



# System of Nudge Theory-Based ICT Applications for Older Citizens: The SENIOR Project

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**Abstract.** *Objective:* Mild Cognitive Impairment (MCI) is rapidly becoming one of the most common clinical manifestation affecting the elderly. The main aim of the SENIOR Project [SystEm of Nudge theory-based Information and Communications Technology (ICT) applications for Older citizens] is the development and validation of a new Nudge theory-based ICT coach system for monitoring and empowering persons with MCI. *Methods:* a multi-center randomized controlled clinical trial (RCT) involving 200 senior citizens with MCI will be implemented. Online assessment of demographic, psychological, neuropsychological, and behavioral outcomes will be carried out through the user's device/smartwatch. A machine learning algorithm-based customized profile will elaborate specific nudge-based notifications and suggestions will be provided to the user via SENIOR app. *Expected results and conclusions:* real-time monitoring and tutoring will decelerate the worsening of clinical condition and will improve the general perceived wellbeing of persons with MCI – also empowering care providers through dissemination of knowledge on the condition functioning and therapy. Moreover, the provision of tailored care actions will contribute to a more sustainable national and local healthcare systems.

**Keywords:** Elderly · Mild cognitive impairment · Nudge theory · Big data · Machine learning

# 1 Background

## 1.1 The Importance of Monitoring and Treating Elderly Using a Biopsychosocial Approach

Globally, population aged 60 or over is growing faster than the number of people in younger age groups, and during the next few decades this percentage is likely to rise to historically unprecedented levels. According to the latest estimates, by 2050 population people older than 60 years will nearly double from 12% to 22% [1]. Older people face special challenges. Moreover, the prevalence of physical, social and mental health increases with age, leading a growing number of elderly living in the community to experience multiple health and social care needs that may restrict their social engagement [2] and self-care abilities – with a higher utilization of long-term care and support services [3, 4].

Particularly, mild cognitive impairment (MCI) is rapidly becoming one of the most common clinical manifestations affecting the older citizens. It is characterized by deterioration of memory, attention, and cognitive functioning that is beyond what is expected based on age and educational level [5]. Characteristic of MCI is: (1) a subjective complaint of a memory disturbance (preferably supported by an informant); (2) objective evidence of a memory deficit; (3) generally preserved cognitive functions; (4) ability to perform basic activities of daily living; and (5) the absence of dementia [6]. MCI can also act as a transitional level of evolving dementia with a range of conversion of 10%–15% yearly [7].

Multidisciplinary professional collaboration in primary care is, therefore, required to optimally support older people with MCI in maintaining their independence and functional capacities, in meeting their health and social care needs, as well as in improving their perceived physical, cognitive, personal and social well-being - while minimizing service utilization and expenditure. However, what remains unclear is how collaboration may be undertaken in a multidisciplinary manner in concrete terms [8].

Research demonstrated that risk of further cognitive decline may decrease by the implementation of physical exercises, social engagement and mental activity [9]. For example, a prospective cohort study identified a significant association between engagement in mentally stimulating activities in late life and decreased odds of MCI in a non-clinical population. In 4 years, the risk of MCI decreased by 30% with computer use, 28% with craft activities, 23% with social activities, and 22% by playing games at least 1 to 2 times per week [10].

Still, while the impact of lifestyle, neuropsychological training and their interactions on aging have been frequently studied, no concrete action has yet been implemented to empower and support senior citizens in their everyday life.

The last decade has seen growing popularity and uptake of self-monitoring technology including wireless sensor devices and mobile apps for the long-term treatment of chronic illness [11, 12]. eHealth may help to improve the management of care for elderly and chronically ill patients by facilitating sharing of treatment plans and online health communities – while helping elderly in better managing their chronic conditions and sustaining an active social life.

## 1.2 From Traditional Mhealth Monitoring to Smart Watches Among Elderly: A New Potential Paradigm

Since 2014, consumer-grade smart watches have penetrated the health research space rapidly and smart watch technical functions, acceptability, and effectiveness in enhancing health outcomes are receiving increasing attention and support in the last years [13]. Rosales et al. (2017) recently suggested wearable technologies as an opportunity to solve problems often related to older people (65+) [14]. Also, Stradolini, Lavallo et al. (2016) proposed an Internet of Things - IoT application to simultaneously and constantly monitor elderly patients and alert healthcare professionals in case of anomalous measured values by using a smart-watch [15].

According to Ehn et al. (2018) devices must be easy to handle – and wearable activity trackers are generally perceived easier to maneuver than tablets or smart-phones, both among elderly and chronic illness patients [16]. However, some of their features - such as tiny screen size, small connectors and reduced power autonomy - can limit the spread of the smartwatches. Also, appropriate user interfaces and dedicated hardware tailored on the potential physical and cognitive impairments experienced by elderly need to be carefully developed.

## 1.3 The Contribution of Nudge Theory

A *Nudge* is the base element used to define a *Choice architecture*, that is a design of diverse ways in which choices can be presented to the user, also considering the impact of how suggestions are presented on the user process of decision-making [17].

The “Nudge Theory” proposes positive reinforcement and indirect suggestions as ways to influence the behavior and decision making of groups or individuals. This framework has demonstrated to be an effective and viable public tool in encouraging healthier eating choices in adults [18]. By reducing the set of choices, therefore decreasing the cognitive effort associated with processing information, Nudges may challenge the needs of elderly people of remembering or doing things, beside promoting healthier behaviours and an active aging lifestyle.

## 1.4 Big Data Analysis in Elderly

Considering the vast amounts of information clinicians need to take into consideration – i.e. the patients’ personal history, familial diseases, genomic sequences, medications, activity on social media, and admissions to hospitals - to guide clinical decision may become an overwhelming task. Analyzing Big Data using a carefully designed statistical model and the machine learning spectrum may improve the knowledge and management of different clinical and sub-clinical conditions in elderly. Gathering all the vital signs of the individuals and detecting any abnormalities, Big Data has a large potential in healthcare and plays major role in monitoring the elderly for earlier diagnosis of health problems [19].

## 1.5 The Added Value and Step Forward of the SENIOR Project

The SENIOR Project will:

- improve the knowledge of elderly citizens through the collection and examination of large data sets containing a variety of data types
- allow elderly patients to be monitored in a continuous and ubiquitous way (smartwatch) without invasive modalities but using a disappearing and not demanding approach
- tailor the feedbacks, suggestions and indications for MCI patients as suggested by the algorithms improved by big data-machine learning approach
- give “Nudges” to MCI elderly patients to improve their social skills

## 2 Main Hypotheses and Objectives of the SENIOR Project

The main hypotheses, tested along the SENIOR project, can be summarized as indicated below:

- the creation of a not-invasive, ergonomic, easy-to-use SENIOR platform (smartwatch-based) will serve to continuously monitor selected biological, psychological, social, and environmental data among elderly with MCI;
- smartwatch-based monitoring of elderly with MCI will improve the knowledge of senior citizens’ characteristics;
- the collection and analysis of several variables using the big data-machine learning approach will allow the creation of advanced algorithms-based profiles for elderly with MCI;
- the Nudge Theory approach will provide tailored feedbacks and strategies to elderly with MCI according to a given profile – and will enhance the cognitive skills, social interactions, and psychological well-being of the person.

Target objectives of the SENIOR Project are:

*Scientific and clinical objectives:*

- to define clinical and psychosocial outcomes for elderly with MCI;
- to develop tools to monitor and assist MCI senior citizens with self-management of their conditions;
- to develop a preventive treatment protocol for elderly with MCI;
- to evaluate the clinical efficacy and effectiveness of the new intervention by statistically comparing the SENIOR platform (experimental condition) with standard care (control condition).
- to evaluate costs and resources of the SENIOR approach through impact analysis.

*Technological objectives:*

- to design a SENIOR virtual coach architecture and platform to manage and record clinical and behavioural parameters of elderly with MCI;
- to develop cooperative architecture and personalized algorithms to support Nudge-based applications for elderly with MCI;

- to identify method(s) to monitor clinical parameters of MCI carriers through a low-cost approach;
- to develop and provide tools and applications for senior citizens with MCI and their caregivers;
- to evaluate the contribution of wearable devices in improving health monitoring in elderly with MCI;
- to create a list of technological specifics for integration with standard software systems.

*Integrative objective:*

- to implement cognitive-behavioural strategies to modify dysfunctional behaviours and beliefs and to improve a healthy lifestyle.
- to determine patients' care pathways and integration of health status monitoring within primary care services.

*Social objective:*

- to improve active socializing to prevent elderly with MCI from a rapid cognitive decline.

### 3 Methods

The SENIOR Project will provide an innovative, scalable, secure and intelligent system by developing a virtual coach tailored on the individual needs of senior citizens with MCI and by using a smartwatch-based technology in the frame of the Nudge Theory.

The project will involve the collaboration of different partners and will be performed in eight realistic and well-balanced work packages (WP). The Istituto Auxologico Italiano IRCCS<sup>1</sup> will coordinate the consortium (WP8: Consortium Management) and will manage the randomized controlled trial, RCT (WP5: Clinical trial Conduction) by recruiting senior citizens with MCI in their structures as in the Auser Milano Volontariato Onlus (AUSER) centers<sup>2</sup>. The resulting dataset will be sent to WP6 (coordinated by the Catholic University of Milan, UNICATT<sup>3</sup>) for evaluation and data analysis. UNICATT will be also devoted to the study of the interaction between humans and synthetic intelligence (WP4) – results that will be evaluated in WP6. In WP1 – coordinated by the Istituto Auxologico Italiano, IRCCS - enhancement of scientific understanding of the overall smartwatch and health platform functionality and requirements will be conducted.

<sup>1</sup> The Istituto Auxologico Italiano IRCCS is one of the main Italian research sites, with four main hospitals and many clinical units located in northern Italy.

<sup>2</sup> AUSER is one of the largest Italian no-profit associations aimed at stimulating active aging through different activities.

<sup>3</sup> The Department of Psychology of the Catholic University of Milan (UNICATT) has a long and notable history of research in the areas of general, developmental, clinical, social and organizational psychology, with extensive expertise in quantitative-qualitative research methodology and statistical analysis.

Results will lead WP2 (coordinated by the University of Milano-Bicocca, UNIMIB<sup>4</sup>) to conduct a market analysis aimed at identifying the adequate equipment of sensors, wearable devices and smartwatches to include in the patients' kit. The software design, development, integration and validation will be carried out in WP3 (UNIMIB) and WP4 (UNICATT). Evaluation and data analysis will be carried out by WP6 (UNICATT). Results will be further discussed and disseminated in WP7 (Dissemination, Demonstration Exploitation and Marketing) led by AUSER.

### 3.1 Evaluation of Clinical Outcomes

In order to provide evidence for the effectiveness of the SENIOR Project, a multi-center RCT involving 200 senior citizens (100 using the SENIOR virtual coach approach and 100 with standard approach-treatment as usual) will be implemented according to the latest CONSORT statements (Consolidated Standards of Reporting Trials - [www.consort-statement.org](http://www.consort-statement.org)). The SENIOR protocol will be evaluated by the new model for assessment of telemedicine (MAST- Methodology to assess telemedicine applications - <https://ec.europa.eu/digital-single-market/en/news/methotelemed-framework-methodology-assess-effectiveness-telemedicine-applications-europe>).

### 3.2 Participants

Participants will be recruited and screened for admission into the study from the Istituto Auxologico Italiano, IRCCS clinical units and the AUSER units on 3-month basis and monitored for the following 12 months.

#### Eligibility Criteria

Patients will be included into the study according to the following criteria: (1) age between 65 and 85 years; (2) diagnosis of MCI as measured by the Mini-Mental State Examination (MMSE) questionnaire [20] and an ad hoc Neuropsychological Test Battery [21]; (3) basic knowledge (entry level) of informatics assessed by the CIDA (Centro Informatico di Ateneo - Catholic University of Milan) test of informatics skills; (4) written and informed consent to participate.

**Exclusion criteria** will be: (1) presence of severe psychiatric disturbance as established by the Diagnostic and Statistical Manual for Mental Disorder <sup>5</sup>th ed. (DSM-5); (2) severe medical conditions that need inpatient treatment and continuous medical surveillance; (3) lack of independence in daily activities; (4) difficulty in sustaining functional movements due to severe medical (orthopedic, neurological, cardiological, etc.) reasons.

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<sup>4</sup> The Department of Informatics, Systems and Communication (DISCo) of the University Milano Bicocca (UNIMIB) has research experience in software engineering and architectures, databases and information systems, with emphasis on data quality and data integration, ICT in life sciences (bio-informatics, systems biology, medical informatics, telemedicine) data mining, computational models of complex systems, artificial intelligence, Computer Supported Cooperative Work and knowledge management. Specifically, the Biomedical Informatics group (BIMIB) and the Innovative Technologies for Interaction and Services Laboratory (ITIS) groups from UNIMIB will be involved.

A customized version of the Structured Clinical Interview for DSM-5 Disorders (SCID) [22] will be first used to screen for the presence of psychiatric disorders and will be administered by an independent clinical psychologist as part of his work.

### 3.3 Randomization Procedure

All participants will be randomly assigned to the intervention or control group. The randomization scheme will be generated by using the Web site Randomization.com: <http://www.randomization.com>. Randomization will take place after the baseline measurement.

### 3.4 Measures

Paper and pencil as well as online self-report questionnaires, inventories and symptoms checklists will be administered to participants in order to collect relevant periodic data - at baseline and at different follow-up points. Online assessment will be carried out through the SENIOR web-platform. Activity trackers and other smartwatch-based sensors will be used to measure physiological variables.

The following *demographic information* will be considered: (1) age; (2) gender; (3) education; (4) civil status; (5) social support (6) social relationships; (7) socio-economic status (SES).

*Physiological-medical outcomes* will be: (1) body mass index (BMI); (2) comorbidity indicators, using the Charlson comorbidity index [23]; (3) physical activity and energy expenditure, measured by the biomedical monitoring device (smartwatch).

Beside personality traits [measured by the MMPI-II Personality Inventory [24] ], *psychological variables* considered in the study will be: (1) the individuals' perceived quality of the experience, measured using traditional and online Experience Sampling Method-Based questionnaires [25]; (2) the individuals' perceived quality of life (QoL), measured by the SF-26 health survey [26] and the European Quality of Life-5 Dimensions (EQ-5D) [27]; (3) the individuals' psychological status and well-being, as means of the Symptom Checklist-90-R (SCL-90-R) [28], the Outcome questionnaire (OQ 45.2) [29, 30], the Beck anxiety inventory (BAI) and Beck depression Inventory (BDI) [31] (4) self-reported sleep quality, through the Insomnia severity index (ISI) [32], the Pittsburgh sleep Quality index (PSQI) [33], the Sleep Disorder Questionnaire (SDQ); (5) users' satisfaction in managing technological devices and platform, using the Telemedicine Satisfaction Questionnaire (TSQ) [34] and the Quebec User evaluation of Satisfaction with Assistive Technology (QUEST) [35, 36]; (6) patients' engagement and empowerment, using the Patient Activation Measure (PAM) [37] and the Patients Health Engagement (PHE) scale [38]; (7) the patients' motivation to change, as means of the University of Rhode Island Change and Assessment Scale (IT-URICA) [39]; (8) social interactions, through the Pennebaker's method of inferring psychological states via language analysis; 9) stressful life events, using the Paykel Scale of Stressful life events [40].

Also, a *neuropsychological assessment* comprising the MMSE questionnaire [20] and the Neuropsychological Test Battery [21] - which includes measures from five cognitive domains (memory, attention, language, visuospatial functioning, and executive

functioning) with at least three measures from each domain (Table 1) - will be undertaken. These tasks will be implemented in both their diagnostic and rehabilitation version to allow the SENIOR virtual coach to identify cognitive difficulties in senior citizens with MCI and to suggest them to undergo an ad hoc training.

Additionally, obese patients will be asked to complete the Weight Efficacy Life Style Questionnaire (WELSQ) and the Impact of Weight in Quality of Life (IWQOL-Lite) [41]. Only to diabetics will be also give the Diabetes Self-Efficacy Scale [42] and Diabetes Empowerment Scale [43].

**Table 1.** Neuropsychological Tests Administered | Retrieved from *Jak, A.J., et al. (2009). Quantification of Five Neuropsychological Approaches to Defining Mild Cognitive Impairment. The American Journal of Geriatric Psychiatry, 17(5), 368–375.*

Memory	Attention	Language	Visuospatial functioning	Executive functioning
WMS-R logical memory	DRS attention	BNT	WISC-R block design	WCST-48-card version
WMS-R visual reproduction	WAIS-R digit span	Letter fluency	D-KEFS visual scanning	TMT, Part B
CVLT trials 1–5 total, long delay free recall	TMT Part A	Category fluency	>D-KEFS Design Fluency >DRS construction >Clock drawing test	>D-KEFS Color-Word Interference Test >D-KEFS fluency switching (visual and verbal)

*Notes:* Boston Naming Test (BNT) [44]; California Verbal Learning Test (CVLT) [45]; Dementia Rating Scale (DRS) [46]; Wechsler Memory Scale-Revised (WMS-R) [47]; Wechsler Adult Intelligence Scale-Revised (WAIS-R) [48]; Trail Making Test (TMT) - Part A; Trail Making Test (TMT) - Part B [49]; Wechsler Intelligence Scale for Children-Revised (WISC-R) [50]; Delis-Kaplan Executive Function System (D-KEFS) [51]; modified Wisconsin Card Sorting Test (WCST-48-card version) [52]; Normative data was drawn from Mayo’s Older Americans Normative Studies (MOANS) [53] or from other published norms [44, 45, 47–52, 54, 55] except for block design, which used age and education adjusted norms drawn from local unpublished data derived from the UCSD Alzheimer Disease Research Center. DRS: Dementia Rating Scale.

*Behavioral outcomes* will be: (1) adherence to healthy diet, measured by the Mediterranean Diet Scale (MDS) and using the METADIETA approach (Meteda©); (2) adherence to physical activity, measured by the Recent Physical Activity Questionnaire (RPAQ) [56], the Physical Activity Recall (PAR) interview [57] and the CronoLife SenseWear® armband advance software [58, 59]. Moreover, the Self-Report Habit Index (SRHI) [60] will be used as index of the patients’ lifestyle; 3) behavioural and functional indicators - by assessment of the basic instrumental activities of daily living using the Lawton Instrumental Activities of Daily Living (IADL)



scale [61] and the WHO Disability Assessment Schedule 2.0 (WH ODAS 2.0) [62] according to the International Classification of Functioning, Disability and Health (ICF) [63].

By integrating target behaviours, a “health score” will be elaborated.

*Cost-effectiveness* of the SENIOR project will be evaluated considering its direct and indirect cost savings, while its cost-utility will take into consideration each users’ needs, abilities, technological skills and psychological profiles reducing costs due to an intelligent algorithm that will increase its performances according to machine learning technique/theory.

### 3.5 The SENIOR Project Architecture

SENIOR final solution will be represented by:

- a smartwatch dedicated app;
- a set of optional environmental sensors;
- a cloud personalized service.

The customer will install the SENIOR app in his/her smartwatch and will access to SENIOR on-line service. The SENIOR service (user monitoring, personalized nudge advice etc.) will be delivered by a health company/structure and will require an annual fee.

The health company/structure will make revenues based on the number of enabled customers. The SENIOR solution can be proposed, for example, by an insurance company.

The user device (a smartwatch or a smartphone) will use two kind of networks: a local wireless network (Bluetooth LE) to dialogue with local sensors and measuring instruments, and a 3G/4G network to send and receive data from the remote back-end server. The device can be used without depending on wireless or Bluetooth connections due to the presence of a SIM card slot on board.

The security of the communications is guaranteed by the protocols used (Secure Pairing and Connections for BTLE and HTTPS for app-to-backend communications). The data privacy is guaranteed by encrypted communications channels and by using encrypted and obfuscated databases.

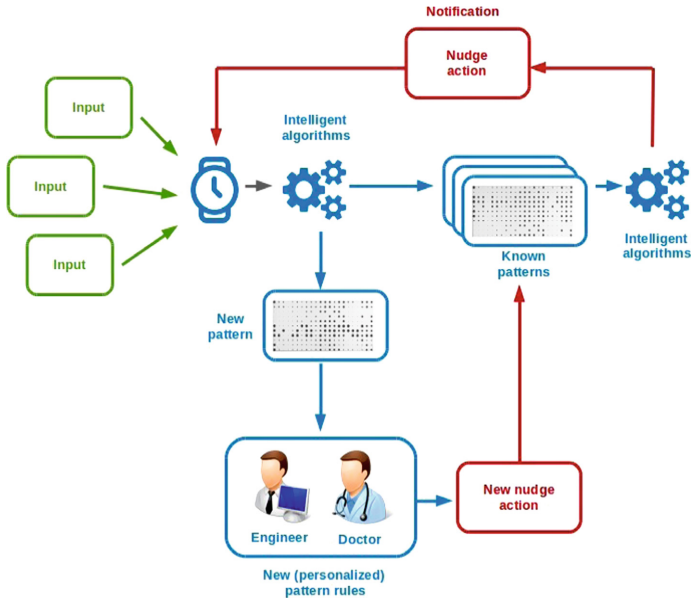
### 3.6 Procedure

In order to help the patient to improve and maintain his/her independence, the personalized virtual coach will elaborate a customized profile (built on the machine learning theory-based algorithm) that will provide the user with specific nudge-based advices-notifications-suggestions.

Different signals will be collected from the user’s device and delivered by the SENIOR app to the remote backend server - whose software will analyze the data (physical activity, psychological wellbeing, risk of social exclusion) in order to elaborate a machine learning algorithm that will identify a given pattern.

The remote backend will also help alert the clinicians in presence of negative/dangerous patterns and will also enable caregivers/professionals to deliver personalized treatments plans new personalized pattern rule.

Then the system will transmit a real-time “nudge action” driven by the SENIOR app to the user (Fig. 1). The SENIOR app is self-adaptive to the patient IT skills and level of engagement.



**Fig. 1.** SENIOR Project IT architecture

### 3.7 Statistical Analysis

According to a-priori power analysis (G\*Power 3.1.3 was used for calculation), 200 participants are required to detect a small interaction effect of treatment  $\times$  time on outcomes with a 90% statistical power. Two-tailed t-tests for continuous variables and Fisher’s exact tests for binary variables will be used for descriptive purposes. Treatment effects (treatment  $\times$  time interaction effects) as well as moderating and mediating effects will be tested with the General Linear Model [64]. Repeated-measure factorial ANCOVAs will be used for each outcome. Critical alpha for the treatment effects will be set to 0.01 in order to limit the inflation of the type I error rate due to multiple tests, while no adjustment will be applied to alpha = 0.05 for the statistical testing of the other effects. Other further analysis, considering all the collected data, will be performed using advanced informatics approaches - considering the big data and machine learning framework - in order to detect the most useful sorting algorithms to understand the different kinds of elderly patients with MCI.

## 4 Expected Results and Conclusion

**Impact for Older Citizens.** Real-time monitoring and tutoring (based on a Nudge theory approach) will decelerate the worsening of mild clinical conditions or the loss of a functional status.

**Impact for Care Providers.** By combining variable (data integration) through predictive analytic methods, health care providers will better understand the impact of several determinants on the seniors' health – so to readjust their approach based on patient's needs for the delivery of preventive actions.

**Scientific and Clinical Impact:** home-based ad hoc seniors' assessments and tailored feedbacks with reliable and intelligent tools will be offered to reduce hospitalization rates and to improve disease self-management of seniors with MCI - with consequent strengthening of their QoL. A more active participation of elderly in the care processes (patient engagement and empowerment) will be also facilitated by increased patient-provider interactions. Moreover, the big data analysis-machine learning approach will improve knowledge of older adults and MCI and allow the identification of more effective treatment strategies.

**Societal and Economic Impact:** citizens will be directly involved in decision-making processes and follow up procedures, as well as in virtual communities where to share experiences, results, difficulties and successes so to reinforce their motivation and self-efficacy. High-quality and personalized care - with better use of the available healthcare resources – will be then provided, thus contributing to a more sustainable national and local healthcare (clinical and social) systems. The cost-effectiveness of the service will be calculated by means of Effectiveness Indicators and Cost Indicators.

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