nudging CHronic disease mANaGemEnt for empowering citizens: the CHANGE project

Giada Pietrabissa[1,2][0000-0002-5911-5748], Vanessa Bertuzzi[2][0000-0002-8541-5357], Emanuele Maria Giusti[1,2][0000-0001-5767-8785], Roberto Cattivelli[1,2][0000-0002-5995-5456], and Gianluca Castelnuovo[1,2] [0000-0003-2633-9822]

[1] Istituto Auxologico Italiano IRCCS, Psychology Research Laboratory, Milan, Italy
[2] Department of Psychology, Catholic University of Milan, Italy
giada.pietrabissa@unicatt.it

Abstract
Objective: Chronic diseases (CDs) are major causes of deaths, disabilities and healthcare expenditure worldwide. Interventions aimed to prevent or mitigate the impact of CDs need to be added to the traditional healthcare methods. The main purpose of the CHANGE project is the development and validation of a new Nudge theory-based Information and Communications Technology (ICT) coach system for monitoring and empowering patients with CDs. *Methods*: A randomized controlled clinical trial involving 200 patients with CDs will be implemented. Online assessment of demographic, psychological, neuropsychological, and behavioral outcomes will be carried out through the users' device (smartwatches). A machine learning algorithm-based profile will elaborate specific nudge-based notifications, and suggestions will be returned to par- ticipants via the CHANGE App. *Expected results*: real-time monitoring and tutoring will prevent/decelerate the worsening of clinical conditions and will improve the physical and psychosocial health of patients with CDs. Moreover, the provision of tailored care actions will contribute to a more sustainable healthcare system.

Keywords: Chronic Diseases; Nudge Theory; Big Data; Machine Learning; Clinical Psychology

1. Background

1.1. The global burden of chronic diseases

Chronic diseases (CDs), including cardiovascular diseases (CVD), obesity, cancer, diabetes and respiratory diseases, are collectively responsible for almost 70% of all deaths worldwide [1]. Characteristic of CDs is to be long lasting and generally slow in progression. They, therefore, require a long period of supervision, observation or treatment, but are not curable [2]. As a result, CDs are widely associated with increased burden of disability, related economic losses, and healthcare expenditure [3].
Research also consistently demonstrates the link between CDs and mental health [1]. Data from the World Health Surveys indicate that people with two or more CDs are seven times more likely to display symptoms of depression than their counterpart [4]. While mental health problems usually occur in people with CDs, there is also strong evidence that existing emotional impairments increase the risk for the onset of a range

of chronic conditions [5]. In fact, enduring stress has a direct impact on the cardiovascular, nervous and immune systems, thus leading to increased vulnerability to a range of diseases [6, 7]
Common causes and manifestations of CDs have been identified and studied, and these conditions have shown to be highly preventable and modifiable [8]. However, healthcare systems around the world are meant to deal with acute episodic care, and interventions aimed to prevent/mitigate the effects of CDs are still scant [9].

1.2. Self-regulation and disease management

According to the World Health Organization (WHO), self-management is a key element of CDs management [10]. It involves the person with CDs "*engaging in activities that protect and promote health, monitoring and managing the symptoms and signs of illness, managing the impact of illness on functioning, emotions and interpersonal relationships and adhering to treatment regimens*" [11]. Lorig and Holman [12] assumed that self-management is also about "*enabling participants to make informed choices, to adapt new perspectives and generic skills that can be applied to new problems as they arise, to practice new health behaviors, and to maintain or regain emotional stability. In chronic medical conditions, this process involves management tasks – management, role management, and emotional management as well as essential management skills - problem solving, decision making, resource utilization, the formation of a patient–provider partnership, action planning, and self-tailoring"* [12].
If this systematic learning and change process is successful, individuals (re-)gain their ability to manage their lives without external professional support services, with consequent increase of their self-efficacy and quality of life [13-15].

1.3. Collaborative - individualized stepped care approach in response to chronic diseases

Systematic reviews have found that multidisciplinary - collaborative care programs can improve the quality of care and improve patients' outcomes [16]. Collaborative care is consistent with the dimensions of the *chronic care model (CCM)* [17], which postulates that four elements are desirable for an effective management of chronic conditions, including patient's self-management and decision support (clinical practice guidelines, clinicians education), delivery system redesign (planned visits, case management, primary care team), and clinical information systems (registries, reminders, clinicians feedback) [18]. Patient's self-management support is aimed to empower individuals to control their own health and their ability to access healthcare. Instead, decision support, delivery system redesign and clinical information systems strategies are meant to reform care and care teams to better meet patients' needs [19]. Research on the implementation of CCM in clinical practice demonstrated its capability to improve health outcomes [20-22].

However, healthcare actions are still often inadequately organized and delivered, and a fundamental problem in organizing the care of patients with CDs remains the provision of the right level of support [23].
In this regards, the use of an *individualized stepped care approach*, defined by Donovan and Marlatt [24] as "the least costly, least intensive, and least restrictive treatment judged sufficient to meet the person's needs and goals should be attempted initially before more costly and restrictive treatments are attempted" [24], has been supported for many CDs, including hypertension [25], obesity and diabetes [26], pain [27-29], and depression [30]. Stepped care is based on three assumptions: 1) different people require different levels of care; 2) finding the right level of care depends on monitoring outcomes; and 3) moving from lower to higher levels of care based on patient outcomes often increases effectiveness and lowers costs [31]. The level or intensity of care required by each patient is selected according to evidence-based guidelines in line with patient goals, treatment preferences, and clinical status [32].

The last decade has also seen growing popularity and uptake of self-monitoring technology including wearable devices, Apps and other communication platforms [33], and the use of machine learning are now likely to revolutionize the delivery of chronic care [34-36]. These technologies may sustain active self-management in patients with CDs by facilitating sharing of treatment plans and online health communities, while leveraging the time and resources of healthcare professionals [37-39].

1.4. Hyper Nudges and Big Data

The nudge approach has emerged from the behavioral sciences to challenge potential pitfalls of traditional regulation in public health strategies - such as costly procedures or ineffective campaigning – so to address modifiable individual-level factors related to the rise of CDs [40]. Thaler and Sunstein [41] defined a nudge as *"a function of (condition I) any attempt at influencing people's judgment, choice or behavior in a predictable way (condition a) that is made possible because of cognitive boundaries, biases, routines, and habits in individual and social decision-making posing barriers for people to perform rationally in their own self-declared interests, and which (condition b) works by making use of those boundaries, biases, routines, and habits as integral parts of such attempts"* (20, p. 37). In other words, a nudge is "*any aspect of choice architecture that alters people's behavior in a predictable way (a) forbidding or adding any rationally relevant choice options; or (b) changing incentives, whether regarded in terms of time, trouble, social sanctions, economics, etc*." [41].
Therefore, the nudge theory proposes positive reinforcement and indirect suggestions as ways to influence the behavior and decision making of groups or individuals without further restricting freedom of choice or imposing mandatory obligations to people [42]. This framework has demonstrated to be an effective and viable public tool in encouraging healthier eating choices in adults [43]. By reducing the set of choices, therefore decreasing the cognitive effort associated with processing information, Nudges may challenge the needs of people of remembering or doing things, beside promoting healthier behaviors and an active lifestyle.

The *big data* concept refers to vast quantities of data created by the adoption of the Internet and digitization of all sorts of information, including health records. Therefore, within the machine learning spectrum, big data-driven nudges allow health data management to be prescriptive, rather than only descriptive [44].

2. Main objectives of the CHANGE project

The main objective of the present work is to describe the protocol of the CHANGE project. It is aimed to provide an innovative, scalable, secure and intelligent system by 1) designing a virtual coach architecture and platform to manage and record selected parameters through the employment of the big data-machine learning approach, and 2) by using a smartwatch-based technology in the frame of the nudge theory to enhance self-monitoring of patients with CDs by providing them with tailored feedbacks and strategies. This will enhance the cognitive, biomedical, psychological, social, and behavioral well-being of patients with CDs via self-management.
The clinical efficacy and effectiveness of the new approach will be evaluated in a randomized control trial (RCT) comparing the CHANGE platform (experimental condition) with standard care (control condition). The costs and resources of the CHANGE approach will be also assessed.

3. Methods

In order to provide evidence for the effectiveness of the CHANGE project, a multicenter RCT involving 200 patients with CDs (100 using the CHANGE 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). The CHANGE protocol will be evaluated by the new model for assessment of telemedicine (MAST- Methodology to assess telemedi- cine applications - https://ec.europa.eu/digital-single-market/en/news/methotelemed-framework-methodology-assess-effectiveness-telemedicine-applications-europe).

3.1. Participants

Participants will be recruited and screened for admission into the study from the Istituto Auxologico Italiano IRCCS[1] on a 3-month basis and monitored for the following 12 months. Patients will be included into the study if: 1) aged between 65 and 85 years; 2) diagnosed with a CDs, 3) have basic knowledge of informatics; 4) will provide written and informed consent to participate. Exclusion criteria, instead, will be the presence of severe 1) psychiatric disturbance according to the Diagnostic and Statistical Manual for Mental Disorder 5th edition (DSM-5); 2) cognitive impairment affecting the participants' self-management opportunities and the reliability of self-report data; or 3) medical conditions that prevent from independent daily activities and need continuous surveillance.

3.2. Randomization procedure

[1] 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.

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.

3.3. Measures

The Structured Clinical Interview for DSM-5 Disorders (SCID) [45] will be used to screen for the presence of psychiatric disorders. Moreover, a neuropsychological assessment comprising the Mini-Mental State Examination (MMSE) questionnaire [46] and the Repeatable Battery for the Assessment of Neuropsychological Status (RBANS) [47, 48] will be administered by two independent psychologists at the beginning of the rehabilitation program to screen patients for inclusion of into the study.

Moreover, the following selected parameters will be collected data at baseline (paper and pencil) and at different follow-up points (through the users' device).
Demographic information: age, gender, education, civil status, and socio-economic status (SES).
Medical outcomes: body mass index (BMI), blood pressure, and presence of comorbidities (Charlson comorbidity index - CCI [49]).
Psychological variables: the individuals' perceived health-related quality of life (HRQoL) - measured by the SF-36 health survey [50] and psychological status (Symptom Checklist-90-R [51]), the Beck anxiety inventory (BAI) and the Beck depression Inventory (BDI) [52], and the Paykel Scale of Stressful life events [53]. The users' general perceived self-efficacy (GSE) [54] will be also registered, together with their sleep quality (Pittsburgh sleep Quality index - PSQI [55]). Patients' engagement and motivation to change will be also evaluated via the Patients Health Engagement (PHE) scale [56] and the University of Rhode Island Change and Assessment Scale (IT-URICA) [57], respectively. The Multidimensional Scale of Perceived Social Support (MSPSS) will be further administered [58]; and the users' satisfaction in managing technological devices and platform assessed using the Telemedicine Satisfaction Questionnaire (TSQ) [59].
Behavioral outcomes: the patients' self-reported lifestyle (Self-Report Habit Index - SRHI [60]), adherence to healthy diet (Mediterranean Diet Scale - MDS), and physical activity level (Recent Physical Activity Questionnaire – RPAQ [61]). Moreover, according to the International Classification of Functioning, Disability and Health (ICF) [62], the individuals basic instrumental activities of daily living will be assessed using the WHO Disability Assessment Schedule 2.0 (WHO-DAS 2.0) [63].
A "health score" will be elaborated by integrating target behaviors.
C*ost-effectiveness* of the CHANGE project will be evaluated considering its direct and indirect cost savings.

Procedure

The users will install the CHANGE App in their smartwatch and will access to the CHANGE on-line service.

Devices (smartwatch or smartphone) will use two different 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.
Different signals will be collected from the user's device and delivered by the CHANGE App to the remote backend server, whose software will 1) analyze the data in order to elaborate a machine learning algorithm able to identify a given pattern, 2) alert the clinicians in case of problems. The system will then transmit a real-time "nudge action" driven by the CHANGE App to the user (Figure 1). In other words, to help patients with CDs to improve their health and social outcomes, the personalized virtual coach will elaborate a customized profile (built on the machine learning theory-based algorithm) providing the users with specific nudge-based advices. The CHANGE App will be self-adaptive to the patient information technology (IT) skills and level of engagement.
The security of the communications will be guaranteed by the protocols used (Secure Pairing and Connections for BTLE and HTTPS for app-to-backend communications), while data privacy will be ensured by encrypted communications channels and the use of encrypted/obfuscated databases.

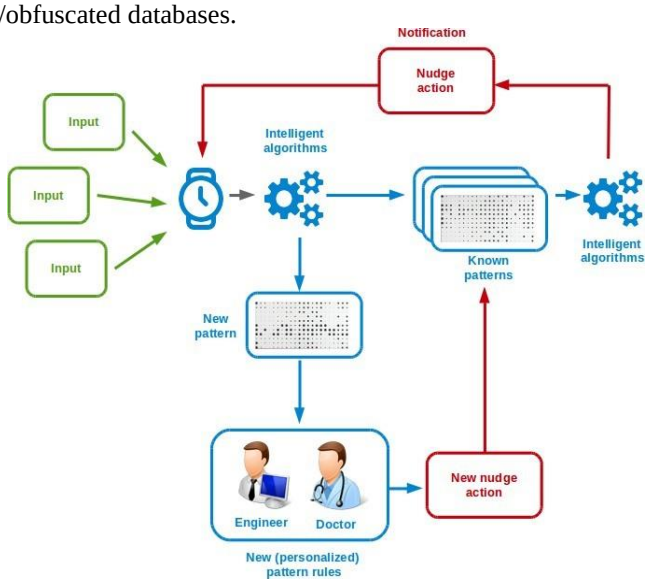

Figure 1. CHANGE Project IT architecture - Retrieved from Pietrabissa G. et al., 2019 [40]

3.4. Sample size and 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 × 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 × time interaction effects) as well as moderating and mediating effects will be tested with the General Linear Model. 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. Further analysis will be performed using advanced informatics approaches to detect the most useful sorting algorithms to understand and address chronic conditions.

4. Expected results and conclusion

Continuous data integration through predictive analytic methods will improve knowledge of CDs and its determinants. Moreover, real-time monitoring and tutoring (experimental condition) are expected to prevent or decelerate the worsening of clinical conditions of patients with CDs – compared to the control condition. Decreased hospitalizations, and improved high-quality care will follow. Increased pa- tient-

provider interactions and direct involvement of patients with CDs in decision- making processes and virtual communities will also enhance individuals' engagement, motivation to change and perceived self-efficacy. In addition, high-quality and personalized care will contribute to a more sustainable healthcare system.

References

1. *Global, regional, and national incidence, prevalence, and years lived with disability for 354 diseases and injuries for 195 countries and territories, 1990-2017: a systematic analysis for the Global Burden of Disease Study 2017.* Lancet, 2018. **392**(10159): p. 1789-1858.
2. World Health Organization, *Global status report on noncommunicable diseases*, 2014: http://www.who.int/nmh/publications/ncd-status-report2014/en/.
3. Adams, M.L., et al., *The impact of key modifiable risk factors on leading chronic conditions.* Prev Med, 2019. **120**: p. 113-118.
4. Moussavi, S., et al., *Depression, chronic diseases, and decrements in health: results from the World Health Surveys.* Lancet, 2007. **370**(9590): p. 851-8.
5. M, D.E.H., et al., *Physical illness in patients with severe mental disorders. I. Prevalence, impact of medications and disparities in health care.* World Psychiatry, 2011. **10**(1): p. 52-77.
6. Yaribeygi, H., et al., *The impact of stress on body function: A review.* EXCLI J, 2017. **16**: p. 1057-1072.
7. Pietrabissa, G., et al., *The MOTIV-HEART Study: A Prospective, Randomized, Single-Blind Pilot Study of Brief Strategic Therapy and Motivational Interviewing among Cardiac Rehabilitation Patients.* Front Psychol, 2017. **8**: p. 83.
8. Jackson, C.A., et al., *Lifestyle and Socioeconomic Determinants of Multimorbidity Patterns among Mid-Aged Women: A Longitudinal Study.* PLoS One, 2016. **11**(6): p. e0156804.
9. Liyanage, H., et al., *The Evidence-base for Using Ontologies and Semantic Integration Methodologies to Support Integrated Chronic Disease Management in Primary and Ambulatory Care: Realist Review. Contribution of the IMIA Primary Health Care Informatics WG.* Yearb Med Inform, 2013. **8**: p. 147-54.
10. *"Stop the global epidemic of chronic disease"--new report, preventing chronic diseases: a vital investment estimates hundreds of billions of dollars at stake.* Indian J Med Sci, 2005. **59**(10): p. 463-5.
11. Center for the Advancement of Health, *An Indexed Bibliography on Self-management for People with Chronic Disease*1996 Washington, D.C: Center for the Advancement of Health,.
12. Lorig, K.R. and H. Holman, *Self-management education: history, definition, outcomes, and mechanisms.* Ann Behav Med, 2003. **26**(1): p. 1-7.
13. Pietrabissa, G., et al., *Addressing motivation in globesity treatment: a new challenge for clinical psychology.* Front Psychol, 2012. **3**: p. 317.
14. Pietrabissa, G., *Group Motivation-Focused Interventions for Patients With Obesity and Binge Eating Disorder.* Front Psychol, 2018. **9**: p. 1104.
15. Cattivelli, R., et al., *ACTonHEALTH study protocol: promoting psychological flexibility with activity tracker and mHealth tools to foster healthful lifestyle for obesity and other chronic health conditions.* Trials, 2018. **19**(1): p. 659.

16. Ouwens, M., et al., *Integrated care programmes for chronically ill patients: a review of systematic reviews.* Int J Qual Health Care, 2005. **17**(2): p. 141-6.
17. Bodenheimer, T., E.H. Wagner, and K. Grumbach, *Improving primary care for patients with chronic illness.* JAMA, 2002. **288**(14): p. 1775-9.
18. Wagner, E.H., et al., *A survey of leading chronic disease management programs: are they consistent with the literature?* Manag Care Q, 1999. **7**(3): p. 56-66.
19. Dunn, P. and S. Conard, *Chronic Care Model in research and in practice.* Int J Cardiol, 2018. **258**: p. 295-296.
20. Berwick, D.M., *Reflections on the Chronic Care Model-23 Years Later.* Milbank Q, 2019. **97**(3): p. 665-668.
21. Kadu, M.K. and P. Stolee, *Facilitators and barriers of implementing the chronic care model in primary care: a systematic review.* BMC Fam Pract, 2015. **16**: p. 12.
22. Wagner, E.H., *Organizing Care for Patients With Chronic Illness Revisited.* Milbank Q, 2019. **97**(3): p. 659-664.
23. Boon, H.S., et al., *The difference between integration and collaboration in patient care: results from key informant interviews working in multiprofessional health care teams.* J Manipulative Physiol Ther, 2009. **32**(9): p. 715-22.
24. Donovan, D.M. and G.A. Marlatt, *Recent developments in alcoholism:behavioral treatment.* Recent Dev Alcohol, 1993. **11**: p. 397-411.
25. Pardell, H., *Antihypertensive strategy: a current and prospective review.* Am J Cardiol, 1990. **65**(17): p. 2H-5H.
26. Castelnuovo, G., et al., *A Stepped Care mHealth-Based Approach for Promoting Patient Engagement in Chronic Care Management of Obesity with Type 2 Diabetes*, in *Transformative Healthcare Practice through Patient Engagement*, G. Graffigna, Editor 2016, IGI Global Editors.
27. Castelnuovo, G. and K.M.G. Schreurs, *Editorial: Pain Management in Clinical and Health Psychology.* Front Psychol, 2019. **10**: p. 1295.
28. Giusti, E.M., et al., *The Economic Utility of Clinical Psychology in the Multidisciplinary Management of Pain.* Front Psychol, 2017. **8**: p. 1860.
29. Tamburin, S., et al., *Pharmacological and non-pharmacological strategies in the integrated treatment of pain in neurorehabilitation. Evidence and recommendations from the Italian Consensus Conference on Pain in Neurorehabilitation.* Eur J Phys Rehabil Med, 2016. **52**(5): p. 741-752.
30. Katon, W., et al., *Stepped collaborative care for primary care patients with persistent symptoms of depression: a randomized trial.* Arch Gen Psychiatry, 1999. **56**(12): p. 1109-15.
31. Von Korff, M. and B. Tiemens, *Individualized stepped care of chronic illness.* West J Med, 2000. **172**(2): p. 133-7.
32. Castelnuovo, G., et al., *Managing chronic pathologies with a stepped mHealth-based approach in clinical psychology and medicine.* Front Psychol, 2015. **6**: p. 407.

33. Liverpool, S., et al., *Engaging Children and Young People in Digital Mental Health Interventions: Systematic Review of Modes of Delivery, Facilitators, and Barriers.* J Med Internet Res, 2020. **22**(6): p. e16317.
34. Sendall, M., et al., *A structured review of chronic care model components supporting transition between healthcare service delivery types for older people with multiple chronic diseases.* Health Information Management Journal, 2016: p. 1-11.
35. Castelnuovo, G., et al., *Obesity and outpatient rehabilitation using mobile technologies: the potential mHealth approach.* Front Psychol, 2014. **5**: p. 559.
36. Castelnuovo, G., et al., *The STRATOB study: design of a randomized controlled clinical trial of Cognitive Behavioral Therapy and Brief Strategic Therapy with telecare in patients with obesity and binge-eating disorder referred to residential nutritional rehabilitation.* Trials, 2011. **12**: p. 114.
37. Sorgente, A., et al., *Web-Based Interventions for Weight Loss or Weight Loss Maintenance in Overweight and Obese People: A Systematic Review of Systematic Reviews.* J Med Internet Res, 2017. **19**(6): p. e229.
38. Castelnuovo, G., et al., *Chronic care management of globesity: promoting healthier lifestyles in traditional and mHealth based settings.* Front Psychol, 2015. **6**: p. 1557.
39. Meeuwissen, J.A.C., et al., *The cost-utility of stepped-care algorithms according to depression guideline recommendations - Results of a state-transition model analysis.* J Affect Disord, 2019. **242**: p. 244-254.
40. Pietrabissa, G., et al., *System of Nudge Theory-Based ICT Applications for Older Citizens: The SENIOR Project*, in *Pervasive Computing Paradigms for Mental Health*, P. Cipresso, S. Serino, and i.D. Villan, Editors. 2019, Springer, Cham: Switzerland.
41. Thaler, R.H. and C.R. Sunstein, *Nudge: Improving Decisions about Health, Wealth, and Happiness.*2009, New Haven & London: Yale University Press.
42. Zoppis, I., et al., *Online Social Space Identification. A Computational Tool for Optimizing Social Recommendations.* Applied Sciences, 2020. **10**(9).
43. Arno, A. and S. Thomas, *The efficacy of nudge theory strategies in influencing adult dietary behaviour: a systematic review and meta-analysis.* BMC Public Health, 2016. 16: p. 676.
44. Jastania, R., et al., *Utilizing Big Data in Healthcare, How to Maximize Its Value.* Stud Health Technol Inform, 2019. **262**: p. 356-359.
45. First, M.B., et al., *Structured Clinical Interview for DSM-5-Research Version (SCID-5 for DSM-5, Research Version; SCID-5-RV)*2015, Arlington, VA: American Psychiatric Association.
46. Folstein, M.F., S.E. Folstein, and P.R. McHugh, *"Mini-mental state". A practical method for grading the cognitive state of patients for the clinician.* J Psychiatr Res, 1975. **12**(3): p. 189-98.
47. Randolph, C., et al., *The Repeatable Battery for the Assessment of Neuropsychological Status (RBANS): preliminary clinical validity.* J Clin Exp Neuropsychol, 1998. **20**(3): p. 310-9.
48. Carlozzi, N.E., et al., *Factor analysis of the Repeatable Battery for the Assessment of Neuropsychological Status.* Appl Neuropsychol, 2008. **15**(4): p. 274-9.

49. Frenkel, W.J., et al., *Validation of the Charlson Comorbidity Index in acutely hospitalized elderly adults: a prospective cohort study.* J Am Geriatr Soc, 2014. **62**(2): p. 342-6.
50. Apolone, G. and P. Mosconi, *The Italian SF-36 Health Survey: translation, validation and norming.* J Clin Epidemiol, 1998. **51**(11): p. 1025-36.
51. Sarno, I., et al., *SCL-90-R Symptom Checklist-90-R Adattamento italiano*2011, Firenze Giunti, Organizzazioni Speciali.
52. Sica, C. and M. Ghisi, *The Italian versions of the Beck Anxiety Inventory and the Beck Depression Inventory-II: Psychometric properties and discriminant power*, in *Leading-Edge Psychological Tests and Testing Research*, M.A. Lange, Editor 2007, NOVA Science Publishers.
53. Baratta, S., C. Colorio, and C. Zimmermann-Tansella, *Inter-rater reliability of the Italian version of the Paykel Scale of stressful life events.* J Affect Disord, 1985. **8**(3): p. 279-82.
54. Zotti, A.M., et al., *Application of the General Perceived Self-Efficacy Scale in cardiovascular rehabilitation.* Monaldi Arch Chest Dis, 2007. **68**(3): p. 178-83.
55. Curcio, G., et al., *Validity of the Italian version of the Pittsburgh Sleep Quality Index (PSQI).* Neurol Sci, 2013. **34**(4): p. 511-9.
56. Graffigna, G., et al., *Measuring patient engagement: development and psychometric properties of the Patient Health Engagement (PHE) Scale.* Front Psychol, 2015. **6**: p. 274.
57. Pietrabissa, G., et al., *Stages of change in obesity and weight management: factorial structure of the Italian version of the University of Rhode Island Change Assessment Scale.* Eat Weight Disord, 2017. **22**(2): p. 361-367.
58. De Maria, M., et al., *Psychometric evaluation of the Multidimensional Scale of Perceived Social Support (MSPSS) in people with chronic diseases.* Ann Ist Super Sanita, 2018. **54**(4): p. 308-315.
59. Yip, M.P., et al., *Development of the Telemedicine Satisfaction Questionnaire to evaluate patient satisfaction with telemedicine: a preliminary study.* J Telemed Telecare, 2003. **9**(1): p. 46-50.
60. Gardner, B., G.J. de Bruijn, and P. Lally, *A systematic review and meta-analysis of applications of the Self-Report Habit Index to nutrition and physical activity behaviours.* Ann Behav Med, 2011. **42**(2): p. 174-87.
61. Golubic, R., et al., *Validity of electronically administered Recent Physical Activity Questionnaire (RPAQ) in ten European countries.* PLoS One, 2014. **9**(3): p. e92829.
62. World Health Organization, *International classification of functioning, disability and health: ICF*2001, Geneva World Health Organization. http://www.who.int/iris/handle/10665/42407.
63. Janca, A., et al., *The World Health Organization Short Disability Assessment Schedule (WHO DAS-S): a tool for the assessment of difficulties in selected areas of functioning of patients with mental disorders.* Soc Psychiatry Psychiatr Epidemiol, 1996. **31**(6): p. 349-54.