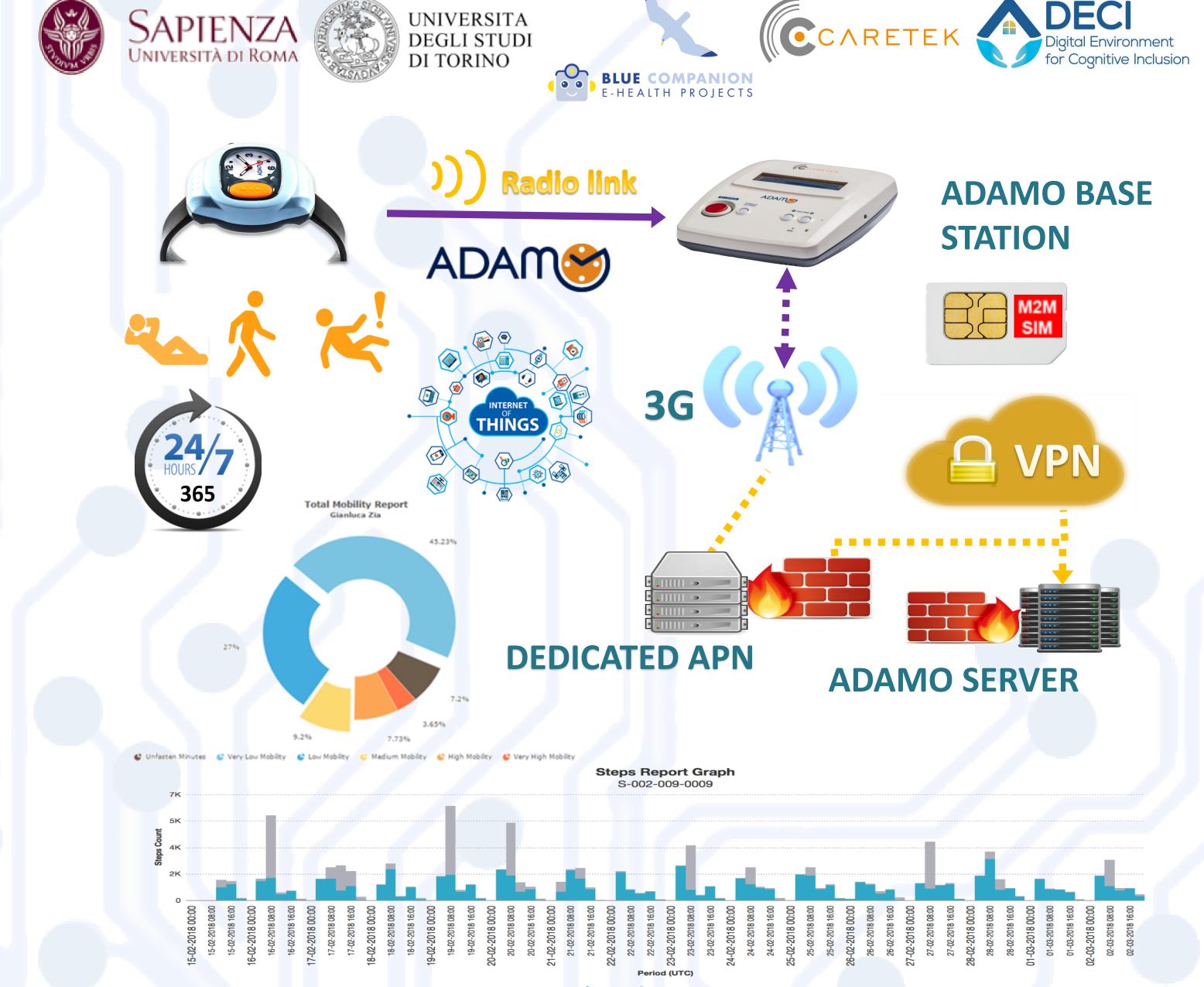
Second Study: DECI participants were followed over 6 months in national pilot studies; the consortium reported intermediate follow-up data up to April 2018. Controls participants received routine care; Group1 was followed via an IT-based organisational model; Group2 was equally followed via an IT-based model and IT-based physical and cognitive exercises with physical activity monitoring via Adamo watch. Baseline description is based the first 15 days from the first worn packet received from a watch; End of Study is calculated on the last 15 days of monitoring until the last worn packet is received.

DECI full methodology is described elsewhere.

Results.

In the first study, controlling for age and gender, ANCOVA showed that frail and robust participants were different for VLM (frail=58.8%, robust=42.0%, p<0.001), LM_MM (frail=25.5%, robust=33.8%, p=0.008), and HM_VHM (frail=15.7%, robust=24.2%, p=0.035). Using cluster analysis, participants were divided into two groups, with higher or lower mobility. Age and gender controlled linear regression showed that the MI clusters were associated with total (β =0.571, p=0.002) and physical frailty (β =0.381, p=0.031); and the 400mWT was associated with total (β =0.404, p=0.043) and physical frailty (β =0.668, p=0.002).





Mobility Index.

The mobility index is a discrete level parameter that tells the amount of activity performed by the user. It gives information about the amount of time spent lying or sitting, standing still or walking with different intensity.

Activity level	Example	Activity	Steps/10 Min	acceleration
VERY LOW	User is lying or sitting while resting	Rest	N/A	<80
LOW	User is lying or sitting performing slight activity	Rest	N/A	>=80
MEDIUM	User is standing still or walking with reduced intensity	Motion	<118	N/A
HIGH	User is walking with normal intensity	Motion	>=118 & <237	N/A
VERY HIGH	User is walking with a certain intensity	Motion	>=237	N/A

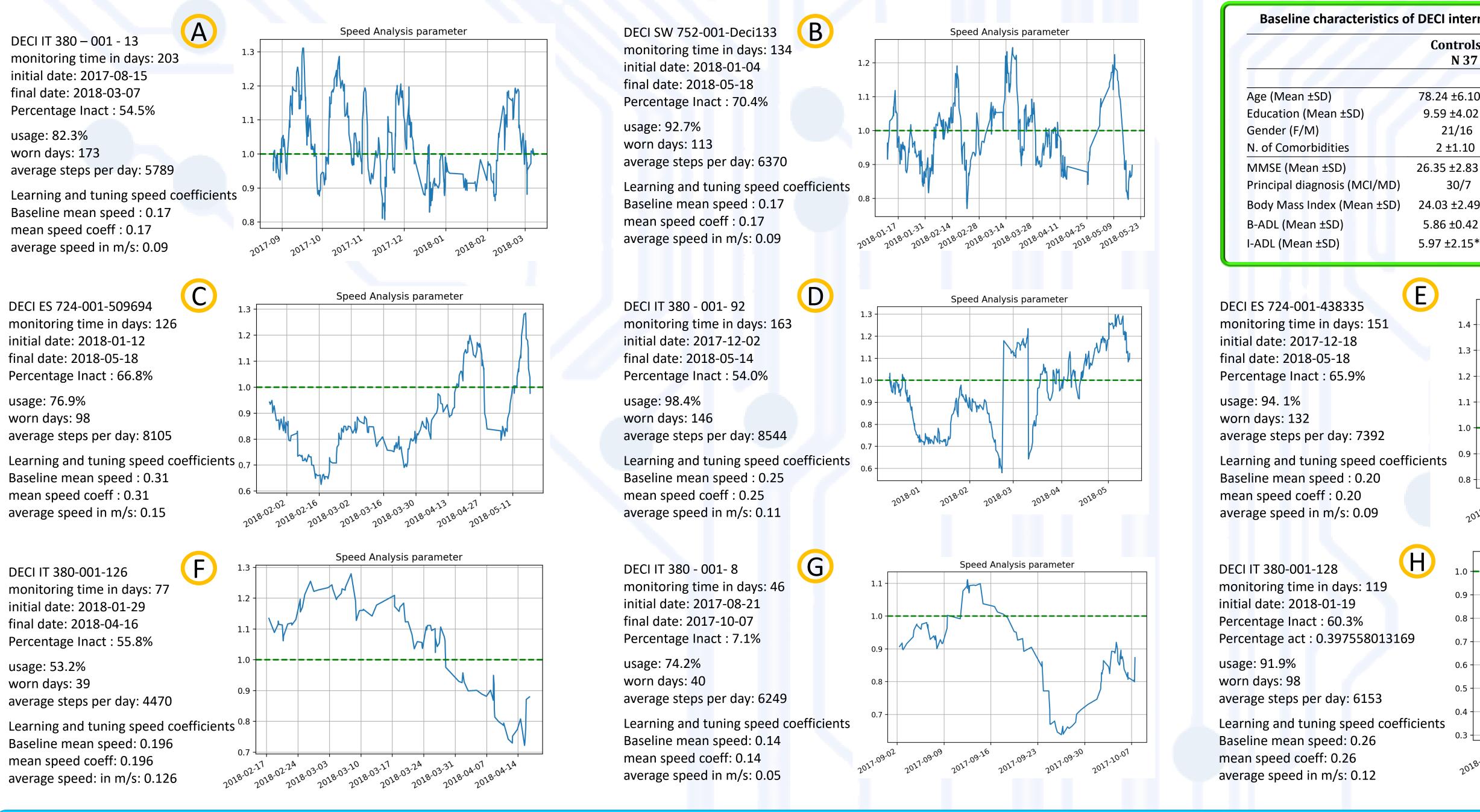
The mobility index is estimated every 10 minutes as follows:

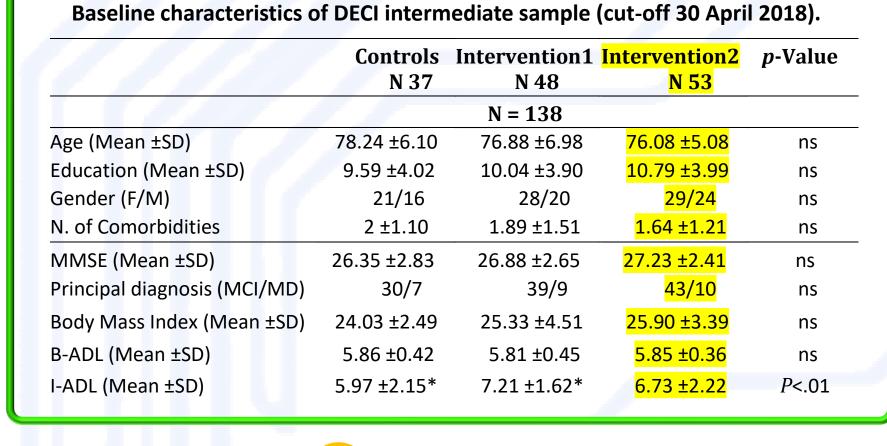
Medium, high and very high levels are related to user motion, while low and very low are related to rest.

If the watch records an orientation compatible with human motion activities, the number of detected steps and cadence are consideredand if more than 237 steps /10 minutes are detected, activity is very high. Else if walking is higher than 118, activity is high. Else activity is medium.

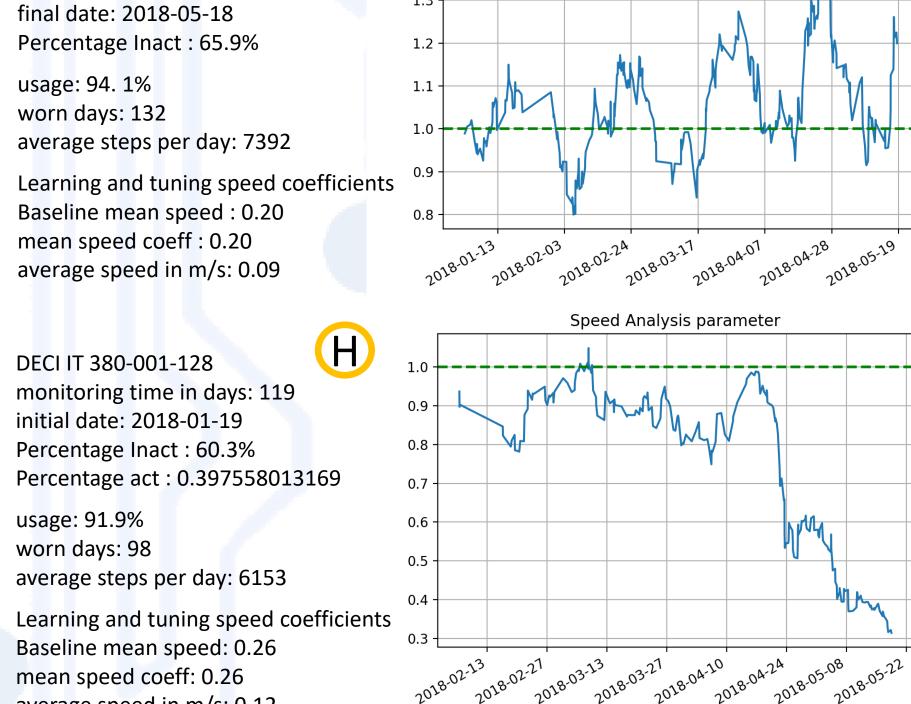
If the watch records an orientation compatible with resting, an acceleration pattern analysis is applied to distinguish between LOW and VERY LOW levels. Each 30 seconds a parameter is computed. Represents the average level of composite acceleration in 30 seconds. This value is inserted into a shift register. Each 10 minutes the mean of the dynamic thresholds values on the shift register is computed. If this mean value is lower than 80, the activity level is VERY LOW, otherwise it is LOW.

Individual Average Speed patterns showing relative stability (A, B), apparent increase of physical function (C, D, E) or progressive decline (F, G, H).





Speed Analysis parameter



Conclusions. Connected ADAMO wristwatch previously demonstrated being a reliable mobility tracking system to record, non-intrusively, continuous data on mobility levels of community dwelling frail older adults. In our initial study with non-cognitively impaired older persons the MI was closely related to objective measurements (400mWT) or self-reported indicators (TFI) of physical frailty. In this second study, we demonstrated that medium/long-term (>90 days) continuous, non- intrusive, remote physical activity monitoring via a wearable device like Adamo watch is feasible and can be

applied in mild cognitive impairment/ early phase of dementia – the DECI study population.

According to intermediate analyses, Mobility Index and Average Speed Pattern could provide additional insight on the medium/long-term decline or stability of physical function in an individual patient suffering from MCI or early phase Dementia.

As a next step, longitudinal studies in homogenous populations suffering from Physical Frailty&Sarcopenia should determine ADAMO MI suitability as an endpoint for clinical trials.

