# **POLITECNICO DI MILANO** School of Industrial and Information Engineering Master of Science in Management Engineering



# POLITECNICO MILANO 1863

Digital Transformation of the Treatment of Eating Disorders: Matching Digital Technologies and Professionals' Psychological Determinants

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### Abstract

### English version

Eating Disorders (EDs) constitute a group of psychiatric disorders involving disturbed body image coupled with eating and/or weight loss behaviors that cause severe distress and impairment to quality of life. EDs cannot be considered just a biological illness but also a social one trigged by the cultural emphasis on thinness which is especially pervasive in Western society. Additionally, the burden of these disorders on the healthcare system is high. In fact, EDs give rise to enormous direct and indirect costs that are way above the average costs for inpatients with other diseases. For these reasons, there is an urgency for the improvement of ED treatment in most industrialized countries. Digital technologies open revolutionary new frontiers in healthcare, but current ED rehabilitation strategies are not taking advantage of the opportunities they offer.

Therefore, the present study has two main objectives. The first is to explore the opportunities provided by digital technologies for the treatment of EDs. In-person interviews have contributed on the identification of how technologies can support the current rehabilitation path of patients and what resulted was the design of an experimental study to be submitted to the ethics committee. The second aim is to explore the factors behind the intention to use digital technologies of the professional figures who treat EDs according to their impact on psychological well-being. A model based on Job Demands-Resources (JD-R) model was extended to reflect the study context and tested through a survey questionnaire distributed at national level. Using collected data, a statistical analysis was performed after transferring the theoretical model into a Structural Equation Model (SEM). Not only results have supported the link between workers wellbeing and the intention to use digital technologies, but also patient trust plays an essential role in this regard and would be worth to be further explored in future studies on digital transformation in healthcare work settings.

In conclusion, the risk of overwhelming and stress on users are elements to be considered in order to sustain the digital transformation in the long-term, hence its positive impact. Keeping that in mind, the adoption phase becomes not only the moment in which technologies are purchased and implemented, but also a reminder of the relevance of a sane and successful human-technology interaction.



### Italian version

I Disturbi del Comportamento Alimentare (DCA) costituiscono un gruppo di disturbi psichiatrici che coinvolgono un'immagine corporea disturbata associata a comportamenti alimentari e/o di perdita di peso che causano grave disagio e compromettono la qualità della vita. I DCA non possono essere considerati solo una malattia biologica, ma anche una malattia sociale a causa dell'enfasi culturale posta sulla magrezza e che è particolarmente pervasiva nella società occidentale. Inoltre, è elevato il carico di questi disturbi anche sul sistema sanitario. Infatti, i DCA causano enormi costi diretti e indiretti che sono di gran lunga superiori ai costi medi dovuti ai pazienti affetti da altre malattie. Per queste ragioni, il progresso della cura dei DCA rappresenta una delle maggiori priorità nei sistemi sanitari dei paesi industrializzati. In questo senso, le tecnologie digitali aprono nuove e rivoluzionarie frontiere ma le attuali strategie riabilitative non sfruttano le opportunità che esse offrono.

Pertanto, il presente studio ha due obiettivi principali. Il primo è quello di esplorare le opportunità offerte dalle tecnologie digitali per il trattamento dei DCA. Una serie di interviste ha contribuito a comprendere come le tecnologie possono supportare l'attuale percorso riabilitativo dei pazienti e ciò che ne è risultato è stato il disegno di uno studio sperimentale da sottoporre al comitato etico. Il secondo obiettivo è quello di esplorare i fattori che stanno alla base dell'intenzione di utilizzare le tecnologie digitali delle figure professionali che trattano i DCA in base al loro impatto sul benessere psicologico. Un modello basato sul Job Demands-Resources (JD-R) model è stato esteso per riflettere il contesto specifico dello studio e testato attraverso un questionario d'indagine distribuito a livello nazionale. Utilizzando i dati raccolti, è stata effettuata un'analisi statistica dopo aver trasferito il modello teorico in un modello di equazioni strutturali (SEM). Non solo i risultati hanno confermato il legame tra il benessere dei lavoratori e l'intenzione di utilizzare le tecnologie digitali, ma in tal senso è emerso anche il ruolo preponderante della fiducia del paziente. Varrebbe la pena di esplorare ulteriormente questo fattore in futuri studi sulla trasformazione digitale in contesti lavorativi in sanità.

In conclusione, il rischio di sopraffazione e stress sugli utenti sono elementi da considerare per sostenere la trasformazione digitale nel lungo periodo, e di conseguenza il suo impatto positivo. Tenendo presente ciò, la fase di adozione diventa non solo il momento in cui le tecnologie vengono acquistate e implementate, ma anche un promemoria dell'importanza di una sana ed efficace interazione uomo-tecnologia.



### **Executive Summary**

The treatment of psychiatric illnesses is beginning to undergo a fundamental change, driven by the widespread availability of digital technologies such as sensors, smart devices, and health information technology. Digital innovation has opened specific and new frontiers, offering clinicians, researchers, and patients new ways of providing and receiving clinical treatment, monitoring progress, and increasing understanding of mental health conditions thanks to the collection of real world data (RWD) on a permanent basis. Even so, little research has examined the deployment of digital technology adopted for other mental illnesses in Eating Disorders (EDs). Also, it is to be considered that digital technologies can be a double-edged sword that produces both positive and negative psychological experiences for professionals, affecting their propension or aversion towards them. Thus, digital transformation should be pursued taking into consideration professionals' psychological well-being.

Given the limited research evidence, the current study aims at exploring the potential of digital technologies in the treatment of EDs while matching it with professionals' psychological determinants.

### Contextual and Theoretical Background

EDs constitute a group of psychiatric disorders involving disturbed body image coupled with eating and/or weight loss behaviors that mostly affect young people, especially females in Western countries. The consequences for patients in terms of physical and mental health are serious, heavily affecting their school and/or occupational careers, and leading to death in the most severe cases. The burden of EDs on the healthcare system is also high as they give rise to enormous direct and indirect cost, way above the average costs for other diseases. Thus, EDs represent a major priority for the healthcare systems of the most industrialized countries.

Meanwhile, huge technological advances give the opportunity to face such challenges. Digital innovation is shaping the healthcare industry through a variety of solutions which encompasses health information technology (HIT), telehealth, sensor and smart technology, mobile health (mHealth), and digital therapeutics (DTx). However, before being adopted in clinical practice, they must face a complex path that passes through development and ends



in validation. In psychiatry, most digital solutions are still tested in clinical trials due to their level of innovativeness. Nevertheless, some of them are extremely promising. In particular, machine learning (ML) and text analytics are becoming increasingly useful in the context of online data analysis for the identification of alarm signals (i.e. *screening*) related to different mental illnesses, such as depression, schizophrenia, and also EDs. Concerning the therapy, different behavior and physical activity can be monitored using technologies both in the clinic and in a home environment. For example, single and multimodal wearable sensors, microphones, ear-sensor, and eye-tracking technologies not only help in decision making but also in producing new information about the psycho-physiological connections. Besides, mobile applications (mHealth) can be used to predict patient's mood, cognitive and motivational states and to deliver Cognitive Behavioral Therapy (CBT) to change unhelpful behaviors.

For successful implementation in clinical practice, not only the feasibility, safety, and effectiveness of these solutions must be proved. Also, it is of fundamental importance that people targeted as users, such as healthcare professionals, are willing to use digital technologies in their work. The propension or aversion of professionals towards digital technologies largely depends on how they affect their psychological well-being. The latter can be explained referring to the Job Demands-Resources (JD-R) model, recognized as one of the leading job stress models. The JD-R model proposes that, whatever the occupational setting, the creation of strain or motivation related to the working task is due to the balance between job demands and job resources; when this equilibrium is broken the employee might experience burnout or engagement, which lead respectively to negative or positive organizational outcomes.

### **Empirical Research**

Starting from the theoretical findings, the study designs a research protocol for an experimental study to be launched in Villa Miralago, a clinic of excellence for the treatment of eating disorders located in Cuasso al Monte (VA), Italy, based on the usage of digital technologies such as wearables, cameras and environmental sensors. In order to reach the objective, an on-field research has been performed. On a second instance, a model based on JD-R is designed and tested through a survey questionnaire distributed to the healthcare professionals of Ananke, a national network of centers that deal with EDs and contemporary



symptoms. The questionnaire also contains an exploratory section to assess the data need and digital literacy of the professional figures and perceived dynamism in the ED domain.

#### **On-field Research**

The collaboration with Villa Miralago started with a round table set with the main stakeholders and experts involved in the study, first of all the health director of the clinic and a professor of Politecnico di Milano expert in digital technologies. According to the literature review, an experiment that uses multiple technologies to support ED rehabilitation in a hospital-setting does not exist. This allowed freedom to design a unique pilot study.

As first step, it was required a data need analysis to define the interests and needs of professionals of Villa Miralago, i.e. the data needed in order to progress in the recovery of each patient. In order to obtain this information, in-person interviews were made to nutritionists, psychiatrists, a rehabilitation activities expert, a nurse, a psychologist, and an educator, for a total of 9 professionals. The output was the identification of seven different categories of data: caloric intake, caloric expenditure, sleep monitoring, compensatory behaviors, emotion tracking, and movements and dynamics.

Secondly, it was necessary to perform a technology analysis to make precise research protocol with defined digital technologies to be used in the trial, based on the need analysis and the digital technologies available on the market, both on technologies used in previous research for the therapy of psychiatric disorders and additional ones. As a result, wrist wearables, sleep monitoring sensors, smart and regular cameras, microphones, and antennas appeared to be the most feasible technologies. Additionally, it is required a customized software that collects data from all the devices, stores them in a platform and simplifies data visualization for professionals.

#### Model Design

From the literature analysis, the JD-R model have been selected as the most proper theory for explaining the dynamics behind employees' psychological well-being and its flexibility is exploited to address the focus of this study. More in detail, the impact of using digital technologies in clinical practice of healthcare professionals working with EDs, such as physicians, psychologists, nutritionists etc., is targeted through the selection of the right variables, connections and outputs.



Beside the traditional main blocks of the JD-R model (i.e. Job Demands, Job Resources, Burnout, and Engagement), the constructs Intention to Use, Psychological Safety and Patient Trust have been selected. In the adapted model, Intention to Use represent the organizational outcome resulting from the balance between Burnout and Engagement. Although job demands and resources have been linked to organizational outcomes such as job performance, organizational commitment, and absenteeism (Bakker & Demerouti, 2007; Rich et al., 2010), it is most important in the present study to understand how job demands and resources relate to intention to use digital technologies, whose adoption would eventually affect the overall healthcare organization. As suggested by previous studies, Psychological Safety is explored as a key mechanism enabling thriving in workplaces that are becoming increasingly digital. Finally, Patient Trust, seen as perceived patient trust of healthcare professionals using digital technologies, together with Burnout and Engagement, is selected as relevant predictor of Intention to Use digital technologies in healthcare work settings.

An additional step has been made to create a model that could explain with a better level of detail the elements in analysis. Specifically, Workload and Cognitive Demand have been considered as good indicators for Job Demands; Autonomy and Professional Development have been selected in relation to Job Resources; Disengagement and Exhaustion have been identified for the study as the most relevant components of Burnout; finally, Vigour and Dedication could best reflect Engagement in the phenomenon under analysis. For each of the specific areas, it has been defined a univocal scale to measure the aspect in question, selected from academic papers and slightly adapted to better fit the study.

Finally, relationships between constructs have been hypothesized, respecting the ones which connected the original blocks of the JD-R model (H1, H2, H3, H4, H5, H6) and establishing new relations for the added blocks (H7, H8, H9):

- H1. Job Demands increases healthcare professional's Burnout
- H2. Job Demands decreases healthcare professional's Engagement
- H3. Job Resources decreases healthcare professional's Burnout
- H4. Job Resources increases healthcare professional's Engagement
- H5. Burnout decreases healthcare professional's Intention to Use



- H6. Engagement increases healthcare professional's Intention to Use
- H7. Psychological Safety decreases healthcare professional's Burnout
- H8. Psychological Safety increases healthcare professional's Engagement
- H9. Patient Trust increases healthcare professionals' Intention to Use

#### Survey Questionnaire

In order to collect first-hand opinions from the potential users of digital technologies, a selfadministered, non-experimental, cross-sectional online survey was created and distributed at national level to professionals of the Ananke network. In order to test the theoretical model, a section was dedicated to the explanatory research with a total of 42 items for measuring the constructs. A scenario of reference was provided to respondents describing a system of digital technologies similar to the one conceived with the digital technology expert. Also, with another section, it has been attempted to conduct an exploratory research about data need, professionals' digital literacy, and perceived environmental dynamism in the ED domain. In total, 102 responses were collected, among which 82 considered valid for data analysis.

### Results

As already said, the final output of the on-field investigation is the research protocol for a Proof of Concept (PoC) to evaluate the feasibility of the usage of the digital technologies defined in the technology analysis in inpatient ED rehabilitation. Since there was the need to have a group of participants more homogeneous and that would have a similar rehabilitation process, it was decided to start a trial dedicated specifically to female patients affected by AN. The experiment will be marked by three main steps: an initial assessment of the patients' condition, an intermediate one to carry out an initial evaluation of the trial feasibility, and, finally, the close-out, which coincides with the end of inpatient care. Within these steps, the patient will be possible to analyze data in relation to the single patient, but also in relation to group of patients for comparing trends, if any, and getting impressions on the general mood and social dynamics in the clinic.

According to the literature, an experiment that uses multiple technologies to support ED rehabilitation, and rehabilitation from any other mental illness, in a hospital-setting does not



exist. Hence, this study opens a new chapter not only in the digitalization of the treatment of eating disorders, but also of psychiatric disorders overall.

For what concerns the exploratory research section, the survey provides a cross section of the Ananke network, considered as a proxy of the national system supporting the cure of EDs.

As for data need, healthcare professionals result to be most interested in clinical information of the patient concerning the emotional, social and psychological areas (i.e. emotions and group dynamics), rather than the nutritional and physiological one (i.e. caloric expenditure and intake). To actually understand this result, it must be considered, first of all, that that the majority of respondents are psychologists-psychotherapists. At the same time, it is true that EDs are primarily psychiatric illnesses. The satisfaction varies according to profession and clinical setting. In particular, most dissatisfaction is shown by nutritionists and psychiatrists, while psychologist show greater confidence. Moreover, less satisfaction is in inpatient settings rather than in outpatient ones, thus the former should be targeted first for the introduction of a system. These structures could adopt a system similar to the one designed for the trial in Villa Miralago. On average, the main reason of dissatisfaction with clinical information results to be its unreliability. In this sense, digital technologies can be leveraged to collect granular and objective real-life data.

Considering digital literacy, it has emerged that the majority of respondents have heard about digital technologies, and this was expected due to the high interest of the public opinion on these topics, but their actual deployment is still very low (around 5%). The lowest awareness concerns telemedicine and digital therapeutics (DTx). Awareness on the latter would be worth to be raised at national level as it emerges as particularly promising from the literature analysis.

With regard to perceived environmental dynamism, the majority of respondents believe that digital technologies will gain more and more relevance in the ED domain. Still, publications on the topic are not widely diffused yet as already emerged from the literature analysis. Additionally, a relevant result has been the high perceived pressure coming from patients (almost 60%) asking for new forms of assistance. Indeed, patients could be the drivers to the change toward a more digitalized rehabilitation path.



Finally, using the data collected with the survey, a multivariate statistical analysis has been conducted on Stata 14 for the testing phase of the explanatory research. First, construct's internal consistency and reliability was measured performing an Exploratory Factor Analysis (EFA) and computing the Cronbach's alphas: as a result, all the constructs have been validated. Secondly, hypotheses were tested in a Structural Equation Model (SEM). Sociodemographic variables were initially assumed as control variables but none of them had any significant influence, hence they were omitted from further analysis. After the validation of the measurement model through Composite Reliability (CR) and Average Variance Extracted (AVE) computation, the path analysis of the structural model revealed that all the hypotheses raised are supported with the exception of H2. Finally, the goodness of fit of the model has been evaluated through the computation of four indices: the Comparative Fit Index (CFI), the Tucker-Lewis Index (TLI), the Root Mean Square Error of Approximation (RMSEA) and the Coefficient of Determination (CD). Overall, the results show a good explanatory capability of the model proposed: the Comparative Fit Index (CFI) value of 0.917 is higher than the recommended value of 0.900, and the Tucker-Lewis Index (TLI) value of 0.904 is higher than the benchmark of 0.900. Additionally, the Root Mean Square Error of Approximation (RMSEA) value of 0.077 belongs to the adequate fit range of 0.05-0.08 (Hair et al.; 2014). Finally, the CD value of 1.000 confirms that the model explains basically the overall variance.

In few words, the explanatory research highlights that not only burnout and engagement significantly affect organizational outcomes, coherently with the literature, but also patient trust play a fundamental role in healthcare. Indeed, it is the best predictor of the chosen organizational outcome, i.e. intention to use digital technologies, and would be worth to be further explored involving patients in future studies on digital transformation in healthcare work settings.

### Limits and Future Research

The study conducted has some limitations, which could be overcome in the future with further research, and many related areas still to be explored.

With respect to the on-field research, the same approach adopted in Villa Miralago should be replicated in outpatient settings in order to identify more precisely specific data needs to monitor patients outside the residential therapy. Technology analysis and a protocol for an



experimental study in outpatient settings should be made accordingly. In Villa Miralago, the customized software for data collection hasn't been developed yet: its interface should be easy and able to give complete and integrated information to extract new significant insights at the same time. Some effort is still required after di acceptance of the ethical committee. Finally, the trial in Villa Miralago will address only patients suffering from AN. Future studies could focus on BN or BED instead.

Concerning the survey questionnaire, the main limitations come from the fact that professionals in the sample where not equally represented: indeed, almost half of them were psychologists and only 12% were psychiatrists. Moreover, data need was assessed but not validated since questions were only close-ended. As for the model, answers were based on a description of a digital system that respondents have never experienced. Thus, the perceived stress, engagement and intention to use could not fully reflect their perception of the real system. To deal with this issue during the development phase of the technology, a prototype or videotape mockup could be used to create a more realistic idea of what the system consists of.

Last but not least, the research should be extended to the patients' side, since they are obviously affected the most by digital health technologies together with professionals and play a fundamental role in their propension towards digital transformation in care delivery.



# **Table of Contents**

1.	Intr	oduction	5
1	.1.	Background and Relevance of the Problem	5
1	.2.	Italian Context	
	.3.	Research Objectives	
_	.4.	Structure of the Thesis	
TH	EOR	ETICAL RESEARCH	
2.	Stat	e of the Art	14
2	.1.	Eating Disorders	14
	2.1.1	. Epidemiology of Eating Disorders	
	2.1.2	. Standard of Care of Eating Disorders	17
2	.2.	Digital Technology in Eating Disorders	27
	2.2.1	. Digital Technology in Healthcare	
	2.2.2		
	2.2.3	. Digital Care of Psychiatric Disorders	
2	.3.	Psychological Well-being of Professionals	
	2.3.1	. Psychological Well-Being: Selection of the Model	
	2.3.2	. Job Demands-Resources Model	
3.	Res	earch Gap	
EM	(PIR)	ICAL RESEARCH	50
4.	Res	earch Questions and Research Objectives	51
5.	Met	hodology	53
5	5.1.	Theoretical Research	
U	5.1.1		
	5.1.2	•	
5	5.2.	On-field Research	
	5.2.1	. Need Analysis	
	5.2.2		
	5.2.3	. Protocol Definition	59
5	.3.	Model Design	60
5	5.4.	Survey Questionnaire	
	5.4.1	. Characteristics of the Questionnaire and Sample Selection	
	5.4.2	τ.	
	5.4.3		
	5.4.4	. Data Preparation	65
	E 4 4		
	5.4.5	. Data Analysis	



6.1.	Context Analysis	72
6.2.	Need Analysis	
6.3.	Technology Analysis	77
6.4.	Results from the On-field Research: Protocol Design	
7. Psv	chological Well-being: Model Design	
7.1.	Hypotheses Development	
	oloratory and Explanatory Research: Survey Questionnaire	
8.1.	Sections description	
	•	
8.1.1	1 5	
8.1.2	2. Explanatory Research Section	
8.2.	Data Analysis and Results	
8.2.1	•	
8.2.2		
0.2.2		
8.3.	Discussion on Survey Results	
8.3.1	1. Discussion on Exploratory Research	
8.3.2	2. Discussion on Explanatory Research	
CONCL	USIONS	
9. Cor	nclusions	
9.1.	Theoretical Contribution	
9.2.	Managerial Contribution	
	imits and Future Research	
11. R	leferences	
11.1.	Bibliography	
11.2.	Sitography	139
13. A	ppendix	
13.1.	APPENDIX 1: In-person Interviews in Villa Miralago	
13.2.	APPENDIX 2: Questionnaire	



# **Index of Figures**

Figure 1: EDs structures' diffusion	7
Figure 2: Pre-market process flow	
Figure 3: JD-R Model	
Figure 4: Research questions and objectives	51
Figure 5: Flow of the study's steps	
Figure 6: SLR steps and number of academic articles	
Figure 7: Visual description of the system used in the survey questionnaire	65
Figure 8: Organization of professional figures in the interventional areas	74
Figure 9: Information flow between professionals	75
Figure 10: Theoretical model proposed	94
Figure 11: Age of the respondents	101
Figure 12: Gender of the respondents	
Figure 13: Education level of respondents	
Figure 14: Profession of the respondents	
Figure 15: Work experience of the respondents	
Figure 16: Territorial distribution of respondents on national level	
Figure 17: Regions where the respondents work	
Figure 18: Clinical setting	
Figure 19: Number of patients that the facility takes in charge	
Figure 20: "Do you follow a prevalent diagnostic category of EDs?"	
Figure 21: "If yes, please specify which one"	104
Figure 22: "It is important to me to know these parameters"	
Figure 23: How frequent the respondents would like to know the parameters	
Figure 24: Current satisfaction of the following parameters	
Figure 25: Reasons for current dissatisfaction	
Figure 26: Current satisfaction of nutritionists	107
Figure 27: Current satisfaction of psychologists	
Figure 28: Current satisfaction of Psychiatrists	
Figure 29: Current satisfaction in Outpatient settings	
Figure 30: Current satisfaction in Inpatient settings	
Figure 31: Digital literacy of the respondents	
Figure 32: eHealth literacy	110
Figure 33: Perceived Environmental dynamism by the respondents	111
Figure 34: Extended JD-R Model	



# **Index of Tables**

Table 1. Number of services per Italian region	8
Table 2: EDs criterias	
Table 3: Screening Questions	19
Table 4: Psychometric tests	20
Table 5: Types of therapies for AN	21
Table 6: Types of therapies for BN	23
Table 7: Types of therapies BED	
Table 8: Psychotherapeutic treatments for EDs	25
Table 9: Criterias for inpatient treatment in BN and BED	26
Table 10: DTx functions	
Table 11: FDA's product evaluations' stages	35
Table 12: Patient path map, with number of articles (NA) and summary of technologie	es (T)
found in the literature classified by mental disorder and patient path phase	38
Table 13: SLR Keywords	55
Table 14: Questions for the interviews to Villa Miralago's professionals	58
Table 15: Questions for the interview to the Digital Technologies' expert	59
Table 16: Structure of the theoretical model	62
Table 17: Survey questionnaire's answers	66
Table 18: Standard of care activities performed by each professional in the clinic	75
Table 19: Information exchange between professionals	76
Table 20: Data need by each professional	77
Table 21: Suggested technologies to be used	
Table 22: Technologies excluded	79
Table 23: Eligibility criteria	81
Table 24: Survey questionnaire's statements	100
Table 25: Number of respondents per segmentation's criteria	107
Table 26: Internal consistency of the scales	112
Table 27: Internal consistency of the constructs	114
Table 28: Convergent validity of the constructs	116
Table 29: Statistical validity of the Hypothesis	117
Table 30: Goodness of Fit of the theoretical model	118
Table 31: Statistical validity of control path	119
Table 32: Effects on Intention to Use	124



# **1. Introduction**

### 1.1.Background and Relevance of the Problem

Eating Disorders (EDs) constitute a group of psychiatric disorders involving disturbed body image coupled with eating and/or weight loss behaviors that cause severe distress and impairment to quality of life. The EDs cannot be considered just a biological illness but also a social one. In fact, there is a cultural emphasis on thinness which is especially pervasive in Western society and that has been argued to be the most powerful socio-cultural factor contributing to body dissatisfaction, and so to EDs.

In particular, the eating disorders Anorexia Nervosa (AN) and Bulimia Nervosa (BN) are of great social significance because they mostly affect young people, especially females in Western countries. The consequences for patients in terms of physical and mental health are serious and heavily affect their school and/or occupational careers. In particular, AN is the psychiatric illness with the highest mortality rates due to organ failure or suicide.

The burden of these disorders on the health care system is also high. In fact, EDs give rise to enormous direct and indirect costs. Costs of  $5300 \notin$  for AN and  $1300 \notin$  for BN per patient per year are to be expected. Haas et al. calculated an average of 4647  $\notin$  in inpatient costs per patient. These costs are way above the average costs for inpatients with other diseases<sup>1</sup>. In light of these considerations, it's no wonder that EDs represent a major priority for the healthcare systems of the most industrialized countries.

At the same time, digital technologies have become a regular part of life for the majority of people in Western countries. Being incorporated in our everyday practices and communication, it is increasingly obvious that digital technologies affect many areas of our lives, including health management.

Current EDs rehabilitation strategies are not taking advantage of the opportunities offered by digital technologies to complement the traditional visits and laboratory tests. For instance, integrating technology and mental health could inform and facilitate targeted policy and initiatives, reduce costs, allow for the identification of people who need help, enable better

<sup>&</sup>lt;sup>1</sup> The Diagnosis and Treatment of Eating Disorders - Stephan Herpertz, Ulrich Hagenah, Silja Vocks, Jörn von Wietersheim, Ulrich Cuntz, Almut Zeeck



performance assessment through timely access to objective data, promote self-management and ensure "right help at the right time".

However, being part of the everyday life and working activity, not only the positive aspects of the technologies must be taken into account. The risk of overwhelming and stress on users are elements to be considered in order to maintain the adoption of digital technologies in the long-term and their consequential effectiveness<sup>2</sup>. Keeping that in mind, the adoption phase becomes not only the moment in which technologies are purchased and implemented, but also a reminder of the relevance of a sane and successful human-technology interaction.

<sup>&</sup>lt;sup>2</sup> https://hrmagazine.co.uk/article-details/technology-increasing-stress-at-work



### 1.2. Italian Context

As we already stated, EDs emerge as a major priority for the healthcare systems of the most industrialized countries, and Italy is no exception. As part of the present research has been conducted at national level and aware of the fact that many different clinical settings exist for the treatment of EDs, an overview of the available services in Italy is presented to understand how the national system works.

#### Public and private services in Italy

It is fully recognized worldwide the complexity of EDs. They concern many areas of human nature, not only organic aspects, but also nutritional as well as psychological and social. Therefore, the healthcare system needs to offer specialized services that have a multidisciplinary approach in order to contemplate all features of the disease.

The first element to be taken into account is the need for this kind of patients to be treated in the proximity of their residence, so that the treatment can be as much as continuous and intense as it needs to be. Consequently, there is the need of a widespread coverage. Focusing on the national level, in Italy there are mainly five levels of intervention:

- 1. Primary care physician or pediatrician;
- 2. Outpatient therapy;
- 3. Intensive outpatient therapy or semi-residential therapy;
- 4. Intensive residential therapy;
- 5. Hospitalization.



Even if the multidisciplinary approach is widely validated, not all Italian regions offer complete services and the distribution on the territorial level is uneven. In fact, as it can be seen in *Figure 1* there are huge differences between regions concerning the number of services offered.

Figure 1: EDs structures' diffusion



REGION	NUMBER OF SERVICES	AMBULATORY	DH	HOSPITALIZATION	RESIDENTIAL THERAPY
ABRUZZO	5	5	2	2	-
BASILICATA	2	2	2	-	1
CALABRIA	3	3	1	-	-
CAMPANIA	7	7	4	2	-
EMILIA ROMAGNA	14	12	9	7	3
FRIULI VENEZIA GIULIA	7	7	2	2	-
LAZIO	10	8	5	3	2
LIGURIA	8	8	4	4	2
LOMBARDIA	21	18	14	13	6
MARCHE	6	6	5	4	-
MOLISE	-	-	-	-	-
PIEMONTE	6	6	4	3	-
PUGLIA	2	2	2	-	-
SARDEGNA	3	3	1	1	-
SICILIA	8	8	5	2	1
TOSCANA	13	10	7	4	4
TRENTINO ALTO ADIGE	8	6	-	1	2
UMBRIA	9	7	5	1	3
VALLE D'AOSTA	2	1	1	1	1
VENETO	10	10	6	4	2
TOTALI	144	129	79	54	27

Table 1. Number of services per Italian region

However, the image does not show the levels of intervention described above. If it is taken into account not only the number, but the "depth" of intervention, many deficiencies can be found even in regions where apparently there is enough number of services (as shown in *Figure2*). The synergy between local associations and institutions can help in this issue: they have the whole picture on the level of the real offer of the healthcare system.



The factors described above have brought to several critical issues:

- The uneven territorial distribution of infrastructures that offer intensive residential therapy and hospitalization. Usually, this issue brings to extra-regional requests from regions that have a lower number of services;
- The multidisciplinary team needed for the rehabilitation process is not always available in all regions. Thus, there is the need of many collaborations between departments that are often not efficient and effective, i.e. many economic resources and time are wasted in order to exchange resources between departments;
- On the national level, there are few services that are able to treat patients under 14 years old. In fact, in Italy there are just 5 residences that accept and are able to treat them;
- Only 9 regions cover all levels of cure, thus in all other regions is not possible to continuously support patients during their healing path. In fact, Molise have an absolute absence of these services and Sardinia offers just hospitalization.

SIRIDAP ("Società Italiana di Riabilitazione Interdisciplinare Disturbi Alimentari e del Peso") stated that the outpatient therapy is in the core of the patient path, since it performs both the diagnosis and the rehabilitation. For this reason, it operates as a filter for other steps (when needed).

For what concerns the financing of the treatments, in Italy there is a tax exception identified with the *code 005*, specifically for AN and BN. However, these economic terms are used to support just some medical examinations, psychotherapeutic sessions and, in case of minors, also psychiatric control sessions.

Therefore, outpatient and residential therapy are not accessible to all people affected by EDs since it is not covered by the public healthcare system. This is highly risky, because people have not access to the cure (only the 68.8% of patients have access to them<sup>3</sup>) and it is highly probable that the patient state will get worse, instead of healing with a proper therapy.

This situation does not concern just patients and their families, but also the public healthcare system, since a chronicity of the cure could lead to higher costs i.e.  $800 \notin$ /day is the cost for an urgent hospitalization, while rehabilitation costs  $250 \notin$ /day.

<sup>&</sup>lt;sup>3</sup> Swanson, 2011



### 1.3. Research Objectives

Given the limited evidences on the topic, the main purpose of the present work is to investigate the above-mentioned potential of digital technologies in the ED domain. The starting point is the assessment of the intention of healthcare professionals operating in this field to adopt such technologies in clinical practice and the way technologies could work in practice in order to take advantages of the opportunities they offer.

In this regard, the research objectives of the present thesis are two, illustrated as follows.

Firstly, the research aims at understanding the potential of digital technologies in ED rehabilitation. For this purpose, an on-field investigation in Villa Miralago, a clinic which represents an exemplary case for the treatment of EDs in Italy, has been conducted. Miralago presents favorable conditions to study technologies' adoption of the different professionals' profiles that operate in the ED domain and to foster the co-creation of a digital system to be implemented in the clinic. Accordingly, it is designed a research protocol for an experimental study to be launched in Villa Miralago, based on a digital system that encompasses the usage of digital technologies such as wearables, cameras, environmental sensors and a platform to aggregate the real world data (RWD) collected. The final beneficiaries of the study will be the patients and the professionals involved, as the study should improve the effectiveness of rehabilitation strategies for EDs and empowering professionals.

Secondly, the research aims at developing and testing an adaptation of Job Demands-Resources (JD-R) model (Demerouti et al., 2001), recognized as one of the leading job stress models. The adapted model considers Burnout and Engagement, together with Patient Trust, as proximal antecedents of the Intention to Use digital technologies in clinical practice. Therefore, Intention to Use represents the Organizational Outcome of the adapted JD-R Model. Within the adapted model, also Psychological Safety in the workplace is taken into account, beside Job Demands and Job Resources. The model is tested at a national level by addressing a survey to Ananke, a national network of centers engaged in the treatment of EDs. Through the questionnaire, it is also assessed the data need and digital literacy of the professional figures together with perceived dynamism in the ED domain.



### 1.4. Structure of the Thesis

The thesis is divided into three main chapters: (1) Theoretical research; (2) Empirical Research; (3) Conclusions.

The theoretical research (1) explores three main sections:

- Eating Disorders;
- Digital technologies in Eating Disorders;
- Psychological Wellbeing of Professionals.

For what concerns the first part, the epidemiology of the diseases is described followed by the current procedures with which these diseases are treated called Standard of Care.

The second part opens with the description of digital technologies applied in the healthcare sector, currently or ready for future applications. There are many different categories of technologies that since they found an application in healthcare are called eHealth. In order to understand how these technologies are developed for reaching potential customers and beneficiaries, a section is dedicated to the Pre-market process and Validation. The conclusion of the second part of the Theoretical Research focuses on the application of the technologies previously introduced for the treatment of psychiatric disorders.

For what concerns the third part, the psychological wellbeing of professionals is introduced. The current study, in fact, aims at understanding the psychological dynamics behind the intention to use digital technologies, thus connecting the acceptance of the innovation to the professional's health and wellbeing. For this reason, the selection of the model and the description of the chosen model i.e. Job Demands-Resources model are presented.

The Empirical Research (2) is divided into two main parts:

- On-field research;
- Model design and testing.

The on-field research opens with the description of the context in which the first part of the research has been carried out i.e. Villa Miralago, a rehabilitation center for patients affected by EDs in the north of Italy. The first section of this part describes the data needed by the different professional figures of the center with the aim to improve the rehabilitation process. The output is the set of information that each professional figure would like to access and currently is not able to collect. Starting from this result, the technology analysis is described. It has been carried out through an in-person interview to a professor of Computer Science,



expert in digital technologies, in order to understand which technology could be used to collect the data needed by professional figures curing EDs. The result is the set of technologies that could be implemented in Villa Miralago in order to fill in the missing information. In order to access the feasibility of the results emerged from the previous analysis, the Proof of Concept has been designed through a clinical trial. For this reason, the on-field research ends with the design of the protocol for this trial to be carried out in Villa Miralago, with a focus on Anorexia Nervosa.

The second part concerns the survey questionnaire. At first a description of the question is available, with the construct used for the theoretical model. Afterwards the descriptive analysis is presented together with a section that describes the current satisfaction of the professional figures on the information emerged from the interviews. In order to access the current digital literacy of professionals, the knowledge and usage of technologies is analyzed. In many studies the knowledge of the environment is a key element for future changes and innovations. For this reason, the environmental dynamism perceived by the respondents of the questionnaire is described. The second part of the empirical research ends with the discussion of the results i.e. the structural relationships between measured variables and latent constructs of an expanded JD-R model were analyzed through a multivariate statistical analysis.

The last section (3) presents the conclusions of the work with the description of the main contributions, limits and future researches emerged throughout the study.



# **THEORETICAL RESEARCH**



# 2. State of the Art

This chapter introduces the highest level of development currently achieved in eating disorders treatment with specific focus on digital innovation. In order to assess it, a detailed analysis of academic literature was performed.

In the present work, State of the Art is organized according to three main blocks:

- 1. First, a general overview of EDs is provided, which examines epidemiology and standard of care of EDs;
- As a complement of the previous block, a review of digital technologies which hold potential in the treatment of psychiatric disorders follows. The analysis has been broadened to psychiatric disorders, which include EDs as well, because of the extreme novelty of the topic in the ED domain;
- Finally, professionals' attitude towards digital technology introduction is considered, under the perspective of its effect on their psychological well-being. In this regard, the traditional Job Demands-Resources (JD-R) Model (Demerouti et al., 2001) and its main components are illustrated.

This contextualization lead to the identification of research gaps and serves as theoretical background for the empirical research conducted in the second part of the thesis, with the final aim to reach the research objectives.

### 2.1. Eating Disorders

Eating Disorders (EDs) are psychiatric disorders defined by abnormal eating habits that negatively affect a person's physical and/or mental health.

According to the *Diagnostic and Statistical Manual for Mental Disorders, Fifth Edition* [DSM-5], EDs include Anorexia Nervosa (AN), Bulimia Nervosa (BN), Binge Eating Disorder (BED), and other specified and unspecified EDs (previously known as ED not otherwise specified or EDNOS)<sup>4</sup>.

<sup>&</sup>lt;sup>4</sup> Until the publication in the year 2013 of the Diagnostic and Statistical Manual of Mental Disorders Fifth Edition (DSM-5), according to which there are six specific diagnoses for EDs: (1) Anorexia Nervosa (AN), (2) Bulimia Nervosa (BN), (3) Binge Eating Disorder (BED), (4) Pica, (5) Rumination Disorder (RD), and (6) Avoidant/Restrictive Food Intake Disorder (ARFID). Moreover, the DSM-5 classification includes two "umbrella" diagnoses: (7) Other Specified Feeding or Eating Disorder (OSFED) and (8) Unspecified Feeding or Eating Disorder (UFED).



- Anorexia Nervosa (AN) is characterized by self-induced malnutrition with weight loss. According to the diagnostic criteria, the body weight is so low that health impairment is to be feared;
- Bulimia Nervosa (BN) refers to the uncontrollable urge for frequent high-caloric food. This is translated into episodes of excessive uncontrolled eating alternate with rigorous fasting, vomiting, and abuse of laxatives and/ or diuretics;
- Binge-Eating Disorder (BED) is characterized by frequent and recurrent binge eating episodes with associated negative psychological and social problems (e.g., problems with self-worth and shame, depression, social phobia), but without subsequent compensatory behaviors (e.g. vomiting).

EDs do not include obesity. In fact, obesity is a chronic condition, which can be related to psychiatric disorders, but not a psychiatric disorder itself.

The determinants and distribution of EDs among the general population and the current treatment guidelines for EDs will be deepened in the upcoming paragraphs.

### 2.1.1. Epidemiology of Eating Disorders

The first topic that needs to be described in-depth is the epidemiology of EDs. The ED field lags behind other psychiatric fields (e.g. mood, anxiety, and psychotic disorders) in the progress of epidemiological research. Reasons for this delay in the research field may include the fact that EDs have been excluded from some large national surveys in favor of other mental illnesses. Furthermore, for epidemiological studies on EDs there are some methodological issues. In fact, the vast majority of people in the community with EDs do not seek or receive treatment. Thus, the identification of affected subjects would require the recruitment and diagnostic assessment of particularly large population samples, a complex and costly task. For these and other reasons, that include factors such as the year of assessment, the population group being sampled, the assessment methodology used (from structured interview to self-report), and the diagnostic classification system that is imposed (e.g. the *Diagnostic and Statistical Manual for Mental Disorders* [DSM] or the *International Classification of Diseases* [ICD]), estimates range considerably between studies.



#### Causes

It has been demonstrated that EDs can be related to some genetic characteristics and personality traits. About 50% of EDs cases are attributable to genetics and an individual who is a first degree relative of someone who has had or currently has an ED is seven to twelve times more likely to have an ED themselves<sup>5</sup>. Personality traits associated with the development of EDs are perfectionistic tendencies, emotional instability, hypersensitivity or obsessive thinking. Moreover, EDs are often related to other mental illnesses such as depression, anxiety, obsessive-compulsive disorder and bipolarity<sup>6</sup>.

Also, environmental influences play a role. Sexual or physical abuse and social isolation have been implicated as triggering factors; parental influence has been shown to be an intrinsic component in the development of EDs of children; in various studies, peer pressure was shown to be a significant contributor to body image concerns and attitudes toward eating among subjects in their teens and early twenties; finally, there is a cultural emphasis on thinness which is especially pervasive in western society. There is a relationship between "thin ideal" social media content and body dissatisfaction and EDs among young adult women. A cultural risk factor so is the world of sports: athletes and EDs tend to go hand in hand, especially concerning sports where weight is a competitive factor.

#### Incidence

In the present paragraph, incidence rates for AN, BN and BED are discussed but not for "other specified and unspecified EDs". In fact, researchers have operationalized "other specified and unspecified EDs" in different ways. Reported incidences are therefore difficult to compare and in community studies the use of limited definitions underestimates the true prevalence of eating pathology that could be classified as "other specified and unspecified EDs".

#### Anorexia Nervosa

AN is estimated to occur ten times more commonly among women than men. In Western countries, it is estimated to affect between 0.9% and 4.3% of women and 0.2% to 0.3% of men at some point in their life. Instead, less information is provided for rates in most of the

<sup>&</sup>lt;sup>5</sup> https://en.wikipedia.org/wiki/Eating\_disorder#Genetics (55 Patel, P; Wheatcroft, R; Park, R; Stein, A (2002). "The Children of Mothers With Eating Disorders". *Clinical Child and Family Psychology Review*. 5 (1): 1–19. doi:10.1023/A:1014524207660. PMID 11993543. 56^ Trace, SE; Baker, JH; Peñas-Lledó, E; Bulik, CM (2013). "The genetics of eating disorders". *Annual Review of Clinical Psychology*. 9: 589–620. doi:10.1146/annurev-clinpsy-050212-185546. PMID 23537489.)

<sup>&</sup>lt;sup>6</sup> Gobierno de México, Guías clínicas: trastornos alimentarios



developing world. Often it begins during the teen years or young adulthood. The average frequency of AN in young women aged between 14 and 20 years varies between 0.2% and 0.8%.

The 10-year mortality in this group is around 5%. This is considerably more than 10 times the mortality from other causes in this age group in the general population. EDs also increase a person's risk of death from a wide range of other causes, including suicide. For what concerns AN, 5% of the affected population die from complications over a ten-year period, a nearly six times increased risk.

A critical factor to be taken into account is the effectiveness of the current treatments. Follow-up studies have shown that around 40% of patients with AN show good treatment success, while 25% have moderate and 30% poor treatment success.

#### Bulimia Nervosa

At 2%, BN has a notably higher prevalence than AN. As in the case of AN, BN affects women in the large majority of cases; men are affected in only 5% to 10% of cases.

According to studies in the USA, about 50% of patients with BN are free of symptoms after more than 5 years from the end of the treatment, while about 20% continue to fulfill all the criteria of the disorder.

#### Binge Eating Disorder

The diagnosis BED was incorporated by the American Psychiatric Association in the fourth revision of the *Diagnostic and Statistical Manual of Mental Disorders (DSM-IV)* in 1994; in *the International Classification of Diseases (ICD-10)* it can only be coded under the category "eating disorder, unspecified".

For this reason, the course of BED has been the object of less research than AN and BN, but its prognosis is better. Remission rates in outpatient psychotherapy range between 50% and 80%.

The prevalence of BED varies in the general population between 0.7% and 4.3%; women are affected about 1.5 times as often as men.

### 2.1.2. Standard of Care of Eating Disorders

In the present paragraph, the standard of care of EDs is illustrated in line to the phases of the "patient path", i.e. the route patients will take if they are referred for treatment by their primary care physician or other health professional. The pathway gives an outline of what is



likely to happen on the patient's journey and can be used both for patient information and for planning services.

Regardless of the patient or disease, the patient path is articulated as follows:

- 1. Screening, i.e. the identification of the disease in the early stage, enabling preventive intervention to reduce mortality and suffer;
- 2. Diagnosis, i.e. the systematic identification and explanation of the individual's symptoms that confirms the information found through the screening;
- 3. Therapy, i.e. actual treatment to relieve or heal the disorder;
- 4. Follow-up, i.e. either continuous or periodic checks that follow the recovery after the therapy.

#### Screening

A preliminary diagnosis of AN is easier than one of BN or BED, mostly because the patient is visibly underweight.

BN can be difficult to detect compared to AN, because bulimics tend to be of average or slightly above or below average weight. Good indicators of BN are female sex, peak manifestation at the age of 18, weight fluctuations, and in particular emotional and mental obsession on body weight, eating, and physical activity.

BED, unlike AN and BN, does not usually reach the level of a disorder except in the context of overweight and obesity, especially when the ED is perceived both subjectively and objectively as counterproductive in the desire to lose weight.

Diagnosis of an ED requiring treatment should be on the basis of positive screening according to the criteria of ICD-10 or DSM-IV (*Table 1*). In addition to measuring height and weight, the screening questions in *Table 2* are appropriate.



### CRITERIA FOR SUSPECTING AN ED

- Low body weight
- Amenorrhea or infertility
- Dental damage, especially in young patients
- Worries about body weight even though it is normal
- Unsuccessful attempts to lose weight in patients who are overweight or obese
- Gastrointestinal disorders that cannot be ascribed to another medical cause
- Delayed growth in children
- Parents worried about their child's weight and eating behavior

Table 2: EDs criterias

#### **SCREENING QUESTIONS**

- "Are you happy with your eating behavior?"
- "Are you worried about your weight or your food?"
- "Does your weight affect your feeling of self-worth?"
- "Do you worry about your figure?"
- "Do you eat in secret?"
- "Do you vomit when you feel uncomfortably full?"
- "Are you worried because sometimes you can't stop eating?"

Table 3: Screening Questions

#### Diagnosis

There are no specific tests to ensure that a person suffers from an ED. The initial diagnosis should be made by the primary care physician. The primary care physician must be skilled in recognizing and diagnosing these disorders, as there are many mental disorders that mimic EDs and comorbid psychiatric disorders.

The diagnostic assessment includes the person's biographical and family history, together with current circumstances and symptoms. The assessment also includes a mental state examination performed by a mental health professional. The clinician conducts a clinical interview and may employ various psychometric tests. Some are general in nature while others were devised specifically for use in the assessment of EDs.

<b>PSYCHOMETRICS TEST</b>				
General				
Hamilton Depression Rating Scale				
Beck Depression Inventory				

Table 4: Psychometric tests

#### Therapy

Treatment varies according to type and severity of ED, and usually more than one treatment option is used. Treatment can take place in a variety of different clinical settings. The American Psychiatric Association (APA) recommends a multidisciplinary team approach to EDs' treatment, as already said above. The team consists usually of a psychiatrist, therapist, and registered dietitian. However, other clinicians may be included.

#### Anorexia Nervosa

The treatment of AN generally involves nutritional rehabilitation and psychotherapy. In fact, the goal of its treatment is normalizing body weight and eating behavior and treating the psychological disorders related to the illness. In addition, patients should be monitored for medical complications.

The possible types of therapies and the appropriate clinical setting for AN are illustrated in *Table 4*.



TYPE OF	DESCRIPTION
THERAPY Nutritional	Nutrition management is the most essential factor to work on with
rehabilitation	people affected by AN, especially at the start of treatment. Diet
	must be tailored to each person's needs. Food variety is important
	when establishing meal plans as well as foods that are higher in
	energy density. People must consume adequate calories, starting
	slowly, and increasing at a measured pace.
Psychotherapy	Standard treatment of AN includes psychotherapy. Although
	several therapies have been adapted or developed to treat the
	disorder, there is no compelling evidence that one therapy is
	clearly superior to the others. The moderate to low level of
	evidence is due to low case numbers, the lack of valid control
	conditions, and the use of multimodal therapy approaches. Thus,
	the choice is based upon availability, patient age, patient
	preference, and cost. The options include Cognitive Behavioral
	Therapy (CBT), Interpersonal Psychotherapy (IPT),
	Psychodynamic Therapy (PT), and Family Therapy (FT). (Table
	8)
Pharmacotherapy	Pharmacotherapy is not an initial or primary treatment for AN.
	However, adjunctive pharmacotherapy is indicated for acutely ill
	patients who do not gain weight despite initial treatment with
	nutritional rehabilitation and psychotherapy.
	Psychopharmaceuticals are occasionally used to treat comorbid
	depressive symptoms.
	CLINICAL SETTING
Treating AN is a long	process and usually requires a management plan including inpatient,
	atient treatment. However, there are no confirmed empirical data that

day patient, and outpatient treatment. However, there are no confirmed empirical data that allow an evidence-based decision for a particular setting. One of the primary factors in deciding upon level of care is severity of weight loss and malnutrition. Body mass index (BMI) is the metric most used to measure weight loss and to determine weight goals.

Table 5: Types of therapies for AN



## Bulimia Nervosa

BN is often accompanied by comorbid psychological disorders, such as depression, anxiety, and personality disorders. Often these must be regarded as separate conditions and they need to be taken into account in the treatment plan. In addition, patients should be monitored for medical complications. Standard treatment for BN includes nutritional rehabilitation, psychotherapy, and pharmacotherapy.

The related information together with clinical setting for BN are reported in *Table 5*.

TYPE OF THERAPY	DESCRIPTION
Nutritional	BN causes dehydration, electrolyte imbalance, anemia, and low
rehabilitation	levels of sodium, potassium, and magnesium in the body. In the
	case of recovery from BN, the medical nutrition therapy must
	include a meal plan that offers sufficient calories, vitamins,
	minerals, essential nutrients and hydration that guarantee adequate
	nourishment and replenishment of any nutrient losses in the body.
	To break the cycle of bingeing and compensation, patients must
	learn to structure and pace meals.
Psychotherapy	Psychotherapeutic treatments have been shown to be effective and
	are the treatment methods of choice. In relation to the core
	symptoms - loss of control in eating and vomiting as
	compensatory behavior - they achieve moderate to large effect
	sizes (mean reduction by 70%). CBT for BN is the
	psychotherapeutic method that has been most researched and for
	which the highest level of evidence exists. IPT shows a
	comparable efficacy to CBT. Although CBT is seen as more cost
	efficient and helps individuals with BN in self-guided care,
	family-based therapy (FBT) might be more helpful to younger
	adolescents who need more support and guidance from their
	families. Other psychotherapies are possible if CBT is not
	available, appears to be ineffective in a particular case, or is not
	wanted. Psychodynamic Therapy (PT) may be recommended as an
	alternative. (Table 8)



Pharmacotherapy	Pharmacotherapy combined with nutritional rehabilitation and	
	psychotherapy is indicated for treatment of BN, as well as	
	comorbid anxiety and depressive disorders. Selective Serotonin	
	Reuptake Inhibitors (SSRIs) represent the first choice of drug	
	therapy in terms of symptom reduction, adverse effects profile,	
	and patient acceptance. However, if nutritional rehabilitation and	
	psychotherapy are not available, pharmacotherapy alone is	
	reasonable, in conjunction with self-help workbooks and	
	educational material for patients and family members to read.	
	Most of self-help therapy manuals contain the essential elements	
	of CBT.	
CLINICAL SETTING		
Inpatient treatment for BN is indicated whether the criteria in <i>Table 9</i> are met.		

Table 6: Types of therapies for BN

## Binge Eating Disorder

Even if treatment of BED generally involves psychotherapy, pharmacotherapy can be considered. For overweight or obese patients with BE, behavioral weight loss therapy may be beneficial. Other treatments for BED include lifestyle interventions like peer support groups and investigation of hormonal abnormalities. In addition, patients should be monitored for medical complications.



TYPE OF THERAPY	DESCRIPTION		
Psychotherapy	Studies of BED are mainly based on CBT. 50 percent of BED		
	individuals achieve complete remission from binge eating. While		
	CBT is very effective in terms of symptoms, i.e. on the frequency		
	of bingeing or the number of days with binges, and of self-image		
	issues and psychiatric comorbidities, e.g., depression, only small		
	effects are shown in terms of weight loss. The same is for more		
	recent studies on IPT. Interventions on the basis of guided self-		
	help manuals largely correspond to those of CBT-BED.		
Pharmacotherapy	There are no drugs officially licensed for the treatment of BED,		
	but three classes of medications are used: antidepressants,		
	anticonvulsants, and anti-obesity medications. Antidepressant		
	medications of the SSRI have been found to effectively reduce		
	<ul><li>episodes of binge eating and reduce weight. Similarly,</li><li>anticonvulsant medications, such as topiramate and Zonisamide,</li><li>may be able to effectively suppress appetite. Trials of</li></ul>		
	antidepressants, anticonvulsants, and anti-obesity medications		
	suggest that these medications are superior to placebo in reducing		
	binge eating. The long-term effectiveness of medication for BED		
	is currently unknown. Pure pharmacotherapy appears inferior to		
	CBT.		
	CLINICAL SETTING		
Inpatient treatm	Inpatient treatment for BED is indicated whether the criteria in <i>Table 9</i> are met.		

Table 7: Types of therapies BED



#### **PSYCHOTHERAPEUTIC TREATMENTS FOR EDs**

- **Cognitive-behavioral therapy (CBT)** CBT encourages patients to change the dysfunctional cognitions (thoughts and beliefs about body weight and shape) and behavioral disturbances (eg, excessive food restriction) that perpetuate anorexia nervosa, and places less emphasis upon the factors that caused the disorder;
- Interpersonal therapy (IPT) IPT aims to tackle problems relating to personal relationships with the idea of reducing the need to comfort eat. Patients are more likely to be referred to this form of treatment if they have recently suffered the loss of loved ones or experienced a big change in their lives;
- Psychodynamic Therapy (PT) Time-limited PT addresses conscious and unconscious meanings of ED symptoms, the effects of symptoms upon current relationships, and the patient's relationship with the therapist, and does not advise patients about eating behaviors;
- Family Therapy (FT) FT can benefit adolescents with AN. Preliminary evidence suggests that it may be efficacious in the treatment of adolescents with BN as well. One type of family therapy is called family-based treatment (FBT), which is used for adolescents and focuses upon weight gain; the treatment initially places parents in charge of making decisions about appropriate eating and related behaviors, with the support of a family therapist. As patients begin to improve, control overeating is gradually transferred back to them, and other issues related to family functioning are addressed. Another type of family therapy for adolescents with AN is called parent-focused treatment, in which a therapist meets with only the parents while a nurse meets with the patient for monitoring.

Table 8: Psychotherapeutic treatments for EDs



#### INDICATION CRITERIA FOR INPATIENT TREATMENT FOR BN AND BED

- Insufficient change during outpatient treatment
- Failure of outpatient or day patient treatment
- Absence of adequate outpatient care facilities near the patient's home
- Extensive psychological and physical comorbidity (e.g., self-harm, type I diabetes mellitus) that necessitates close monitoring by a physician
- Severe disease (e.g., poor motivation, strong habituation of symptoms, very chaotic eating behavior)
- Significant conflict in the social and family environment
- Suicidal tendencies
- Requirement for treatment by a multiprofessional team with hospital-type treatment methods (inpatient intensive care)

Table 9: Criterias for inpatient treatment in BN and BED

## Follow-up

A variety of issues come to bear in determining how to define EDs recovery, so the end of treatment with subsequent follow-up practices. Many physical, behavioral, and psychological variables need to be considered, and related indices to assess the recovery haven't been defined in any standardized way across studies. Generally, EDs can have a very long course. For AN and BN especially, full recovery is rare: there can be periods characterized by improvements, but in many cases a certain level of mental suffering and a tendency to have disturbed concerns and behavior regarding food and body remains in the long-term (i.e. after more than five years). Sometimes the disease become a chronic condition. Over the long-term, the primary care physician or other clinicians in charge of the patient should offer a physical and mental health review at least annually to people who are not receiving ongoing treatment for their ED. For example, the review should include:

- Weight or BMI (adjusted for age if appropriate);
- Blood pressure;
- Relevant blood tests;
- Any problems with daily functioning;
- Assessment of risk (related to both physical and mental health);
- An ECG, for people with purging behaviors and/or significant weight changes;
- A discussion of treatment options.



# 2.2. Digital Technology in Eating Disorders

After the description of EDs, for the purposes of the research there is the necessity to understand how digital technologies are affecting the cure of EDs.

First, the topic is contextualized through an overview of digital technologies that are shaping the healthcare sector overall. On a second instance, health technology development is illustrated: it is important to illustrate this process as it leads to commercialization, thus to the actual adoption of such technologies in clinical practice. Finally, a review of digital technologies deployed in psychiatric care, which encompasses also the ED domain, is presented. The review is not targeted exclusively to EDs, being an extremely new field of research supported by scarce evidence.

# 2.2.1. Digital Technology in Healthcare

In the current work it is needed to define as far as possible the digital health landscape even if, due to the novelty of the topic, it is in continuous transformation. Indeed, the terminology used to with regard to digital technologies in the medical field is becoming widely broad. Nevertheless, these terms have different definitions and could be used in a broader or narrower way according to the authors' different points of views. The following pages try to provide clear definitions and several example for each of these terms.

## Definitions

## eHealth

In its broader definition, eHealth could be adopted as the term that refers to different ways in which digital and electronic technologies are applied in the healthcare sector. Since the first 2000s (and also in the late 90s), several digital technologies have been used to improve health outcomes in many ways, from the diagnosis phase to the follow-up and even in prevention.

As a matter of fact, they could have been intended for one or more of the following claims:

- Prevent a medical disorder or disease;
- Optimize medication;
- Treat a medical disease or disorder;
- Customize treatment (personalized healthcare).



The main difference between technologies could lie in the aim for which they are used. Other differences could be in the type of technology applied, the degree of autonomy of the technology (e.g. the technology could communicate directly the results to the patient or it could communicate data to physicians in order to support decision making processes) or simply in the set of users (e.g. physicians and/or patients).

In the following paragraphs, the most common digital technologies applied in the healthcare sector are described through their definition and some examples of applied devices.

## Health Information Technology (HIT)

HIT (sometimes called "Health Informatics") refers to technologies that deal with the storage, retrieval, sharing and use of medical information or data. They come from the junction of two different fields, i.e. the medical and the computer science ones. Their usage enables to improve efficiency, effectiveness and safety of the services provided in healthcare. Indeed, using data through HITs means higher accuracy of the services' provision, lower costs and reduced idle times.

For example, technologies included are consumer health IT applications, electronic medical record (EMR) systems, electronic prescriptions, and clinical decision support.

## Artificial Intelligence, Machine Learning, Deep Learning

Artificial Intelligence (AI) usually refers to machines that can carry out functions usually linked to the human nature, such as learning and problem solving. For example, they can understand what people write and say, while also distinguishing facial expressions<sup>7</sup>.

Machine Learning (ML) is a subgroup of AI and refers to an algorithm that allows machines to perform a specific task without any explicit instruction, through "learning data". Indeed, it is based on Artificial Neural Network (ANN), a computational model based on the structure and functions of biological neural networks. For what concerns the medical field, ML has been mostly applied in precision diagnosis.

Deep Learning (DL) is a part of ML methods that uses multi-layered (i.e. "deep") ANN to deliver high accuracy in the analysis of "emotional" input data such as videos, images, texts and conversations. Most of the time, these data come from social media such as Facebook, Instagram or Twitter: in this case, it is common to talk about Social Media Analytics (SMA). Among others, fields in which DL has been applied are speech recognition, natural language processing, object detection and bioinformatics. Specifically, in healthcare it can be used in

<sup>&</sup>lt;sup>7</sup> https://www.experiencematters.it/2-edizione/ (September 2019)



the screening phase, in order to detect certain behavioral or social characteristics of the population. This is possible through the recognition of similarities between users' online content and input data.

#### Devices, sensors and wearables

Wireless and/or wearable devices have been spreading quickly in the last decades, thanks to the diffusion of the broadband. Most of these devices come from the industrial field, but they are quickly finding applications in healthcare. In this sector, they are usually employed to collect data and to monitor parameters related to patients - from physiological, to social and behavioral ones. The fast adoption of these kind of technologies is due to the fact that their prices are dropping and there is a higher availability of open libraries<sup>8</sup>. These technologies are useful to physicians as they can remotely program devices, have access to and monitor data even if patient's and physician's locations are different. Some examples are biometric sensors and diagnostic products. From the patients' perspective, the most diffused devices are wrist wearables, used to monitor parameters useful for fitness purposes such as heart rate and blood pressure.

#### Telehealth

Telehealth refers to the use of electronic information and telecommunication technologies to support long-distance clinical health care. Nowadays, there is not a clear definition of the term and which functions telehealth covers. Indeed, the Health Resources and Services Administration separates Telehealth from Telemedicine, which refers to clinical remote services such as diagnosis or monitoring, while the World Health Organization uses them as synonyms. In this regard, example of technologies adopted are video conferencing, streaming media, and terrestrial and wireless communications<sup>9</sup>.

Usually these technologies are required when patients and professionals have different locations, mostly in support of the population that lives in rural areas or in situations in which there are no means for transportation. Other gaps that have prescribed the diffusion of these technologies are the decreasing of funds and the restrict access to care. Primarily, what has allowed the propagation of Telehealth has been the increasing reliability of broadband connection.

<sup>&</sup>lt;sup>8</sup> https://www.iotforall.com/connected-wearable-devices-healthcare/

<sup>&</sup>lt;sup>9</sup> https://www.hrsa.gov/rural-health/telehealth/index.html



There are many different sub-groups according to the functions for which they have been created: for example, "telerehabilitation" delivers rehabilitation services through telecommunication networks, while "tele-nutrition" concerns on-line lessons or consultation by a nutritionist or a dietitian.

As for delivery, the main modes are:

- Store-and-forward ("asynchronous"): according to this model, data are collected from the patient to be analyzed offline by physicians, as well as other professional figures, once they are available. It has been proved to be a useful model in dermatology and radiology;
- Live video ("synchronous"): according to this model, patients and professionals work in a "synchronous" way, online;
- Remote patient monitoring (RPM): it allows professionals to monitor remotely their patients, using different devices. It is used mostly for the treatment of chronic diseases, such as heart diseases or diabetes, through the usage of telehealth blood pressure monitor. For example, patients with cardiovascular diseases can use a blood pressure cuff<sup>10</sup>.

The fourth model that has been defined is Mobile Health (mHealth). Due to its diffusion, a dedicated paragraph follows.

## Mobile Health

A definition used for Mobile Health (mHealth) at the 2010 mHealth Summit of the Foundation for the National Institutes of Health (FNIH) was "the delivery of healthcare services via mobile communication devices"<sup>11</sup>. This group includes all treatments delivered through a mobile device, in which patients directly receive information and/or tips. The high population growth, the low density of population (especially in rural areas) and the limited financial resources of the healthcare sector are the main factors that brought to the diffusion of these technologies. Additionally, in the last decades the diffusion of mobile devices has increased exponentially, and not only in developed countries<sup>12</sup>. Using mobile phones in

<sup>&</sup>lt;sup>10</sup> https://www.ruralhealthinfo.org/toolkits/telehealth/2/care-delivery/nontraditional-settings (September 2019)

<sup>&</sup>lt;sup>11</sup> https://www.microsoft.com/en-us/research/video/what-is-mhealth/ (video)

<sup>&</sup>lt;sup>12</sup> https://web.archive.org/web/20121203014521/http://vitalwaveconsulting.com/pdf/2011/mHealth.pdf (September 2019)



healthcare means having the opportunity to reach a part of the population that previously was isolated and had low and difficult access to medical services.

Nevertheless, mobile applications form the majority of treatments delivered through mobile devices - both from patients' and physicians' side - and their number of users doubles each year<sup>13</sup>.

Several opportunities in the medical field emerge from the usage of these technologies, such treatment customization through patient-centered services, decreased public expenses and focus on prevention phase<sup>14</sup>. The UN Foundation and Vodafone Foundation report of 2009 presents seven application categories within the mHealth field<sup>15</sup>:

- Education and awareness;
- Helpline;
- Diagnostic and treatment support;
- Communication and training for healthcare workers;
- Disease and epidemic outbreak tracking;
- Remote monitoring;
- Remote data collection.

For example, these technologies could be used to inform patients on how the treatment will be delivered, help them keeping track of some parameters relevant for behavioral changes (e.g. for fitness and nutritional reasons), or to keep in contact with a professional figure who could customize the treatment.

## Digital Therapeutics

Broadly, the term Digital Therapeutics (DTx) addresses a treatment or therapy that uses digital technologies in order to change patient's behavior.

In a more accurate way, the Digital Therapeutics Alliance states that DTx deliver evidencebased therapeutic interventions to patients that are driven by high quality software programs to prevent, manage, or treat a broad spectrum of physical, mental, and behavioral conditions<sup>16</sup>.

<sup>&</sup>lt;sup>13</sup> https://papers.ssrn.com/sol3/papers.cfm?abstract\_id=2284448

<sup>&</sup>lt;sup>14</sup> https://ec.europa.eu/digital-single-market/en/news/green-paper-mobile-health-mhealth

<sup>&</sup>lt;sup>15</sup> https://web.archive.org/web/20121203014521/http://vitalwaveconsulting.com/pdf/2011/mHealth.pdf

<sup>&</sup>lt;sup>16</sup> https://www.dtxalliance.org/dtx-solutions/ (August 2019)



Consequently, DTx differ from the common usage of digital technologies in the need of rigorous clinical evidence to prove changes in the health state. It can be used as a stand-alone practice or in conjunction with other therapies, with the aim to maximize the delivered outcomes. Across the healthcare field, DTx could satisfy unmet needs with new options, enhance and support current medical treatments and be integrated into best practices.

The usage of advanced technologies requires a deeper study in the design and usability of the technologies, clinical validation and data security. Additionally, due to the risks that could be generated, before using these technologies, regulative bodies have to approve the therapy. The technologies adopted could be, for example, mobile devices, apps, sensors, cameras and different IoT devices that collect jointly different types of data - from physiological parameters, to behavioral or social patterns.

For example, one study has adopted DTx to treat Attention Deficit Hyperactivity Disorder (ADHD) through video games supported by adaptive sensory stimulus software. Another study used a calculator to optimize the dose of insulin for an adult affected by Type 2 diabetes. Together with clinicians and other healthcare providers, an app could address a Substance Use disorder through Prescription Digital Therapeutic that provides cognitive behavioral therapy through on-line lessons, a dedicated space to track the substance's intake and another one to store clinic data.

There are three main types of functions that can be carried out through DTx, that are: automated functions, communicative functions, and supplementary functions (illustrated in *Table 10*).



AUTOMATED	COMMUNICATIVE	SUPPLEMENTARY
FUNCTIONS	FUNCTIONS	FUNCTIONS
<ul> <li>Use of enriched information environment, such as videos and games</li> <li>Automated feedback tailored through the monitoring of the individual's progresses</li> <li>Automated follow-up messages such as tips, reminders and encouraging messages</li> </ul>	<ul> <li>Possibility to request advice from an expert, e.g. through a chat session</li> <li>A scheduled contact with an advisor through emails or messages</li> <li>Peer-to-peer support through forums or live chats</li> </ul>	<ul> <li>Telephone</li> <li>Videoconferencing</li> </ul>

Table 10: DTx functions

# 2.2.2. Pre-market Process and Validation

After the description of the most innovative technologies in the digital health landscape, it is interesting to understand how the path through product development and validation works for such technologies. In fact, this is the process that lead to commercialization, thus to the actual adoption of digital health technologies in clinical practice.

Digital health includes categories such as health information technology (IT), wearable devices, telehealth, mobile health (mHealth), and digital therapeutics (DTx). Therefore, its scope is very broad. Moreover, being a recent concept in continuous evolution, a specific regulation has not been established yet. Indeed, the terms "product" and "solution" in this chapter could refer to a variety of subjects: medical devices, mobile health apps, treatments, drugs, etc.

The picture below (*Figure 3*) clarifies the main activities carried out by the actors involved in the pre-market process. To simplify, three actors are represented: the developer, the independent evaluator (that varies from state to state), and the marketplace (that, in this case, stands for all stakeholders involved in the implementation and usage of the product).

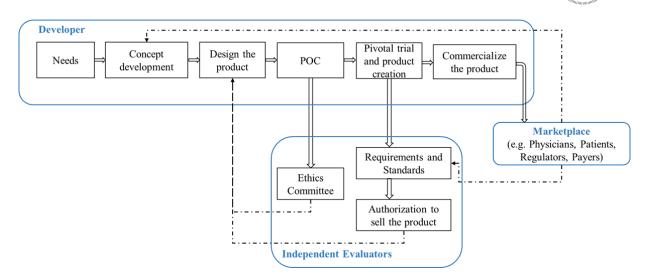


Figure 2: Pre-market process flow

Indeed, the value created through these kinds of technologies can make a difference only when validated and available to customers and patients. Since both the novelty and the required level of quality of these technologies are high, and the implications on health significant, there are many additional activities to be performed with respect to traditional products. Therefore, it is mostly important to pay attention to them. In the following paragraphs, these differential elements will be described more in detail.

## Product Design, Development and Manufacturing

For what concerns the product design, development and manufacturing phases, the Digital Therapeutics Alliance has highlighted a few points to keep in mind. First of all, during the product design there is the need, most of the times, to incorporate data-driven interventional pathways, in order to customize the service to the single patient. Having to enter a market where the quality of the product must satisfy high requirements, the developer must know in advance (i.e. from the design phase) the national and international standards, certifications and requirements to be observed and respected. Last but not least, a human-centered approach is recommended in the first phases of the product life cycle. Indeed, this perspective will ensure that the technology will address the actual main actors' needs, being aware of the environment in which they will be implemented and the possible interferences to be faced.

Many studies focused on EDs have implemented successfully these steps. For example, a mobile application has been designed for BN in order to digitalize Cognitive Behavioral Therapy (CBT). One study has been designed to prove that mobile devices would enable the



patient to follow a personalized program (human-centered orientation), with just-in-time interventions (data-driven interventional pathways).

Following these indications, a prototype could be implemented and the pre-market product would be available. However, some other steps must be performed in order to enter the market.

## Product Evaluation

Product evaluation in healthcare is carried out through clinical studies. They need the authorization from the ethical committee proving that the trial is carried out in an ethical and legal manner.

With regard to medical devices, the Food and Drug Administration (FDA) recognizes three stages for product evaluation: 1) an exploratory stage, 2) a pivotal stage, and 3) a post-market stage. A brief explanation of each of them is reported in *Table 11*. In this section, only 1) and 2) are explained more extensively as they belong to the pre-market phase, on the contrary of 3). Not all products go through all stages.

	STAGE	DESCRIPTION
PRE-MARKET	Exploratory stage	First-in-human and feasibility/pilot studies conducted, characterized by iterative learning and product development. These studies are carried out through Proof of Concepts (PoC)
	Pivotal stage	Definitive study to support the safety and effectiveness evaluation of the medical device for its intended use
POST-MARKET	Post-market stage	Includes studies intended to better understand the long-term effectiveness and safety of the device, including rare adverse events

Table 11: FDA's product evaluations' stages



In the on-field research, a Proof of Concept (PoC) is developed to prove the feasibility of the solution or to answer basic research questions. More in detail, PoC studies is where initial data from a small number of tests is gathered to validate and inform the continual development of the technology.

If the PoC is validated (immediately or after some iterations) another clinical trial is carried out in the pivotal stage. Designed to assess both safety and effectiveness of the product, the pivotal trial is considered successful if both the safety and effectiveness endpoints are met. This stage is usually the most time-consuming, due to the need of collecting consistent data for the evaluation. As highlighted by Roberto Ascione, an international opinion leader in the field of digital health, it is important to notice that the time to validate the pivotal trial is an unpredictable variable, and has a great impact on the commercialization of the product, especially if the goal is to be the first to enter the market.

## Pre-market Approval

After approval, the independent evaluator gives its authorization to sell the product and its guidelines must be complied. The qualified bodies differ from one nation to another.

In the United States, it is required to fill a pre-market request and wait for the authorization of the FDA. For what concerns mobile applications, the FDA has a dedicated portal. Therapies delivered through apps are classified by FDA as moderate to high risk therapies. They are very recent in approval: indeed, the first "digital pill" has been approved by FDA in 2017. It consists on an app with a 12-week program for the treatment of addiction to psychotropic substances, such as cannabis, cocaine and alcohol, followed by a specific app for the treatment of opioid addiction, a real epidemic that kills more than 70,000 people a year.

In Europe, no specific directive is dedicated to digital health. At the present time, digital health technologies refer to the latest regulations on medical devices (2017/745) and the directive on computer security (2016/679). Meanwhile, the European Commission is working on the development of a dedicated policy with the objective to reach a "Digital Single Market". In line with it and with the Cybersecurity Act, the organ has published the "Communication on Digital Transformation of Health and Care in the Digital Single Market", a document that will be the base of the future work, giving direction to EU activities. All member states will have to pay attention to three main aspects in the validation process:



- 1. Enabling citizens to have access to their data, even across borders;
- 2. Using data infrastructures shared at European level, in order to guarantee access to personalized medicine in all member states;
- 3. Using digital tools in order to empower citizens, stimulating prevention and encouraging feedback and interaction with the new technologies and producers.

Italy, as a member state, must apply the European legislations. Most of the time, these regulations need from 3 to 5 years to be fully implemented. For this reason, the regulations described above are not expected to be implemented before 2020.

# 2.2.3. Digital Care of Psychiatric Disorders

The original purpose of this section was to investigate the deployment of digital technologies for the treatment of EDs. However, being an extremely new field of research with only few clinically significant results, the analysis was broadened to other mental disorders, such as depression and schizophrenia. Indeed, technologies adopted for other mental disorders could have potential application for the treatment of EDs as well.

Consistently with the "Standard of Care of Eating Disorders" section, the analysis focuses on the support of digital technologies along the overall patient path, divided into four phases: 1) Screening, 2) Diagnosis, 3) Therapy, and 4) Follow-up. With regard to Therapy, digital technologies can be divided into three different scopes of intervention: 3.1) Monitoring: through collection of data, 3.2) Support to decision-making: by increasing the availability and timeliness of information to professionals that work in the field, and 3.3) Digital therapeutics: to support changes in patient behavior. Therefore, the present analysis follows a structure which also embeds the mentioned subsections of Therapy.

In *Table 12*, it is possible to find a recap of the academic papers and digital technologies found in relation to each area of analysis.



			THERAPY			
	SCREENING	DIAGNOSIS	Monitoring	Decision support	Digital Therapy	FOLLOW -UP
ANOREXIA NERVOSA	NA: 3 T: Social Media Analysis, Machine Learning	NA: 0 T: -	NA: 5 T: Wearable sensors, wireless technology, Bluetooth beacons, Machine Learning	NA: 2 T: Mobile app	NA: 1 T: Mobile app	NA: 0 T: -
EATING DISORDERS	NA: 2 T: Social Media Analysis	NA: 0 T: -	NA: 5 T: Wearable sensors, Bluetooth beacons, Machine Learning	NA: 1 T: Mobile app, Machine Learning	NA: 6 T: Website, mobile support, mobile app, Machine Learning, Virtual Reality	NA: 2 T: Website , mobile monitoring , Social Media Analysis
OTHER (e.g. depression)	NA: 4 T: Social Media Analysis, Machine Learning	NA: 1 T: Brain scans	NA: 2 T: Wearable sensors, phone sensors, Bluetooth beacons, Machine Learning, mobile app	NA: 0 T: -	NA: 0 T: -	NA: 0 T: -

 Table 12: Patient path map, with number of articles (NA) and summary of technologies (T) found in the literature classified by mental disorder and patient path phase

## Screening

Recent studies reveal that user-generated content on social media provides useful information in understanding mental disorders. Online social platforms allow people to share their thoughts and feelings freely and publicly. Thus, the information available is a rich source for sentiment analysis or inferring symptoms associated with mental illnesses. For example, people with EDs can be identified by the usage of certain keywords that characterize and promote these conditions.

Machine learning and text analytics seem increasingly useful in the context of analyzing online data for disease epidemics and warning signs of a variety of mental health issues. Particularly, predictive models built to perform the automated analysis of social media (SM) can help to overcome the limitations of traditional surveys, by providing finer-grained features of ED with a large number of samples.

Several computational methods have been proposed to study EDs and other mental illnesses. Most studies focus on identifying signs of a mental illness from user-generated content in SM but some studies have explored also the social ties and interactions between mentally ill peers, showing that people's concerns and behaviors can be influenced by peer pressure.



Data is usually collected with surveys and from the social network account or from public online sources like Twitter, Facebook or Reddit. However, also a snowball sampling method has been developed to automatically gather individuals self-identified eating disordered in their profile descriptions, as well as their social network connections with one another.

#### Diagnosis

The mental health issues are typically classified and diagnosed by researchers and clinicians according to written manuals. To avoid the possible human mistakes, digital technologies could provide a novel and efficient tool for the diagnosis. With technology, the symptomatology of each disorder could be detected and the collected data would support the diagnosis made by a clinician. In the future, maybe even the machine itself would be able to diagnose the patient.

In EDs, the symptomatology and severity vary between each patient and the differentiation between disorders may not be so straightforward. Some patients may have several comorbidities, such as depression, and the symptomatology of more than one eating disorder may be present. The few physical parameters, such as Body Mass Index (BMI), are not sufficient for the diagnosis and thus the technology should be able to detect multiple variables including behavioral activity. No such technologies exist yet for the diagnosis of EDs. However, schizophrenia has been diagnosed by machine learning technology using images acquired from the brain scans. Similar technology is suggested to be used, for instance, for the diagnosis of Parkinson disease, depression, and binge drinking.

#### Therapy

#### Monitoring

The monitoring of patients during the treatment period provides clinicians valuable information related to the symptoms. In EDs, different behavior and physical activity can be followed using various technologies. The data not only helps in decision making but also produces new information about the psycho- physiological connections. Digital technologies can be used both in the clinic and in a home environment which is may be more convenient for some patients and prevent succumbing to hospitalism.

To recognize and monitor different activities at home, a multimodal wearable sensor together with wireless Bluetooth beacons have been used for AN and BN. The correlation between the locomotor activity and psychological and behavioral activity in hospitalized anorexic



patients has been monitored with an armband. Also, the eating behavior when eating different food has been studied with a wearable electromyographic (EMG) sensor and microphone system. The sensor is placed behind the ear and from the collected data, it is possible to detect whether the patient has been only chewing or also swallowing the food. Similar ear-sensor together with a sensor placed on a hand and wireless module to observe the body movement have been used to further detect the eating behavior. Also, various eyetracking technologies have been used to study the behavior and patterns of attention towards the food stimuli as well as body stimuli and social information. Most of the eye movement tracking systems consist of contact- free, infrared based cameras integrated on tablemounted PC monitors but also head-mounted "goggles" are used. What comes to the physiological symptoms, the cardiac functions, especially the Heart Rate (HR) and Heart Rate Variability (HRV) have been monitored with wearable electrocardiogram (ECG) systems in patients with anorexia. The chest band and wireless technology enable to collect a long-term data and is more convenient to use compared to conventional 12-lead ECG measurements performed in a hospital environment. Similar wearable 3-lead ECG recorder has been used to study the comorbid effects of depression in anorexia. Also, the stress levels in anorexic patients have been studied in an ambulatory setting using wearable sensors that are based on the Galvanic Skin Response (GSR).

In addition to EDs, digital technologies are used for monitoring of other mental health issues, such as Alzheimer and depression. For instance, mobile application and phone sensors have been used to identify different mental states in depressed people. The interactive phone application is able to predict patient's mood, emotions, and cognitive and motivational states in different environmental and social contexts.

#### **Decision Support**

The digital technology enables the clinician to receive reliable data of the patient and thus it supports in decision making. In EDs, patients often lie and it is the BMI and physical condition that guide the clinicians to make decisions in the treatment pathway. With digital technology, this decisioning could be made more reliable and efficient as more data of the patient's condition is received. There are few phone applications available for clinical decision support in EDs. One of them tracks the food and emotions and helps in meal planning. The interactive application asks the patient to fill in the information about the eating situations and the data is sent to the psychotherapist. Another smartphone application



has similar manual data entry, but it also collects information automatically about the location and physical activity. In addition to a real-time data visualization in the clinician portal, the application provides a Cognitive Behavioral Therapy (CBT) based self-help learning modules and coping strategies for the patients.

#### Digital Therapeutics

Digital health technologies are commonly used in the treatment of mental health problems. In EDs, several online programs have been developed such as personal phone-based coaching accessible via mobile apps and web-based programs. These platforms track eating habits and compensatory behaviors, other self-monitoring tools, psychoeducational learnings, interactive multimedia tools (e.g. audio-guided exercises, interactive tools), and CBT techniques. Particularly, CBT is a psycho-social intervention that focuses on challenging and changing unhelpful cognitive distortions and behaviors and the development of personal coping strategies. Originally designed to treat depression, CBT has also become the first line of treatment for EDs such as BN and eating disorders not otherwise specified (EDNOS). Smartphone applications (i.e. mHealth interventions) are well suited to disseminate CBT while also addressing many of the limitations in both in-person and selfhelp treatments: the pervasive usage of mobile phones provide the motivation for delivering weight management interventions on a large scale and in an ecological manner. Mobile or mHealth interventions for weight management have demonstrated promising results across various studies. However, they face two important limitations. Most studies report up to 50% dropout in the use of existing mHealth. A potential solution would be to increase the interactivity and attraction via gamification. A second limitation is a lack of available application or scientific trial targeting maladaptive eating habits. This initiates the need for portable, evidence-based, integrated, and interactive applications for weight management. Body image disturbance is a significant maintenance and prognosis factor in EDs and existing treatments, such as CBT, can benefit from direct intervention in patients' body image. For this reason, a study has compared CBT for EDs with and without a component for body image treatment using Virtual Reality (VR) techniques. Results showed that the patients who used VR together with CBT improved more than the group with only CBT, and the improvement was maintained in post-treatment and at one-year follow-up.



## Follow-up

There are few follow-up studies utilizing digital technologies for patients with chronic AN or EDNOS. Usually, clinicians have cautioned their patients of keeping in touch with treatment peers, as such contact could trigger the symptoms. Patients compare their weight, shape, and eating habits during the treatment. If it continues outside the hospital, the risk of relapse increases.

The rapid expansion of SM enables comparison outside of the hospital. A study of the use of Facebook among ED individuals with a treatment history revealed the relationship between the symptomatology and SM use in those comparing their body, eating, or exercise. As a result, it emerged that comparison to peers on Facebook was associated with greater ED psychopathology and ED-related impairment. Conversely, positive interaction with treatment peers on Facebook was associated with lower ED psychopathology and ED-related impairment. Individuals who had been in treatment longer, more frequently, and more recently had more Facebook friends from treatment and ED related organizations and they spent more time in ED group pages on Facebook. Interactions on Facebook could affect patients' recovery and potential for relapse. Thus, the use of Facebook and its potential benefits and drawbacks should be discussed with patients preparing for discharge from group treatment.

# 2.3. Psychological Well-being of Professionals

In the previous chapter, digital technologies used for eating and mental disorders have been described and reviewed. By testing extremely experimental solutions, the above-mentioned studies are generally contextualized in product development and design settings. In order to reach the market, it is necessary to assess the feasibility, the safety and effectiveness of the solution conceived.

However, these conditions are not enough for a successful implementation in clinical practice. Indeed, it is of fundamental importance that people targeted as users, such as healthcare professionals, are able and willing to use digital technologies in their work. The propension or aversion of professionals towards digital technologies largely depends on how they affect their psychological well-being. Researchers have repeatedly found that the use of digital technology is a double-edged sword that produces both positive and negative psychological experiences for employees (Fujimoto et al., 2016). That is, while it enhances workers' job satisfaction, organizational commitment, and perceived control, it also produces



workers' work- life conflicts, technostress, anxiety, frustration, work overload, and work intensification (Diaz et al., 2012).

The current chapter will illustrate the Job Demand-Resources (JD-R) model, an influential framework to understand how job characteristics foster employee psychological well-being.

# 2.3.1. Psychological Well-Being: Selection of the Model

The Job Demands-Resources (JD-R) Model (Demerouti, Bakker, Nachreiner, & Schaufeli, 2001) is recognized as one of the leading job stress models, along with Job Demands Control (JD-C) model (Karasek, 1979) and Effort Reward Imbalance (ERI) model (Siegrist, 1996).

- JD-C model considers job strain as a result of the combination of high job demands and low job controls. Therefore, a basic premise of this model is that employees that are autonomous in deciding how to meet job demands do not experience job strain;
- As an alternative, the ERI model emphasizes the reward rather than the characteristics of work. In this case, the hypothesis is that job strain emerges when the efforts are not compensated by the reward;
- Finally, the JD-R model assumes that employee health and well-being result from a balance between positive (resources) and negative (demands) job characteristics.

Yet, unlike the JD-C and ERI models, the JD-R model does not restrict itself to specific job demands or job resources. It assumes that any demand and any resource may affect employee health and well-being. Thus, the scope of the JD-R model is much broader than other models. The JD-R model is also more flexible and can be tailored to a much wider variety of work settings, making it the most appealing for both practitioners and researchers.

Finally, in contrast with the previous models which focused almost exclusively on negative aspects of the working activity, the JD-R model integrates a positive focus on work engagement (motivational process) with a negative focus on burnout (energetic process) into a balanced and comprehensive approach. The model predicts that job demands are not necessarily detrimental for workers psychophysical state as far as the individuals are provided with the necessary resources to bring forward the task. Moreover, oppositely to JD-C and ERI, JD-R gives the right importance to job resources even on their own, thus beyond the simple buffering effect on job demands impact. In other words, the development of job



resources is not important just to mitigate high job demands but also when the job demands are not so relevant.

There is actually no single JD-R model. Instead of relating well-defined and specific sets of concepts to each other (as applies to the ERI and JD-C models), the JD-R model is heuristic in nature and represents a way of thinking about how job (and recently also personal) characteristics may influence employee health, well-being, and motivation.

In conclusion, the heuristic use of the JD-R model in combination with its broad scope, flexibility and completeness makes the JD-R model the most appropriate when trying to assess the balance of strain and engagement in professionals.

# 2.3.2. Job Demands-Resources Model

The JD-R model proposes that, whatever the occupational setting, working conditions can be categorized into two broad categories, job demands and job resources, that are differentially related to specific outcomes.

The core principle on which the JD-R is build is that the creation of strain or motivation related to the working task is due to the balance between job demands and job resources; when this equilibrium is broken the employee might experience burnout or engagement (Bakker & Demerouti, 2007; Demerouti et al., 2001; Schaufeli & Bakker, 2004).

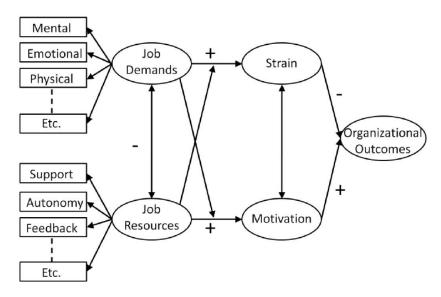


Figure 3: JD-R Model

In order to better understand the JD-R, the main components of the model are described.



## Burnout and engagement

Burnout exemplifies a state of mental weariness characterized, according to the MBI– General Survey (MBI-GS: Schaufeli, Leiter, Maslach, & Jackson, 1996), by three dimensions: (a) exhaustion, which measures fatigue without referring to other people as the source of one's tiredness; (b) cynicism, which reflects indifference or a distant attitude towards work in general, not necessarily with other people; (c) professional efficacy, which encompasses both social and non-social aspects of occupational accomplishments. High scores on exhaustion and cynicism, and low scores on professional efficacy, are indicative of burnout.

Empirical evidence suggest that commonly found job stressors play a significant role in burnout and that commonly found stress reactions have similar antecedents as burnout. Stress is defined as a disruption of the equilibrium of the cognitive-emotional-environmental system led by external factors, called stressors when they are related to an increasing of stress level of an individual (Demerouti et al., 2001).

According to Schaufeli and Bakker, engagement is a positive, fulfilling, work-related state of mind that is defined, again, by three dimensions: (a) vigor, which is characterized by high levels of energy and mental resilience while working, the willingness to invest effort in one's work, and persistence also in the face of difficulties; (b) dedication, which encompasses a sense of significance, enthusiasm, inspiration, pride, and challenge; (c) absorption, which reflects the state of full concentration and happy engrossment in one's work, whereby time passes quickly and one has difficulties with detaching oneself from work.

Burnout and engagement are considered each other's opposites, particularly as far as exhaustion and vigor, and cynicism and dedication are concerned. In addition, burnout and engagement both include a third constituting characteristic that is, respectively, reduced professional efficacy and absorption.

## Job demands and job resources

Job demands refer to those physical, psychological, social, or organizational aspects of the job that require sustained physical and/or psychological (cognitive and emotional) effort or skills and are therefore associated with certain physiological and/or psychological costs. Although job demands are not necessarily negative, they may turn into job stressors when meeting those demands requires high effort from which the employee has not adequately recovered (Meijman and Mulder, 1998).



Examples are a high work pressure, an unfavorable physical environment, and emotionally demanding interactions with clients.

In few words, job demands represent the "things that have to be done" (Schaufeli & Bakker, 2004).

In order to face difficult and challenging jobs, protecting factors, called job resources, are introduced to mitigate the effects of job demands.

In fact, job resources refer to those physical, psychological, social, or organizational aspects of the job that are either/or: (a) Functional in achieving work goals; (b) Reduce job demands and the associated physiological and psychological costs; (c) Stimulate personal growth, learning, and development. Hence, resources are not only necessary to deal with job demands, but they also are important in their own right.

Job resources may be located at the level of the organization at large (e.g. pay, career opportunities, job security), the interpersonal and social relations (e.g. supervisor and co-worker support, team climate), the organization of work (e.g. role clarity, participation in decision making), and at the level of the task (e.g. skill variety, task identity, task significance, autonomy, performance feedback).

In few words, job resources refer to the resources necessary to "get things done" (Schaufeli & Bakker, 2004a, p.296) and are mainly characteristics of the environment.

Apart from job resources, the JD-R model can be expanded to take into consideration also personal resources, that are "aspects of the self that are generally linked to resiliency and refer to individuals' sense of their ability to control and impact upon their environment successfully" (Xanthopoulou, Bakker, Demerouti, Schaufeli, 2007). Three typical personal resources are self-efficacy, organizational-based self-esteem, and optimism, all of which have been recognized by Hobfoll (2002) as fundamental components of individual adaptability.

## Health impairment process and motivational process

Job demands and job resources work categories evoke two relatively independent psychological processes that are, respectively, the health impairment process and the motivational process.

According to the health impairment process, high job demands may exhaust employees' resources and lead to energy depletion and health problems. For example, specific job



demands (e.g. workload or emotional demands) have been repeatedly found to predict exhaustion (i.e. severe fatigue) among various occupational groups (e.g. Bakker, Demerouti, & Euwema, 2005; Bakker, Demerouti, & Schaufeli, 2003a).

On the contrary, according to the motivational process, the availability of job resources leads to organizational commitment and work engagement (Schaufeli & Bakker, 2004). Job resources, due to their intrinsic and extrinsic motivational potential, foster employees to meet their goals. In turn, employees may become more committed to their job, because they derive fulfillment from it (Hackman & Oldham, 1980).

It has been demonstrated (Bakker et al., 2003a; Hakanen et al., 2006) that several job resources (e.g., support or coaching) lead to work engagement, defined as "the positive, fulfilling, and work-related state of mind that is characterized by vigor, dedication and absorption" (Schaufeli & Bakker, 2004).

## Interaction between job demand and job resources

In addition to these main effects, the JD-R model proposes that job resources buffer the relationship between job demands and exhaustion. Under demanding work conditions, employees who hold high levels of resources dispose more supplies and, thus, are more capable of dealing with these demands. As a result, they experience lower levels of exhaustion (Bakker et al., 2005).



# **3.**Research Gap

What we found from the literature is that, indeed, digital technology has opened specific, new frontiers in healthcare. The broad categories of eHealth encompass multiple technological domains, including health information technology, mobile health (mHealth) telehealth, wearable medical devices, and applications of AI techniques. All these technologies offer clinicians, researchers and patients new ways of providing and receiving clinical treatment, monitoring progress, and increasing understanding of psychiatric illnesses. Eventually, they may be part of efforts to improve access, reduce costs, reduce inefficiencies, increase quality of care, and facilitate personalized medicine for patients (U.S. FDA 2018, Digital Health).

However little research has examined the deployment of digital technology in the ED domain. Nevertheless, technologies adopted for other mental disorders, such as depression and schizophrenia, hold strong potential for the advancement of research, assessment, and treatment in the ED field as well.

With regard to EDs, which are particularly difficult to identify and assess due to their heterogeneous and covert nature, the use of digital technology could lead to earlier identification, a more accurate clinical picture, and better understanding of how shifts between ED diagnoses occur. Sensor technology, using both wearable and smartphone sensors, can also be utilized broadly to understand patterns of daily behavior that may be indicative of trends or changes in factors related to mental health, including sleep, mood, and stress (Javelot et al., 2014; Mohr et al., 2017). Additionally, digital health interventions could predict behavioral changes and provide in-the-moment interventions or alerts delivered via smartphone applications, helping to detect and prevent harmful behaviors before they occur (Aung et al., 2017).

Also, as the deployment of digital technology in EDs is a new field of research, there is not much evidence yet on healthcare professionals and patient adoption rates, on the consequences of their psychological well-being and/or how the application of this technology affects healthcare professional-patient relationship. In fact, the investigation on this topic usually stops at the research level and any solution conceived is far from reaching the market and mainstream adoption.



Accordingly, two main research gaps were identified: (1) the potential of digital technology, especially the ones already tested with other psychiatric illnesses, in the ED domain, and (2) professionals' psychological determinants behind the usage of digital technologies.

As a consequence, the research objectives of our work are the ones illustrated in detail in the next chapter.



# **EMPIRICAL RESEARCH**



# 4. Research Questions and Research Objectives

In order to fill the research gaps described in *Chapter* 3, the present work aimed to answer the following research questions: (1) Which digital technologies hold potential in the ED domain? (2) Which are the psychological dynamics of professionals behind the intention to use digital technologies?

From this starting point, a collaboration with Villa Miralago, a center of excellence in Italy for in-patient treatment of EDs, and with an expert of digital technologies from Politecnico di Milano, has been started. The focus on the rehabilitation center deepened the analysis of the data needed by the professionals limiting the research to the ones that could be collected by on-the-market digital technologies. Due to the novelty of the topic, a pivot trial was needed to start developing the product. For this reason, a protocol had to be prepared in order to submit it to the ethical committee.

#	<b>RESEARCH QUESTION</b>	RESEARCH OBJECTIVE
1	Which digital technologies hold potential in the treatment of EDs?	Protocol design based on a set of digital of technologies potentially relevant to the treatment of EDs
2	Which are professionals' psychological determinants behind the intention to use digital technologies?	Assessment of healthcare professionals' intention to use in the ED field digital technologies through stress model and perception of patient trust

Figure 4: Research questions and objectives

To answer research question (1), a "demand-pull" approach rather than a "technology-push" one, was followed. The starting point was the variables healthcare professionals in the ED field take into consideration to evaluate the health status of patients. They emerged by the round table and on-field interviews and were converted into parameters to be measured, collected and analyzed through digital technologies definable accordingly. The experience and knowledge of professionals on the patients have been useful to give on-the-field evidence on the data need.

With this in mind, they were incorporated in the survey questionnaire submitted to professionals of Ananke, in order to test the interest of a broader sample.



The following step was to interview the Professor of Computer Science. Indeed, he has helped to narrow down the parameters identified during the interviews in order to consider just the ones that ideally could be detected by already on-the-market technologies. The output of this exploratory research was the data that are needed by professionals in Villa Miralago and that can be collected by existing digital technologies (research objective 1a). Finally, in order to enter the PoC phase (see paragraph *Pre-market process and validation*), mandatory before launching the system on the market, the protocol for the future trial to be submitted to the ethical committee and implemented in Villa Miralago has been designed.

As for research question (2), a model based on JD-R model formed by suitable constructs whose aim is to connect research objectives with measurable variables and a validated scale have been applied. To test the model, the measurable variables were submitted to healthcare professionals of Ananke, a national network of centers which deal with the clinic of EDs, through a survey questionnaire. The measurable variables, which will be used to test the model, are selected accordingly to the goal and key constructs here defined.

The model designed by the researchers includes the four core constructs of JD-R model: Job Demands; Job Resources; Burnout; and Engagement. Intention to Use digital technologies was selected as organizational outcomes, when JD-R usually consider organizational outcomes in terms of job performance, organizational commitment, and absenteeism (Bakker & Demerouti, 2007; Rich et al., 2010). Besides, Psychological Safety and Patient Trust, have been added. The constructs of the models and the process used in order to translate them in measurable variables will be explained more in detail in next chapters.



# 5. Methodology

This chapter describes the methodology, i.e. the specific procedures and tools used to carry out the study (both theoretical and empirical research). The aim is to provide a clear vision of the logical connections between the different phases and to explain the purposes and the modalities of the research.

Figure 6 illustrates the steps followed.

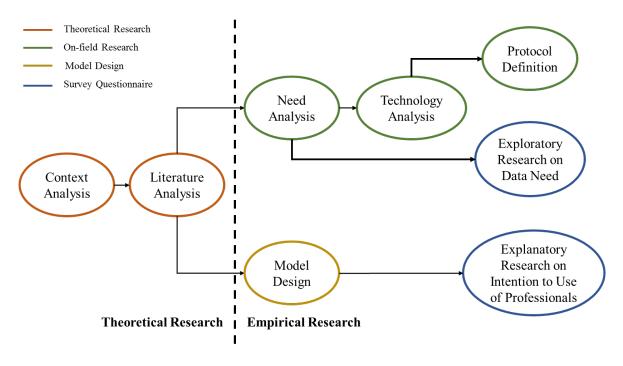


Figure 5: Flow of the study's steps

# 5.1. Theoretical Research

# 5.1.1. Context Analysis

In the earlier stage of the study, the focus was on understanding the setting of the research and getting comfortable with the topic. Indeed, having a broader view on the study field and some fundamental pillars before starting a structured research was the first objective to be reached. The main activity performed in order to reach this objective was a "snowball research" on the Internet mostly based on grey literature. As output of this step, an idea on the relevance of EDs in terms of diffusion and volumes has been developed together with the general changes in the sector regarding digital technologies.



# 5.1.2. Literature Analysis

For the purposes of the literature analysis, several approaches have been used according to the topics to be deepened. The main research areas investigated in the study have been three: 1) Eating Disorders; 2) Digital technology for Eating Disorders; and 3) Psychological wellbeing of professionals. From the context analysis, it was possible to understand that 1) and 3) were quite consolidated research areas, while for 3) it appeared difficult to find relevant material on freely accessible web search engines and databases and to trace it without a systematic method. Thus, Systematic Literature Review (SLR) was selected as the proper method to investigate 3), while for 1) and 2) this approach wasn't replicated being easier to trace information. For each topic, the modalities of literature research are better described in the following paragraphs.

Overall, the main outputs of this step have been the definition of an evidence-based foundation on which the empirical research could be based and the research gap identification, which is described in the homonymous paragraph.

## Eating Disorders

Information on EDs was collected through web-based research mainly based on Google Scholar. In this way, it was possible to obtain comprehensive and reliable information both from grey literature (such as research reports, theses and dissertations, conference proceedings) and academic articles. Eating Disorders have been described mostly in terms of Epidemiology and Standard of Care. Examples of keywords typed for these subtopics are respectively:

- Epidemiology of Eating Disorders: "eating disorders epidemiology", "eating disorders diagnoses", "eating disorders causes", "eating disorders incidence", "anorexia nervosa incidence", "bulimia nervosa incidence", "binge-eating disorders incidence" etc.;
- Standard of Care of Eating Disorders: "eating disorders standard of care", "patient path", "patient path phases", "eating disorders screening", "eating disorders psychometric tests", "eating disorders treatment", "anorexia nervosa treatment", "bulimia nervosa treatment", "binge-eating disorders treatment" etc.



# Digital Technologies in Eating Disorders

In order to provide an overview on the development of digital health technologies for the treatment of EDs, a Systematic Literature Review (SLR) has been conducted. The SLR is a review of a clearly formulated question that uses systematic and explicit methods to identify, select and critical appraise relevant research, and to collect and analyze data from the studies that are included in the review.

The first step was the selection of the data sources. Scopus and Pubmed have been highlighted as the main sources: the first for academic literature in general, the latter for medical one.

A set of keywords (showed in *Table 13*) has been chosen in order to respect the replicability of the model. They are the result of the combination of two words coming from the two domains of interest for the research, i.e. the clinical and the technological dimensions.

CLINICAL DIMENSION	TECHNOLOGICAL DIMENSION
Anorexia	Connected care
Eating disorder	Social media
Feeding disorder	Wearable
	Camera
	Big data
	Digital
	Internet of Things OR IoT
	Real World Data OR RWD
	Real World Evidence OR RWE
	Facebook
	Twitter
	Instagram
	Online/on-line communities
	Whatsapp
	Telegram
	Sensors
	Арр

Table 13: SLR Keywords



Examples of QUERY on Scopus and Pubmed are: Anorexia AND "connected care", Anorexia AND "social media", etc.

In order to direct the research to articles that could be potentially relevant, some filters have been used. Both for Scopus and Pubmed, the language was limited to English, the publication dates to years 2010-2019, the typologies of sources to articles and conference papers, and the subject area to Medicine, Neuroscience, Psychology, Computer Science, Social Sciences and Nursing.

After the removal of duplicates, three exclusion criteria have been applied in order to narrow the research scope and improve the appropriateness of the articles: 1) "Too limited", 2) "Off topic", and 3) "Too broad".

Figure 7 shows the number of articles found following the flow of this methodology.

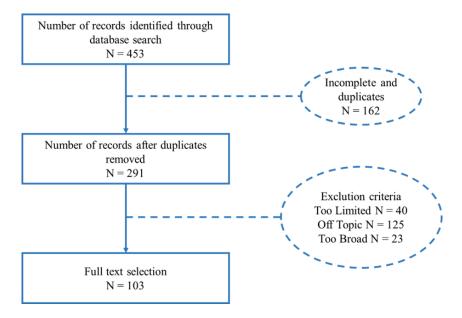


Figure 6: SLR steps and number of academic articles

By reading the selected articles, it was possible to identify the most innovative digital solutions which hold potential for the treatment of EDs together with clinical parameters typically measured by these technologies to improve the treatment of patients.

## Psychological Well-being of Professionals

Information on models regarding the psychological well-being of professionals was collected through web-based research mainly based on Google Scholar. Since the beginning of the research, Job Demands-Resources (JD-R) model (Demerouti et al., 2001) emerged as the most influential model in describing the relationship between job stressors and protecting factors. By analyzing the topic, it was evident the heavy presence of the first three authors



of the JD-R model in 2001 (Schaufeli, Bakker. and Demerouti) also in following academic articles about the model. Indeed, the theory behind the JD-R model have been deeply developed and consolidated.

# 5.2. On-field Research

# 5.2.1. Need Analysis

This step's objective is to analyze the needs of the professionals dealing with patients affected by EDs. The focus has been on the data need.

The starting point was Villa Miralago, a rehabilitation center for EDs in the north of Italy where all the different professional figures are present and work with a multi-functional approach.

At first, a round table has been set with the main experts involved in the study, i.e. digital technology expert, Health director, psychiatrists and manager. It has been decided to carry out structured interviews. *Table 14* shows the structure of the interviews, where general questions have been submitted to all professionals' profiles while specific questions are customized according to their area of competence. The questions concern not only the data need, but also the Standard of Care of the clinic and the internal exchange of information.

GENERAL QUESTIONS					
1. Which activities do you perform inside the clinic and how often?					
2. Which kind of meetings do you have with the patients (individual, group activities, other)?					
3. How often (how many times) do you meet the patients in group?					
4. How often (how many times) do you meet the patient individually?					
5. How long does it take a meeting with the patient?					
6. When you meet the patient, what do you ask to him?					
7. Which information do you want to get from their answers?					
8. Do you measure some parameters, or everything is qualitative?					
9. Which are the possible considerations that you do after a visit?					
10. Which information would you like to get that you don't get at the moment?					
11. Which colleagues do you cooperate the most with?					
12. Which information do you want to collect from your colleagues (from each category)?					
13. How do you exchange information? Do you have a digital platform? Would you think it					
could be useful to exchange information in real time?					
SPECIFIC QUESTIONS					
Educator					
14. Which criteria do you use to split the patients in groups?					
15. Do you think that tracking emotions could add some relevant information to be used during					
group activities or during treatment in general? If yes, which ones?					



16. Would it be useful to have information about the social interactions inside the building? if					
yes, how and why?					
Nutritionist					
14. Who attends the meals?					
15. What do they do during assisted meals?					
16. Which criteria do you use to choose or change menus?					
Nurse					
14. What do you do during meals?					
15. Which are the signals that tell you when a patient needs you?					
16. Which parameters you would need to monitor?					
Psychologist					
14. Do the patients keep a diary?					
15. Would it be useful to know what they do during the day and night?					
16. Would it be useful to know how they interact between them?					
17. Would it be useful to have a digital interface to talk with the patient also outside the sessions?					
18. Would it be useful to know if they lie during the sessions?					
Psychiatrist					
14. If you could have a list of things that the patient did during the day and her sleeping activity, how useful would it be?					
15. If you could have information about social interactions in the building, how useful would it be?					
16. How and in which cases do you use the metabolic holter?					
17. Which parameters does the metabolic holter measure?					
18. Which are the factors according to the pharmacological therapy is decided?					
19. What do you ask to parents during the meetings with them?					
Rehabilitation activity expert					
14. Do you need additional information on the physical activity?					
15. Would it be useful to understand social dynamics?					
16. What is the difference between micro and macro equipe?					

Table 14: Questions for the interviews to Villa Miralago's professionals

The outputs of these activities have been the comprehension of the Standard of Care in Villa Miralago, the internal exchange of information regarding the patients' path and a deep dive in the data need for each function.

The interviews were carried out to 3 psychiatrists, 2 nutritionists, 1 psychologist, 1 educator, 1 rehabilitation activity expert and 1 nurse.

# 5.2.2. Technology Analysis

With the data from the Literature Research and the Need Analysis, a semi-structured interview has been conducted with the digital technology expert involved in the study, professor at Politecnico di Milano of Computer Science. The aim of the interview was to understand if there are technologies already feasible on the market and effective to collect the kind of data emerged from the previous interviews. Also, it was taken into account their



appropriateness with regard to the patients, for example by selecting the less invasive technologies. *Table 15* shows the questions of the in-person interview.

### INTERVIEW TO DIGITAL TECHNOLOGIES' EXPERT

1. Are there feasible technologies for the caloric intake? If yes, which device is the best for the caloric intake (best trade-off between performance and cost)?

2. Are there feasible technologies for the caloric expenditure? If yes, which device is the best for the caloric expenditure (best trade-off between performance and cost)?

3. Are there feasible technologies for keeping track of the movements? If yes, which device is the best for it (best trade-off between performance and cost)?

4. Are there feasible technologies for vomit detection? If yes, which device is the best for it (best trade-off between performance and cost)?

5.Are there feasible technologies for sleep monitoring? If yes, which device is the best for it (best trade-off between performance and cost)?

6. Are there feasible technologies for the recognition of general feelings? If yes, which device is the best for it (best trade-off between performance and cost)?

7. Which other metrics/data do you think could be interesting to measure/collect? With which devices?

8. Is there any possibilities to transfer the collected data (analyzed/visualized or not) straight to "patients' files"?

9. Can we face ethical questions or even legality questions using these technologies in this context?

10. If patients know they are being monitored, does their behavior change?

Table 15: Questions for the interview to the Digital Technologies' expert

Accordingly, a web-based research has been carried out in order to select the most appropriate technologies, beside potential suppliers, and to calculate the budget needed to purchase them.

# 5.2.3. Protocol Definition

In order to set a Proof of Concept (PoC) for the collection of the data set needed to the professionals with the technologies selected, the protocol for the trial has been designed. It is a PoC and for this reason the aim of the trial is the feasibility of the system tested. At first a web-based research has been carried out in order to set the structure of the protocol design. In the table below, the structure of the protocol is shown. The protocol followed the structure described in the *SPIRIT 2013 standards explanation and exploration: guidance for protocols of clinical trials*.

All the information needed were provided by the professionals of Villa Miralago and discussed in a meeting with the director of the clinic and the responsible for the coordination of researches. From this meeting two elements have been set. Firstly, the protocol focuses



on testing the technologies selected on patients affected by Anorexia Nervosa. The decision on testing on one disease has been taken because of the clinical setting. In fact, this inclusion criteria has been useful in order to set the trial with an homogeneous standard of care, making sure it was easier to compare the results of different patients and isolate results connected to digital technologies. Secondly, in the protocol only female patients are selected, since male patients are a minority in the community and it is difficult to forecast how many male patients will be present in the structure at the moment the trial will start.

The output of this step is the protocol to be submitted to the ethical committee for a future trial to be carried out in Villa Miralago.

# 5.3. Model Design

From the literature analysis, the JD-R model have been selected as the most proper theory for explaining the dynamics behind employees' psychological well-being. However, some adaptation has been done for the specific purposes of the research.

Beside the traditional main blocks of the JD-R model (i.e. Job Demands, Job Resources, Burnout, and Engagement), the constructs Intention to Use, Psychological Safety and Patient Trust have been considered.

In the adapted model, Intention to Use represents the "organizational outcome" resulting from the balance between Burnout and Engagement. Although job demands and resources have been linked to organizational outcomes such as job performance, organizational commitment, and absenteeism (Bakker & Demerouti, 2007; Rich et al., 2010), it is most important in the present study to understand how job demands and resources relate to intention to use digital technologies, whose adoption would eventually affect the overall healthcare organization.

As suggested by previous studies (e.g. Coetzee, 2019), Psychological Safety is explored as a key mechanism enabling thriving in workplaces that are becoming increasingly digital. Finally, patients have been identified by Adjekum (2018) as the most prominent stakeholder of trust in digital health together with healthcare professionals. In this study, patient trust in digital health is seen through the lenses of patient trust in healthcare professionals using digital technologies. Indeed, patients' trust in their healthcare professionals is central to clinical practice (Birkhauer et al., 2017) and rapid changes in the healthcare system are feared by many to be threatening it (Pearson & Raeke, 2000).



Then, relationships between constructs have been hypothesized, respecting the ones connected to the original blocks of the JD-R model and establishing new relations for the added blocks.

An additional step has been made to create a model that could explain with a better level of detail the above-mentioned relationships. The original blocks of the JD-R model have been broken up in different parts. Specifically, Workload and Cognitive Demand have been considered as good proxy to assess Job Demands; Autonomy and Professional Development have been selected in relation to Job Resources; Disengagement and Exhaustion have been identified for the study as the most relevant components of Burnout; finally, Vigour and Dedication could best reflect Engagement in the phenomenon under analysis.

For each of the specific areas in analysis, it has been defined a univocal scale to measure the aspect in question. These scales have been selected from academic papers and slightly adapted to better fit the study. In particular, the original Patient Trust scale, i.e. the *Trust in Physician Scale* (TPS) by Anderson and Dedrick (1990) has been most revisited. First, the original TPS has been conceived for assessing the trust in the primary care physician, while in the present study the scale addresses all relevant healthcare professionals for the treatment of EDs. Secondly, the TPS takes the perspective of the patient (e.g. "I doubt that my doctor really cares about me as a person"), while in the adapted scale the perspective has been overturned in favor of the healthcare professional perspective (e.g. "the patient will doubt that I really care about him/her as a person"). *Table 16* illustrates the final structure of the model with reference to the meaning of the different constructs and to the academic papers from which the scales utilized in the measurements have been extracted.



GENERAL AREA	CONSTRUCT	SPECIFIC AREA	ACADEMIC REFERENCE	
Psychological	Job Demands	Workload	Spector & Jex, 1998	
well-being		Cognitive Demand	Kristensen et al., 2005	
	Job Resources	Autonomy		
		Professional		
		Development		
	Burnout	Disengagement	Demerouti et al., 2001	
		Exhaustion		
	Engagement	Vigour	Schaufeli & Bakker,	
		Dedication	2004	
Behavioral	Intention to Use		Venkatesh & Davis,	
intention			2000	
Interpersonal risk	Psychological Safety		Mura et al., 2016	
taking				
Patient-physician	Patient Trust		Anderson & Dedrick,	
relationship			1990	

Table 16: Structure of the theoretical model

# 5.4. Survey Questionnaire

This step had the objective to investigate the characteristics and interests of healthcare professionals' working in the ED domain in terms of clinical data need, digitalization and psychological determinants of the intention to use digital solutions. Indeed, the results of this investigation represent the base for the design of the tailored solution, for the further development of the solution conceived for the PoC. In particular, a survey questionnaire has been submitted to professionals operating in the ED domain for the purposes of an exploratory research on data need and an explanatory research on their intention to use.

# 5.4.1. Characteristics of the Questionnaire and Sample Selection

The survey instrument consisted in a self-administered, non-experimental, cross-sectional and online survey created on *Qualtrics*. Two types of sections have been designed: an exploratory section and an explanatory one. The survey was anonymous, so that respondents could feel free to express themselves reducing the risk of biased answers (Bush & Hair, 1985).

With this typology of questionnaire, the respondents had more flexibility in terms of timing and location to fill the questions and the researchers had the opportunity to reach a broader and geographically diverse sample. The study is considered non-experimental since there was not the possibility to control, manipulate or alter the respondents and the independent



variables. Since the data of the representative subset has been collected in a specific point in time, the research can be considered cross-sectional. Finally, a part of the survey was intended to explore the interest of professionals on the data set obtained by the previous steps of the study, i.e. literature analysis. In another section, relationships between two or more variables of the theoretical model developed in the current study were tested in order to determine cause-effect relationships. Thus, this section is considered as an explanatory survey.

The sample selected has been the healthcare professionals of the Ananke network. The reason behind this selection is that Ananke is formed by a group of 19 Italian centers dedicated to the treatment of EDs, spread in 11 regions (in detail, Campania, Lazio, Liguria, Lombardy, Marche, Piedmont, Apulia, Sardinia, Sicily, Tuscany, and Veneto). Indeed, Ananke represents one of the major realities at the national level for the cure of EDs.

# 5.4.2. Structure of the Questionnaire

The questionnaire is divided into 5 main section.

The first section has been designed to collect socio-demographic information and additional information about the clinical context, the number of patients followed by the organization, and ED specialization of professionals (if any). This information describes respondents in general terms and it's useful for making more in-depth analysis through segmentation (for descriptive analysis) and control variables (for explanatory analysis, i.e. model assessment).

The second section focuses on understanding the interest of professionals in clinical data that emerged as relevant and feasible to collect with digital technologies during the in-person interviews. However, in this section the interest was assessed without making references to specific digital technologies able to collect them.

The third section concerns the "digital literacy" of professionals, i.e. their level of digitalization both in general terms and in the work setting. In case a digital solution is developed, it is of fundamental importance that people targeted as users, in this case EDs professionals, are able to use and implement it in their activity. For this reason, it is essential to consider this information in the design and development of a digital system.



The fourth section aims at understanding the perceived "environmental dynamism" i.e. the extent to which frequent changes occur concerning technology, provided services and market regulations in the treatment of EDs. In fact, while stable environments might legitimate the establishment and persistence of routines, environmental changes push organizations and groups into searching for innovative solutions.

The last section is composed by the questions, which forms the scales of the constructs used in the adapted JD-R model to measure the Intention to Use digital technologies of professionals. The constructs' scales have been adapted to the current study. The questions refer to the perceived changes in the professionals' work with the usage of a system that collects real life data of the patients and analyzed for single patient or group of patients. This hypothetical system has been imagined as an app that would be implemented in the clinical setting where the professionals work. *Figure 8* was incorporated in the questionnaire in order to give an idea of the digital solution (i.e. the "system") to which they should refer, together with its description:

"Imagine this "system" as a platform where numerous real-life data of patients (e.g. caloric intake and consumption, quality of sleep, heart rate and blood pressure, group movements and dynamics, emotions) are collected by digital technologies (e.g. smartwatch, sensors, antennas, environmental cameras) and analyzed referring either to the individual patient or to a group of patients. This information can be communicated to professionals through a mobile app on his/her smartphone or through a software installed on the computers of the facility where he/she work.

Imagine, for the sole purpose of this research, that this system will be adopted shortly by the facility where you work. By identifying yourself with this scenario, please indicate your degree of agreement with the following statements..."





Figure 7: Visual description of the system used in the survey questionnaire

# 5.4.3. Data Collection

The questionnaire filling would take approximately 13 minutes, resulting an appropriate length to have a high response rate.

The questionnaire has been released online and spread by the health director of Villa Miralago through email on October 27<sup>th</sup>. The answers have been collected over a week, i.e. until November 3<sup>rd</sup>. The recipients have been healthcare professionals of the Ananke network. Eventually, the obtained questionnaire's responses were 102. *Qualtrics* would collect all responses automatically.

# 5.4.4. Data Preparation

Once collected the answers from the survey, several checks and adjustment were made in order to structure the data and making them usable for the statistical analysis.

The first step concerned with the download of an Excel file with all the individual answers from the platform used to distribute the questionnaire, i.e. Qualtrics. At the moment of closing the survey, 102 answers have been recorded. The compilation of all the responses has not been mandatory, thus it left the possibility to professionals to leave blank spaces. In fact, 20 questionnaires out of 102 were left completely blank or blank in the sections related



to the model, thus they were excluded for the purpose of the analysis. In total, 82 answers were selected by the researcher as valid. Among them, 72 have been completed in all the sections (*Table 17*).

	NUMBER	DESCRIPTION		
Total Answers	102	All questionnaires recorded at the		
		moment of closing the survey		
Valid Answers	82	All questionnaires filled at least in the		
		section related to the model		
<b>Complete Answers</b>	72	Questionnaires filled in all the sections		

Table 17: Survey questionnaire's answers

Once selected the valid questionnaires, each column has been renamed with an appropriate variable name and the layout of the file has been modified to be clearer. To guarantee the consistency between answers, all the scales have been arranged in order to have high scores of the items corresponding to high value of the construct. For example, for a question asking the agreement to "I will discover new and interesting aspects of my job", within the Burnout construct, the scale of the answer has been inverted to obtain that if I strongly disagree with the previous statement (answered 1 in the scale), it must be transformed into a 5 to correspond to a high Burnout of the respondent.

# 5.4.5. Data Analysis

# Descriptive analysis

In the descriptive analysis section are reported the results coming from the exploratory research on data need, digital literacy, and environmental dynamism. In order to extrapolate and visualize information, graphs such as bars charts and pie charts have been deployed as main tools.

In particular, most bars charts have been created starting from close-ended questions with Likert scale from 1 to 5. In these cases, graphs reported the percentages of respondents who answered 4 (e.g. "Agree") or 5 (e.g. "Strongly Agree") to the question.

Also, to create pie charts sometimes data have been aggregated to obtain a broader sample to be represented in the chart. In particular, age, work experience, regions, and patients followed by the facility have been clustered.

• Age was split in three categorical variables referring to generations typically recognized in the Western world ("Millennials", "Generation X") and "Over 60";



- Regions were classified according to three categorical variables as "North", "Centre" and "South";
- Finally, categorical variables for work experience and patients followed by the facility were decided by researcher as any specific classification didn't exist.

# Statistical analysis

Successively to the preparation of the Excel database, the next step was the construct measurement, i.e. all the measurement scales of the theoretical model were evaluated to ensure construct validity and reliability. Finally, the structural model has been tested through a multivariate statistical analysis. The combination of factor analysis and multiple regression analysis is the Structural Equation Modelling (SEM) technique.

All these analyses have been undertaken using the software *Stata 14*. In the following pages, the specific steps are explained.

## Scale measurement

Before validating the constructs, the internal consistency of the single scales chosen for the specific areas has been measured using the Cronbach's alpha. i.e. the Cronbach's alpha has been calculated for: Workload and Cognitive Demand; Autonomy and Professional Development; Disengagement and Exhaustion; Vigour and Dedication; Intention to Use; Psychological Safety; Patient Trust.

At this point, no items were removed to try improving the Cronbach's alpha values. Indeed, the objective of this step was simply to make an assessment. What ultimately matters for the validity of the model tested with SEM is the internal consistency of the constructs, which have been measured, improved and validated as illustrated in the next paragraph.

# Construct measurement

For each construct, an Exploratory Factor Analysis (EFA) was performed in order to understand how to improve constructs' consistency, followed by the computation of the Cronbach's alpha, to assess and validate the constructs. The difference between constructs and scales is that constructs can be composed by more than one scale (e.g. Job Demands is a multi-scale construct composed by Workload and Cognitive Demand scales), even if in some cases there is coincidence (e.g. Intention to Use is a single-scale construct). Eventually, constructs represent the latent variables of the SEM model in *Stata 14*.



EFA is a technique within factor analysis whose aim is to identify the underlying relationships between measured variables. Specifically, a Principal Component Analysis (PCA) was used in conjunction with the application of the Kaiser rule for factor retention (1960), which drops all the components with eigenvalues under 1.0.

In order to facilitate the interpretation of the factor loadings, an orthogonal rotation was done to find clusters of variables that are highly correlated with a particular factor and define it. Also, with the Stata command *sortl* it was possible to put in decreasing order the factor loadings. For the items, factor loadings were required to be greater than 0.7 - meaning that the items were consistent - and the differences between factor loadings on distinct factors to be greater than 0.2 - meaning that cross-loading was not occurring. Items have been removed when not respecting this condition with a subsequent improvement of constructs' consistency.

Following EFA, Cronbach's alpha was computed to assess internal consistency and reliability. The general rule requires Cronbach's alpha to be equal or greater than 0.70. However, Cronbach's alpha does come with some limitations: constructs that have a low number of items associated with them tend to have lower reliability and results are sensitive to sample size. Therefore, in the present study the threshold value for Cronbach's alpha have been set to 0.60 in the cases where the scales were composed of three items and there was no possibility to improve the values. Accordingly, constructs with values of alpha above 0.60 have been validated.

## Structural Equation Modelling

The section of the questionnaire concerning the model have been transferred into a Structural Equation Model (SEM) to analyze the causal relationships between the constructs. The SEM Builder of *Stata 14* was used for this purpose.

SEM can examine different statistical methods simultaneously, i.e. multiple regression analysis and factor analysis. According to Hair et al. (2014), SEM models can be characterized by:

- 1. Estimation of multiple and interrelated dependence relationships;
- 2. An ability to represent unobserved concepts in these relationships and account for measurement error in the estimation process;
- 3. Defining a model to explain the entire set of relationships.



Thus, SEM allows to model and test both measurement properties and hypotheses about theoretical relationships among variables, which may be unobservable latent variables that cannot be measured directly. In fact, SEM can conduct analysis on both measurement models, in which latent variables are connected to observable variables (i.e. constructs and items), and structural models, in which relationships between latent variables are tested (i.e. relations and hypotheses between constructs).

According to the SEM technique, it is essential to validate both the measurement model and the structural model.

#### Measurement model

Convergent and discriminant validities are two fundamental aspects of the measurement model validity.

Convergent validity refers to how closely a variable is related to variables and measures of the same construct. The criterion of Fornell-Larcker (1981) has been used to assess the degree of shared variance between the latent variables of the model. According to this criterion, the convergent validity of the measurement model can be assessed by the Average Variance Extracted (AVE) and Composite Reliability (CR).

- AVE measures the level of variance captured by a construct versus the level due to measurement error. Values above 0.7 are considered very good, whereas, the level of 0.5 is acceptable;
- CR is a less biased estimate of reliability than Cronbach's alpha. The acceptable value of CR is 0.7 and above.

AVE and CR were calculated with the following formulas:

$$AVE_{j} = \frac{\sum_{i=1}^{p} L_{i}^{2}}{p}$$
$$CR_{j} = \frac{(\sum_{i=1}^{p} L_{i})^{2}}{(\sum_{i=1}^{p} L_{i})^{2} + \sum_{i=1}^{p} V(e_{i})}$$

Where:

- j is the construct taken under analysis
- is the factor loading of the item i and represents the relationship from the construct j to the item i
- $V(e_i)$  is the error variance in the variable i and is given by:  $V(e_i) = 1 L_i^2$



Not only should the construct correlate with related variables but it should not correlate with dissimilar, unrelated ones. This aspect is tested through discriminant validity. Discriminant validity is assured when the value of the AVE is above the threshold value of 0,5 and when the square root of AVE is larger than correlations among the constructs (El-Wajeeh et al., 2014).

#### Structural model

The hypotheses were confirmed or rejected according to the p-value. The p-value expresses the probability of erroneously rejecting a true null hypothesis, thus assuming a significant path coefficient when it is not significant.

In a range from 0 to 1, the smaller the p-value the stronger the statistical significance of the hypothesis. A p-value of 0.05 represents the standard cut-off for statistical significance; if the p-value is under 0.01 results are considered very significant; finally, if it's below 0.001 they are considered extremely significant. Hypotheses characterized by p-values within these ranges have been marked respectively with one (\*), two (\*\*) and tree asterisks (\*\*\*). In this study, the threshold value has been set at 0.1, meaning that there is a 10% probability

of error if the path coefficient considered is significant at a 10% level. Hypotheses characterized by p-values between 0.1 and 0.05 have been marked with four asterisks (\*\*\*\*).

Finally, in order to assess the goodness-of-fit (GOF) of the structural model four indices were considered: the Comparative Fit Index (CFI), the Tucker-Lewis Index (TLI), the Root Mean Square Error of Approximation (RMSEA), and the Coefficient of Determination (CD). RMSEA is an absolute fit index, in that it assesses how far a hypothesized model is from a perfect model. On the contrary, CFI and TLI are incremental fit indices that compare the fit of a hypothesized model with that of a baseline model, i.e. a model with the worst fit.

- The CFI analyzes the model fit by examining the discrepancy between the data and the model adjusting for the issues related to sample size inherent in the chi-squared test. The recommended value is equal or higher than .90;
- The TLI ranges between 0 and 1, with larger values indicating better relative fit. Bentler and Bonett (1980) recommend that TLI > .90 indicates an acceptable fit;
- The RMSEA avoids issues of sample size, analyzing the discrepancy between the hypothesized model and the covariance matrix. Values between .05 and .08 indicate and adequate fit (Hair et al.; 2014);



• The overall model CD, otherwise called R-squared (R<sup>2</sup>), is a measure of global fit representing the proportion of the dependent variable's variance predictable by the model. It is considered acceptable above .80.



# 6. Digital Technologies for Eating Disorders: Onfield Research

The first part of the empirical section is an on-field research in order to shape a new system of digital technologies on the real needs of the Healthcare system in Italy.

As emerged from the paragraph *Italian context*, one of the most relevant issues on the national level is the lack of multidisciplinary support to the cure and care of the patients affected by EDs in most of the regions. Moreover, the costs for this form of treatment are high and are not covered by the public system. The current study aims at finding a practical solution to increase the accessibility and the quality of the treatment for EDs.

The starting point of the current study is an Italian excellence Villa Miralago, a rehabilitation center accredited with Regione Lombardia that receives both adults and minors.

They have a complete overview on the treatment of patients affected by EDs since their équipe covers all aspects of the disease and all professionals' figures involved are present in the structure. Moreover, the rehabilitation center is a steppingstone for all other clinical settings since it has a complete knowledge of both the curing and the caring aspects of the treatment, and it is the only clinical setting able to follow the patient throughout his/her path. The medical director of the clinic showed enthusiasm for the study of digital technologies for the treatment of EDs and consequently the project with Villa Miralago has been defined. The final objective of the project is to carry out a trial in the structure involving all professional figures and around 20 patients to access the feasibility of a digital system. For this purpose, the structure is willing to allocate  $30.000 \in$  for the technologies' purchase and involve patients in this study throughout their staying (on average 8 months). The first milestone and the objective of the current study is to develop the protocol for the trial to be submitted to the regional ethical committee to access if the trial is set in an ethical and legal manner.

# 6.1.Context Analysis

Villa Miralago is a center destined to therapeutic rehabilitation for people who suffer from AN, BN, BED and obesity. It has a total of 61 beds distributed in 4 communities: Camelia and Gardenia communities, for adults; Ginestra community, for adults in most severe conditions; finally, Primavera community, for minors. The age range of patients is 12 to 50,



being the average age between 16 and 24. Confirming what has been told in the paragraph above, the majority of patients affected by AN are female.

All the communities share the same professional figures that are psychiatrists, psychologists, nutritionists, nurses, professional educators, kinesiologists and art therapists. The techniques used in the residence are based on an integrated, multidisciplinary and psychoanalytically oriented method: the treatment is not focused on the corrections of eating behaviors, but on the profound psychological and mental aspects whose improvement can produce a clinical improvement and guarantees a more stable future. Every schedule or process in the residence is personalized for each patient depending on his/her necessities.

Villa Miralago already uses some digital technologies to have a better vision and data of the state of each patient, such as anthropometric measures, the body composition, the rest metabolism and the physical activity. Further implementation of digital technologies could guarantee a constant and more precise monitoring of the state of the single patients and of the general atmosphere inside the clinic through the collection and visualization of real world data (RWD) on a permanent basis.

# 6.2. Need Analysis

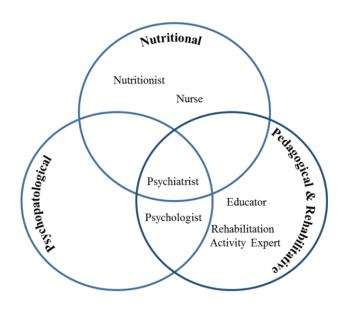
The need analysis was required for mapping which data is relevant for the trial to be launched in Villa Miralago. According to the literature review, similar experiment that uses multiple technologies to support EDs rehabilitation in a hospital-setting does not exist. This allows freedom to design a unique pilot study.

However, it is necessary to define the interests and needs in this specific project setting, i.e. which data the professionals of Villa Miralago need in order to progress in the recovery of each patient. In order to obtain this information, interviews to 9 different professionals from Villa Miralago were carried out. Particularly, they were made to nutritionists, psychiatrists, a rehabilitation activities expert, a nurse, a psychologist, and an educator.

# Standard of care

The activities are distributed in three intervention areas: the nutritional area, the psychopathological area, and the pedagogical/rehabilitative area. Each professional of Villa





Miralago can be assigned to three areas, as illustrated in *Figure 9*. Each professional has precise activities in Villa Miralago that cover all the areas necessary for the recovery of the patients (*Table 18*).

*Figure 8: Organization of professional figures in the interventional areas* 

FUNCTION	ACTIVITIES			
Psychiatrist	<ul> <li>First visits of potential patients</li> <li>Interface with the sending services</li> <li>Planning of therapeutic rehabilitation project</li> <li>Periodic meetings with patients, relatives and teams</li> <li>Prescription of drugs</li> <li>Prescriptions of laboratory analyses and preparation of tests</li> <li>Compilation and updating of the medical record</li> <li>Post-release collaboration services</li> </ul>			
Psychologist	<ul> <li>Individual meetings</li> <li>Psychotherapeutic group meetings</li> <li>Meetings with the patient's family</li> <li>Psychotherapeutic tests</li> <li>Psychological and nutritional state measuring in the follow-up</li> </ul>			
Nutritionist	<ul> <li>Meals assistance in the three dining rooms (critical patients, stable patients and patients with greater autonomy)</li> <li>Assessment of nutritional status</li> <li>Decision of food therapy (which can be autonomously or by nasogastric tube)</li> <li>Individual meeting with patients and "weight times"</li> <li>At the beginning of the staying and when needed they decide menus and energy intake according to the patients</li> <li>Assessment of nutritional status: weight, body mass index, calorimetry, lean and fat mass</li> </ul>			



Nurse	<ul> <li>Administration of therapy</li> <li>Help in moments of crisis (more frequently in the Ginestra community, so they work closer to the patients)</li> <li>Help patients during mealtime to prepare the table</li> <li>Assist patients during mealtimes (4 times/day)</li> <li>Put the nasogastric tube</li> </ul>
Educators	<ul> <li>Meals assistance</li> <li>Community rules instructions</li> <li>Contact with families and external bodies</li> <li>Distribution of telephones and "regulated" objects</li> <li>Follow rehabilitation activities (artistic, playful, psychomotricity)</li> </ul>
Rehabilitation activity expert	<ul> <li>Organization of individual and group activities in the gym</li> <li>Organization of the individual and group activities in the swimming pool</li> </ul>

Table 18: Standard of care activities performed by each professional in the clinic

# Internal exchange of information

The second part of the interviews was focused on the internal exchange of information between professionals in Villa Miralago. To have a good overview of the state of the patient, all the main figures need to communicate about the patients' conditions (*Table 19*). The information flow is clarified in *Figure 10*.

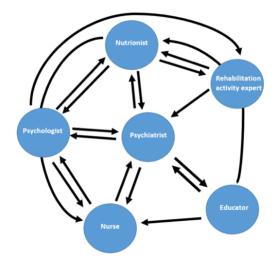


Figure 9: Information flow between professionals

FUNCTION	INFORMATION EXCHANGE			
Psychiatrist	<ul> <li>Micro and macro <i>equipe</i> meetings</li> <li>Nutritionist: how many times BIA, nutritional framework, if the patient eats</li> <li>Psychologists: therapy progress</li> <li>Educator: how the patient behaves in the community and in the common spaces, how much money the patient has spent</li> <li>Rehabilitation activity expert: which motor activity the patient carries out</li> <li>Nurse: if the therapy is regularly taken.</li> </ul>			
Psychologist	<ul> <li>Micro and macro <i>equipe</i> meetings</li> <li>Nutritionist: ask for the weight trend</li> <li>Nurse: how the patient behaved during the meal</li> <li>Psychiatrist: information about the therapy</li> </ul>			
Nutritionist	<ul> <li>Micro and macro <i>equipe</i> meetings</li> <li>Educators: ask about daily routine</li> <li>Rehabilitation activity expert: ask about physical activity</li> <li>Psychiatrist: information about the therapy</li> <li>Psychologists: therapy progress</li> <li>In general, there's a great cooperation to evaluate the energy consumption</li> </ul>			
Nurse	<ul> <li>Psychiatrists: the therapy (orally and through diaries)</li> <li>Nutritionists: the menu for the weekend</li> <li>Educators: how to deal with the crisis, which activities the patients should do and when to give them their smartphones</li> </ul>			
Educator	• Micro and macro <i>equipe</i> meetings			
Rehabilitation activity expert	<ul> <li>Micro and macro <i>equipe</i> meetings</li> <li>Nutritionists: the menu, they can help deciding the activities and the frequency</li> <li>Psychologists: what a certain activity could mean to the patient (if there is a trauma or an episode in their life related to that activity; if it is possible to do group works)</li> </ul>			

Table 19: Information exchange between professionals

# Data need of each function

The purpose of these interviews was to identify which data is needed from each professional (*Table 20*). The data are separated in seven different categories: 1) Caloric intake: calories actually eaten, 2) Caloric expenditure by physical activity, 3) Sleep monitoring: quantity and quality of sleep (three stages: awake, sleep, deep sleep), 4) Vomit detection, 5) Emotion tracking, 6) Movements and dynamics: for example, social interaction between the patients.



	CALORIC INTAKE	CALORIC EXPENDITURE	SLEEP MONITORING	VOMIT DETECTION	EMOTION TRACKER	MOVEMENTS AND DYNAMICS
Psychiatrist	х	Х	Х	х	х	Х
Psychologist	x	Х			х	
Nutritionist	х	Х	Х	Х		Х
Nurse			Х	Х		
Educators					Х	Х
Rehabilitatio n activity expert	х	х				

Table 20: Data need by each professional

# 6.3. Technology Analysis

It is necessary to perform a technology analysis to make precise research protocol with defined digital technologies to be used in the pilot experiment. Nowadays, there is a great number of different digital health technologies for both professional and consumer use, as described in *Digital Technologies in Healthcare*. Thus, it is important to specify the needs as well as the limitations to find the appropriate devices.

The technology analysis is based on the interests of the health professionals in Villa Miralago and the preferences of the expert of digital technologies of the project. In addition, the results of the literature analysis (*Chapter 2.2*) were considered. According to the interests presented in *Table 20*, the possible technologies were mapped by interviewing the IT-professional from Politecnico di Milano. For the caloric intake, there are few image-based technologies e.g. video cameras able to analyze the caloric content of the food the patient is eating from the captured images. Cameras could be used also for the movement and dynamics measurements inside the clinic and microphones placed together with these cameras could enable general mood and language. Emotions can be tracked also during the psychiatrist meeting with a frontal video camera. For the caloric expenditure, there are numerous different wearables mostly fitness trackers that measure the physical activity and calculates the expenditure basing on the input data in the related device. Special antennas capturing signals from the wearables can be spread in the common rooms to measure the position of the patients and the distance between them. GPS integrated in some of these fitness trackers could also be used for the movement tracking. Also sleep can be followed with the fitness trackers but for



more accurate measurements and additional data, specific sensors placed under the mattress are available for both professional and private use. There is no technology available for the vomit detection but theoretically the pH inside the toilet seat could be followed. However, this method would be neither practical nor a digital technology.

Overall, current smart applications integrated with the wearables enable multiple parameter tracking but they encounter the problem of data acquisition in a personal device. This evokes the need for a customized software that collects data from all the devices used in the trial, stores them in a platform and simplifies data visualization for professionals. For the data storing, there are few platforms available to integrate all the collected data. These platforms can be used also for storing the information, for example, about the diagnostics, medications, and care plans. It is possible to use them in various contexts, such as Electronic Health Record (EHR) -based data sharing, server communication in larger institutional healthcare providers, and phone applications.

For each technology, the overall cost and technical specifications were evaluated. The technical specifications were related to the accuracy and battery duration of the device, and to the collection, transfer, storing, analyzation and visualization of the data. The last two criteria are important for the health professionals not specialized in technology as it helps to understand the raw data collected by the device. The preliminary cost evaluation (*Table 21*) is based on the given budget and includes also the approximated purchase and maintenance costs.



PARAMETER	CALORIC INTAKE	CALORIC EXPENDITURE	SLEEP MONITORING	VOMIT DETECTION	EMOTION TRACKER	MOVEMENT AND DYNAMICS
Device	Camera placed in dining room	Wearable fitness tracker	Sensor placed under the mattress	-	Frontal camera in psychiatrist's room, microphone placed in common rooms	Camera and antenna placed in common rooms (wearable fitness tracker)
Number of devices (pcs)	5	20	20	0	4 camera, 4 microphones	4 camera, 20 antennas
Evaluated costs	7000- 10000 €	1200-1300€	6000-7000 €	0	600-800 €, 200-2000 €	600-800 €, 1000-1500 €
Overall costs	Overall costs:         16 600 € - 23 400 €					

Table 21: Suggested technologies to be used

Technologies used in previous research for screening, diagnosis, and follow-up are not in the main focus of this experiment as the aim of the project is to provide data during the patients' stay in the clinic. As explained in the in-person interviews, patients' use of personal smartphones is limited and thus any technology leaning on the smartphone application is excluded as it would not provide continuous data to professionals.

	SCREENING DIAGNOSIS		MONITORING	DECISION SUPPORT	DIGITAL THEREPEUTICS	FOLLOW-UP
Excluded technologies	Social media analysis by machine learning	Brain scanner	- Wearable sensors (ECG, HR, HRV, GSR, eating behavior) - Smartphone applications	Smartphone applications	-mHealth -VR	-Social media analysis
Reason for exclusion	Not in focus	-Not in focus -Invasive	-Invasive -Limited data	Limited data	-Limited data -Not in focus	-Not in focus

Table 22: Technologies excluded



# 6.4. Results from the On-field Research: Protocol Design

Since one of the gaps emerged from the literature analysis was the scarcity of evidences to understand in which extend digital technologies could improve the effectiveness of the rehabilitation process, the first result of the study has been the protocol design for the Proof of Concept to be implemented in Villa Miralago. The following paragraphs will describe how this clinical trial will be set.

### Study design

This is a Proof of Concept (PoC) to evaluate the feasibility of the usage of digital technologies for monitoring female patients affected by AN during inpatient rehabilitation. Since there was the need to have a group of participants more homogeneous and that would have a similar rehabilitation process, it was decided to start a trial dedicated to female patients affected by AN. This would enable the comparison between patients concerning the results of digital technologies' application. The objectives of the PoC are not in line with the definition of a control group, that therefore hasn't been identified. It is not a randomized trial since partially the results will be visualized on the dedicated patient folders accessible to all professionals.

In the following paragraphs, the patients involved in the trial will be defined as treated patients, while the remaining as Standard of Care (SoC) patients. The length of the trial will vary according to the period of stay of the single patient; on average, as communicated by the director of the clinic, it is expected to be 8 months. The protocol was structured following *SPIRIT 2013 standards explanation and exploration: guidance for protocols of clinical trials*.

## Study setting

Patients will be recruited from the Italian rehabilitation center for EDs Villa Miralago (Cuasso al Monte, VA).

## Patients screening and recruitment

Eligible patients will be identified according to the inclusion and exclusion criteria described in *Table 23*. Once eligibility has been established, patients will be invited to join the study by the health director of Villa Miralago. The enrolment phase will be run as follows: at first, a meeting will be organized in which the health director will introduce and illustrate the



study to the patients. Two students from Politecnico di Milano involved in the ideation of the study and the responsible for the coordination of researches in Villa Miralago will attend this meeting as well: the first to better describe the purpose of technologies, the latter because he will be the reference figure during the implementation of the study. Together with the health director, they will answer to doubts and questions from the patients. Afterwards, patients will receive a written description of the study and the informed consent form. Patients will be given enough time to consider participation and they will be advised that they can discuss the study with the health director and the responsible of coordination of researches prior to making a final decision. If patients agree to participate, written informed consent will be obtained during the enrolment day. In the case of minors, both the parents have to agree and come to the clinic, filling the written informed consent for their daughters. The same day, patients will receive adequate instructions and detailed information about the wearable usage by the responsible of coordination of research.

INCLUSION CRITERIA	EXCLUSION CRITERIA
1. Patients suffering from AN	1. Patients recovered in the Ginestra community, which is reserved to the most severe cases
2. Female patients only	2. BMI < 12
<ul> <li>3. Patients willing to provide informed consent to participate in the study; in case of minors (age &lt;18) the consent has to be given by both the parents</li> </ul>	3. Patients already included or about to join other clinical trials
4. Priority to new patients	

#### Table 23: Eligibility criteria

## Intervention

While the patients will be introduced to the study and will give their consent, the professional figures will meet divided by functions with two students of Politecnico di Milano and the IT expert. The aim of the meetings will be to help the different functions understanding which are the data collected by the technologies and how to read them through the data visualization software. The IT expert will be available to solve possible doubts and issues together with the health director of the clinic, after the meeting and throughout the trial, prior notice.

Some devices will be assigned to the single patient, while others will be shared among the treated group. Consequently, it will be possible not only to visualize single patient data to improve the personalized Individual Therapeutic Plan (ITP), but also aggregated ones to



understand the general mood in the structure and the group dynamics. Moreover, it is important to point out that also professionals and SoC patients will come in contact with devices such as cameras and microphones installed in common rooms: due to privacy reasons, this issue will be submitted to a Labour Inspectors' Committee and all the professionals and patients of the structure will have to give their consent to the usage of the previously mentioned technologies. After the collection of the consent from all figures involved in the study, it will be possible to start the trial. The trial itself will be marked by three main steps: a first assessment (performed at week 0), an intermediate assessment (performed at week 12) and, finally, the close-out (period not defined ex-ante). Within these steps, the patient will be constantly monitored through the digital technologies adopted in the trial. The execution of the trial is described in detail below.

#### Step 1: First assessment (week 0)

An initial assessment of the patient's condition will be performed. The nutritionists and nurses will measure **anthropometric indicators** such as BMI and weight, while psychologists will submit **psychometric tests**. Together with the tests already performed in the SoC (see *Standard of Care*), patients will be subjected to the ones that concern depression and anxiety level i.e. BDI (Beck Depression Inventory, 1967, Beck) and BAI (Beck Anxiety Inventory, 1988, Beck), since they are agile tests that add knowledge about the patient status, feasible to be replicated also in the intermediate assessment. Afterwards, the reference figure for the study (i.e. the responsible for the coordination of researches) will give to each patient a **technology acceptability questionnaire** (still to be defined): at this stage, the questionnaire aims at capturing the degree of prejudice against technology by the patients. It will be composed by two parts: ease of use and perceived usefulness of the digital devices during therapy. The same questionnaire will be subjected to professionals with the same dual structure. The two will differ mainly in the object of interest. For the patients, it is focused more on the experience of use while for the professionals, it is whether the technology and new data available improve the accuracy of their decision-making process or not.

#### Monitoring (week 0 - 12 and week 12 until Close out)

During the first meeting with the health director and the reference figure, a **wrist wearable** will be assigned to each patient to be worn in daytime during the period of stay. Patients will be explained that during the night they may need to charge the device. In the past trials, it has been proven that they are reliable in this task. The wearables will be used to track the



caloric expenditure, HR, and body temperature. This information will be transferred in real time directly to the platform and stored for further learning of the device and decision making. It is relevant to underline that the data collected have to be available for professionals but not for the patients due to the tendency of anorexic patients to over-control every aspect of their life. Precise information about the daily activities would endanger their rehabilitation process.

During the night, data will be collected by **sleep monitoring sensors**, installed under patients' mattresses in their bedrooms. These devices are able to detect the number of sleeping hours and the quality of sleep in terms of HRV, sleep stages (REM, deep, light, awake), breathing rate, sleep score, tossing and turning, movement activity, time in bed and sleep, and Autonomic Nervous System (ANS) balance. These parameters allow professional to deduct significant information about the emotive and psychological state of the patient, possibly improving the accuracy in personalized drug prescription. Additionally, it will be possible to know if patients will do excessive exercise during nights, a characteristic symptom of AN.

In the dining room, **smart cameras** will be placed over the tables of the patients involved in the trial. Through image recognition, the quantity of food in the plate at the end of the meal is detected and the actual caloric intake is calculated by comparing this value with the personalized menu. Due to privacy reasons and the high cost of these devices, the treated patients will be joined together in tables identified for the trial. According to a rough estimation of the participants in the trial (= 20 patients), 5 smart cameras need to be installed, one for each table composed by 4 people. These cameras will not be visible due to their small size comparable to the one of a smartphone. They can be fixed in objects, such as lamps above the tables in the dining room.

Also, **regular video cameras** will be installed in common spaces of the building. 3 cameras will be installed in the hall to detect group movements and dynamics: one in the entrance, one in the dining room door, and one at the beginning of the corridor. They will record indistinctly all the patients and professionals and will be switched on during the day. Thus, the privacy concerns have to be taken in consideration. Other places to be monitored are those where patients usually meet without professionals' supervision. They will be identified by the educators to see what happens when operators are not around. Also, frontal cameras will be deployed during the meetings with psychiatrists to capture the emotional state of the patient. They will be placed in the four offices for psychiatric visits present in Villa Miralago



and switched on only during the meetings with the patients. Additionally, another camera will be placed in a common room where the group therapy takes place. Also in this case, it will be necessary to join all the treated patients in one or more groups specifically dedicated to the trial.

In the hall, **microphones** collect data of the general mood and used words. Positions of these microphones has to be defined with the health director to identify the most common meeting spots hidden from the personnel and catch the type of language the patients use between each other.

Finally, **antennas** will detect movements and group dynamics both inside and outside of the building. Distances between the antennas and personal devices, i.e. wearables, are calculated to understand where patients are with respect to the antennas and to each other. The desired coverage of the clinic's area has to be defined to know the positions of the antennas and the number of antennas needed.

#### Step 2: Intermediate assessment (week 12)

An intermediate assessment will be performed after 3 months (i.e. week 12) because typically the tolerance of devices, such as wearables becomes critical after this period. The main objectives of the intermediate assessment will be 1) to carry out an initial evaluation of the trial's feasibility: hardware and software installation and integration; data collection, data visualization and returned information; digital technologies management; acceptance of digital technologies by patients and professionals, 2) to modify and adjust the way in which the trial is carried out according to patients' and professionals' feedbacks, 3) possibly, to verify if a correlation exists between the data collected by the devices in first weeks and the results deriving from the psycho-physiological analysis. Patients will be submitted again the BAI and BDI questionnaires, already performed at the beginning of the treatment (week 0) and the anthropometric parameters will be taken weekly during the treatment.

#### Step 3: Close-out (not defined ex-ante)

The close-out coincides with the end of inpatient care and will not take place simultaneously for all patients involved: the experiment will end when each patient has been discharged from the clinic that depends on the state of health and their progress (on average, after 32 weeks). Patients who have not dropped out will be subjected to the last psycho-physiological evaluation through all the questionnaires carried out at week 0, i.e. SF-36 (Short Form Health



Survey, 1992, Ware et al.), BUT-1 (Body Uneasiness Test, 2006, Cuzzolaro et al.), EDI-3 (Eating Disorder Inventory, 1984, Garner et al.), MMPI-2 (Minnesota Multiphasic Personality Inventor, 1942, Hathaway et al.), CORE (Clinical Outcome Routine Evaluation, 2002, Evans), BDI and BAI. Patients and professionals will be subjected to the technology acceptability questionnaire, evaluating the ease of use and the perceived usefulness of the digital devices for patients and of the new data available for professionals. Therefore, it will be possible to evaluate the feasibility of the project, how the technology acceptability has changed during the trial, and how digital technologies have improved the accuracy of the ITP.

### Standard of care

Standard of Care (SoC) consists in the treatment currently carried out in the clinic. The rehabilitation path is personalized according to each patient's condition, evaluated through the following standard practices. On their admission to the clinic, patients are subjected to a psychometric assessment (BUT-1, EDI-3, MMPI2, SF36, CORE tests) to evaluate their general health condition. During the week, each professional figure comes in contact with the patients under their responsibility, both individually and in group. Then, weekly multidisciplinary equipe meetings are organized, where the professional figures in charge of the same patients perform a qualitative evaluation for each of them. The discussion is based on the visits and every-day life observations collected during the week, and consideration of two quantitative parameters (weight, BMI). The primary aim of the multidisciplinary meeting is to adapt the patient's treatment to his/her current condition and the output is the updated ITP. Once the patient is discharged, the psychometric assessment is performed again to understand how the health condition of the patient has changed during his/her permanence in the clinic.

#### Outcome

This trial will be evaluated in terms of (1) dropouts, (2) technology acceptability, (3) anthropometric measurements, (4) psycho-physiological measurements for the patient side, (5) easiness of use, and (6) perception of usefulness of technology devices regarding the professional side.



#### Dropouts

A dropout is a subject in a clinical trial who, for any reason, fails to continue in the trial until the last visit required by the study protocol. The following two cases will be classified as dropouts: 1) a patient who decides to discharge him- or herself, interrupting the treatment and consequently the participation in the trial. For adult patients, the permanence in the clinic is voluntary while minors willing to leave need the consensus of both the parents, 2) a patient continues the inpatient care path in the clinic but decides to quit the trial in favor of the SoC treatment. This outcome is the earliest indicator of run-in failure because it reflects also the feasibility of the study. There are a number of factors which influence the subject to drop out from the trial: (1) lack of motivation to comply, (2) dissatisfaction of the individual, (3) exasperation due to trial related procedures. The outcome will be measured by counting the patients that call to withdraw from the trial or by counting participants that entirely stop using the wearable device.

#### Anthropometric measurements

Anthropometric measurements are used to assess the size, shape and composition of the body. The most important parameters are weight and BMI that are measured once a week in the SoC, so the evaluation will be a comparison between the patients involved in the trial and the SoC patients.

### Psychometric assessment

Psychometric assessment is done by subjecting patients to five different questionnaires to establish the general health condition, SF-36, BUT-1, EDI-3, MMPI-2 and CORE tests. These tests are already submitted to all the patients in the SoC at the beginning and possibly at the end of the treatment (there are problems with early self-disposals). As with the anthropometric measurements, the most interesting part of this evaluation will be the comparison between the treated patients and the SoC patients.

### Technology acceptability

Treated patients will have the opportunity to provide feedback on strengths and weaknesses of the trial, including unintended/unexpected effects. Use and adoption metrics are important process outcomes to understand the mechanism of action of the intervention. To test user satisfaction, an acceptability questionnaire, generalized for all the technologies, will be



subjected to both patients and professionals. The one for patients will investigate the acceptability of all the different digital technologies in terms of physical resistance to the wrist wearables, sensation to be overcontrolled by the devices and feeling of stigma with respect to the SoC patients. For the professionals, the acceptability of additional data and information about the current state of patients and the group dynamics is questioned. The questionnaires will be constituted of two parts: ease of use and perceived usefulness, described below.

#### Ease of use of technology devices

The ease of use of a product is evaluated by the users. It describes how easily specific goals with effectiveness, efficiency, and satisfaction in a specified context of use of the product could be achieved. Questionnaire will be administered to professionals and patients involved in the trial at week 12 and at the close-out (not defined ex-ante).

### Perception of usefulness

Perceived usefulness is literally defined as the degree to which a person believes that using a particular system would enhance his or her job performance. It will be administered, as the previous one, to both professionals and patients involved in the trial at week 12 and at the close-out (not defined ex-ante).

### Data analysis

At this stage of the study the available information is not enough to describe the detailed planning and management of data. However, it is important to point out, at least broadly, the major issues to be faced in this regard and what the data analysis will consist of.

### Issue 1: Aggregation of data in a unique platform

First of all, it is evident that each device is originally programmed to collect data in its own platform/software. It would be more effective to collect all types of data in a unique platform, programmed and managed by the IT expert and accessible from the computers used by the professionals in the clinic. As mentioned in the *Intervention*, it is fundamental that the patients cannot have access to the data, for example, through smartphone applications associated to the devices. Still, the degree of feasibility of the data collection in a unique platform must be assessed.



### Issue 2: Integration of data within the electronic clinical folders

Villa Miralago is planning the adoption of electronic clinical folders, each of them containing the information related to a single patient. Not only written notes by the professional and traditional documentation, but also the information extrapolated by the data collection through digital technologies should be conveyed in the electronic folders, automatically and in real-time.

## Data analysis 1: Visualization of data related to the single patient

The first aim of the collection and analysis of data is to get objective information attributable to the single patients of the study. The information will be taken into account during the weekly multidisciplinary equipe meeting to establish with greater precision the ITP of each patient. At the end of the trial, it will be interesting to analyse how data from the same patient change in time. If patients were conscious about the technologies at the beginning and consequently felt treated in a different way, it would be interesting to understand if they actually changed their daily behaviours, either improving their physical and mental condition, or returning to the same habits as before the trial started.

Ideally, the information coming from the data related to the specific patient would be automatically inserted in the electronic clinical folder that Villa Miralago is going to implement.

# Data analysis 2: Connection of information from data and results of the psychophysiological and anthropometric assessments related to the single patient

The information given by the data collected with technologies should be compared to the outputs from the psychometric tests submitted at week 12 and at the close-out to assess the degree of correlation between them. As explained in the *Outcome*, one of the aims of the project is to understand the correlation between the results of the assessment and the data collected, since it could prove the strict correlation between physical and mental state of the patients.

## Data analysis 3: Statistical analysis

Last but not least, it would be important to evaluate if some type of data follows similar trend when comparing the samples, i.e., treated patients along their overall path in the clinic. The closer the conditions and the permanence in the clinic of the patients the more significant the comparison becomes.



### Data analysis 4: Movements and dynamics in the clinic

Data concerning group dynamics and movements will be collected and presented in the data visualization software. Professionals will know the general mood in a certain day and its trend, the common words used among all the patients (both SoC and treated ones), and social dynamics. For example, does a treated patient meet always with the same people? Is she isolated from the group most of the time, etc.?

## Ethics and dissemination

The protocol will be subjected to an ethical committee identified by the clinic. The dissemination strategy still has to be defined, but trial results are likely to be spread through publications in scientific journals and presentations during seminars and conferences.



# 7. Psychological Well-being: Model Design

JD-R model (Demerouti et al., 2001) has been defined as the proper model to analyze the psychological state of professionals and its flexibility is exploited to address the focus of this analysis. More in detail, the impact of introducing digital technologies in clinical practice of healthcare professionals working with EDs (i.e. physicians, psychologists, nutritionists etc.) is targeted through the selection of the right variables, connections and outputs.

# 7.1. Hypotheses Development

The introduction of digital technologies could result in significant and beneficial outcomes for the job of healthcare professionals, but it could also give rise to a new source of stress to the ones that are not familiar with the use of digital technologies or who fear that the number of activities to perform their job will grow consequently.

In order to measure the impact of this change on a psychological level in all its dimensions, a set of variables attributable to the core constructs of JD-R (Job Demands; Job Resources; Burnout; Engagement) have been defined.

For what concerns the *Job Demands* dimension, the workload and cognitive demand factors have been considered.

**Workload** represents the sheer volume of work required of an employee (Spector and Jex, 1998). Digital technologies might impact on healthcare professionals' workload in two ways. On one hand, they might reduce the workload thanks to computer-aided activities and the automated extraction and communication of relevant insights from real-world datasets. On the other hand, the new responsibilities and roles coming from the introduction and use of digital technologies, such as supervising the ICT system and supporting the patients in technology adoption, might significantly increase the healthcare professional's workload.

**Cognitive demand** refers to the overall amount of mental effort used during the working activity. Indeed, it is arguable that learning new skills and capabilities such as the digital ones requires mental efforts, and that bearing the cognitive demand to manage all the new activities in which healthcare professionals are involved might be relevant.

Overall, the following hypotheses were proposed:



#### H1. Job Demands increases healthcare professional's Burnout

#### H2. Job Demands demand decreases healthcare professional's Engagement

As for *Job Resources*, two main variables have been identified: Autonomy and Professional development.

**Autonomy** is defined as a high degree of control over the execution of the task (Bakker, Demerouti, & Verbeke, 2004). Autonomy represents one of the most effective elements to cope with job demands because it allows freedom and independence when working. Autonomy has been selected because it might be strongly affected by the introduction of digital technologies. In fact, in it is expected an increase of autonomy for any healthcare professional due to the fact that digital technologies enable information sharing and a comprehensive view on the health status of the patients. Therefore, the knowledge of the professional is enhanced as some information is made available quickly and more precisely, and the necessity to ask for such information to other colleagues is reduced. This aspect seems especially important in the Italian context since the multidisciplinary team needed for the rehabilitation process is not always available in all regions (as reported in the *Italian Context* chapter). In conclusion, the higher degree of autonomy might help the professional role in better organizing the work and better face the demands of its role.

**Professional development** is defined as opportunity to learn new things and possibility to develop himself/herself at work (Bakker, Demerouti, & Verbeke, 2004). Professional development allows to provide a meaning and a personal attachment to the job, thanks to the growth achievable by the individual. It is generally accepted that every time changings happens, personal development occurs. New challenges, new learning opportunities, new competences, new tools may profoundly shake the "bean counter" job making it always more satisfying and appealing for the new generations of healthcare professionals, enabling the development of a more skilled and traversal professional role able to interact and manage always more different aspect of the patient care.

As a whole, the following hypotheses have been formulated:

#### H3. Job Resources decreases healthcare professional's Burnout



#### H4. Job Resources increases healthcare professional's Engagement

Eventually, the JD-R model is used to predict organizational outcomes. For the purposes of the study, **Intention to Use** was selected as organizational outcome. Intention to Use is based on Fishbein and Ajzen's (1975) definition of behavioral intention: "the strength of one's intention to perform a specified behavior". In particular, the present model wants to assess Intention to Use technologies in healthcare organizations dealing with EDs.

More in detail, organizational outcomes are predicted by the JD-R model considering the balance between Burnout and Engagement. Respectively, these constructs are studied in the present work through two main determinants defined by Demerouti et al. (2001): Exhaustion and Disengagement, and Vigour and Dedication. The selection of just two main determinants of Burnout and Engagement is led by the optimal solution found in solving the length/completeness trade-off proper of every questionnaire.

**Exhaustion** have been defined by Demerouti, Bakker, Vardakou, and Kantas (2003) as an extreme form of fatigue as a consequence of prolonged and intense physical, affective, and cognitive strain caused by prolonged exposure to spe- cific working conditions (or stressors; cf. Aronson, Pines, & Kafry, 1983; Lee & Ash- forth, 1993; Shirom, 1989).

**Disengagement** refers to distancing oneself from one's work, work objects (e.g., computers, recipients), or work content (e.g., software programming, providing services). It represents an extensive and intensive reaction in terms of an emotional, cognitive, and behavioral rejection of the job and it delineates an occupational disillusionment (Bakker et al., 2004).

**Vigour** is characterized by high levels of energy and mental resilience while working, the willingness to invest effort in one's work, and persistence even in the face of difficulties (Demerouti & Vergel, 2014).

**Dedication** refers to being strongly involved in one's work and experiencing a sense of significance, enthusiasm, and challenge (Demerouti & Vergel, 2014).

Accordingly, vigor and dedication are considered direct opposites of exhaustion and disengagement, respectively, the two core symptoms of Burnout (Demerouti & Vergel, 2014).

In particular, the researchers propose the following direct relations with Intention to Use:

H5. Burnout decreases healthcare professional's Intention to Use



H6. Engagement increases healthcare professional's Intention to use

Besides the traditional four main blocks of JD-R (Job Demands, Job Resources, Burnout, Engagement), two additional core blocks have been included in the model: Psychological Safety and Patient Trust.

In particular, **Psychological Safety**, together with Job Demands and Job Resources, could have a relevant influence on Burnout and Engagement.

Psychological safety describes people's perceptions of the consequences of interpersonal risks in their work environment (Edmondson, 1999). If individuals feel psychologically safe, they may engage in their work without fear of negative consequence to self-image, status, or career (Kark & Carmeli, 2009). Edmondson (1999) demonstrated that psychological safety leads to team learning and increased team performance. This is especially important in a context where work practice is interactive and based on an integrated and multidisciplinary approach, as it occurs in the treatment of EDs. On the opposite, a scarce sense of psychological safety could reduce engagement, or worse, lead to disengagement and exhaustion typical of burnout.

Therefore, the proposed hypotheses concerning Psychological Safety are:

#### H7. Psychological Safety decreases healthcare professional's Burnout

#### H8. Psychological Safety increases healthcare professional's Engagement

Finally, we suggest that **Patient Trust**, together with Burnout and Engagement, have a relevant influence on Intention to Use.

Trust is a defining element in any interpersonal relationship but is particularly central to the patient-physician relationship (in broader terms, to patient-healthcare professional relationship). Although evidence shows that the majority of patients continue to trust physicians to act in their best interest, concern is growing that the rapid and far-reaching changes in the healthcare system, among which digitalization, have placed great pressure on that trust and may be undermining it (Pearson & Raeke, 2000). The new concerns about patient trust triggers a better understanding of its role on Intention to Use digital technologies.



In this perspective, the final hypothesis suggested is:

#### H9. Patient Trust increases healthcare professionals' Intention to Use

Consistently with the above discussion, *Figure 11* shows the adapted JD-R model, proposed by the researchers to study the Intention to Use digital technology of healthcare professionals. Blue blocks represent the traditional JD-R model components and related hypotheses, while the green ones represent the added (Psychological Safety, Patient Trust) or adapted (Intention to Use as organizational outcome) constructs and new relationships.

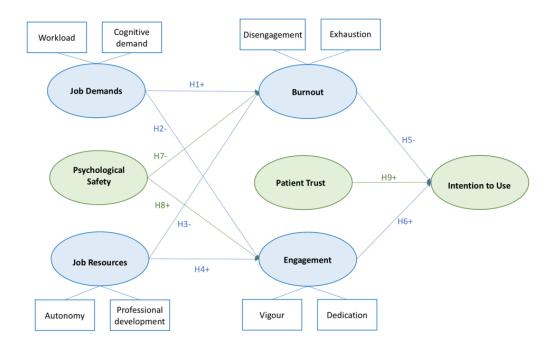


Figure 10: Theoretical model proposed



# 8. Exploratory and Explanatory Research: Survey Questionnaire

# 8.1. Sections description

## 8.1.1. Exploratory Research Sections

#### Socio-demographic variables

Socio-demographic variables selected were aimed at identifying the characteristics of the respondents and contextualizing the results of the questionnaire. Also, these variables could be potentially selected as control variables to increase the explanatory power of the theoretical model once tested.

In particular, the respondents were classified according to: (1) Gender; (2) Age; (3) Level of education; (4) Profession; (5) Professional experience; (6) Geographical region; (7) the type of structure, with regard to the clinical setting, where he/she works; and (8) the capacity of the structure for patients affected by EDs.

Here the answers to the questions were closed-ended, i.e. nominal scales, and open-ended. In total, 9 questions made up this section (D91-D99).

#### Data need assessment

24 questions have been addressed to the professionals in order to assess with a broader sample the interest in the data need emerged from the in-person interviews with professionals in Villa Miralago (D2-D28).

Firstly, respondents were asked to specify their clinical specialization among AN, BN, and BED, if any. Then, for each type of data (i.e. caloric intake, caloric expenditure, sleep monitoring, vomit detection, emotion tracker, and movements and dynamics) four questions have been submitted to the respondent, regarding the information relevance, frequency of assessment, current satisfaction and, when not satisfactory, the reason of dissatisfaction. They are close-ended questions, with a Likert scale that differs for the 4 types of questions.

#### Digital literacy

To ensure that digital technologies not only could have a potential impact for the advancement of research, assessment, and treatment in the ED field but also a real one, it is



necessary that target users are confident in their usage. Hence, a set of questions regarding the current ability of the professionals in using such technologies is needed.

6 closed-ended questions (D29-D35) with a Likert scale from 1 to 5, where 1 is "I highly disagree" and 5 is "I highly agree" have been posed.

Furthermore, in order to understand the level of awareness and implementation of the new technologies developed in the sector, one statement has been created for each digital health technology described in *Paragraph 2.2.1*, with the following options (D42-D47): (1) Never heard about it; (2) I heard about it, but I never used it; (3) I heard about it and I used it; (4) I heard about it and I use it. From this section, many information could be useful in order to understand the current level of innovativeness of the healthcare sector for what concerns the usage of new technologies.

#### Environmental dynamism

A dedicated section has been created to understand the changes that are taking place in the ED domain in relation to the introduction of digital technologies (D42-D47). D42 addresses the matter in a broader way, asking for the perception of changes in the ED domain in order to obtain the general perceived dynamism of the sector. D44, D45 and D46 focus on the perception of change for what concerns the interest in the adoption of digital technologies. Finally, D43 and D47 address the pressure towards the adoption of digital technologies of other stakeholders that are directly involved in the decisional process, i.e. the patients and the healthcare system.

They are close-ended questions with a Likert scale from 1 to 5, where 1 is "I highly disagree" and 5 is "I highly agree".

# 8.1.2. Explanatory Research Section

#### Psychological well-being

The following section describes the constructs of the adapted JD-R model. It consists of 42 closed-ended questions (D49-D90) with a Likert scale from 1 to 5 where 1 is "I highly disagree" and 5 is "I highly agree".

Workload (WL) and Cognitive Demand (CD) are used to obtain Job Demands; Autonomy (AU) and Professional Development (PD) are the two components used to obtain Job Resources; Disengagement (DIS) and Exhaustion (EX) are used to test Burnout; Vigour



(VIG) and Dedication (DED) are used to access Engagement. The questions used are just an extract of 3 items per component from standard JD-R model questionnaires, e.g. COPSOQ (Kristensen et al., 2005), QWI (Spector & Jex, 1998), UWES (Schaufeli & Bakker, 2004), and OLBI (Demerouti et al., 2001).

Then, Psychological Safety (PSAF), Patient Trust (PT) and Intention to Use (ITU) have been added to the model in order to fit in the current study. The PSAF scale consist in 4 questions coming from the study *Behavioral operations in healthcare: a knowledge sharing perspective* (Mura et al., 2016). For what concerns PT, the items have been adapted from the *Trust in Physician Scale* (TPS) (Anderson & Dedrick, 1990) formed by a total of 11 questions. ITU is a component of the Extended TAM model (Venkatesh & Davis, 2000) and the questions used are 3.

All the statements have been adapted to the specific context and the corresponding items, question numbers and constructs are described in *Table 24*.

CONSTRUCT	QUESTION	ITEM	STATEMENT		
With the introduction of the "system" (Figure 8):					
	D49	WL1	Your work will be heavier		
	D50	WL2	Your work will take longer		
	D51	WL3	You will be required to do more work than you can do properly		
Job Demands	D52	CD1	You will need to pay attention to more information while working		
	D53	CD2	You will need to store more information		
	D54	CD3	You will have to make more difficult decisions		
LLD	D55	AU1	You will have greater autonomy in carrying out your work		
Job Resources	D56	AU2	You will be able to do your job with greater freedom and independence		



	D57	AU3	You will be given more freedom to decide how to do your job
	D58	PD1	You will be asked to take more initiatives
	D59	PD2	You will have more opportunities to learn new things while working
	D60	PD3	You will have more opportunities to develop your skills
	D61	EX1	You will take longer to relax after work
	D62	EX2	You will be able to better withstand the pressure of its work
Deserves	D63	EX3	You will be able to manage your work better
Burnout	D64	DIS1	You will discover new and interesting aspects of your work
	D65	DIS2	You will speak negatively of your work more frequently
	D66	DIS3	You will feel more and more involved in your work
	D67	VIG1	You will feel more like going to work when you wake up
	D68	VIG2	You will be able to work for longer periods of time
Engagement	D69	VIG3	At work you will be more persevering even when things are not going well
Ligagement	D70	DED1	You will give more meaning and value to your work
	D71	DED2	You will be more enthusiastic about your work
	D72	DED3	Your work will inspire you more



	D73	PSAF1	You will never worry that your mistakes will be unfairly criticized by your colleagues
	D74	PSAF2	You are sure that no colleague will ever act voluntarily against you
Psychological Safety	D75	PSAF3	In the facility where you work, you will be able to discuss your work- related problems without difficulty
	D76	PSAF4	In the structure where you work, you will face many problems if you ask for help
	D77	PT1	The patient will doubt that you are taking care of him as a person
	D78	PT2	The patient will doubt that his/her needs will be put first by you
	D79	PT3	The patient will trust you so much that he will always try to follow your advice
	D80	PT4	The patient will believe you if you tell him/her that things are in a certain way
Patient Trust	D81	PT5	The patient won't always trust you and will like to ask for a second opinion
	D82	PT6	The patient will trust your judgment on the therapy
	D83	PT7	The patient will have the sensation that you're not doing everything you can to cure him/her
	D84	PT8	The patient will be confident that his/her clinical needs will be put above all other considerations by you in dealing with his/her health problems



	D85	PT9	The patient will consider yourself a true expert in the treatment of health problems similar to his/hers
	D86	PT10 The patient will believe t would tell him/her if a mist made about his/her therapy	
		The patient will be concerned about the privacy of the data you hold	
D88 ITU		ITU1	You will consider the possibility to use the system
Intention to Use	D89	ITU2	You are going to use the system
	D90	ITU3	You forecast that, having the opportunity to access the system, you will have the intention to use it

Table 24: Survey questionnaire's statements

# 8.2. Data Analysis and Results

The following chapter contains the results obtained from the delivery of the questionnaires to Villa Miralago and the centers belonging to Rete Ananke. Within the 102 questionnaires received back, 82 have been considered eligible for the purpose of the analysis, i.e. when filled at least in the sections related to the model, and 72 are completed in all the sections.

Firstly, it is presented the descriptive analysis: in this section, the socio-demographic characteristics and the clinical specialization of the participants, the validation of data need emerged in Villa Miralago, and the degree of knowledge and usage of digital technologies by the respondents will be illustrated through the use of graphs.

Successively, the outcome of the statistical analysis of the model is presented and the indexes regarding the validity of the model, the robustness of constructs and the path coefficient among them are disclosed.



#### 8.2.1. Results from the Exploratory Research: Descriptive Analysis

#### Socio-demographic variables

In order to contextualize the results of the questionnaire, the socio-demographic characteristics of the respondents are presented. As specified in the methodology chapter, the survey have been distributed at a national level to healthcare professionals working in Ananke centers.

First of all, sex and age are considered. As it is possible to see from *Figure 12*, the majority of the respondents is composed of female respondents (71%). This percentage perfectly reflects national statistics, according to which women dominate the healthcare sector in this proportion<sup>17</sup>.

With regard to the age, three categories have been considered: 25-40 years old, 41-60 years old and up to 60 years old, coherently respectively to the locutions of "Generation Y" (otherwise called "Millennials"), "Generation X" and "Over 60". This distinction has been adopted as it reflects different attitudes towards digital technologies and different visions of job, among many other aspects which do not concern the object of investigation. No one in the sample belongs to "Generation Z" (0-25 years old), therefore this category hasn't been considered. From *Figure 13*, it emerges that more than half of the respondent belongs to the 25-40 years old category. Very few are Over 60 (5%), as expected considering the proximity to pension.

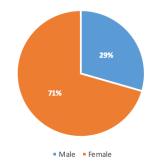


Figure 12: Gender of the respondents

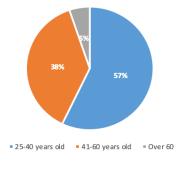


Figure 11: Age of the respondents

<sup>&</sup>lt;sup>17</sup>http://www.salute.gov.it/portale/news/p3\_2\_1\_1\_1.jsp?lingua=italiano&menu=notizie&p=dalministero&id =3845



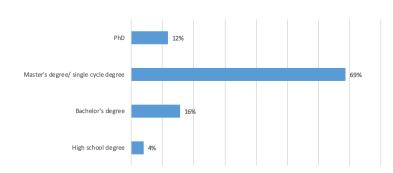
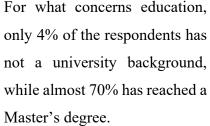
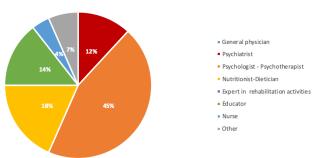


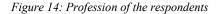
Figure 13: Education level of respondents

This is coherent with the professional profiles explicitly contemplated in the questionnaire, which are the same identified in Villa Miralago: Psychiatrists and GPs among the medical figures; then psychologists/psychotherapists,

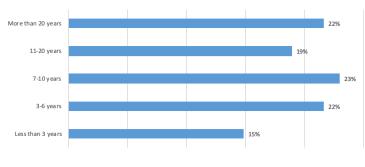
nutritionists/dieticians, educators, experts in rehabilitation activities, and nurses. "Other" was included as possible choice







for professions ignored by the researchers. As it is possible to see in *Figure 15*, no GPs and experts in rehabilitation activities have participated to the survey, while almost half of the respondents belongs to the Psychologist-Psychoterapist profile. In decreasing order, the other figures are 18% Nutritionistis-Dieticians, 14% Educators and 12% Psychiatrists.



Moving on to the years of work experience, professionals involved are quite equally distributed along the work experience categories defined (*Figure 16*).

Figure 15: Work experience of the respondents

As it has already been stated, Ananke represents one of the major realities at the national level for the cure of EDs. Specifically, it is distributed in the following 11 regions: Campania,



Lazio, Liguria, Lombardy, Marche, Piedmont, Apulia, Sardinia, Sicily, Tuscany, and Veneto. Considering the geographical location of respondents, half of respondents works in Lombardy (50%), while Sardinia and Tuscany have no representatives. Overall, the North is represented by 63% of respondents, the Centre by 9% of respondents, and the South by almost a third of respondents (30%).

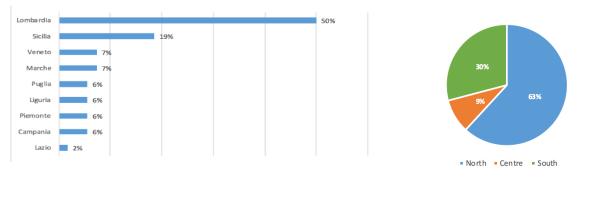


Figure 17: Regions where the respondents work

Figure 16: Territorial distribution of respondents on national level

#### **Clinical specialization**

In this paragraph, the characteristics of the clinical setting where the respondents operate, the number of patients followed by the facility where they work, and the typology of ED in which they are specialized are illustrated.

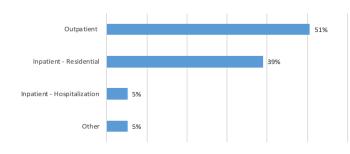


Figure 18: Clinical setting

From *Figure 19*, a balance between outpatient care (51%) and inpatient care (44%) emerges, where the latter is in turn divided in residential care (39%) and hospitalization (5%).



The facilities where patients are treated vary in terms of number of patients taken in charge (*Figure* 20). 10% of facilities represented by the respondents are very big ones, being in charge of at least 100 patients at the same time; on the contrary, one third can manage until 20 patients per time.

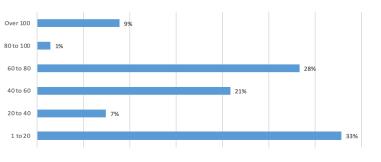


Figure 19: Number of patients that the facility takes in charge

Finally, before the data need validation section, it has been asked to the respondent ED in which they are specialized, if any. When specialized (42%), half of the healthcare professionals involved deals with AN (51%), followed by BN (33%) and BED (13%) (*Figure 21* and *Figure 22*).

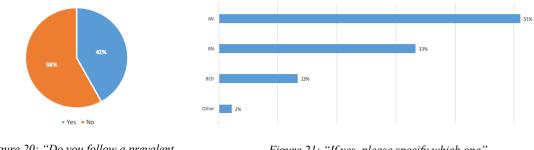
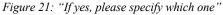


Figure 20: "Do you follow a prevalent diagnostic category of EDs?"



#### Data need assessment

Following the on-field research conducted in Villa Miralago, it has been assessed if the same data needed by professionals in Villa Miralago were relevant also for professionals belonging to Ananke. In particular, through the survey instrument the importance, the frequency of monitoring and the satisfaction regarding the clinical information in question were investigated.



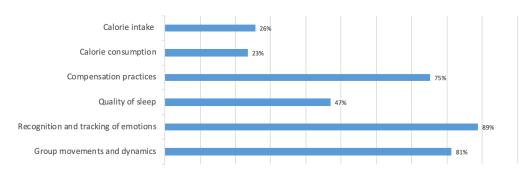


Figure 22: "It is important to me to know these parameters"

According to the professionals of the Ananke network, it is mostly important to have knowledge about emotions (it is important for 89% of respondents), group movement and dynamics (81% of respondents) and compensation practices (75%) rather than caloric intake and caloric expenditure (respectively 26% and 23%). Moreover, about half of the respondents considers relevant the information about the quality of sleep (47%) (*Figure 23*). The most significant information for professionals is that they are interested in monitoring most frequently: in fact, the intention is to trace, at least once a week, emotions (47% of respondents), group movements and dynamics (41%), and compensation practices (33%), against the 22% interested in assessing at least weekly the quality of sleep, the 11% of the caloric intake and the 9% of the caloric expenditure. Comprehensively, "once a week" is the frequency most required by the professionals, as it can be observed by the extension of the yellow bars in *Figure 24* compared to the other colors.

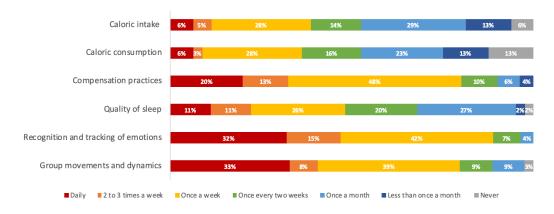


Figure 23: How frequent the respondents would like to know the parameters

Not only the importance was to be investigated, but also the satisfaction about the information they are currently able to gather: in fact, despite a high interest in the data,



professionals could be already satisfied with the current procedures of collecting the information and, as a consequence, digital technologies could be not relevant for them.

In this sense, whatever the data considered, the majority of the healthcare professionals involved seems quite satisfied, against up to 20% who aren't (*Figure 25*). The satisfaction is least in detecting movements and dynamics (41%)



Figure 24: Current satisfaction of the following parameters

are not satisfied). In particular, the availability and timeliness of this information should be improved, while for the rest of the data the unreliability of information is the major reasons of dissatisfaction (orange bars in *Figure 26*). Other causes of dissatisfaction not contemplated by the researchers should be investigated, especially for emotions tracking and group movements and dynamics (grey bars in *Figure 27*).

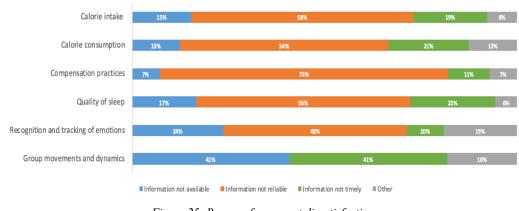


Figure 25: Reasons for current dissatisfaction

As dissatisfaction in current information may lead healthcare professionals to embrace digital technologies, it is important to conduct deeper analysis in this regard. In particular, two kind of segmentations were performed for the purposes of the analysis (*Table 25*):

• The first segmentation concerns the therapeutic areas involved in the treatment of EDs, previously specified in *Standard of Care (paragraph 2.1.2)*: the nutritional rehabilitation area, the psychotherapy area, and the pharmacotherapy area. Coherently, results have been segmented according to the professional figures of reference of each area: respectively, nutritionists-dieticians, psychologists, and psychiatrists (profession segmentation);



• The second segmentation regards the clinical setting were respondents operate. In particular, outpatient and inpatient (i.e. residential + hospitalization) settings have been differentiated (clinical setting segmentation).

	CRITERIUM FOR SEGMENTATION	RESPONDENTS SEGMENTS	NUMBER OF RESPONDENTS
Segmentation 1	Profession	Nutritionist- dietician	14
		Psychologist- pyschotherapist	34
		Psychiatrist	9
Segmentation 2	Clinical setting	Outpatient	39
		Inpatient	34

Table 25: Number of respondents per segmentation's criteria

With regard to profession segmentation, results can be seen in the graphs below. The main findings reveal that nutritionists-dieticians (*Figure 27*) together with psychiatrists (*Figure 29*) are less satisfied than the average (*Figure 25*), while the great majority of psychologists-psychotherapists (*Figure 28*) considers themselves satisfied. Thus, digital technologies could mainly meet the unsatisfied needs of the first two categories of healthcare professionals.

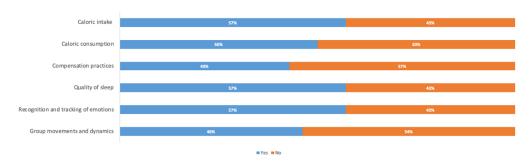


Figure 26: Current satisfaction of nutritionists



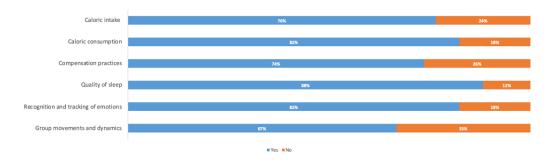


Figure 27: Current satisfaction of psychologists

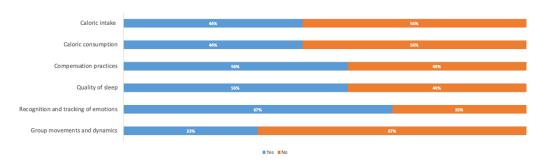


Figure 28: Current satisfaction of Psychiatrists

Finally, with regard to clinical setting segmentation, results are reported in the following graphs. Overall, it emerges how in inpatient settings (*Figure 30*), there is less satisfaction on the information compared to outpatient settings (*Figure 31*). Especially, *group movements and dynamics* would like to be better understood in inpatient settings. This result reflects expectations: indeed, it is reasonable to suppose that in inpatient setting group dynamics between treatment peers, i.e. patients, play a key role as such contact could trigger the symptoms. Thus, it is of fundamental importance to monitor as effectively as possible peer group dynamics in the rehabilitation process.

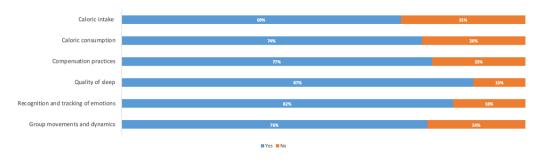


Figure 29: Current satisfaction in Outpatient settings



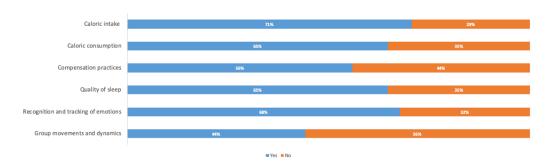


Figure 30: Current satisfaction in Inpatient settings

#### Knowledge and usage of technologies

In this section, both the ability and confidence of professionals in using technologies in daily life ("Digital Literacy") and their knowledge and deployment of digital technologies in their clinical practice ("eHealth Literacy") is presented.

For what concerns Digital Literacy (*Figure 32*), the confidence with digital technology is very high referring to communication tools and online services (beyond 90% of respondents), high referring to social media (79% are aware of them and 72% use them for sharing knowledge ), and medium referring to security programs and default settings (54% and 43% respectively).

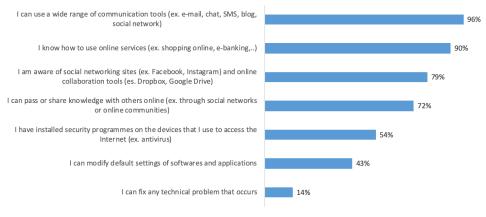


Figure 31: Digital literacy of the respondents

For the investigation of the degree of knowledge and usage of eHealth, the researchers have asked in the questionnaire about the digital technologies mentioned in the state of the art chapter: Health Information Technology (HIT), such as electronic medical record systems; Telemedicine; Mobile Health (mHealth), such as apps dedicated to fitness and well-being, informative apps, apps for the management of chronicity and treatment; Digital

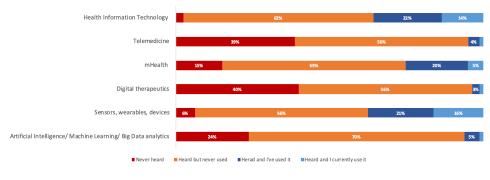


Therapeutics (DTx); sensors, wearables and devices; finally, Artificial Intelligence (AI), Machine Learning (ML), and big data analytics.

As it emerges from *Figure 33*, respondents have the highest awareness about AI, ML and big data analytics: this is not surprising considering the popularity these technologies have gained today in all field of research and applications. However, their actual deployment is still very low (around 5%). Together with Digital Therapeutics, which is extremely recent in conception, the lowest awareness concerns Telemedicine, despite its origin dates back to the 1970s.

For what regards the usage, Health Information Technologies together with sensors, wearables and devices are the most widespread (respectively, 36% and 37% of respondents use or have used it).

Overall, the mainstream adoption of eHealth technologies in clinical practices in the ED field is dawning.





#### Environmental dynamism

The expression "environmental dynamism" refers to the fact that a specific field of research or a work sector could be subjected to frequent changes and innovations or that, on the contrary, could be quite stable, if not static.

The results are summarized in *Figure 34*. In particular, the present research wanted to assess the perception of environmental dynamism in the ED field by the healthcare professionals involved, concerning mainly digital innovation.

According to the 74% of respondents, intense changes are underway in the sector. With specific reference to digital technologies, almost 40% of respondents perceive a widespread interest in the use of digital technologies in the ED field, which is destined to increase in the future according to more than half of respondents (53%). However, a minority agree to the statement "In the ED domain, there are more and more publications concerning the usage of



digital technologies". Finally, two statements in this section (D43, D47) were aimed at evaluating the pressure in the adoption of new solutions by the patients and the healthcare system. The pressure of the former is perceived by about 60% of participants, while the latter is perceived to push scarcely towards the adoption of digital solutions in the ED domain (19% of participants perceive the pressure).

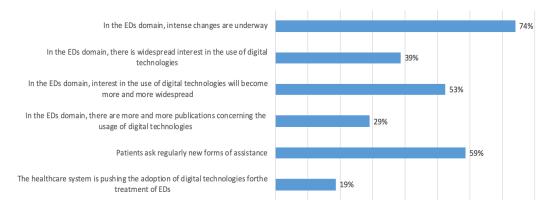


Figure 33: Perceived Environmental dynamism by the respondents

#### 8.2.2. Results from the Explanatory Research: Statistical Analysis

#### Scales measurement

First, the internal consistency of the single scales considering all the items has been measured by computing the Cronbach's alpha. *Table 26* summarize the results. At this point, no items were removed even when Cronbach's alpha was under the acceptability threshold fixed by researchers at 0.60. Indeed, what ultimately matters for the validity of the model tested with SEM is the internal consistency of the construct, assessed in the next paragraph.

SCALE	ITEM	CRONBACH'S ALPHA
	WL1	
Workload	WL2	0.85
	WL3	
	CD1	
<b>Cognitive Demand</b>	CD2	0.67
	CD3	
	AU1	
Autonomy	AU2	0.91
	AU3	
Professional	PD1	
	PD2	0.66
Development	PD3	
Disengagement	DIS1	0.68



	DIS2	
	DIS3	
	EX1	
Exhaustion	EX2	0.57
	EX3	
	VIG1	
Vigour	VIG2	0.87
	VIG3	
	DED1	
Dedication	DED2	0.94
	DED3	
	PSAF1	
Psychological Safety	PSAF2	0.55
1 Sychological Safety	PSAF3	0.55
	PSAF4	
	PT1	
	PT2	
	PT3	
	PT4	
	PT5	
Patient Trust	PT6	0.78
	PT7	
	PT8	
	PT9	
	PT10	
	PT11	
	ITU1	
Intention to Use	ITU2	0.95
	ITU3	

Table 26: Internal consistency of the scales

#### Construct measurement

Secondly, the internal consistency of the constructs has been verified. In particular, for each construct an Exploratory Factor Analysis (EFA) using Principal Component Analysis (PCA) has been performed and the Cronbach's alpha computed.

For the PCA, factor loadings were required to be greater than 0.7 - meaning that the items were consistent - and the differences between factor loadings on distinct factors to be greater than 0.2 - meaning that cross-loading was not occurring. Items have been removed when not respecting these conditions.

For what concerns Patient Trust, two factors with valid items were determined, thus the construct split in two possible scales. In fact, the two scales revealed to have two different meanings: one referred to trust in the expertise of the healthcare professional, i.e. in its ability



to "cure" the disease (items PT3, PT4, PT6), while the second to trust in the healthcare professional's consideration of the patient at 360°, i.e. in its ability to "care" for the person (items PT1, PT2, PT7). Among these, the second scale was chosen as EDs are very complex diseases which concern many aspects of human nature.

Finally, the Cronbach's alphas have been computed again in order to verify the internal consistency of the constructs formed by the items selected through the EFA. Results are reported in *Table 27*. Cronbach's alphas of all the constructs are higher than 0.60, thus all the constructs are consistent.

CONSTRUCT	ITEM	FACTOR LOADING	CRONBACH'S ALPHA	
	WL1	0.7826		
Lik Daman da	WL2	0.8302	0.92	
Job Demands	WL3	0.8604	0.82	
	CD2	0.7347		
	AU1	0.8531		
Job Resources	AU2	0.9034	0.91	
	AU3	0.9037		
Durmout	DIS1	0.8996	0.74	
Burnout	DIS3	0.8996	0.74	
	VIG1	0.8251		
Engagement	VIG2	0.7521	0.92	
	VIG3	0.8345		
Dedication	DED1	0.9057	0,94	



	DEDA	0.9604		
	DED2	0.8694		
	DED3	0.8604		
	PSAF1	0.7430		
Psychological Safety	PSAF2	0.7539	0.63	
	PSAF3	0.7773		
	PT1	0.8084		
Patient Trust	PT2	0.8363	0.88	
	PT7	0.8561		
	ITU1	0.9337		
Intention To Use	ITU2	0.9556	0.95	
	ITU3	0.9631		

Table 27: Internal consistency of the constructs

#### Measurement model

The quality of the measurement model has been assessed through the computation of the convergent validity, which defines how well the items of a construct converge on the construct itself, and the discriminant validity, which expresses the extent to which a construct is truly distinct from other constructs by empirical standards.

The threshold of 0.5 of the factor loading have been respected in all the cases, meaning that there was a high correlation between the observed variable and the latent one. Then, convergent validity has been assessed through two indicators: composite reliability (CR) and average variance extracted (AVE).

As it is possible to notice from *Table 28*, the values of AVE and CR of all the constructs are higher than the desired threshold of respectively 0.5 and 0.7, confirming the convergence validity of all the items taken into consideration and demonstrating that they are a very good



proxy for the measurement of the construct to which they belong. The only exception is represented by Psychological Safety.

CONSTRUCT	ITEM	FACTOR LOADING	AVE	CR
	WL1	0.7448		
Job Demands	WL2	0.7833	0.584	0.845
500 Demands	WL3	0.9266	0.504	0.045
	CD2	0.5565		
	AU1	0.7731		
Job Resources	AU2	0.9953	0.304	0.905
	AU3	0.8744		
Burnout	DIS1	0.6823	0.587	0.891
Dumout	DIS3	0.8588		
	DED1	0.9365		
	DED2	0.8837	0.587	0.891
Engagement	DED3	0.8965		
Engagement	VIG1	0.6096		0.071
	VIG2	0.5043		
	VIG3	0.6587		
	PSAF1	0.5587		
Psychological Safety	PSAF2	0.5682	0.304	0.567
	PSAF3	0.5265		



	PT1	0.9350		
Patient Trust	PT2	0.9453	0.7273	0.8862
	PT7	0.6435		
	ITU1	0.8673		
Intention to Use	ITU2	0.9939	0.8358	0.9385
	ITU3	0.9396		

Table 28: Convergent validity of the constructs

Successively, it has been verified the discriminant validity. Discriminant validity is assured when the value of the AVE is above the threshold value of 0,5 and when the square root of AVE is larger than correlations among the constructs (El-Wajeeh et al., 2014). According to these conditions, discriminant validity is not respected by Psychological Safety, while the variance extracted has been higher for all the other constructs of the model revealing that these constructs are distinct.

#### Structural model

With the objective of assessing the validity of the hypotheses made, it has been conducted an estimation of the model.

In order to confirm the hypotheses, the p-value has been taken in consideration. The smaller the p-value, the stronger the evidence supporting the hypothesis. In this study, p-values lower than 0.1 have been accepted. Then, four levels of statistical significance have been defined: p-values lower than 0.1 are indicated with 4 asterisks; the ones lower than 0.05 with 1 asterisk; the ones lower than 0.01 with 2 asterisks; finally, the ones lower than 0.001 with 3 asterisks.

All the hypotheses apart from H2(-) have been confirmed and classified as statistically supported. The full results of the analysis can be found in *Table 29*.



HYPOTHESIS	PATH COEFFICIENT	P-VALUE	STATISTICAL VALIDITY
H1(+): Job Demands $\rightarrow$ Burnout	0.2816	0,034*	Supported
H2(-): Job Demands → Engagement	- 0.0659	0,578	Not supported
H3(-): Job Resources $\rightarrow$ Burnout	- 0.4691	0,000***	Supported
H4(+): Job Resources → Engagement	0.3952	0,001***	Supported
H5(-): Burnout $\rightarrow$ Intention to Use	- 0.3285	0,032*	Supported
H6(+): Engagement $\rightarrow$ Intention to Use	0.2184	0,089****	Supported
H7(-): Psychological Safety → Burnout	- 0.4240	0,028*	Supported
H8(+): Psychological Safety → Engagement	0.4553	0,018*	Supported
H9(+): Patient Trust $\rightarrow$ Intention to Use	0.5072	0,000***	Supported

The research model explains 47% ( $R^2 = 0.4698706$ ) of variance of the Intention to Use the "system" (*Figure 8*), and the Coefficient of Determination (CD), which is like a  $R^2$  for the whole model, is 1.000, meaning that the model explains basically the overall variance.

Through the STATA command *teffect*, it has been performed an additional analysis, evaluating quantitatively the indirect effects between constructs. Only one statistically significant indirect effect (p-value equal to 0.002) have been found, which is the positive influence of Job Resources on Intention to Use (path coefficient equal to 0.1947).

With the objective of assessing the goodness-of-fit (GOF) of the structural model, four indices were considered: the Comparative Fit Index (CFI) and Tucker-Lewis Index (TLI), the Root Mean Square Error of Approximation (RMSEA) and the Coefficient of Determination (CD). The results show that it has a good fit as indices largely comply with the prescribed acceptable ranges: the Comparative Fit Index (CFI) value of 0,917 is higher than the recommended value of 0,9, and the Tucker-Lewis Index (TLI) value of 0,904 is higher than the benchmark of 0,9. Additionally, the Root Mean Square Error of



Approximation (RMSEA) value of 0,077 belongs to the adequate fit range of 0,05-0,08 (Hair et al.; 2014). Finally, CD value of 1,000 is above the 0.08 that determines its acceptance.

Overall, the results show a good adaptability of the model and very good capability in explaining the phenomenon (*Table 30*).

FIT INDEX	RANGES OF ACCEPTANCE	RESULT
CFI	≥ 0.9	0.917
TLI	≥ 0.9	0.904
RMSEA	0.05 - 0.08	0.077
CD	> 0.8	1.000

Table 30: Goodness of Fit of the theoretical model

#### Control variables

In order to validate the model, control variables were checked. "Gender", "Age", "Education", "Profession", "Work Experience" of the respondents and "Clinical Context" of the facilities where respondents worked were chosen as control variables of the model. Control variables were coded as dummy variables (0 and 1), or indicator variables (categorical) in case of more than two categories. Being Intention to Use the dependent variable of the model, it have been assessed the influence that these variables had on Intention to Use. As shown in *Table 31*, analysis revealed that none of the path coefficients had statistical validity.



CONTROL PATH	PATH COEFFICIENT	P-VALUE	STATISTICAL VALIDITY
Gender $\rightarrow$ Intention to Use	- 0.033856	0.740	Not supported
Age $\rightarrow$ Intention to Use	- 0.0502163	0.637	Not supported
Education $\rightarrow$ Intention to Use	- 0.0490738	0.740	Not supported
Profession $\rightarrow$ Intention to Use	- 0.0221734	0,880	Not supported
Work Experience $\rightarrow$ Intention to Use	- 0.0107017	0.954	Not supported
Clinical Setting $\rightarrow$ Intention to Use	-0.0400483	0.819	Not supported

Table 31: Statistical	validity of	f control	nath
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This analysis led to the conclusion that chosen control variables were not substantially related to the model components, and that inclusion of these variables in the structural equation model did not significantly affect the results.

# 8.3. Discussion on Survey Results

In this chapter are drawn the conclusions of the investigations carried out through the questionnaire involving Ananke's healthcare professionals, such as psychiatrists, psychologists/psychotherapists, nutritionists/dieticians, educators, and nurses.

The first part of the questionnaire concerned the exploratory research about data need, knowledge of digital technologies, and perceived environmental dynamism which lead to the descriptive analysis previously presented. In the first part of this chapter the most relevant considerations in this regard, with references to the supporting literature and to the on-field analyses, are reported.

Instead, the second part had the objective to conduct an explanatory research by collecting answers for the model to be tested. Regarding the model, after the general definition and the presentation of the main parameters that characterize it, the verification of the hypotheses, the coherence between them and the analyzed literature, and the new contributions given are discussed.



### 8.3.1. Discussion on Exploratory Research

The exploratory research provides a cross section of the Ananke network. This network can be considered as a good proxy of the national system supporting the cure of EDs being diffused in many Italian regions.

As for data need, healthcare professionals result to be most interested clinical information of the patient concerning the emotional, social and psychological areas (i.e. emotions and group dynamics), rather than the nutritional and physiological one (i.e. caloric expenditure and intake). To actually understand this result, it must be considered first of all that the majority of respondents are Psychologists-psychotherapists. At the same time, it is true that EDs are primarily psychiatric illnesses. Anyway, in the technology analysis performed for the on-field research in Villa Miralago, it was pointed out how cameras could be used for movement and dynamics measurements and microphones placed together with these cameras could enable general mood and language in inpatient clinical settings. Always in inpatient settings, specific antennas capturing signals from wearables devices could be spread in the common rooms to measure the position of the patients and the distance between them. GPS integrated in some of these fitness trackers could also be used for the movement tracking. Finally, emotions could be tracked during psychiatrist meeting with a frontal video camera whatever the clinical settings.

It was found out that satisfaction varies according to profession and clinical setting. In particular, most unsatisfaction is shown by Nutritionist-dieticians and Psychiatrists, while Psychologist-psychotherapist are very confident. Moreover, in inpatient settings there is less satisfaction on the information compared to outpatient settings. This result suggests that organizations for in-patient treatment should be targeted first for the introduction of a system similar to the one designed in Villa Miralago. Indeed, Villa Miralago itself is a clinic for in-patient rehabilitation.

On average, the main reason of dissatisfaction with clinical information results to be its unreliability. In this sense, digital technologies can be leveraged to collect granular and objective real-life data.

Considering digitalization, it has emerged that the majority of respondents have heard about digital technologies and this was expected due to the high interest of the public opinion on these topics. However, their actual deployment is still very low (around 5%). The lowest



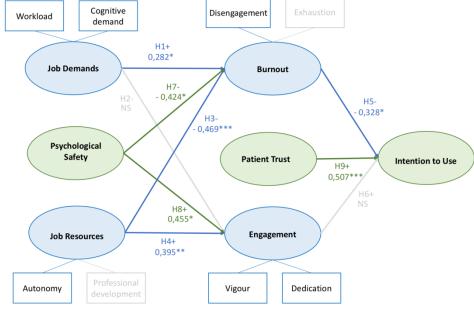
awareness concerns telemedicine and digital therapeutics (DTx). From the literature, it has emerged that DTx in particular hold sgnificant potential for the treatment of EDs as these softwares are able to track eating habits and compensatory behaviors and apply CBT techniques. Thus, awareness on DTx would be worth to be raised at national level in the ED domain.

For what regards the usage, Health Information Technologies together with sensors, wearables and devices are the most widespread: respectively, 36% and 37% of respondents use or have used it in clinical practice. It would be interesting to further investigate how and why the latter have been deployed, to see if there is coherence with applications seen in the literature and defined for the Proof of Concept (PoC) in Villa Miralago.

Environmental dynamism aims at describing the perception of professional figures of changes in the environment. It could be a good proxy for understanding the actual changes that are affecting the sector. First of all, the majority of respondents believe that digital technologies will gain more relevance in the ED domain, meaning that the attention to this topic is on and it is not perceived to end soon. From the scientific research community to the healthcare system it is expected to improve studies and collaborations for a better knowledge and application of these technologies. Additionally, a relevant result has been the high perceived pressure coming from patients' side (almost 60%). Indeed, patients could be the drivers to the change of a more digitalized rehabilitation path.



# 8.3.2. Discussion on Explanatory Research



Verification of the hypotheses of the model

Figure 34: Extended JD-R Model

The assessment of JD-R research model is completed. The evaluation of the measurement model has allowed demonstrating the reliability and the validity of the model. Then, the evaluation of the structural model has allowed going further and analyzing deeply the different variables and relationships within the model.

*Figure 35* comprehensively illustrates the results that have been obtained by performing the SEM through the software Stata 14. In the above-mentioned image, the path coefficients (i.e. standardized  $\beta$ ) of the validated hypotheses of the model are reported. The number of asterisks close to the path coefficients reflect the p-values. The grey arrow corresponds to the hypothesis that has not been confirmed statistically. For this reason, it does not report any value of the path coefficient.

Therefore, *Figure 35* allows to review and to provide final considerations about the hypotheses at the basis of the model, built from the literature in the previous chapters.

H1. Job Demands increases healthcare professionals' Burnout



Consistently with theory, Job Demands as workload and cognitive demand has a direct positive effect on Burnout (standardized  $\beta = 0.282$ , p < 0.05). Therefore, the hypothesis is validated.

#### H2. Job Demands decreases healthcare professionals' Engagement

Job Demands had no statistically significant relationships with Engagement. Therefore, this hypothesis was not validated within this research.

#### H3. Job Resources decreases healthcare professionals' Burnout

Job Resources as autonomy strongly and negatively affects Burnout (standardized  $\beta = -0.469$ , p < 0.001). Instead, it was not possible to assess the professional development component of Job Resources consequently to the results of the Exploratory Factor Analysis (EFA). Overall, the hypothesis is confirmed by the model.

#### H4. Job Resources increases healthcare professionals' Engagement

Job Resources as autonomy has a quite high positive influence on Engagement (standardized  $\beta = 0.395$ , p < 0.01). As above, professional development does not contribute to the validation of the hypothesis, but the hypothesis as a whole is confirmed.

#### H5. Burnout decreases healthcare professionals' Intention to Use

Healthcare professionals' Intention to Use is positively influenced by Burnout (standardized  $\beta = -0.328$ , p < 0,05) as Disengagement. The Exhaustion component of Burnout has been excluded by the researcher during the construct measurement (Cronbach's alpha below 0.6). Anyway, the hypothesis as a whole is validated.

#### H6. Engagement increases healthcare professionals' Intention to Use

This hypothesis is accepted within the research as its path coefficient respects the threshold value fixed for statistical validity. Among the confirmed hypothesis, it is the one with the least statistical validity (standardized  $\beta = 0.089$ , p < 0.10).

#### H7. Psychological Safety decreases healthcare professionals' Burnout

As supposed by researchers, Psychological Safety has a role in influencing negatively Burnout of healthcare professionals (standardized  $\beta = -0.424$ , p < 0.05). Therefore, the hypothesis is confirmed.



H8. Psychological Safety increases healthcare professionals' Engagement

Psychological Safety influences Engagement, in this case positively (standardized  $\beta = 0.455$ , p < 0.05). Again, the hypothesis is confirmed.

#### H9. Patient Trust increases healthcare professionals' Intention to Use

Finally, Patient Trust has a positive influence, and also the strongest one, on Intention to Use (standardized  $\beta = 0.507$ , p < 0.001). The hypothesis is validated.

#### Contribution to the theory

Overall, eight out of nine research hypotheses have been validated within the research model, investigated through a research questionnaire and the application of SEM methodology. Once again, the validity of the modelling features of JD-R and the possibility to apply it in many fields has been proven. In particular, this work provides evidence of the adequacy of the model also in healthcare settings.

At the same time, the current study opens a new field of study thanks to the integration in the traditional model of new constructs and cause-effect links.

Focusing on the input and output of the whole model, the validated paths with their effect on the output (i.e. Intention to Use) are reported in *Table 32* and discussed below. The effect is defined as "positive" if an increase of the input leads to an increase in Intention to Use, otherwise as "negative".

VALIDATED PATH (INPUT-OUTPUT)	EFFECT ON OUTPUT
Job Demands $\rightarrow$ Burnout $\rightarrow$ Intention to Use	Negative
Job Resources $\rightarrow$ Burnout $\rightarrow$ Intention to Use	Positive
Job Resources $\rightarrow$ Engagement $\rightarrow$ Intention to Use	Positive
Psychological Safety $\rightarrow$ Burnout $\rightarrow$ Intention to Use	Positive
Psychological Safety $\rightarrow$ Engagement $\rightarrow$ Intention to Use	Positive
Patient Trust $\rightarrow$ Intention to Use	Positive

#### Table 32: Effects on Intention to Use

The first path confirms what have been observed in many studies. In the design of a digital solution to be applied in healthcare contexts, attention must be paid to the user-friendliness and ease of usage of the system, so that it can be introduced as smoothly as possible in



organizations. When not completely avoidable, the organization should manage the change, for example by supporting professionals with proper digital education. If not, the introduction of the system could generate Burnout due to an excessive increase in Job Demands as workload and cognitive demand. Obviously, this result would negatively affect the propension towards the usage of technologies.

Fortunately, the potential negative effects can be counter-balanced by many positive ones.

First of all, digital technologies could be perceived as Job Resources in the way they can increase autonomy in clinical practice. Indeed, a digital system as the one described in the questionnaire could provide each professional a comprehensive view of the patients in every moment, thus reducing the necessity to ask colleagues for information not directly under their control and enabling better decision-making. This is mostly important whether a multidisciplinary team is not available, as it is in many regions as mentioned in the paragraph *Italian Context*. In few words, such digital systems could empower professionals to an extent that Burnout as disengagement is buffered and Intention to Use finally increased. Even, Job Resources could give new meaning to the work, i.e. increase Engagement and consequently Intention to Use. From the analysis of the indirect effects, it also emerged the relationship between Job Resources and Intention to Use through the mediating role of Engagement. Again, it shows that when professionals perceive that the digital technology will make them work in a more autonomous way, they will be more inclined to use the technology.

As supposed by researchers, Psychological Safety well suits to the basic model: indeed, it has an influence on both Burnout and Engagement. In fact, it is common to fail in the usage of an unfamiliar technology, and if the work environment does not tolerate mistakes the individual could be restrained in risk-taking and become detached from innovation, i.e. disengaged. On the contrary, a work culture where failure is accepted helps teams to experiment, work better together and to be more adaptable to change. Thus, the result of the current study confirms the relevance of a safe environment in a multidisciplinary setting and reveals the connection between the individual wellbeing and the organizational environment.

Finally, the main highlight of the explanatory research concerns the fact that perceived Patient Trust by healthcare professionals is the best predictor of the chosen organizational outcome. Indeed, it is an element worth to be further explored in future studies on behavioral



intention in healthcare. In this research, the core meaning is that if the perceived Patient Trust is not lowered by the introduction of new technologies, professionals are willing to use the technologies.

Only the following path has been rejected:

• Job Demands  $\rightarrow$  Engagement  $\rightarrow$  Intention to Use

Indeed, it appears that increased Job Demands does not negatively affect Engagement as expected, thus Intention to Use through Engagement. A possible interpretation is that, in addition to being potentially stressful, Job Demands may also be challenging to some point so that lowering Job Demands would result in less challenging jobs and hence lower levels of Engagement.



# CONCLUSIONS



# 9. Conclusions

This chapter summarizes the results achieved in this thesis, with particular concern for their theoretical and managerial implications.

# 9.1. Theoretical Contribution

The first aim of the thesis was the understanding of the potential of digital technologies for EDs rehabilitation in clinical practice. For this purpose, Villa Miralago, the largest center in Italy for the treatment of EDs, was selected as case study to conduct an on-field research. Such research was carried out according to two kind of analyses. First, a data need analysis was performed to identify the set of data currently needed in the clinic. Structured interviews were carried out with all the various categories of actors, so that the answers could be reliably aggregated and that comparisons could be made with confidence between different professional subgroups. Secondly, a technology analysis was accomplished to understand which technology could be used to collect the data previously highlighted.

The main output of the research has been the design of a Proof of Concept (PoC), i.e. a feasibility study, of a system that encompasses the usage of digital technologies such as wearables, cameras, environmental sensors and a platform to aggregate the real world data (RWD) of the patients. Indeed, the experimental study designed represents the first of its kind: in fact, no comprehensive digital technology system has ever been designed for EDs rehabilitation. The protocol is now ready to be submitted to the regional ethical committee in order to obtain their authorization to start the clinical trial.

The second objective of this study was the investigation of healthcare professionals propension to use digital technologies according to how digital technologies affect their psychological well-being. This goal has been reached through the development and testing of a theoretical model based on JD-R and adapted to fit healthcare organizations for ED treatment. In addition to the traditional JD-R model building blocks (i.e. Job Demands, Job Resources, Burnout, Engagement), Psychological Safety and Patient Trust were postulated as important factors affecting the chosen organizational outcome, i.e. Intention to Use. An online survey was distributed at national level through the Ananke network to collect the perceptions of healthcare professionals operating in the ED field on digital technologies. In particular, a section in the survey questionnaire illustrated a digital technology system



similar to the one designed for Villa Miralago and respondents were asked to identify themselves with a scenario where this system was adopted in their organization. Besides, a section was added to assess the importance and satisfaction on the data need emerged in Villa Miralago and the perceived environmental dynamism in the ED field. Data collected was used to test the proposed model and to collect insights.

From the qualitative analysis of the survey, it emerges that the majority of the sample population consider itself satisfied with clinical information. However, dissatisfaction increases in psychiatrists and nutritionists and in inpatient settings. Thus, it can be argued that these professional and clinical setting segments should be addressed first for the introduction of digital technologies able to improve the availability, the timeliness, and the reliability of the data. Reliability in particular is the main reason of dissatisfaction. Anyway, as emerged from perceived environmental dynamism and in concordance with the evidence from the literature, digital technology in the ED field is still very much on the cutting edge, also in the scientific community, but arguable to be ever-increasing.

As for the adapted JD-R model, it has been confirmed its applicability in explaining the organizational outcome chosen, i.e. Intention to Use. The model tested in this study has extended the one found in literature. In fact, not only Burnout and Engagement significantly affect organizational outcomes, coherently with the literature, but also Patient Trust play a fundamental role in healthcare settings. Moreover, the study found out that Psychological Safety influences Burnout and Engagement beside Job Demands and Job Resources in a context where multidisciplinarity, thus collaboration with colleagues, is fundamental for effective ED rehabilitation.

In conclusion, the usage of the technology depends on its consequences on psychological well-being and on the reaction of the patient, i.e. if patients will continue to trust professional figures in their work, healthcare professionals will be motivated to use digital technologies.

# 9.2. Managerial Contribution

Currently, product development is still far from maturity and a real market does not exist yet, but it is safe to say that digital technology for the treatment of EDs actually hold great potential in terms of effectiveness and integration in clinical practice. In fact, in Villa Miralago it has been possible to design a Proof of Concept (PoC) - the first ever not only in the ED field but also in the psychiatric one - centered on digital technologies that is going to be implemented in constrain of the clinical, ethical and technological contexts observed.



Anyway, feasibility must be assessed before making any other consideration in managerial terms.



# **10.** Limits and Future Research

The study conducted has some limitations, which could be overcome in the future with further research. Indeed, it must be considered that the topic investigated is an extremely new one, to the point that the present contribution is one of the first ever.

The first ones regard the on-field research in Villa Miralago.

If fact, the need analysis carried out in Villa Miralago shows the clinical information of interest for operators in inpatient settings, where patients stay much more in contact with professionals and peers suffering from the same disease and there are specific constraints. Thus, the same approach used in Villa Miralago should be replicated in outpatient settings in order to identify more precisely the variables that could affect the condition of the patients outside the day hospital. Then, technology analysis and a specific protocol for a Proof of Concept (PoC) should be made accordingly.

As for the protocol, it is still to be developed how data will be visualized by professionals and this should be easy interface able to give complete and integrated information from where to extract new significant insights. Finally, the PoC in Villa Miralago will eventually address only patients suffering from AN. Future studies could focus on BN or BED instead.

The second group regards the survey questionnaire.

The main limitations come from the characteristics of the sample. Professionals where not equally represented: indeed, almost half of them belonged to the psychologist category and only 9 of the respondents were psychiatrists. Also, it would have been better to have a larger sample size so that statistical validity could be more robust. In future development, other organizations and professionals apart from the ones belonging to Ananke should be reached, better in Italy to complete the research in the Italian context. In a second instance, extending the delivery also to foreign organizations could allow interesting comparison with the readiness of other countries.

Then, the section on data need was only formed by close-ended questions. Thus, it was possible to assess data need from Villa Miralago but not to validate it. Validation could have been done by inserting open-ended questions to verify coincidence or divergence of answers, i.e. to see if new data needs emerged or not, between Villa Miralago professionals and the other Ananke professionals. As for the digital literacy section, it would have been interesting to ask which digital technologies are already implemented in the Italian structures where



respondents work, and why. However, researches put a limit to open-ended questions to solve the length/completeness trade-off proper of every questionnaire.

Concerning the model, answers were based on a description of a digital system that respondents actually don't know. Thus, the perceived stress, engagement and intention to use could not fully reflect their reaction to the real system. To deal with this issue during the development phase of the technology, a prototype or videotape mockup should be used to create a more realistic idea of what the system consists of. In this way, target users could better understand how it works by a brief exposure to a prototype system or by watching the training video to acquire well-formed beliefs. Some of the constructs of the present study could include multiple aspects in addition to what has been assessed. Attempt to improve should start from the constructs whose internal consistency is lower, such as Psychological Safety, and that are connected with hypotheses whose statistical validity is lower, such as Engagement.

Overall, the research should be extended to the patients' side, which of course are affected the most by digital health technologies together with healthcare professionals. In the current study they have not been taken into account as they are more difficult to reach, and at first the priority was to understand if demand was pulled by professionals, or at least if they had dissatisfied data needs. But indeed, patients are fundamental stakeholder and play a fundamental role also in the propension of professionals towards the digitalization of ED care.



# **11. References**

# 11.1. Bibliography

Alarchon D., Sanchez J., "Assessing convergent and discriminant validity in the ADHD-R IV rating scale: User-written commands for Average Variance Extracted (AVE), Composite Reliability (CR), and Heterotrait-Monotrait ratio of correlations (HTMT)", (2015)

Bakker A., Demerouti E., "Burnout and Work Engagement: The JD-R Approach" (2014)

Bakker A., Demerouti E., "USING THE JOB DEMANDS-RESOURCES MODEL TO PREDICT BURNOUT AND PERFORMANCE", (2004) Human Resource Management

Bi, S., Wang, T., Davenport, E., (...), Sorber, J., Kotz, D. (2017). WearSys 2017 -Proceedings of the 2017 Workshop on Wearable Systems and Applications, co-located with MobiSys 2017

Billeci, L., Tartarisco, G., Brunori, E., Crifaci, G., Scardigli, S., Balocchi, R., ... & Morales,
M. A. (2015). The role of wearable sensors and wireless technologies for the assessment of heart rate variability in anorexia nervosa. Eating and Weight Disorders-Studies on Anorexia, Bulimia and Obesity, 20(1), 23-31.

Birkhauer J., Gaab J., "Trust in the health care professional and health outcome: A metaanalysis", (2017) Plos one

Castellini Elisabetta, "Disturbi alimentari, c'è fame di cure"

CampbellG.,FDA Guidance:"Design Considerations for Pivotal Clinical Investigations for Medical Devices", (2013)

CD-10 classification of mental and behavioural disorders, Clinical descriptions and diagnostic guidelines, WHO, 2010 update



Coetzeen, "Thriving in Digital Workspaces: Emerging Issues for Research and Practice", (2019) Springer Nature Switzerland

Crifaci, G., Billeci, L., Tartarisco, G., (...), Maestro, S., Morales, M.A. (2013). ECG and GSR measure and analysis using wearable systems: Application in anorexia nervosa adolescents. International Symposium on Image and Signal Processing and Analysis, ISPA, and Anna M. Bardone-Cone and Kamila M. Cass. Investigating the Impact of Pro-Anorexia Websites: a pilot study. (2006).

De, D., Bharti, P., Das, S.K., Chellappan, S. (2015). Multimodal wearable sensing for finegrained activity recognition in healthcare. IEEE Internet Computing, Volume 19, Issue 5, 1 September 2015, Article number 7155432, Pages 26-35

Dunne B., Greenwald J., "Psychological safety and engagement: Clarity through the lens of Social Exchange Theory" (2014)

European Eating Disorders Review 14, 256–262 (2006)

Fairburn CG, Harrison PJ. Eating disorders. Lancet. 2003; 361:407-416

Farooq, M., Fontana, J.M., Boateng, A.F., McCrory, M.A., Sazonov, E. (2013). A comparative study of food intake detection using artificial neural network and support vector machine. Proceedings - 2013 12th International Conference on Machine Learning and Applications, ICMLA 2013

Fedorowich, "Does treatment setting affect reduction of symptoms and remission rates for people with eating disorders?", (2019) Students for best evidence

Feris, "Clinical trials for medical devices: FDA and the IDE process", (2015)

Genc, "Notes on Artificial Intelligence, Machine Learning and Deep Learning for curious people", (2019)

Gobierno de México, Guías clínicas: trastornos alimentarios



Hategan A., Giroux C., "Digital Technology Adoption in Psychiatric Care: an Overview of the Contemporary Shift from Technology to Opportunity", (2019) Journal of Technology in Behavioral Science

Herpertz S., Hagenah U., Vocks S., "The Diagnosis and Treatment of Eating Disorders" (2011), Dtsch Arztebl Int

Hixon, Todd, "Digital Therapeutics Have Huge Promise And They Are Real Today", Forbes (2015)

Jelinek, H. F., Spence, I., Cornforth, D. J., Tarvainen, M. P., & Russell, J. (2018). Depression and cardiac dysautonomia in eating disorders. Eating and Weight Disorders-Studies on Anorexia, Bulimia and Obesity, 23(3), 369-374.

Juan M. Fontana ; Muhammad Farooq ; Edward Sazonov. Automatic Ingestion Monitor: A Novel Wearable Device for Monitoring of Ingestive Behavior. (2014).

Juarascio, A.S., Goldstein, S.P., Manasse, S.M., Forman, E.M., Butryn, M.L. Perceptions of the feasibility and acceptability of a smartphone application for the treatment of binge eating disorders: Qualitative feedback from a user population and clinicians. (2015). International Journal of Medical Informatics.

Kerr-Gaffney, J., Harrison, A., & Tchanturia, K. (2019). Eye-tracking research in eating disorders: A systematic review. International Journal of Eating Disorders, 52(1), 3-27.

Kolar, D.R., Hammerle, F., Jenetzky, E., Huss, M. Smartphone-Enhanced Low-Threshold Intervention for adolescents with Anorexia Nervosa (SELTIAN) waiting for outpatient psychotherapy: Study protocol of a randomised controlled trial. (2017). BMJ Open, Volume 7, Issue 10, 1 October 2017, Article number e018049.

Lesener T., Gusy B., Wolter C., "The job demands-resources model: A metaanalytic review of longitudinal studies",



Levinson C., Christian C., "Sensor technology implementation for research, treatment, and assessment of eating disorders" (2019) International Journal of Eating Disorders 52(10)

Makeyev, O., Lopez-Meyer, P., Schuckers, S., Besio, W., Sazonov, E. (2012). Automatic food intake detection based on swallowing sounds. Biomedical Signal Processing and Control.

Manderscheid, R. W., Ryff, C. D., Freeman, E. J., McKnight-Eily, L. R., Dhingra, S., & Strine, T. W. (2010). Peer reviewed: Evolving definitions of mental illness and wellness. Preventing chronic disease, 7(1)

Marco, J. H., Perpina, C., & Botella, C. Effectiveness of cognitive behavioral therapy supported by virtual reality in the treatment of body image in eating disorders: one year follow-up. (2013). Psychiatry Research, 209(3), 619-625

Michie S1, Prestwich A., "Are interventions theory-based? Development of a theory coding scheme", (2010) Health Psychol

Mike Conwaya, Daniel O'Connorb. Social Media, Big Data, and Mental Health: Current Advances and Ethical Implications (2016). Curr Opin Psychol. Jun;9:77-82.

Mitchison D.Hay P., "The epidemiology of eating disorders: genetic, environmental, and societal factors", (2014) Clin Epidemiol.

Mohr, D.C., Burns, M.N., Schueller, S.M., Clarke, G., Klinkman, M. (2013). Behavioral Intervention Technologies: Evidence review and recommendations for future research in mental health. General Hospital Psychiatry.

Mura M., Radaelli, "The effect of social capital on exploration and exploitation: Modelling the moderating effect of environmental dynamism", (2014) Journal of Intellectual Capital 15(3)



Nahrgang J.,Hoffman H., Morgenson F., "Safety at Work: A Meta-Analytic Investigation of the Link Between Job Demands, Job Resources, Burnout, Engagement, and Safety Outcomes", (2010) Journal of Applied Psychology

Nysveen, "Intentions to Use Mobile Services: Antecedents and Cross-Service Comparisons", (2005) Journal of the Academy of Marketing Science

Nitsch, M., Dimopoulos, C.N., Flaschberger, E., (...), Taylor, C.B., Jones, M. A Guided Online and Mobile Self-Help Program for Individuals With Eating Disorders: An Iterative Engagement and Usability StudyOpen Access. (2016). Journal of Medical Internet research.

Paul S., Kalyani J.S., Basu T., "Early detection of signs of anorexia and depression over social media using effective machine learning frameworks" (2018).

Person S.D., Raeke LH., "Patients' trust in physicians: many theories, few measures, and little data", (2000) J Gen Intern Med

"Policy for Device Software Functions and Mobile Medical ApplicationsGuidance for Industry and Food and Drug Administration Staff", (2019)

Ramírez-Cifuentes, D., Freire, A. (2018). UPF's participation at the CLEF eRisk 2018: Early risk prediction on the internet

Saffran, K., Fitzsimmons-Craft, E.E., Kass, A.E., (...), Taylor, C.B., Trockel, M. Facebook usage among those who have received treatment for an eating disorder in a group setting. (2016). International Journal of Eating Disorders

Schaufeli W., Taris T.W.,ACriticalReviewoftheJobDemands-Resources Model: Implications for Improving Workand Health,(2014)Springer Science+Business Media Dordrecht

Schaufeli W., Bakker A., "Job demands, job resources, and their relationship with burnout and engagement: a multi-sample study", (2004) Journal of Organizational Behavior



Smink F.,van Hoeken, Hoek H.,"Epidemiology of Eating Disorders: Incidence, Prevalence and Mortality Rates", (2012) Current Psychiatry Reports

Simms, T., Ramstedt, C., Rich, M., (...), Martinez, T., Giraud-Carrier, C. (2017). Detecting Cognitive Distortions Through Machine Learning Text Analytics

Šmahel, D., Macháčková, H., Šmahelová, M., Čevelíček, M., Almenara, C.A., Holubčíková, J. Digital Technology, Eating Behaviors, and Eating Disorders.

Šmahel D., Černíková M., Čevelíček M. Eating Disorders and Digital Technologies. (2017)

Thornthon L.,MazzeoS.,"The Heritability of Eating Disorders: Methods and Current Findi ngs", (2010), Behavioral Neurobiology of Eating Disorders pp 141-156

Walsh K., Bechara J Saab and Norman, (2019) "Effects of a Mindfulness Meditation App on Subjective Well-Being: Active Randomized Controlled Trial and Experience Sampling Study", JMIR Ment Health

Wang, T., Brede, M., Ianni, A., Mentzakis, E. (2017) "Detecting and characterizing eatingdisorder communities on social media", Proceedings of the 10th ACM International Conference on Web Search and Data Mining

Webb T., Joseph J., Yardley L., Michie S. (2010), Using the Internet to Promote Health Behavior Change: A Systematic Review and Meta-analysis of the Impact of Theoretical Basis, Use of Behavior Change Techniques, and Mode of Delivery on Efficacy, JMIR Vol12,N1.

Xia Y., Yang Y., "RMSEA, CFI, and TLI

in structural equation modeling with ordered categorical data: the story they tell depends on the estimation methods", (2018) Psychonomic Society, Inc. 2018.

Yager J., "Eating disorders: Overview of prevention and treatment", (2019)



# 11.2. Sitography

https://en.wikipedia.org/wiki/Anorexia\_nervosa

http://www.villamiralago.it

https://www.curadisturbialimentari.it/it/home/

https://www.dtxalliance.org/wp-content/uploads/2018/09/DTA-Report\_DTx-Industry-Foundations.pdf

http://digitalhealthitalia.com/il-futuro-della-medicina-terapie-digitali/

http://digitalhealthitalia.com/app-mediche-e-strategie-di-mercato/

https://en.wikipedia.org/wiki/Machine\_learning

https://en.wikipedia.org/wiki/Artificial\_intelligence

https://www.medicoeleggi.com/elaborati/20205.htm

https://en.wikipedia.org/wiki/Eating\_disorder#Diagnosis

https://www.cambridgeshireandpeterboroughccg.nhs.uk/health-professionals/patientpathways/

https://en.wikipedia.org/wiki/Eating\_disorder#Diagnosis

https://en.wikipedia.org/wiki/Binge\_eating\_disorder#Treatment

https://www.nice.org.uk/guidance/ng69/chapter/Recommendations#physical-health-assessment-monitoring-and-management-for-eating-disorders

https://www.techopedia.com/definition/5967/artificial-neural-network-ann



https://www.statista.com/statistics/274774/forecast-of-mobile-phone-users-worldwide/

https://en.wikipedia.org/wiki/Exploratory\_factor\_analysis

https://en.wikipedia.org/wiki/Factor\_analysis

https://www.statisticssolutions.com/cronbachs-alpha/

https://www.iwh.on.ca/what-researchers-mean-by/statistical-significance

https://www.graphpad.com/guides/prism/7/statistics/extremely\_significant\_results.htm?toc =0&printWindow

https://www.investopedia.com/terms/c/coefficient-of-determination.asp

# 13. Appendix

# 13.1. APPENDIX 1: In-person Interviews in Villa Miralago

# **GENERAL QUESTIONS**

About their activities in Villa Miralago

1. Which activities do you perform inside the clinique and how often?

#### About visits with the AN patient

- 2. Which kind of meetings do you have with the patients (individual, group activities, other)?
- 3. How often (how many times) do you meet the patients in group?
- 4. How often (how many times) do you meet the patient individually?
- 5. How long does it take a meeting with the patient?
- 6. When you meet the patient, what do you ask to him?
- 7. Which information do you want to get from their answers?
- 8. Do you measure some parameter or everything is qualitative?
- 9. Which are the possible considerations that you do after a visit?
- 10. Which information would you like to get that you don't get at the moment?

#### About collaboration with the other members of the equipe

11. Which colleagues do you cooperate the most with?

12. Which information do you want to collect from your colleagues (from each category)?

13. How do you exchange information? Do you have a digital platform? Would you think it could be useful to exchange information in real time?



# **INTERVIEW 1 (EDUCATOR)**

## GENERAL QUESTIONS

Daily: meals assistance, community rules instructions, contact with families and external bodies, distribution of telephones and "regulated" objects. 4 times per week: follow rehabilitation activities (artistic, playful, psychomotricity).

Individual meetings, micro and macro group activities.

?

Individual meeting: 1 a week, meals assistance: 2 per day.

Individual meeting: 30 min, group activities: 1h.

Questions about organization of trips in the weekend, organization within the community, day setting. Individualized projects, giving goals decided with the patient (e.g. self-care, room care, improvement from dysfunctional behaviors, physical activity agreements, verify that agreements are respected)  $\rightarrow$  Behavioral approach towards symptoms.

Well-being state of the patient at 360°: not only the symptoms but also relationships (with parents, peers) and attitude towards activities (volunteering, school, work)  $\rightarrow$  Concrete and tangible infos.

Qualitative.

Conclusions: verify improvements, verify if the goals set were achieved it (e.g. How does he fill his time? What does he do during the day? Socializing, improving relationships with peers or family, taking care of their appearance and their spaces, study in the right way (very often at the two extremes, either do not study or perfectionists)).

Social media analysis (e.g. instagram, ask): time spent, what they look for. When they go to sleep.

Psychologists, psychiatrists, nutritionists, nurses. But overall the educator is very much a transversal figure.

Comprehensive and general questions about the area of competence of each to get a overview, comparison on their own interventions.

Oral communication, whatsapp. Once there was a diary, now they are building a digital platform/electronic folder that will work as a diary, it's going to be very useful.



#### SPECIFIC QUESTIONS

14. *Which criteria do you use to split the patients in groups?* For most of the activities: minors vs adults. Patients of "Ginestra" (nucleus with the most critical patients) have special needs so some special activities are dedicated to them.

15. Do you think that tracking emotions could add some relevant information to be used during group activities or during treatment in general? If yes, which ones? We work a lot on emotions with the patients, many of them have "frozen emotions": Tracking emotions, also ex-post, could be useful more for group activities rather than individual meeting, as it could help to assess the effectiveness of the activity.

16. *Would it be useful to have informations about the social interactions inside the building? if yes, how and why?* The communitary institution helps, but if the group dynamic is wrong it can intensify the discomfort.

17. *Kind of bedrooms?* Almost all double, 3-4 triple. Convivono bene? Dipende, la convivenza a volte è difficile: all'inizio si fa un lavoro educativo sulla convivenza, poi se non funziona cambiamo le stanze. Ogni tanto usiamo i cambi stanza per creare dinamiche diverse.

# **INTERVIEW 2 (NUTRITIONIST 1)**

#### GENERAL QUESTIONS

Working time is half a day's work from Monday to Friday, plus one Sunday per month. Daily activity: meals assistance (3 time in a day, the most important and difficult moment of the day). Once a week: individual meeting with patients and weighs. At the beginning of the staying and when needed they decide menus and energy intake according to the patients. There are 3 types of menus: A, 1400kcal (minimum), B, 1800kcal, C, 2000kcal.

Both individual and in small groups. Groups are divided by age, there are the adults groups and minors groups.

Once a week for minors and adults. Also, for adults there's a psycho-nutritional meeting every two weeks. Every week there is an interview regarding the meals during the weekend (non-supervisionised time).

Once a week.



It takes 45 min - 60 min in groups, 20 - 30 minutes individually

They ask how it goes in the dining room and what their fears are. They talk about weight, the weekly menu, calories and also ask questions about physical activity.

Targeted questions to understand their anxieties.

Quantitative parameters are weight, BIA and calorimetry. In the menus are calculated the energy and protein ratios and the ratios of macro and micro-nutrients.

?

They would like a dynamometer, a tool to evaluate force and muscle tone.

Colleagues with whom they have a closer collaboration: educators, because they take care of their daily lives with them. They also have a close confrontation during the day with the kinesiologists.

From the educator they want to understand the activities that patients do during the day, what are the unsupervised outings, and what kind of physical activity they do.

Once a week they have a meeting in micro teams to talk about the individual patient in charge, while informally they also talk every day. They have a file on the internal server where they record information about the interviews carried out: this is very useful and they can know what the patients have done with their colleagues.

#### SPECIFIC QUESTIONS

*Who attends the meals?* Nutritionists, educators, OSS and there are sometimes even nurses. In addition, the psychologist on duty is available in the dining room.

*What do they do during assisted meals?* They check that the meals are correct in relation to the indication given and are there to answer any questions such as "Is that right? Do I have to eat this?" When the perceived anguish is too strong, the psychologist comes into play.

*Which criteria do you use to choose or change menus?* The physical issue is very important, but the main issue is related to anxiety and the ability to cope with the meal. Sometimes it is necessary to collude with what the patient wants in order to bring about a minimum of improvement.

They have a metabolic holter to evaluate physical activity and daily energy expenditure of the patient, and depending on that intervene in the change of menu.

They suggest that it would be useful to control the activity of vomiting, because now it is only seen during blood testing.



# **INTERVIEW 3 (PSYCHIATRIST 1)**

#### GENERAL QUESTIONS

Activities: first visits of possible patients who could enter the clinic, compilation and updating of the medical record, prescription of drugs, periodic interviews with patients, relatives and teams, interface with the sending services, planning of therapeutic rehabilitation project, post-release collaboration services, prescriptions of laboratory analyses and preparation of tests.

Only individually, or with relatives.

no

Once a week.

30 minutes.

They ask the patient to take stock of the whole situation, sometimes they do not ask any questions not to force the patient. Meetings with parents are essential to understand the psychological family dynamics in place. Some typical questions concern schooling, family, quality of sleep, whether the patient smokes or not (general background).

They try to look in depth to find the real problem and try to get information that patients unconsciously reveal.

no.

no.

The main problem is the relationship with distant people (for example now there is a father who can't be contacted in any way); sometimes families are without any tools for communication.

They cooperate with every member of the equipe.

They want to have information regarding the area of competence of each colleague. For example, from the nutritionist they would like to understand how the patient eats and what kind of menu he follows, from the kinesiologist if he carries out motor activity and from the educator how he behaves in the community and in the common spaces.

Orally, via mail and whatsapp and with the internal server.

## SPECIFIC QUESTIONS



Sleep monitoring can be useful, especially with regard to the duration and quality of sleep. Patients usually sleep too little, which can affect depression (many patients take medication to sleep).

The problem is the patient's awareness of himself: something would be needed to make them account for how they appear and what social interactions they have. Technology can be a good means because it has a lot of effect on young people, even apps that they can use themselves *(problem data not true?)*. A colleague already uses apps on dysmorphobia and body image. Also, for them it would be important to track patients' activities on social media.

# **INTERVIEW 4 (NURSE)**

# GENERAL QUESTIONS

1. *Daily*: administration of therapy, help in moments of crisis (in the Ginestra group more frequently, so they work closer to the patients). Help patients during meal time to prepare the table if needed and assist them during meal times (4 times/day). *When needed* they put the nasal-gastric tube.

2. Individual meetings that happen daily for therapy administration and to help them when needed. No representative nurse. It could happen that patients form groups on their own for therapy administration.

3. Never

4. Daily

5. It depends, if just for therapy administration, some minutes.

6. It depends on the relationship with the patient: they could not talk or if there is not the psychologist and they need to talk, they talk with the nurses.

7. None in particular

8.

9. If they have taken the therapy or not.

10. Nurses lack of many informations because they don't have time to participate in the equipe meetings. They can't have many informations that other professionals have because they have to stay with the patients to control if they have crisis also when the equipe meets



and since they are not representative for one patient, they don't know in which equipe they should go.

11. In Ginestra there is a closer relationship with all functions, but typically closer with psychiatrists, nutritionists and educators.

12. Psychiatrists for the therapy. During the weekend nutritionists are not there to follow the patients, so it is important to know what the patients have to eat. Educators to know how to deal with the crisis, which activities the patients should do and when to give them their smartphones.

13. Orally or through whatsapp groups. They read the equipes' memorandum. They use a diary to communicate with the psychiatrists for the therapy.

## SPECIFIC QUESTIONS

14. *What do you do during meals*? They assist to control crisis moments, since meal times are the hardest for patients. Their work is more important in the weekends, when nutritionists are not there.

15. Which are the signals that tell you when a patient need you? It depends on the relationship with the patients, sometimes they ask for help.

16. *Which parameters you would need to monitor*? Blood saturation and pressure, heart rate. Heart rate could be useful to understand if there is a moment of crisis. It would be useful to know when they really sleep and when they vomit. Objective measure of how much they move.

## **INTERVIEW 5 (PSYCHOLOGIST)**

#### GENERAL QUESTIONS

1. Once or twice a week, at clinical level, individual meetings. There are also psychotherapeutic group meetings. *When needed*, meetings with the patient's family. *At the beginning and at the end of the therapy*, psychotherapeutic tests. Also in the follow-up they control the psychological and nutritional state measuring, for example, the BMI.

2. Both individually and in group.

3. Group meetings once a week.



4. The frequency of individual ones depend on the gravity of the patient, it could be once or twice a week, or 15 minutes every day. At the beginning, the sessions last for 40 or 50 minutes and when they get better also 20 minutes.

5. From 15 minutes to 50 minutes.

6. What we do is to discuss with the patients to understand what there is behind the events. They would talk about the weight and if they want to eat or not. Usually, they talk about how difficult it is to recognize themselves in the mirror.

7. What there is behind the events.

8. Qualitative, tests are used to make data more quantitative.

9. Personal data could predict what will happen to the patient. They do hypothesis: since x is similar to a, it is probable that i happens. There are similarities during their history and there are certain family's dynamics that could be used to do hypothesis. The objective of the therapy is to help the patient to do these considerations, making her more aware of reality. 10. None.

11. We work with the equipe. CLoser relation with psychotherapists, since they are part of the same area.

12. The weight trend to the nutritionist. To the nurse or the OSS the psychologist could ask how the patient behaved during the meal. To the psychiatrist: could the drug change this? For example, is the patient sleepy due to the drugs?

13. Orally. Next year there will be a digital platform.

#### SPECIFIC QUESTIONS

14. Do the patients keep a diary? They have a diary to plan appointments and what they eat. It could happen that they lie, so they talk with the nutritionists that ask questions to know if they lie or not.

15. Would it be useful to know what they do during the day and night? Not for the psychologist.

16. Would it be useful to know how they interact between them? It is already clear during group sessions.

17. Would it be useful to have a digital interface to talk with the patient also outside the sessions? Personally not.

18. Would it be useful to know if they lie during the sessions? Lie is an important element of the therapy.



# **INTERVIEW 6 (PSYCHIATRIST 2)**

#### GENERAL QUESTIONS

 Activity: psychiatrist, coordinator of my team. Frequency: team meetings once a week for 2 or 2.5 hrs. With patients weekly meetings, later in the rehabilitation once every two weeks.
 Individual meetings with the patient or patient + team in certain decisive moment; meetings with the patient's relatives.

3. - (no group meetings)

4. Weekly meetings, later in the rehabilitation once every two weeks.

5.30 min.

6. Psychiatric-medical interview aimed at: evaluation of the rehabilitation path state, mood, body perception, sleep-wake rhythm, "ideazione" (i.e. content of thoughts), obsessive and symptomatic forms, disperception; drug therapy setting.

7. 360° photograph of the patient because I'm responsible for the coordination of all the areas: psychopathological situation, nutrition, socialization and interpersonal relationships (e.g. family relations), physical problems (e.g. bad digestion, issues related to repeated vomiting); medical symptoms to arrange examinations and tests to be done.

8. 9.

10. Compensatory behaviors: vomiting (at the moment you can evaluate it approximately looking at the serum potassium levels (i.e. "potassiemia")), laxative use and motor activity; sleeping state (at the moment measured occasionally with the holter).

11. Micro-equipe.

12. Multidisciplinary work but above all interdisciplinary. Nurse: if the therapy is regularly taken. Nutritionist: how many times BIA, nutritional framework, if the patient eats. Educator: as it went in the activity or in the exit, educators manage the money of the patient: how much money the patient has spent (spending is a possible symptom, they tend to spend a lot). Psychologists: therapy progress.

13. Oral communication (e.g. micro-equipe meetings), server to exchange information (each one fill its own clinical part) managed by dieticians. We are building an electronic folder.



#### SPECIFIC QUESTIONS

14. *If you could have a list of things that the patient did during the day and her sleeping activity, how useful would it be?* Would be useful: the monitoring when they go out on their own; the use of the mobile phone in the afternoon (when they pick up their mobile phone they can do anything, e.g. put photos from which they are contacted for their illness. Not assessable because many profiles are private, also privacy policies).

15. *If you could have informations about social interactions in the building, how useful would it be?* Useful to assess group dynamics (in fact the community model can work positively but also as a reinforcement of negative symptomatic behaviors. Rooms and tables dispositions depends on this and are often changed).

16. *How and in which cases do you use the metabolic holter*? We use it when what the patient eats doesn't correspond to the weight gain and therefore there's the suspect of compensation mechanisms (e.g. hyperactivity). For anorexic patients, for example, typically when the patient wears it, in order not to be discovered, stays very calm and therefore put on weight. In this way we have confirmation of the compensatory behavior.

17. *Which parameters does the metabolic holter measure?* It evaluates the number of steps, quality of sleep, calories expenditure. The problem is that the patients is aware of the device so its behavior is not spontaneous.

18.

19. Which are the factors according to the pharmacological therapy is decided? State of anxiety, depression, dis-perception, insomnia, mood stability. Also, decided according to the effects the drugs can have on the metabolic state (for example they make you gain weight). 20. What do you ask to parents during the meetings with them? First meetings: family and patient history, parents in charge of psychiatric service, psychiatric family history, mental illness in the family. After: we understand the patient-relatives relationship through meetings, calls or visits of the parents to Villa Miralago (at the beginning we go out with the parents not alone, but with an educator as well. During the visits we observe: mode of interaction, family support to the therapy (not rarely they are unsupportive, they bring food, mobile phones, laxatives, diuretics, etc.).



# **INTERVIEW 7 (REHABILITATION ACTIVITIES EXPERT)**

# GENERAL QUESTIONS

1. I organize the physical activity at the gym and in the swimming pool.

2. Meetings both in groups and individually.

3. Everyday there is a group activity at the gym or in the swimming pool.

4. If they need individual meetings, we organized based on the patient's needs. Typically, twice a week or everyday for 30 minutes. When they are ready, they can do group activities. For those who use the gym, after  $\frac{2}{3}$  weeks we meet to change the exercises.

5. From 30 minutes.

6.

7.

8. Tapis roulant measure the heart rate through sensors.

9.

10. It would be useful to know in advance which drugs they take, because they could influence the weight and their physical activity.

11. The physical activity is related to all areas: psychological, nutritional and behavioral. Depending on the patient's needs there could be additional meetings with another professional. For example, working in the swimming pool with the psychologist's support. 12. Nutritionists know the menu, so they can help deciding the activities and the frequency. Psychologists: what a certain activity could mean to the patient, if there is a trauma or an episode in their life related to that activity; if it is possible to do group works 13. Orally.

# SPECIFIC QUESTIONS

14. Do you need additional information on the physical activity? At the moment not, because we do not care of the actual activity, but we focus more on the behavior behind. For example, low BMI does not mean the girl cannot train, because in reality she does exercises. So, it is useful to work with her at the gym, because otherwise she would train in her room.
15. Would it be useful to understand social dynamics? It is something that can be seen in the gym, because it is a small environment. Also the girls directly talk about this things already.



16. *What is the difference between micro and macro equipe*? The micro equipe is dedicated to one community (Ginestra, Primavera and Camelia). Macro equipe is formed by all professionals of Villa Miralago.

#### **INTERVIEW 8 (HEALTH DIRECTOR)**

#### GENERAL QUESTIONS

1. Activities as health director: I take care of: the first visit of the patients prior to hospitalization; planning and execution of the program of each guest; supervise, evaluate that the PT ("Piano Terapeutico", i.e. therapeutic plan) is performed consistently with the internal protocols and in accordance with the general therapeutic orientation of Villa Miralago; coordination of the clinical part of the equipe; interface with external institutions; exceptionally, visits to patients.

2. -

3. -

4. -

5. -

6. How it is going; clinical questions: specific questions related to food, psychopathological aspects (anxiety, mood, obsessive behaviors).

7. Adherence to the treatment; motivation and effectiveness of the care (motivation: comfort and discomfort of the patient being hospitalized, both are the extremes are signals of something that is going wrong. effectiveness: are there any medical-nutritional and psychopathological changes? if yes, how they are tolerated); particular situations that obstacle the treatment (e.g. a coeliac can involve complications and a different management). 8. Only qualitative.

9. At the beginning: how much the patient is ready; in the middle: how much the patient is compliant to the treatment; in the end: if releasing the patient is the right decision.

10. History of the tris-generational family. Useful clinical data during the rehabilitation: grilina, leptin for food intake; content and frequency on phone calls with family members; caloric intake and spending; data to understand problem with no responder to drugs (for metabolic problems or not responder because they are categories of drugs that do not work? To know it we should measure the drugs concentration in urine and blood. In very



malnourished subjects some drugs do not work because there are no receptors so there are doubts about the effectiveness).

11. -

12. -

13. Oral communication (vis-a-vis, mobile phone), whatsapp

# SPECIFIC QUESTIONS

14. *If you could have a list of things that the patient did during the day and her sleeping activity, how useful would it be?* Sleep state: the sleep in eating disorders is particular indicator of improvement or worsening, therefore fundamental for us. would be nice to dose orexine according to the analysis of sleep and hunger. Other activities/actions: hyperactivity; frequency of vomiting and of hidden food episodes; self-harm ("autolesionismo"): understand if there are predictive factors (emotional, behavioral, environmental), frequency, repetitiveness.

15. If you could have informations about social interactions in the building, how useful would it be?

Emotions when the staff is not present, because they are manipulative and easily influenced by the context.

# **INTERVIEW 9**

## GENERAL QUESTIONS

Daily activities: assessment of nutritional status and decision of food therapy, which can be by mouth, by integration or artificially. They work in teams and their main objective is to respect the various balances, of which the psychological one is the most important. The most important decision are made in micro equipe. Assessment of nutritional status: weight, body mass index, calorimetry, lean and fat mass: together they assess the basal energy consumption. They regularly attend meals in the three dining rooms (serious patients, stable patients and patients with greater autonomy).

Meetings both in groups and individually.



Once a week. There are 3 types of groups (nutritional, pyscho-nutritional and edunutritional).

It depends on the patient's needs, ranging from 3 interviews per day for the most serious cases up to one per week.

It's very flexible, from 5 minutes up to an hour.

Questions and objective of the meeting: knowing the whole history of the patient, making a detailed food history, understanding how he was treated previously, if there are allergies and / or intolerances evaluated by a doctor and if there are phobic foods.

First of all, they try to find a dialogue point with the patient to help him changing the relationship with food and eating, and then they establish the technical food requirements. It is very important to understand what adherence can have to the menu.

••

••

They would like more information about hyperactivity, concealment of food, if the patient does not behave as he should during the outings, if he abuses laxatives or "metabolism activating" drugs and if he vomits.

They have closer contact with psychiatrists, psychologists and physical activity managers.

Information from the area of expertise. There's a great cooperation to evaluate the energy consumption.

Orally or through whatsapp groups. There will be a digital platform.

## SPECIFIC QUESTIONS

One of the things they are working on is finding an instrumentation/app that gives correct information about the diet, so as to counteract the distorted information that is found on the internet. They would like an app that can help patients make food choices, including during weekend outings and follow up periods. An app that shows portions and energy supplies could be very useful.

They are interested in tracking all physical activity (even at night), collecting data constantly on calorie intake and sleep.



# 13.2. APPENDIX 2: Questionnaire

(Italian language)

SECTION	#	QUESTIONS	SUB-QUESTIONS	RESPONSE	OPTION OF NOMINAL SCALE
Introduzione		Gent.ma/Egr. la ringraziamo per il tempo che dedicherà a questa ricerca. La compilazione completa del questionario richiede meno di 15 minuti. Le chiediamo di rispondere a tutte le domande così da poter costruire una base informativa completa. Alcune domande possono sembrare ripetute, ciò nonostante le chiediamo di rispondere a tutte le domande poiché esse fanno riferimento a scale validate. Precisiamo che non ci sono risposte corrette o sbagliate, ciò che conta è la sua opinione. A tal proposito, la informiamo che i dati forniti saranno trattati in maniera anonima e conforme alla normativa europea GDPR (UE 2016/679) per il Trattamento dei Dati Personali. I dati raccolti dal questionario saranno pertanto analizzati senza la possibilità alcuna di ricondurli ai relativi rispondenti. La invitiamo a confermare la sua volontà a partecipare alla ricerca ed esprimere il suo consenso al trattamento dei dati forniti. Per ogni dubbio la invitiamo a scrivere a: Dott. Leonardo Mendolicchio, Direttore Sanitario di Villa Miralago – direzionesanitaria@villamiralago.itProf. Emanuele Lettieri, Responsabile Scientifico della ricerca – emanuele.lettieri@polimi.it			
Parametri rilevanti nella cura dei DCA		Ha una prevalente categoria diagnostica di DCA che segue? (DCA = Disturbo del Comportamento Alimentare) In caso di risposta affermativa, specificare quale:		Nominal scale Nominal scale	Sì; No AN; BN; BED; Altro
	D4	Nel rispondere alle seguenti domande, consideri esclusivamente il suo interesse a conoscere il parametro indicato, indipendentemente dalla reale capacità della struttura di rilevarlo:			
	D5		per lei conoscere l'ASSUNZIONE CALORICA della persona assistita?	Likert scale 1-5	
	D6	ASSUNZIONE CALORICA	interessato a conoscere l'ASSUNZIONE CALORICA della persona assistita?		Giornalmente; 2-3 volte a settimana; 1 volta a settimana; 1 volta ogni 2 settimane; 1 volta al mese; meno di 1 volta al mese; meno di una volta al mese; Mai
	D7		Attualmente è soddisfatto delle informazioni di cui	Nominal scale	Sì; No



		dispone relativamente all'ASSUNZIONE CALORICA della persona assistita?		
D8		Se NON è soddisfatto, perché?	Nominal scale	Informazione non disponibile; informazione non affidabile; informazione non tempestiva
D9		Quanto è importante per lei conoscere la QUANTITA' DI CALORIE CONSUMATE dalla persona assistita?	Likert scale 1-5	
D10	CALORIE CONSUMATE	Con quale frequenza è interessato a conoscere la QUANTITA' DI CALORIE CONSUMATE dalla persona assistita?	Nominal scale	Giornalmente; 2-3 volte a settimana; 1 volta a settimana; 1 volta ogni 2 settimane; 1 volta al mese; meno di 1 volta al mese; meno di una volta al mese; Mai
D11		Attualmente è soddisfatto delle informazioni di cui dispone relativamente alla QUANTITA' DI CALORIE CONSUMATE dalla persona assistita?	Nominal scale	Sì; No
D12		Se NON è soddisfatto, perché?		Informazione non disponibile; informazione non affidabile; informazione non tempestiva
D13		Quanto è importante per lei tenere traccia delle PRATICHE DI COMPENSAZIONE (vomito, uso di lassativi ecc.) della persona assistita?	Likert scale 1-5	
D14	PRATICHE DI COMPENSAZIONE	Con quale frequenza è interessato a conoscere le PRATICHE DI COMPENSAZIONE (vomito, uso di lassativi ecc.) della persona assistita?	Nominal scale	Giornalmente; 2-3 volte a settimana; 1 volta a settimana; 1 volta ogni 2 settimane; 1 volta al mese; meno di 1 volta al mese; meno di una volta al mese; Mai
D15		Attualmente è soddisfatto delle informazioni di cui dispone relativamente alle PRATICHE DI COMPENSAZIONE (vomito, uso di lassativi etc.) della persona assistita?	Nominal scale	Sì; No
D16		Se NON è soddisfatto, perché?	Nominal scale	Informazione non disponibile; informazione non affidabile; informazione non tempestiva
D17	QUALITA' DEL SONNO	Quanto è importante per lei il monitoraggio della QUALITA' DEL	Likert scale 1-5	



				South and the second se
		SONNO della persona assistita?		
D18		Con quale frequenza è interessato alla QUALITA' DEL SONNO della persona assistita?	Nominal scale	Giornalmente; 2-3 volte a settimana; 1 volta a settimana; 1 volta ogni 2 settimane; 1 volta al mese; meno di 1 volta al mese; meno di una volta al mese; Mai
D19		Attualmente è soddisfatto delle informazioni di cui dispone relativamente alla QUALITA' DEL SONNO della persona assistita?	Nominal scale	Sì; No
D20		Se NON è soddisfatto, perché?	Nominal scale	Informazione non disponibile; informazione non affidabile; informazione non tempestiva
D21		Quanto è importante per lei RICONOSCERE E TRACCIARE LE EMOZIONI (ansia, paura, disagio, coinvolgimento, serenità ecc.) della persona assistita durante una seduta terapeutica?	Likert scale 1-5	
D22	RICONOSCIMENTO E TRACCIAMENTO EMOZIONI	· · ·	Nominal scale	Giornalmente; 2-3 volte a settimana; 1 volta a settimana; 1 volta ogni 2 settimane; 1 volta al mese; meno di 1 volta al mese; meno di una volta al mese; Mai
D23		Attualmente è soddisfatto delle informazioni di cui dispone relativamente alle EMOZIONI (ansia, paura, disagio, coinvolgimento, serenità ecc.) della persona assistita durante una seduta terapeutica?	Nominal scale	Sì; No
D24		Se NON è soddisfatto, perché?	Nominal scale	Informazione non disponibile; informazione non affidabile; informazione non tempestiva
D25	MOVIMENTI E DINAMICHE DI GRUPPO	Quanto è importante per lei conoscere I MOVIMENTI E LE DINAMICHE DI GRUPPO delle persone assistite all'interno della struttura?		
D26		Con quale frequenza è interessato a conoscere I MOVIMENTI E LE DINAMICHE DI	Nominal scale	Giornalmente; 2-3 volte a settimana; 1 volta a settimana; 1 volta ogni 2



			GRUPPO delle persone assistite all'interno della struttura?		settimane; 1 volta al mese; meno di 1 volta al mese; meno di una
		on anulu.		volta al mese; Mai	
	D27		Attualmente è soddisfatto delle informazioni di cui dispone relativamente ai MOVIMENTI E ALLE DINAMICHE DI GRUPPO delle persone assistite all'interno della struttura?	Nominal scale	Si; No
	D28		Se NON è soddisfatto, perché?	Nominal scale	Informazione non disponibile; informazione non affidabile; informazione non tempestiva
			So usare vari strumenti per comunicare (es. e- mail, chat, SMS, blog, social networks)	Likert scale 1-5	
	D30		So usare servizi online (es. shopping online, e- banking)	Likert scale 1-5	
	D31	n I I I I I I I I I I I I I I I I I I I	So usare diversi social network (es. Facebook, Instagram) e strumenti di collaborazione (es. Dropbox, Google Drive)	Likert scale 1-5	
	D32		So comunicare, scambiare informazioni e conoscenze online (es. tramite social network o community online)	Likert scale 1-5	
Conoscenza e	D33		So modificare le impostazioni predefinite di software e applicazioni	Likert scale 1-5	
utilizzo di tecnologie	D34			Likert scale 1-5	
	D35			Likert scale 1-5	
		Quali di queste tecnologie conosce o ha usato nella sua pratica clinica?		Likert scale 1-5	
	D37 D38		Telemedicina Mobile Health (es. app dedicate al fitness e al wellness, app informative, app per la gestione della cronicità e per la cura)	Likert scale 1-5 Likert scale 1-5	
	D39 D40		Terapie digitali Sensori e dispositivi indossabili (es. smartwatch)	Likert scale 1-5 Likert scale 1-5	
	D41		\/	Likert scale 1-5	



Evoluzione tecnologica nel mondo della cura dei DCA	D43 D44 D45 D46		dei DCA, sono in corso cambiamenti intensi Le persone da noi assistite chiedono regolarmente nuove modalità di assistenza Nel mondo della cura dei DCA, è diffuso l'interesse nell'utilizzo di tecnologie digitali Nel mondo della cura dei DCA, si diffonderà sempre più l'interesse nell'utilizzo di tecnologie digitali Nel mondo della cura dei DCA, ci sono sempre più pubblicazioni riguardanti l'utilizzo di tecnologie digitali	Likert scale 1-5 Likert scale 1-5 Likert scale 1-5 Likert scale 1-5	
	D47		Il sistema socio sanitario fa pressione per l'adozione di tecnologie digitali nella cura dei DCA	Likert scale 1-5	
Tecnologia e benessere psicologico nella pratica lavorativa		Nelle seguenti affermazioni viene menzionato un "sistema". Immagini questo "sistema" come una piattaforma dove sono raccolti numerosi dati real life relativi ai pazienti (es. assunzione e consumo calorico, qualità del sonno, battito cardiaco e pressione arteriosa, movimenti e dinamiche di gruppo, emozioni) tramite tecnologie digitali (es. smartwatch, sensori, antenne, telecamere ambientali) e analizzati per singolo paziente o gruppi di pazienti, distribuendo questa informazione ai professionisti o tramite App sul cellulare o tramite un software installato sui computer della sua struttura. Immagini, ai soli fini di questa ricerca, che tale sistema venga adottato a breve dalla struttura presso cui lavora. Immedesimandosi in questo scenario, indichi il suo grado di accordo con le seguenti affermazioni. <u>Con l'introduzione di questo sistema:</u>		Likert scale 1-5	
	D50		li suo lavoro richiederà più tempo		
	D51		Le sarà richiesto un carico di lavoro maggiore rispetto a quello che riesce a svolgere in modo adeguato	Likert scale 1-5	
	D52	COGNITIVE DEMAND	Dovrà prestare attenzione ad una quantità maggiore di informazioni mentre lavora	Likert scale 1-5	



D5	53		Dovrà memorizzare una quantità maggiore di informazioni	Likert scale 1-5
DS	54		Dovrà prendere decisioni più difficili	Likert scale 1-5
DS	55	AUTONOMY	Avrà una maggiore autonomia nello svolgere il suo lavoro	Likert scale 1-5
D	56		Si troverà nelle condizioni di svolgere il suo lavoro con maggiore libertà e indipendenza	Likert scale 1-5
DS	57		Le sarà concessa una maggiore libertà nel decidere come svolgere il suo lavoro	Likert scale 1-5
D5	58		Le verrà richiesto di prendere più iniziative	Likert scale 1-5
DS	59	PROFESSIONAL DEVELOPMENT	Avrà più opportunità di imparare cose nuove durante il lavoro	Likert scale 1-5
De	60		Avrà più opportunità di sviluppare le sue competenze	Likert scale 1-5
De	61		Impiegherà più tempo per rilassarsi dopo il lavoro	Likert scale 1-5
De	62	EXHAUSTION	Riuscirà a reggere meglio la pressione del suo lavoro	Likert scale 1-5
De	63		Riuscirà a gestire meglio il suo lavoro	Likert scale 1-5
De	64	DISENGAGEMENT	Scoprirà nuovi e interessanti aspetti del suo lavoro	Likert scale 1-5
De	65		Parlerà negativamente del suo lavoro più frequentemente	Likert scale 1-5
De	66		Si sentirà sempre più coinvolto nel suo lavoro	Likert scale 1-5
De	67		Avrà più voglia di andare a lavoro al suo risveglio	Likert scale 1-5
De	68	VIGOUR	Riuscirà a lavorare per periodi di tempo più lunghi	Likert scale 1-5
De	69		Al lavoro sarà più perseverante anche quando le cose non vanno bene	Likert scale 1-5
D7	70		Darà più significato e valore al suo lavoro	Likert scale 1-5
D7	71	DEDICATION	Sarà più entusiasta del suo lavoro	Likert scale 1-5
D7	72		Il suo lavoro la ispirerà maggiormente	Likert scale 1-5



D73       Non si preoccuperà mai Likert scale 1-5 che i suoi errori vengano criticati ingiustamente dai suoi colleghi         D74       E' sicuro che nessun collega agirà mai volontariamente contro di lei         D75       PSYCHOLOGICAL SAFETY         Nella struttura dove lavora, sarà in grado di discutere senza difficoltà sui suoi problemi legati al lavoro         Nella struttura dove lavora, andrà incontro a molti problemi se chiederà aiuto         D76       Considererà la possibilità di usare il sistema	
D74       che i suoi errori         D74       E' sicuro che nessun         D74       E' sicuro che nessun         D75       PSYCHOLOGICAL SAFETY         Nella struttura dove       Likert scale 1-5         alificoltà sui suoi       problemi legati al         avoro       Nella struttura dove         Likert scale 1-5       Likert scale 1-5         D75       PSYCHOLOGICAL SAFETY         Nella struttura dove       Likert scale 1-5         avora, sarà in grado di discutere senza       Likert scale 1-5         Nella struttura dove       Likert scale 1-5         D76       Considererà la         D76       Considererà la         D76       Considererà la	
D74       ingiustamente dai suoi colleghi         D74       E' sicuro che nessun collega agirà mai volontariamente contro di lei         D75       PSYCHOLOGICAL SAFETY         Nella struttura dove lavora, sarà in grado di discutere senza difficoltà sui suoi problemi legati al lavoro       Likert scale 1-5         Nella struttura dove lavora, andrà incontro a molti problemi se chiederà aiuto       Likert scale 1-5         D76       Considererà la possibilità di usare il sistema	
D74       Colleghi       Colleghi         D74       E' sicuro che nessun collega agirà mai volontariamente contro di lei       Likert scale 1-5         D75       PSYCHOLOGICAL SAFETY       Nella struttura dove lavora, sarà in grado di discutere senza difficoltà sui suoi problemi legati al lavoro       Likert scale 1-5         D76       Considererà la possibilità di usare il sistema       Likert scale 1-5       Likert scale 1-5	
D74       E' sicuro che nessun collega agirà mai volontariamente contro di lei       Likert scale 1-5         D75       PSYCHOLOGICAL SAFETY       Nella struttura dove lavora, sarà in grado di discutere senza difficoltà sui suoi problemi legati al lavoro       Likert scale 1-5         D76       Considererà la possibilità di usare il sistema       Likert scale 1-5       Likert scale 1-5	
D75       PSYCHOLOGICAL SAFETY       Nella struttura dove lavora, sarà in grado di discutere senza difficoltà sui suoi problemi legati al lavoro       Likert scale 1-5         D76       Considererà la possibilità di usare il sistema       Likert scale 1-5	
D75       PSYCHOLOGICAL SAFETY       Nella struttura dove lavora, sarà in grado di discutere senza difficoltà sui suoi problemi legati al lavoro       Likert scale 1-5         Nella struttura dove lavora, andrà incontro a molti problemi se chiederà aiuto       Likert scale 1-5       Likert scale 1-5         D76       Considererà la possibilità di usare il sistema       Likert scale 1-5       Likert scale 1-5	
D75       PSYCHOLOGICAL SAFETY       Nella struttura dove lavora, sarà in grado di discutere senza difficoltà sui suoi problemi legati al lavoro       Likert scale 1-5         D76       Considererà la possibilità di usare il sistema       Likert scale 1-5	
PSYCHOLOGICAL SAFETY       lavora, sarà in grado di discutere senza difficoltà sui suoi problemi legati al lavoro         Nella struttura dove lavora, andrà incontro a molti problemi se chiederà aiuto       Likert scale 1-5         D76       Considererà la possibilità di usare il sistema       Likert scale 1-5	
PSYCHOLOGICAL SAFETY       lavora, sarà in grado di discutere senza difficoltà sui suoi problemi legati al lavoro         Nella struttura dove lavora, andrà incontro a molti problemi se chiederà aiuto       Likert scale 1-5         D76       Considererà la possibilità di usare il sistema       Likert scale 1-5	
discutere senza         difficoltà sui suoi         problemi legati al         lavoro         Nella struttura dove         lavora, andrà incontro a         molti problemi se         chiederà aiuto         D76         Considererà la         possibilità di usare il         sistema	
difficoltà sui suoi problemi legati al lavoro       Likert scale 1-5         D76       Considererà la possibilità di usare il sistema	
problemi legati al lavoro       Likert scale 1-5         Nella struttura dove lavora, andrà incontro a molti problemi se chiederà aiuto       Likert scale 1-5         D76       Considererà la possibilità di usare il sistema	
Iavoro       Iavoro         Nella struttura dove lavora, andrà incontro a molti problemi se chiederà aiuto       Likert scale 1-5         D76       Considererà la possibilità di usare il sistema       Likert scale 1-5	
lavora, andrà incontro a molti problemi se chiederà aiuto       Iavora, andrà incontro a molti problemi se chiederà aiuto         D76       Considererà la possibilità di usare il sistema	
lavora, andrà incontro a molti problemi se chiederà aiuto       Iavora, andrà incontro a molti problemi se chiederà aiuto         D76       Considererà la possibilità di usare il sistema	
D76     Considererà la possibilità di usare il sistema     Likert scale 1-5	
D76 D76 D76 D76 D76 D76 D76 D76 D76 D76	
D76 Considererà la possibilità di usare il sistema	
possibilità di usare il sistema	
sistema	
D77 Avrà intenzione di Likert scale 1-5	
usare il sistema	
INTENTION TO USE	
D78 Prevede che, avendo la Likert scale 1-5	
possibilità di accedervi,	
avrà intenzione di usarlo	
usario	
D79 Con l'utilizzo di questo sistema, la	
persona assistita:	
D80 Dubiterà che lei se ne Likert scale 1-5	
prenda cura come	
D81 Dubiterà che i suoi Likert scale 1-5	
bisogni vengano messi	
al primo posto da lei	
D82 Si fiderà a tal punto di Likert scale 1-5	
lei da provare sempre a	
seguire i suoi consigli	
D83 Le crederà qualora lei Likert scale 1-5 le dica che le cose	
stanno in un certo	
modo	
D84 Non si fiderà sempre di Likert scale 1-5	
lei e vorrà chiedere una	
D85 Si fiderà del suo Likert scale 1-5	
D85 Si fiderà del suo Likert scale 1-5 PATIENT TRUST giudizio sulla terapia	
D86 Avrà la sensazione che Likert scale 1-5	
lei non faccia tutto il	
possibile per curarla	
D87 Confiderà che le sue Likert scale 1-5	
esigenze cliniche vengano messe da lei al	
di sopra di tutte le altre	
considerazioni trattando	
i suoi problemi di	
salute	
D88 La riterrà un vero Likert scale 1-5	
esperto nella cura di problemi di salute	
simili ai suoi	
D89 Confiderà che lei gli Likert scale 1-5	
dica se è stato fatto un	
errore sulla sua terapia	



	D90		Si preoccuperà della privacy dei dati che lei possiede	Likert scale 1-5	
Variabili socio- demografiche	D91	Sesso:		Nominal scale	M; F
	D92	Età:		Open-ended	
	D93	Ultimo titolo di stufi conseguito:		Nominal scale	Terza media; Diploma; Laurea triennale; Laurea magistrale/ a ciclo unico; Dottorato
	D94	Professione:		Nominal scale	Medico generale; Psichiatra; Psicologo- psicoterapeuta; Nutrizionista- dietista; Esperto in attività riabilitative; Educatore; Infermiere; Altro
Ŭ	D95	Indichi da quanti anni pratica questa professione:		Open-ended	
	D96	Indichi la regione in cui lavora:		Open-ended	
	D97	Indichi il contesto clinico in cui opera nella struttura dove lavora:		Nominal scale	Ambulatorio; Day hospital; Ricovero ospedaliero; Ricovero residenziale; Altro
	D98	In caso abbia risposto "Altro", specificare quale:		Open-ended	
	D99	Indichi approssimativamente il numero di persone che la struttura dove lavora assiste:		Open-ended	
Conclusione	D100	Gent.ma/Egr. la informiamo che ha concluso con successo il questionario. Rinnoviamo i nostri ringraziamenti per il tempo dedicatoci ed il suo prezioso contributo. Per ogni dubbio la invitiamo a scrivere a: Dott. Leonardo Mendolicchio, Direttore Sanitario di Villa Miralago – <u>direzionesanitaria@villamiralago.it</u> Prof. Emanuele Lettieri, Responsabile			
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