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CORSO DI DOTTORATO DI RICERCA IN SCIENZE BIOMEDICHE

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XXX CICLO

DIABETES AND MEDICAL DEVICES: WHICH DEVICE FOR WHICH PATIENT

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Anno Accademico 2016 – 2017

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Diabetes care costs amount to 8% of all national healthcare expenditure referred to hospitalization (50.1%), outpatient services (17.4%), other drugs (21.3%), drugs for diabetes (6.9%) and medical devices (4.3%) (De Berardis, et al., 2012).

Insulin therapy is a pharmaceutical treatment option used to lower blood glucose in all patients with type 1 diabetes (T1D) and in a part of patients with type 2 diabetes (T2D). For insulin-treated patients blood glucose optimisation can be managed by different types of insulin that can be integrated in various medical devices technologies such as insulin pumps (Continuous Subcutaneous Insulin Infusion, CSII) and insulin pens (Multiple Daily Insulin Injection, MDI).

Aim

To draw the profile of patients in insulin therapy with insulin pumps and with multiple daily injections by identifying the variables that influence the use and the choice of two different medical devices.

Tools and Methods

We developed the PLDI questionnaire to rate clinical and physical characteristics of these patients, their way of life, their lifestyles in general. The Explorative Factor Analysis (EFA) was performed to define the profiles of insulin-treated patients with diabetes enrolled in our study and the Confirmatory Factor Analysis (CFA) was performed to validate the relationships between the factors that identify the profiles that are defined with the EFA. Regression Models were performed to estimate the effects of demographic variables, clinical data, lifestyles and behaviour on the choice of medical device and its cost.

Results

The whole PLDI questionnaire has a good internal items consistency (α=.85.

Thanks to EFA three factors were lastly extracted: “General Characteristics”, “Employment Information” and “Eating Habits” that were finally accepted and confirmed by CFA. General Characteristics and Eating Habits also resulted the independent variables highlighted in the regression models’ results.

Conclusions

The results provide supporting evidence that there are many, but not only clinical, characteristics of patients with diabetes useful to the appropriate choice of medical device for insulin treatment.

This study is not devoid of limitations and the main is based on the sample and its composition, which limits the generalizability of results. Therefore, next development is to make the results more generalizable in order that they can be used by policy makers in healthcare for a better management of resources and the best appropriateness of patients’ eligibility at the use of CSII technology.

Acknowledgements

First, and foremost, I would like to express my sincere gratitude to my advisor Giuliana Solinas, for her immense knowledge, patience, continuous support and invaluable guidance throughout these years, as well as her immense goodness of mind. I could not have imagined having a better advisor and mentor for my Ph.D. studies.

I am truly grateful to dr. Francesco Mastinu for his support defining the research planning, as well as all staff in the Department of Diabetology at the San Martino Hospital in Oristano.

I also want to thank Barbara Podda and Donatella Garau for the suggestions they provided on my research.

Finally, I gratefully acknowledge the Biomedical Department of the University of Sassari for everything I have accomplished with this path and what I can achieve.

Introduction

Diabetes is a chronic disease that occurs either when the pancreas does not produce enough insulin or when the body cannot effectively use the insulin it produces. Insulin is a hormone that regulates blood sugar. During 2016, there are over 3 million 200 thousand people in Italy who claim to be suffering from diabetes, the 5.3% of the entire population (16.5% among the people of 65 years and beyond) (ISTAT, 2017). Diabetes care costs amount to 8% of all national healthcare expenditure referred to hospitalization (50.1%), outpatient services (17.4%), other drugs (21.3%), drugs for diabetes (6.9%) and medical devices (4.3%) (De Berardis, et al., 2012).

Insulin therapy is a pharmaceutical treatment option used to lower blood glucose in all patients with type 1 diabetes (T1D) and in a part of patients with type 2 diabetes (T2D) whose pancreas don't produce enough amounts of the hormone insulin.

For insulin-treated patients blood glucose optimisation can be managed by different types of insulin that can be integrated in various medical device technologies such as insulin pumps (Continuous Subcutaneous Insulin Infusion, CSII) and insulin pens (Multiple Daily Insulin Injection, MDI). Both CSII and MDI are forms of intensified insulin treatment, but CSII mimics a physiological situation better (Jeitler, et al., 2008).

CSII technology was introduced in the 1970s to achieve normoglycaemia in people with type 1 diabetes mellitus (Pickup, et al., 1978). The first insulin pump had to be worn like a backpack, whereas nowadays a traditional CSII device includes: the pump and its controls, the processing module, the batteries, a disposable reservoir for insulin, a disposable infusion set, a cannula for subcutaneous insertion (under the skin) and a tubing system to interface the insulin reservoir to the cannula. The pump delivers insulin in two ways:

- a basal dose which is infused continuously to correct the basal rate;
- the bolus doses which are infused "on-demand" to cover food eaten or to correct a high blood glucose level.

The main difference between CSII than MDI treatment is obviously the basal dose, that is not provided in MDI.

According to the third Italian survey, the number of patients with T1D and T2D that use CSII increased by 396% between 2005-2013 (Bruttomesso, et al., 2015). These values might keep increasing, and more work is needed to ensure uniform treatment strategies throughout the country. In fact, the spread of CSII resulted really uneven between Italian regions and even between different diabetes care centres of the same region.

1.1 Related literature

CSII is recommended as a possible treatment for patients who attempt to achieve target haemoglobin levels following high levels of HbA1c (8.5% or above) with MDI despite carefully managing their diabetes (NICE, 2008).

Candidates for CSII include patients with type 1 diabetes and patients with type 2 diabetes who are insulin dependent and have inadequate control with MDI.

CSII should only be used in patients who are motivated, knowledgeable in diabetes self-care, take insulin multiple times per day, assess blood glucose levels multiple times daily, are motivated to achieve tighter glycaemia control, are willing, intellectually and physically able to undergo the rigors of insulin pump therapy initiation and maintenance (AACE/ACE Diabetes Guidelines, 2015). The American Diabetes Association (ADA) annually publishes its standards of medical care for patients with diabetes: for glycaemia treatment it is recommended that individuals who have been successfully using CSII should have continued access after they turn 65 years old (American Diabetes Association, 2016).

Italian standards recommend the advice of expert panels who have the task of selecting candidate patients for the use of the insulin pumps. These patients must have poor glycaemia control and/or recurrent hypoglycaemia despite an optimal basal-bolus regimen (level III strength, strength of recommendation B) (AMD-SID, 2014).

Furthermore, there is a lot of considerable research and tools designed to assess patient satisfaction, diabetes knowledge and diabetes QoL (Burroughs, et al., 2004; Eigenmann, et al., 2011; Paddock, et al., 2000).

Aim

The aim of this study is to draw the profile of patients in insulin therapy with insulin pump (CSII) and with multiple daily injections (MDI) by identifying the variables that influence the use and the choice of two different medical devices. We rate clinical and physical characteristics of these patients, their way of life, the work they do and its organization, their qualifications, physical activity and other recreational interests practiced, their marital status, the parity of pregnancies and the number of children (only for women), their lifestyles, eating and behavioural habits.

2.1 Research planning

A cross-sectional study was planned and has involved people in insulin treatment using MDI and CSII for at least six months, residents in Sardinia during the period of study (since 2015) and being treated at diabetes centres in the same region.
The patients enrolled in the study are adult patient (≥18 years old). The date of birth will be considered to calculate the age (years) of the enrolled patients.

The informed consents for the participants at the study are reported in Appendix A in Italian language.
Data collection includes patients' clinical data and non-clinical data gathered by the structured questionnaire with a majority of closed questions.
The form of clinical data available only in Italian language is reported in Appendix B.
A structured interview is used as a method of data collection proposed to each patient enrolled in the study. The interview is conducted by the same person. Although the interaction between interviewer and interviewee is face-to-face, enrolled patients don't

take direct vision of the questionnaire; in this way the emotional independence of the answers to the questionnaire and the consequent absence of conditioning by previously reading of the whole text is ensured.

The final research is preceded by a pilot study designed, to reveal deficiency in the proposed structured questionnaire (to check the comprehensibility of the questions and the logical structure of the same, as well as to monitor the time of detection information) and to validate it.

A pilot study is understood as a pre-testing or 'trying out' for further epidemiological studies (Baker, 1994). It should be recognized that the pilot studies may have a number of limitations and as a chance to make inaccurate forecasts or assumptions related to the sample size. Although pilot study findings may offer some indication of the likely size of the response rate in the main survey, they cannot guarantee this because they don't have a statistical foundation and are nearly always based on small numbers (Van Teijlingen & Hundley, 2001).

2.2 Ethical Approval

Before conducting the study, we requested the ethical approval from the Local Health Authority of Sassari' Ethic Committee, Sardinia Region (Italy). We have obtained the ethical approval to conduct this research and to use documents reported in Appendix A, Appendix B, Appendix C[1].

[1] In Appendix C is reported the 2nd version of the questionnaire, after piloting test.

Tools and Methods

3.1 Patients' Lifestyle with Diabetes Insulin-treated (PLDI) Questionnaire

Currently, for my knowledge, there are no recommended standards which enable to correlate patients' lifestyle with insulin therapy and technology used. Because no tools are available to assess the choice of medical device for insulin treatment based on patients' lifestyle, we developed a questionnaire to study the way of life of patients with diabetes in insulin-treatment. We call this tool *Patients' Lifestyle with Diabetes Insulin-treated* (PLDI) questionnaire.

The PLDI questionnaire was validated after the pilot study (see Appendix C) in Italian language and contains questions about perception of health, satisfaction of medical device and patient's lifestyle. To make sure that the items of PLDI questionnaire were understandable, an expert panel of healthcare professionals reviewed the tool and all items.

Moreover, the PLDI questionnaire contains questions about medical device for insulin treatment used, the length of their use and general information of the patients with type 1 and type 2 diabetes. There are also demographic items providing information about professional activity, marital status, qualification, length of time since diagnosis of diabetes and for women also the number of pregnancies. There are in total 25 items.

For questions on the perception of health and some on the patient's lifestyle (eating habits, sport, qualification, etc.) the ISTAT survey questionnaire multipurpose was considered (Istat, 2015).

The PLDI questionnaire is the same for patients with type 1 and type 2 diabetes. Every item is measured using Likert scale scores expressed in 5 dimensions from 1 to 5 with the assumption of ordinals from low risk to high risk.

3.1.1 Pilot testing

For the pilot test of the PLDI questionnaire, all detailed information of the study was provided to prospective participants and written consents were obtained. People with type 1 and type 2 diabetes were recruited from a Primary Health Care Centre of Sardinia (Italy) (see 4.2.1).

Health professionals of diabetes were asked to introduce the pilot study to patients with type 1 and type 2 diabetes and to request them if they would take part in the survey. The PLDI questionnaire was submitted under interview form to patients interested to participate and who had signed the informed consent. The PLDI questionnaire was performed, for each insulin-treated patient, by the same interviewer.

The interaction between interviewer and interviewee was face-to-face and patients enrolled in the study didn't take direct vision of the questionnaire; in this way the emotional independence of the answers was ensured to the questionnaire and the consequent absence of conditioning by previously reading it too.

The internal consistency of the items of the PLDI questionnaire was assessed by Cronbach's Alpha (α) index (Armitage & Colton, 1998) using STATA 14. The α value was calculated for the whole questionnaire. We performed also a descriptive analysis by medical device used, gender, age, qualification and marital status.

3.2 Statistical Analysis

The Explorative Factor Analysis (EFA) was performed to define the profiles of insulin-treated patients with diabetes enrolled in our study and the Confirmatory Factor Analysis (CFA) was performed to validate the relationships between the factors that identify the profiles that are defined with the EFA.

The Regression Models were performed to estimate the effects of demographic variables, clinical data, lifestyles and behaviour on costs related to medical devices.
The EFA and the Regression Models were implemented in SPSS 24, while the CFA was ran with AMOS 24.

Univariate analyses preceded multivariate analyses. For the univariate analyses, descriptive statistics (mean, standard deviation, minimum and maximum values, frequencies) are calculated for quantitative and qualitative variables, respectively.

3.2.1 Exploratory Factor Analysis

Exploratory Factor Analysis (EFA) is a type of factor analysis, and the purpose is to identify the underlying dimensional structure of a set of measures summarizing data so that relationships and patterns can be easily interpreted and understood. So that, EFA tries to uncover complex patterns by exploring the dataset and testing predictions (Yong & Pearce, 2013). Factor analysis is useful for studies that involve a few or hundreds of variables, items from questionnaires, or a battery of tests (Rummel, 1970).

In EFA, measurable and observable variables can be reduced to fewer "latent variables" that share a common variance, are unobservable and non directly measured but are used to represent variables (Bartholomew, 1980). These variables are interdependent: there are no dependent or independent variables, but they are correlated.

For each factor or latent variable we define:

- *factor loading*, a measure of how much a observed variable contributes to the factor (the larger the factor loading the more the variable has contributed to that factor);
- *factor score*, the weights of each observed variable in producing a score representing each factor;
- *eigenvalue*, the sum of the squared factor loadings for a given factor;
- *communality*, the variance in the observed variables which are accounted for by a common factor (shows how much each variable can be predicted the extracted factors).

The variance is equal to the square of the factor loadings (Child, 2006).

In the mathematical model, p denotes the number of variables (X_1, X_2,…, X_p) and m defines the number of underlying factors (F_1, F_2,…,F_m). Xj is the variable represented in latent factors. Thus, this model assumes that there are m underlying factors whereby each observed variables is a linear function of these factors together with a residual variant.

$$X_j = a_{j1}F_1 + a_{j2}F_2 +_{.....} + a_{jm}F_m + e_j$$

The factor loadings are a_{j1}, a_{j2},…, a_{jm} which denotes that a_{j1} is the factor loading of j^{th} variable on the 1^{st} factor. The specific or unique factor is denoted by e_j.
The communality is denoted by h^2 and is the summation of the squared factor ladings:

$$h_j^2 = a_{j1}^2 + a_{j2}^2 +_{....} + a_{jm}^2$$

The *unique variance* is denoted by u^2 and is the proportion of the variance that excludes the common factor variance which is represented by the formula:

$$u_j^2 = 1 - h_j^2$$

Thus, u_j^2 is the variance due by variable j.
If you know that unique variance is split into specific variance and error variance, the formula of the total variance is:

$$V_{Total} = V_{Common} + V_{Specific} + V_{Error}$$

Factor loadings are very similar to weights in multiple regression analysis, and they represent the strength of the correlation between the variable and the factor. Factor analysis uses matrix algebra when computing its calculations. The basic statistic used in factor analysis is the correlation coefficient which determines the relationship between two variables. Generally, a factor analysis performed using a correlation matrix produces standardized data, thus it is recommended for variables that are not meaningfully comparable (e.g., items from different scales). On the other hand, factor analysis performed using a covariance matrix is conducted on variables that are similar (e.g., items from the same scales). The basic idea behind this model is that factor analysis tries to look for no correlations between any pairs of X_i and Xj because the factors themselves will account for the correlations. This means that all pairs of any two observed variables (X_i, X_j,…, X_p), are conditionally independent given the value of F_1, F_2,…, F_m (Yong & Pearce, 2013).

The process of conducting an EFA involves three steps:

1. extraction and rotation;
2. evaluation goodness of the model;
3. interpretation of results.

1. Extraction refers to the process of determining how many factors best explain the observed covariation matrix within the data set. The best is the fewest number of factors that explains the largest amount of variation of the observed variables. There are many methods for conducting an exploratory factor analysis: principal components (PC) unweighted least squares (ULS), generalized least squares (GLS), maximum likelihood (ML), principal axes factoring (PAX), alpha factoring (AF) and image factoring (IF). Information on relative strengths and weaknesses of these techniques is scarce, often only available in obscure references. It is often hard to figure out which method a textbook or journal article author is describing, and whether or not it is actually available in the software package the researcher is using (Costello, 2005).
If data is relatively normally distributed, maximum likelihood is the best choice; if the assumption of multivariate normality is severely violated one of principal factoring methods is recommended (Costello, 2005).
Two methods to determine the appropriate number of factors to extract are the Kaiser's Criterion and the Scree Test. The Kaiser's Criterion suggests retaining all factors that are above the eigenvalue of 1 (Kaiser, 1960). In fact, because we are interested in explaining as much variance in observed indicators as possible, we can decide to retain only those latent variables with sufficiently high eigenvalues. Scree Test is based on scree plot and considers the number of factors above the point of inflexion, but is often hard to interpret and is subjective and open to different interpretations.

Factors are rotated for better interpretation. The goal of rotation is to attain an optimal simple structure which attempts to have each variable load on as few factors as possible, but maximizes the number of high loadings on each variable (Rummel, 1970). There are orthogonal and oblique rotation. Orthogonal rotation is when the factors are rotated 90° from each other and it is assumed that the factors are uncorrelated, oblique rotation is when the factors are not rotated 90° from each other and it is assumed that the factors are correlated (Rummel, 1970). Two common orthogonal techniques are Quartimax and Varimax rotation: Quartimax involves the minimization of the number of factors needed to explain each variable, while Varimax minimizes the number of variables that have high loadings on each factor and works to make small loadings even smaller. The common oblique rotation techniques are Direct Oblimin and Promax. Direct Oblimin attempts to simplify the structure and the mathematics of the output, while Promax involves raising the loadings to a power of four which ultimately results in greater correlations among the factors and achieves a simple structure (Yong & Pearce, 2013). Conventional wisdom advises researchers to use orthogonal rotation because it produces interpretable results more easily (Costello, 2005).

So, if we decide that our factors should be correlated then we select an oblique solution, whereas if you decide that our factors should not be correlated then we select an orthogonal solution.

2. Among evaluation goodness of the model we consider Kaiser-Meyer-Olkin (KMO) test, Bartlett's tests and Goodness-of-fit Test. KMO test is a measure of how suited your data is for factor analysis. The test measures sampling adequacy for each variable in the model and for the complete model. The statistic is a measure of the proportion of variance among variables that might be common variance. KMO returns values between 0 and 1. A rule of thumb for interpreting the statistic:
    - KMO values less than 0.6 indicate the sampling is not adequate and that remedial action should be taken;
    - KMO values between 0.6 and 0.69 are mediocre;
    - KMO values between 0.7 and 0.79 are middling;
    - KMO values between 0.8 and 1 indicate the sampling is adequate.

   Bartlett's test shows the homogeneity of variance: the null hypothesis is all the population variances (k populations being compared) are equal or the correlation matrix is an identity matrix. The alternative hypothesis is the population variances are not all equal. This means at least one is not equal to the others. The test does not explicitly determine which one is different, just that at least one is different.

   The Goodness-of-fit Test determines if the sample data (correlations) is likely to arise from the correlated factors. In this situation we want the probability value of the Chi-

Square statistic to be greater than the chosen alpha (generally .05), or that is accepted the null hypothesis that the model fits the data.

3. The interpretation is naming the factors using our psychological knowledge to provide a meaningful understanding of the common feature among the relevant items.

   Among requirements, to be labelled as a factor it should have at least 3 variables; a factor with 2 variables is only considered reliable when the variables are highly correlated with each other ($r > .70$) but fairly uncorrelated with other variables (Yong & Pearce, 2013). Generally, the correlation r must be .30 or greater to suggest a very weak relationship between the variables (Tabachnick & Fidell, 2007).

   As a rule of thumb, a bare minimum of 10 observations per variable is necessary to avoid computational difficulties. Also, the theory states that the number of variables used in a study should be much greater than the number of extracted factors. Generally, it is considered a good over determination condition of factors when the proportion between observed used variables and extracted factors is 4-5 to 1 (Pannocchia & Giannini, 2007).

EFA can provide an infinitive number of possible solutions and the method of determining the appropriate number of factors to retain is very subjective. EFA is also a highly data-driven rather than a theory-driven method of investigation.

3.2.2 Confirmatory Factor Analysis

Confirmatory Factor Analysis (CFA) is a type of factor analysis, and the purpose is to test whether a dimensional structure is consistent with the structure obtained in a particular set of measures. In CFA, the researchers look for what they expect to find before doing the analysis and then seek to confirm this using the appropriate techniques (Stewart, 2001).

During CFA, the researchers use a hypothesized model that can be the result of a previously conducted analysis (i.e. EFA) or a priori built-in model based on knowledge of the studied phenomenon and the related literature. Both cases, CFA attempts to confirm hypotheses and represent variables and factors using path diagram. Often CFA results and their measurement model are used for testing a Structural Equation Model (SEM).

It is common to display confirmatory factor models as *path diagrams*. CFA uses distinct categories of variables that are termed in different ways. *Observed variables* are also named measured, indicator and manifest. Researchers and software traditionally use a square or rectangle to designate them graphically. *Unobserved variables* are also named latent factors, factors or constructs. Researchers and software traditionally use circles or ovals to designate them graphically. Figure 1 shows a generic path diagram where the unobserved or latent variables are represented as circles at the top and the observed variables are represented as rectangles in the middle.

The circles at the bottom are the *unique factors* or measurement errors in the variables. The unique factors differ from factors because their effect is associated with one only observed variables. Each unique factor effects only a single variable and incorporates the variance in each observable variable not captured by the latent factors, such as measurement error. The straight lines pointing from each factor to the observed variables indicates the causal effect of each latent variable on the observed variables: in factor analysis the researchers almost always assume that the latent variables "cause" the observed variables. The scores of the relationship between factors and observed variables are the factor loadings (see 3.2.1). The two-headed curved arrow between factors indicates that they are correlated.

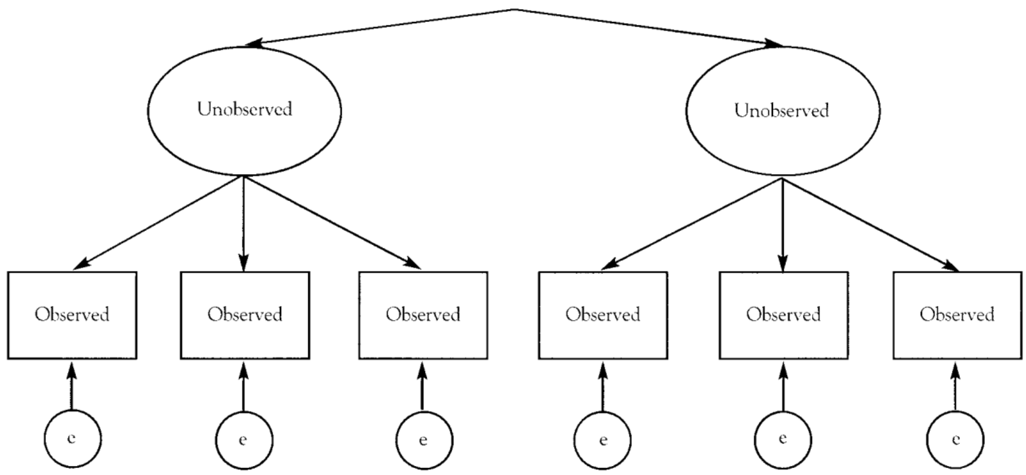

Figure 1. Generic path diagram of CFA

CFA is theory-driven and it's possible to place substantively meaningful constraints on the factor model, such as setting the effect of one latent variable to equal zero on a subset of the observed variables. The advantage of CFA is that it allows to test hypotheses about a particular factor structure (Albright, 2006-2008).

The graphic representation is the hypothesized model that is to be tested to see how well it fits the observed data.

The confirmatory factor model can be summarized by the equation

$$x = \Lambda\xi + \delta$$

in which x is the vector of observed variables, Λ is the matrix of loadings connecting each ξ_i to the x_i, ξ is the vector of factors and δ is the vector of unique factors. It is assumed that the unique factors have a mean of zero (E(δ)=0), and that the factors and unique factors are uncorrelated (E($\xi\delta'$)=0). The equations of the model for Figure 1 can be written as:

First Factor	*Second Factor*
$x_1 = \lambda_{11}\xi_1 + \delta_1$	$x_4 = \lambda_{42}\xi_2 + \delta_4$
$x_2 = \lambda_{21}\xi_1 + \delta_2$	$x_5 = \lambda_{52}\xi_2 + \delta_5$
$x_3 = \lambda_{31}\xi_1 + \delta_3$	$x_6 = \lambda_{62}\xi_2 + \delta_6$

The equations of the model are similar to regression analysis, but the primary difference between these factor equations and regression analysis is that ξ_i are unobserved. The sample covariance matrix Σ for x can be decomposed as follows (when the x variables are measured as deviations from their means):

$$\Sigma = \Lambda\Phi\Lambda' + \Theta$$

where Φ is the covariance matrix of the ξ factors and Θ is the covariance matrix of the unique factors δ (Bollen, 1989). Several different fitting functions exist to determine the closeness of the implied covariance matrix to the sample covariance matrix and maximum likelihood is among the most common.

The first step in CFA is determining whether the specified model is identified. In fact, if the model is unidentified it means that it is impossible to come up with unique parameter estimates. That is when the factors model can make true for infinite number of values. In CFA, a model is identified if all of the unknown parameters can be rewritten in terms of the variances and covariances of the x variables (Bollen, 1989). Without introducing some constraints any confirmatory factor model is not identified because the latent variables are unobserved and hence their scales are unknown. It therefore becomes necessary to set the metric of the latent variables in some manner; the two most common constraints are to set either the variance of the latent variables or one of their factor loadings to one.

The second step is to assess how well the model matches the observed data. About simple size, it is important because it relates to the stability of the parameter estimates, but there is no exact rule for the number of participants (Shreiber, et al., 2006). About handling of missing data, in general, pairwise deletion is not recommended and listwise deletion is problematic unless the missing data has proved to be missing at random (Shreiber, et al., 2006). The core of the second step, apart from representing the impact of one latent construct on another or the latent construct on the observable variables, is the examination of the coefficients of hypothesized relationships of whether the hypothesized model is a good fit to the observed variables (Shreiber, et al., 2006).

The model adequacy is measured with the conventional overall test of fit, χ^2 statistic, where the null hypothesis under test is that the model fits the data.

In reference to model fit, there are used numerous goodness-of-fit indicators to assess a model. Fit indexes can be classified into absolute and incremental fit indexes (Hu & Bentler, 1999) also known tests of relative fit. The absolute fit indexes assess how well a priori model reproduces the sample data. Examples of absolute fit indexes include the Goodness-of-Fit Index (GFI), the Adjusted Goodness-of-Fit Index (AGFI), the Root Mean Squared Residual (RMR) and the Root Mean Square Error of Approximation (RMSEA).

The incremental fit indexes measure the proportionate improvement in fit by comparing a target model with a more restricted, nested baseline model. Examples of incremental fit indexes are the Normal Fit Index (NFI), the Tucker-Lewis Index (TLI) and the Bentler’s Comparative Fit Index (CFI).

Fit indexes were designed to avoid some of the problems of sample size and distributional misspecification associated with the conventional overall test of fit (the χ^2 statistic) in the evaluation of the model. However, this promising claim that fit indexes would more unambiguously point to model adequacy as compared to the χ^2 test has little empirical support (Hu & Bentler, 1999).

The pressing issue is the selection of the “rules of thumb” conventional cutoff criteria for given fit indexes used to evaluate model fit; researchers often question the adequacy of these conventional cutoff criteria due to lack of empirical evidence and compelling rationale for these rules of thumb. Many studies evaluated conventional cutoff criteria for fit indexes, but finally they should be considered only as rules of thumb. Table 1 reports a chart with the conventional cutoff criteria related fit indexes of the model (Shreiber, et al., 2006; Hu & Bentler, 1999). About conventional overall test of fit χ^2 statistic in the evaluation of the model, so that the null hypothesis can be accepted, we hope to find a small, non-significant χ^2 value for this test. So, failure to reject the null hypotheses is therefore a sign of a good model fit.

Fit Statistic	**Recommended Value**
Absolute Fit Indexes	
GFI	>.90
AGFI	>.90
RMR	<.05
RMSEA	<.05
Incremental Fit Indexes	
NFI	>.90
TLI	>.90
CFI	>.90

Table 1. Fit statistics of the measurement model

3.2.3 Regression Analysis

Regression analysis is a set of techniques for estimating relationships between variables. It can be discriminated between *simple linear regression* and *multiple linear regression*. The equation for the *simple linear regression* model is listed below, where x is called the independent variable or predictor variable and y is called the dependent variable or response variable.

$$y = \beta_0 + \beta_1 x$$

Regarding quantities from the fit, β_0 is the intercept of the line and β_1 is the slope of the line that corresponds at regression coefficient. A value of the slope very close to zero indicates little to no relationship, large positive or negative values indicate large positive or negative relationships, respectively.

In *multiple linear regression* there are more variables. In this case instead of just a single scalar value x, there is a vector $(x_1, \dots, x_p)$ for every data point i.

The linear equation model for *multiple linear regression* model is:

$$y = \beta_0 + \beta_1 x_1 + \beta_2 x_2 + \dots + \beta_p x_p$$

Typically, we will use an *analysis of variance (ANOVA)* test to measure this. If the ANOVA test determines that the model explains a significant portion of the variability in the data, then we can consider testing each of the hypotheses and correcting for multiple comparisons.

Results

4.1 Pilot Study: PLDI questionnaire validation

Thirty-three patients with diabetes of type 1 and 2 were randomly selected from the database of a Primary Health Care Centre of Sardinia (Italy). After validation, only 32 questionnaires were considered for statistical analysis because during PLDI questionnaire validation one item was modified. Therefore, 97% of demographic information of the 33 patients interviewed were considered.

A value of α=.85, calculated for the whole questionnaire, indicates a good internal items consistency.

Slightly more than half the respondents are female (55%), 7 (22%) use CSII and 25 (78%) use MDI (see Table 2).

Age of 32 respondents range from 21 to 70 years old with a mean of 52 years. Qualification ranges from a completed doctoral or university degree to no qualifications, with 50% having completed just a secondary school degree.

In examining respondents' marital status, 16 (50%) are married and live with their spouse.

Examining respondents' insulin treatment, the use of MD ranged from 6 months to 20 years and 87.5% are more than satisfied.

The mean of time of the interviews is 13.10 minutes ($CI_{95\%:}$ 11.90-14.29).

Gender	MD CSII	MDI	Total
Female	4	13	17
%r	23.53	76.47	100.00
%c	57.14	52.00	54.84
Male	3	12	15
%r	21.43	78.57	100.00
%c	42.86	48.00	45.16
Total	7	25	32
%r	21.88	78.12	100.00
%c	100.00	100.00	100.00

Table 2. Descriptive results by Gender and Medical Device (MD)

4.2 Final Study

4.2.1 The Sample

We used the database of Diabetes Centre of ASSL of Oristano as a sampling frame to obtain access to the population of interest. This population is composed by patients with diabetes in insulin therapy.

During the 2016, adult patients (age ≥18 years old) with diabetes in insulin treatment were 2402, of which 180 were using CSII technology.

We random selected a sample of 134 patients with diabetes in insulin therapy from this database. Of these insulin-treated patients, 19 use CSII technology and 115 use MDI one.

If we consider a subgroup of patients in insulin treatment born afterwards 01.01.1946, the number of patients from the database of Diabetes Centre of ASSL of Oristano is 1056, of which 160 patients use CSII technology. Calculating that the percentage of patients enrolled in the study is 12.7% of the total patients with diabetes and in insulin treatment, then 11.9% of which use CSII and 12.8% of which use MDI.

Six patients of the 134 interviewed were excluded from the study for different reasons:

- 1 was under the age of 18 years old;
- 1 had already been excluded during the validation of the PLDI questionnaire (see 4.1);

- 2 were excluded because their diabetes were not categorized as type 1 or type 2, but as other;
- 4 were excluded because they had been using the device for less than 6 months (see 2.1).

4.2.2 Descriptive Analysis

The sample was analysed by gender, age, type of diabetes, years by diagnoses of disease, type and years of using medical devices (MDI or CSII). The sample is made from 126 patients, 46% females (see Table 3) with the mean age of 54 ± 3 (years) and 54% males with the mean age of 50 ± 3 (years). The mean age of the whole sample is 52 ± 2 (years).

Gender	Freq.	Percent
Female	58	46.03
Male	68	53.97
Total	126	100.00

Table 3. Distribution of the sample by Gender

Regarding the type of diabetes (1 or 2), 54% of the sample is represented by patients with T1D diabetes, of which mean year of diagnosis of disease is 22 ± 13 (years) and 46% of the sample is represented by patients with T2D diabetes, of which mean year of diagnosis of disease is 13 ± 8 (years). The mean year of diagnosis of disease in all patients is 18 ± 12 (years); for males is 19 ± 11 (years) while in females is 17 ± 13 (years).

About medical devices, 110 (87.3%) patients use MDI technology of which 57.3% are male; 16 (13.7%) use insulin pump (CSII) of which 68.8% are female (see Table 4). Those who use MDI discovered their disease 18 ± 12 years ago (min 1, max 47), whereas who use CSII discovered the disease 21 ± 12 years ago (min 4, max 44).

The association between gender and medical device used although not statistically significant highlights a relationship (χ^2=3.81, p=.051).

Gender	MD MDI	CSII	Total
Female	47	11	58
%c	42.73	68.75	46.03
Male	63	5	68
%c	57.27	31.25	53.97
Total	110	16	126
%c	100.00	100.00	100.00

Pearson chi2(1) = 3.8076 Pr = 0.051

Table 4. Relationship between gender and Medical Devices (MD)

Of the sixteen patients that use CSII technology, 94% are affected by T1D diabetes (ten females and five males), while only 6% are patients with T2D diabetes (a female) (see Table 5). This is in according to international guidelines that recommend the use of CSII in people with T1D diabetes (ADA, 2014; NICE, 2010).

Type of Diabetes	MD MDI	CSII	Total
1	53	15	68
%c	48.18	93.75	53.97
2	57	1	58
%c	51.82	6.25	46.03
Total	110	16	126
%c	100.00	100.00	100.00

Fisher's exact = 0.001

Table 5. Relationship between type of diabetes and Medical Devices (MD)

The sixty-three men that use MDI have a mean age of 51 ± 13 (years) with a minimum age of 24 and a maximum age of 66. These men have been using MDI technology for a mean of 109 ± 81 months with a minimum value of 6 and a maximum of 360 months. The five men that use CSII have a mean age of 41 ± 23 (years) with a min of 21 and a max of 66. These men have been using CSII technology for a mean of 53 ± 46 months with a minimum of 12 and a maximum of 108 months.

The forty-seven women that use MDI have a mean age of 56 ± 11 (years) with a minimum age of 23 and a maximum age of 70. These women have been using MDI technology for a mean of 88 ± 85 months with a minimum of 6 and a maximum of 312 months. The eleven women that use CSII have a mean age of 48 ± 13 (years) with a minimum age of 27 and a maximum age of 64. These women have been using CSII technology for a mean of 70 ± 44 months with a minimum of 12 and a maximum of 144 months.

The Skewness/Kurtosis test was performed to determine the normality of age by MD groups. The hypothesis of normality for age is rejected (p=0.0021) so, the Mann-Whitney U test was applied to compare age's medians in each group and the result shows a not significant value (p=0.126).

The difference of proportions by MD groups was tested by Z test and the result showed a high significant z value (z=6.71, p<0.001).

As regards the PLDI questionnaire's replies we calculated the frequency for each question and evaluated the relationships between them and the type of diabetes, medical devices and gender. We reported in Tables 6-8 the modal value of each item by each medical devices group and for the whole sample. The corresponding frequencies are reported in brackets.

Regarding perception of health we had asked to patients how their health was, if they check their weight and how often (questions 1-2 respectively).

Questions about perception of health			
Item	**CSII**	**MDI**	**Whole Sample**
1	To be fine (75%)	To be fine (44.6%)	To be fine (48.4%)
2	Check their weight at least once per month (31.3%)	Check their weight at least once per year (33.6%)	Check their weight at least once per month (32.5%) Check their weight at least once per year (32.5%)

Table 6. Modal values and corresponding frequencies of items for Perception of Health in patients by medical devices groups

Regarding questions about satisfaction of medical device, we had asked patients which was the reason why they used this device, how satisfied they were to use it and how much the device influenced their couple's life (questions III, V, 19 respectively).

Questions about satisfaction of Medical Device			
Item	**CSII**	**MDI**	**Whole Sample**
III	Use the device advised by the doctor (75%)	Use the device advised by the doctor (90%)	Use the device advised by the doctor (88.1%)
V	Satisfied of device used (100%)	Satisfied of device used (75.5%)	Satisfied of device used (78.6%)
19	Does not influence (62.5%)	Does not influence (78.0%)	Does not influence (76%)

Table 7. Modal values and corresponding frequencies of items for Satisfaction of Medical Device in patients by medical devices groups

Regarding questions about patient's lifestyle we had asked patients what their main meal was, if they had breakfast and what they ate, where they had lunch, how often they ate different kinds of foods, how often they drank different kinds of drinks, if they smoked, how often they did different kinds of activities, if they did sport, where and how often they did physical activity, the reasons why they didn't do sport or physical activity, what their job was and how it was organized, and during free time what they preferred doing (questions 3-9, 12-18 respectively).

Questions about patient's lifestyle			
Item	**CSII**	**MDI**	**Whole Sample**
3	The main meal is lunch (93.8%)	The main meal is lunch (78.4%)	The main meal is lunch (80.5%)
4	Eat and drink for breakfast (43.8%)	Eat and drink for breakfast (67.3%)	Eat and drink for breakfast (64.3%)
5	Have lunch at home (93.8%)	Have lunch at home (94.6%)	Have lunch at home (94.4%)

6	Eat carbohydrates more times per day (43.8%) Eat carbohydrates one time per day (43.8%)	Eat carbohydrates more times per day (41.8%)	Eat carbohydrates more times per day (42.1%)
	Eat cold cuts a few times per week (43.8%)	Eat cold cuts a few times per week (52.7%)	Eat cold cuts a few times per week (51.6%)
	Eat meat few times per week (81.3%)	Eat meat few times per week (72.7%)	Eat meat few times per week (73.8%)
	Don’t drink milk (31.3%)	Drink milk once time per day (43.6%)	Drink milk once time per day (41.3%)
	Eat dairy products few times per week (56.3%)	Eat dairy products few times per week (63.6%)	Eat dairy products few times per week (62.7%)
	Eat eggs few times per week (68.8%)	Eat eggs few times per week (54.6%)	Eat eggs few times per week (56.4%)
	Eat fish few times per week (75%)	Eat fish few times per week (50.9%)	Eat fish few times per week (54.0%)
	Eat vegetables few times per day (62.5%)	Eat vegetables few times per day (52.7%)	Eat vegetables few times per day (54.0%)
	Eat fruits few times per day (56.3%)	Eat fruits few times per day (66.4%)	Eat fruits few times per day (65.1%)
	Eat legumes few times per week (81.3%)	Eat legumes few times per week (58.2%)	Eat legumes few times per week (61.1%)
	Eat potatoes few times per week (56.3%)	Eat potatoes few times per week (65.5%)	Eat potatoes few times per week (64.3%)

	Eat snacks less than once a week (43.8%)	Eat snacks less than once a week (48.2%)	Eat snacks less than once a week (47.6%)
	Eat desserts less than once a week (50%)	Eat desserts less than once a week (50.9%)	Eat desserts less than once a week (50.8%)
7	Drink water over one litre per day (68.8%)	Drink water over one litre per day (71.8%)	Drink water over one litre per day (71.4%)
	Drink rarely sodas (56.3%)	Drink rarely sodas (50.9%)	Drink rarely sodas (51.6%)
	Drink rarely beer (68.8%)	Drink rarely beer (47.3%)	Drink rarely beer (50%)
	Don't drink wine (50%)	Don't drink wine (40.9%)	Don't drink wine (42.1%)
	Don't drink other spirits (62.5%)	Don't drink other spirits (70%)	Don't drink other spirits (69.1%)
	Drink two/three coffees per day (25%) and use sweetener (46.2%)	Drink three coffees per day (23.8%) and use sweetener (58.9%)	Drink three coffees per day (24.0%) and use sweetener (57.3%)
8	Ex-smokers (68.8%)	Ex-smokers (40%)	Ex-smokers (43.7%)
9	Listen to the radio every day (81.3%)	Listen to the radio every day (43.6%)	Listen to the radio every day (48.4%)
	Watch TV every day (87.5%)	Watch TV every day (92.7%)	Watch TV every day (92.1%)
	Watch DVDs and VDTs few times per year (56.3%)	Don't watch DVDs and VDTs (46.4%)	Watch DVDs and VDTs few times per year (45.2%)

	Don’t play videogames (56.3%)	Don’t play videogames (81.8%)	Don’t play videogames (78.6%)
	Browse the internet every day (75%)	Browse the internet every day (43.6%)	Browse the internet every day (47.8%)
	Use PC every day (43.8%)	Don’t use PC (53.6%)	Don’t use PC (49.2%)
	Use smartphone every day (93.8%)	Use smartphone every day (83.6%)	Use smartphone every day (84.9%)
	Read every day (56.3%)	Read every day (41.8%)	Read every day (43.7%)
	Go to the theatre or cinema few times per year (75%)	Don’t go to the theatre or cinema (56.4%)	Don’t go to the theatre or cinema (52.4%)
	Don’t participate in recreational activity (68.8%)	Don’t participate in recreational activity (66.4%)	Don’t participate in recreational activity (66.7%)
	Do food shopping more times a week (50%)	Do food shopping more times a week (33.9%)	Do food shopping more times a week (36%)
	Take a walk every day (43.8%)	Take a walk every day (36.4%)	Take a walk every day (37.3%)
	Don’t use public transport (87.5%)	Don’t use public transport (87.3%)	Don’t use public transport (87.3%)
12	Don’t do any sports (68.8%)	Don’t do any sports (82.7%)	Don’t do any sports (81%)

13	Don't do any physical activity (43.8%)	Don't do any physical activity (52.7%)	Don't do any physical activity (51.6%)
14	Don't do any sport neither physical activity (37.5%)	Don't do any sport neither physical activity (43.6%)	Don't do any sport neither physical activity (42.9%)
15	Don't do much sport or physical activity due to the health (31.3%)	Don't do much sport or physical activity due to the job (30%)	Don't do much sport or physical activity due to the job (28.6%)
16	Don't work (37.5%) Have a subordinate work (37.5%)	Don't work (52.7%)	Don't work (50.8%)
17	Have all week the same shifts (31.3%)	Decide how to organize work shifts themselves (25.5%)	Decide how to organize work shifts themselves (25.4%)
18	During free time prefer to take a walk (56.3%)	During free time prefer to take a walk (30%)	During free time prefer to take a walk (33.3%)

Table 8. Modal values and corresponding frequencies of items about patient's lifestyle in patients by medical devices groups

In Table 9, as regards clinical parameters, the percentages of outliers patients from standard values for blood tests of Laboratory of ASSL Oristano are reported.

The relationship between categorized BMI (0=normalweight; 1=over/underweight) and medical device is statistically significant (χ^2 =4.0216; $p <.05$). The relationships between gender and the following categorized variables (0=normal; 1=outlier standard values) creatinine, HDL cholesterol, triglyceride, are statistically significant ($p<.05$). Also, the relationships between the type of diabetes and the categorized variables (0=normal; 1=outlier standard values) ACR, triglyceride, BMI, cardiac anomalies are highly statistical significant ($p<.001$).

Finally, the relationships between the age of patients and the categorized variables (0=normal; 1=outlier standard values) ORD, BMI, cardiac anomalies, are statistical significant ($p<.005$).

Also, 47.2% take cholesterol medications, 29.4% take anticoagulants drugs, 43.7% are treated with hypertension drugs and 52% take other drugs.

The relationship between the type of diabetes and the assumption of anticoagulants, hypertension and other drugs are statistically significant ($p<.05$).

The relationships between age of patients and the assumption of drugs is resulted highly statistical significant ($p< .001$).

The relationship between the type of diabetes and the assumption of anticoagulants drugs is statistically significant ($p<.05$).

Clinical variables	**% of outliers**
Creatinine (mg/ml)	66.9 %
Creatinine Albumin Ratio, ACR (mol/mmol)	5.7 %
Glutamic-Pyruvate Transaminase, GPT (UI/L)	27.4 %
Cholesterol (mg/dl)	29.5 %
HDL Cholesterol (mg/dl)	18.9 %
Triglyceride (mg/dl)	10.7 %
LDL Cholesterol (mg/dl)	50.4 %
Glycated Hemoglobin, HbA1c (%)	88.1 %
Body Mass Index, BMI	71.2 %
Diabetic Retinopathy, ORD	38.1 %
Cardiac Anomalies	49.2 %

Table 9. Percentage of patients with outliers values for clinical parameter

Furthermore, we analysed the relationships between the items of the PLDI questionnaire, clinical variables and age. In Table 10 only the statistical significant relationships at significant level 0.05 are shown.

Item of PLDI questionnaire	Clinical Variable
1	ACR
	Triglyceride
	BMI
	Take other drugs
6 – eat carbohydrates	Cardiac anomalies
6 – eat cured meat	ACR
	Take cholesterol medications
	Take antihypertensive drugs
6 – eat meat	Creatinine
	HbA1c
6 – drink milk	HDL
	BMI
6 – eat dairy product	Triglyceride
	Take cholesterol medications
	Take antihypertensive drugs
	Take other drugs
	ORD
	Cardiac anomalies
6 – eat vegetables	GPT
6 – eat snacks	Take cholesterol medications
	BMI
6 – eat desserts	Take antihypertensive drugs
	ORD
	BMI
7 – drink water	GPT

Item of PLDI questionnaire	Clinical Variable
7 – drink beer	ACR
	Take cholesterol medications
	Take anticoagulant drugs
	Take antihypertensive drugs
	Take other drugs
	Cardiac anomalies
	BMI
7 – drink wine	ACR
	Take cholesterol medications
	Take anticoagulant drugs
	Take antihypertensive drugs
7 – drink other spirits	Take cholesterol medications
	Take antihypertensive drugs
	BMI
8	Take cholesterol medications
	Take antihypertensive drugs
	Take other drugs
	BMI
	Cardiac anomalies
	Age

Table 10. Significant relationships between items of PLDI questionnaire and clinical variables and age

4.2.3 EFA results

We conducted an Exploratory Factor Analysis (EFA) of the questionnaire responses and demographic information (age, MD and type of diabetes) to further understand and identify characteristics of people with T1D and T2D in insulin treatment. The number of cases used in the EFA analysis was 125 because, by default, SPSS does a listwise deletion of incomplete cases.

The observable variables used for the analysis were 12: *Age* (years), *MD*, *Type of Diabetes*, *Breakfast*, *Lunch*, *Fruits Vegetables*, *Technology*, *Qualification*, *Sport*, *Physical Activity*, *Work* and *Work Shifts*. We respected the rule of thumb of 10 observations per variable (Pannocchia & Giannini, 2007). The other variables of the questionnaire had been progressively excluded to get the best model that fits the data.

The mean *Age* of respondents was 52 ± 13. *MD* is 0 for MDI technology and 1 for CSII technology. Responses in the Likert scale was based on five points ranging from low risk to high risk. Variable *Sport* reported 0 for answer "don't sport" (Likert scale points 4, 5) and 1 for answer "do sport" (Likert scale points 1, 2, 3). For variables *Fruits Vegetables* and *Technology* we did the average of the questionnaire questions indicated for each respondents. Each of the 12 observed variables received equal weight.

Three major sequential steps were undertaken for EFA.

Step 1 involved identifying the number of meaningful factors to retain based on Kaiser's Criterion (eigenvalue >1) and the percentage of common variance accounted for by a given factor. We used maximum likelihood extraction's method because we have assumed that the measured variables are the best representative of the measurable variables of the population that is the results are extendable to population. We involved a varimax (orthogonal) rotation on the retained factors because it minimizes the number of variables that have high loadings on each factor and works to make small loadings even smaller. Furthermore, varimax rotation was applied because a correlation between factors had previously been hypothesized, but it hadn't been supported by oblimin rotation.The factors were selected if their eigenvalue was > 1, as is the Kaiser's criterion.

As showed in Table 11, a four-factor solution was supported by the 62% percentage of variance accounted. The first factor accounted for 27% of the variance and the second, the third and the fourth factor accounted for an additional 14%, 12%, 9% respectively. Subsequent factor independently accounted for progressively lower percentages of variance.

Total Variance Explained									
Factor	Initial Eigenvalues			Extraction Sums of Squared Loadings			Rotation Sums of Squared Loadings		
	Total	% of Variance	Cumulative %	Total	% of Variance	Cumulative %	Total	% of Variance	Cumulative %
1	3.265	27.208	27.208	1.257	10.476	10.476	2.100	17.497	17.497
2	1.662	13.852	41.061	2.270	18.919	29.396	1.777	14.806	32.303
3	1.416	11.800	52.861	1.390	11.587	40.983	1.024	8.533	40.836
4	1.085	9.038	61.899	.847	7.057	48.040	.865	7.204	48.040
5	.859	7.158	69.057						
6	.793	6.611	75.668						
7	.675	5.627	81.294						
8	.619	5.155	86.449						
9	.578	4.818	91.267						
10	.544	4.530	95.797						
11	.349	2.905	98.702						
12	.156	1.298	100.000						
Extraction Method: Maximum Likelihood									

Table 11. Total variance explained by factors in EFA

The common variance assessed, which is always smaller than the total variance, was 48%. After varimax rotation the percentages of variance accounted was redistributed over the four extracted factors (rotation sums of squared loadings, Table 11).

The proportion of variance of each item that is explained by the factors is reported in Table 12. Communalities were calculated of the initial solution and then after extraction. They are the reproduced variances from the factors that we extracted. Variables with high values are well represented in the common factor space, while variables with low values are not well represented.

Variables with communality <.20 have unique variance and don't contribute to explain variance for factors. So, *MD* and *Lunch* don't contribute to explain variance for factors.

Communalities		
	Initial	Extraction
Age	.450	.554
MD	.161	.194
Type Diabetes	.292	.338
Breakfast	.163	.326
Lunch	.144	.181
Qualification	.385	.428
Physical Activity	.142	.952
Work	.723	.796
Work Shifts	.711	.897
Fruits Vegetables	.161	.304
Technology	.432	.521
Sport	.239	.274

Table 12. Communalities of observed variables in EFA

Step 2 involved evaluation of the goodness of the model. We considered Kaiser-Meyer-Olkin and Bartlett's Tests and the goodness of adaptation test.

KMO and Bartlett's Test		
Kaiser-Meyer-Olkin Measure of Sampling Adequacy		.705
Bartlett's Test of Sphericity	Approx. Chi-square	382.153
	Df	66
	Sig.	.000

Table 13. Goodness of fit Indices of the model

A value of .71 for KMO test suggested a mid-suiting model for the data in EFA. Significant χ^2 for Bartlett's test shows not homogeneity of variance. Taken together, these tests provide a minimum standard which should be passed before a factor analysis should be conducted.

The Chi Square test (χ^2=19.228) revealed that the four factors model is a good description of the data (p=.74).

Step 3 involved interpreting the rotated solution by identifying which observable variables load on each retained factor. Table 14 contains the rotated ordered factor loadings which represent both how variables are weighted for each factor but also the correlation between the variables and the factors. Because these are correlations, possible values range from +1 to -1.

Rotated Factor Matrix				
	Factor			
	1	2	3	4
Technology	.666			
Age	.661			
Qualification	.589			
Type Diabetes	.575			
Sport	-.455			
MD	-.408			
Work Shifts		.928		
Work		.846		
Physical Activity			.965	
Breakfast				.552
Fruits Vegetables				.524
Lunch				.352

Extraction Method: Massimum Likelihood
Rotation Method: Varimax with Kaiser Normalization
4 factors extracted
25 iterations requested

Table 14. Rotated Factor Matrix of EFA

Items allocated to a specific factor were based on a loading of ≥ .30 on that factor. This makes the output easier to read by removing the clutter of low correlations that are probably not meaningful anyway.

As you can see by the footnote of Table 14 four factors were extracted according to the variance explained (see Table 11). Factor 1 consisted of 6 items (*Technology*, *Age*, *Qualification*, *Type Diabetes*, *Sport*, *MD*) and was labeled “General Characteristics”. Factor 2 consisted of 2 items (*Work Shifts*, *Work*) and was labeled “Employment Information”. It was considered reliable because the variables are highly correlated with each other (r = .833). Factor 3 consisted of 1 item (*Physical Activity*) so it wasn’t considered as a factor. Factor 4 consisted of 3 items (*Breakfast*, *Fruits Vegetables*, *Lunch*) and was labeled “Eating Habits”.

According with orthogonal rotation, such as the varimax, the factors are not permitted to be correlated (they are orthogonal to one another).

The theory about the proportion between observed used variables and extracted factors is respected because we used a mean of four observed variables for one factor.

4.2.4 CFA results

Confirmatory Factor Analysis (CFA) was performed to test the model defined by the EFA as well as a three-factor model using the maximum likelihood estimation method. Thus, we tested two primary hypothesis:

- H_1, the profile is explained by three dimensions (EFA result);
- H_2, the profile is explained by four dimensions (EFA result and clinical factor).

Figure 2 displays the path diagram based on EFA's results. Observed variables are represented with rectangles and unobserved variables are represented with ovals (factors) and with circles (unique factors, measurement errors in the variables).

Factor *General Characteristics* is connected with six observed variables *Technology*, *Age_Cat*, *Qualification*, *Type Diabetes*, *Sport*, *MD* with straight lines pointing from the factor. Differently from EFA, we used the observed variable *Age_Cat* that is a categorization of the variable *Age*. This choice was taken to ensure homogeneous units of measure of observed variables. Table 15 shows the corresponding categorization of the age used in the CFA analysis. For greater clarity, the results showed on the path diagram (Figure 2) are essentially the same as the CFA using the variable *Age* (years).

Age	*Age_Cat*
≤ 30 years old	1
31 ≤ years old ≤ 50	2
51 ≤ years old ≤ 70	3

Table 15. Categorization of observed variable Age considered into CFA model

In the path diagram, Factor *Employment Information* is connected with two observed variables *Work Shifts*, *Work* with straight lines pointing from the factor. Factor *Eating Habits* is connected with three observed variables *Breakfast*, *Fruits Vegetables*, *Lunch* with straight lines pointing from the factor.

Each error is connected with each only observed variable to which is associated with a straight line pointing from the unique factor.

The three factors *General Characteristics*, *Employment Information*, *Eating Habits* are connected by two-headed curved arrows.

The specific model in Figure 2 is identified, so it is possible to come up with the unique parameter estimates.

That is, AMOS 24 introduced some constraints to identify the model because the scales of latent variables were unknown and had to be estimated. It set the weights of *MD*, *Work*, *Lunch* and the variances of unique factors to one.

The CFA results support our hypothesis realized on EFA model.

The model matches the observed data very well; the model adequacy measured with the conventional overall test of fit χ^2 statistic reveals that the model fits the data (χ^2=46.57; df=41; p=.254).

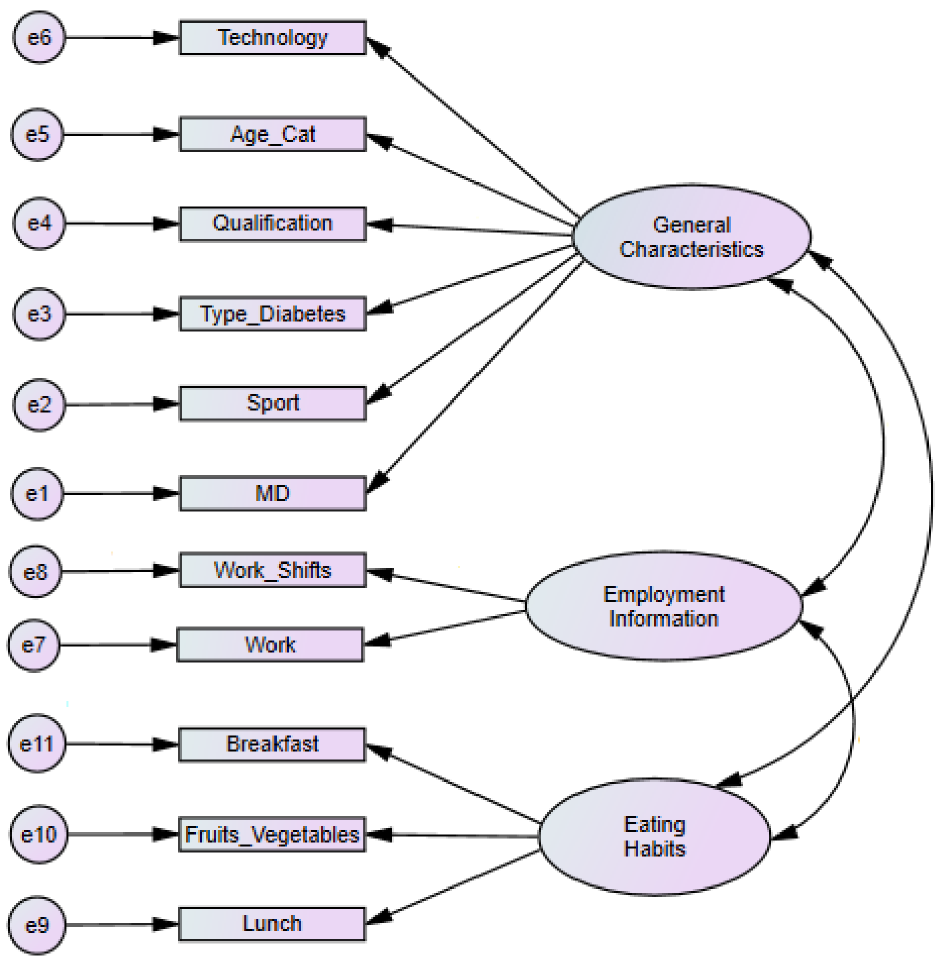

Figure 2. Path diagram based on EFA results

Table 16 shows the obtained absolute and incremental fit indexes compared with the recommended values.

Fit Statistic	Recommended Value	Obtained Value
	Absolute Fit Indexes	
GFI	>.90	.938
AGFI	>.90	.900
RMR	<.05	.047
RMSEA	<.05	.033
	Incremental Fit Indexes	
NFI	>.90	.872
TLI	>.90	.976
CFI	>.90	.982

Table 16. Absolute fit indexes value obtained in CFA

These results indicate overall a very appropriate fit of the factors model.

Under Hypothesis 2, in our study we tested the three-factors model above with the addition of another factor named *Clinical Information* regarding observed variables about HbA1c (glycated hemoglobin), ACR (creatinine albumin ratio), GPT (glutamic-pyruvate transaminase) values, cholesterol and other medication intake, heart abnormalities, BMI (body mass index) and ORD (diabetic retinopathy).

This model is unidentified, so it was not possible to come up with unique parameter estimates and we finally accepted the model under Hypothesis 1, showed in Figure 2.

Correlations between factors in the standardized model of path diagram in Figure 2 are reported in Table 17.

	Factors		Estimate
General Characteristics	←→	Employment Informations	-.462
Employment Informations	←→	Eating Habits	-.187
General Characteristics	←→	Eating Habits	-.033

Table 17. Correlations of factor model with standardized parameters

Standardized parameter estimates are reported in Table 18 and shown in Figure 3.

The path diagram with standardized parameter estimates shows existing relationships between observed variables and latent variables and between the three factors.
The weights are all high, specifically those related to factor *Employment Information*. There is also an important correlation between the factors *Employment Information* and *General Characteristics*, while *Eating Habits* has not significant correlation values with the other factors.

Observed Variable		Factor	Estimate
MD	←	General Characteristics	.387
Sport	←	General Characteristics	.446
Type Diabetes	←	General Characteristics	-.548
Qualification	←	General Characteristics	-.684
Age_Cat	←	General Characteristics	-.598
Technology	←	General Characteristics	-.696
Work	←	Employment Information	.979
Work Shifts	←	Employment Information	.851
Lunch	←	Eating Habits	.442
Fruits Vegetables	←	Eating Habits	.425
Breakfast	←	Eating Habits	.561

Table 18. Standardized Regression Weights

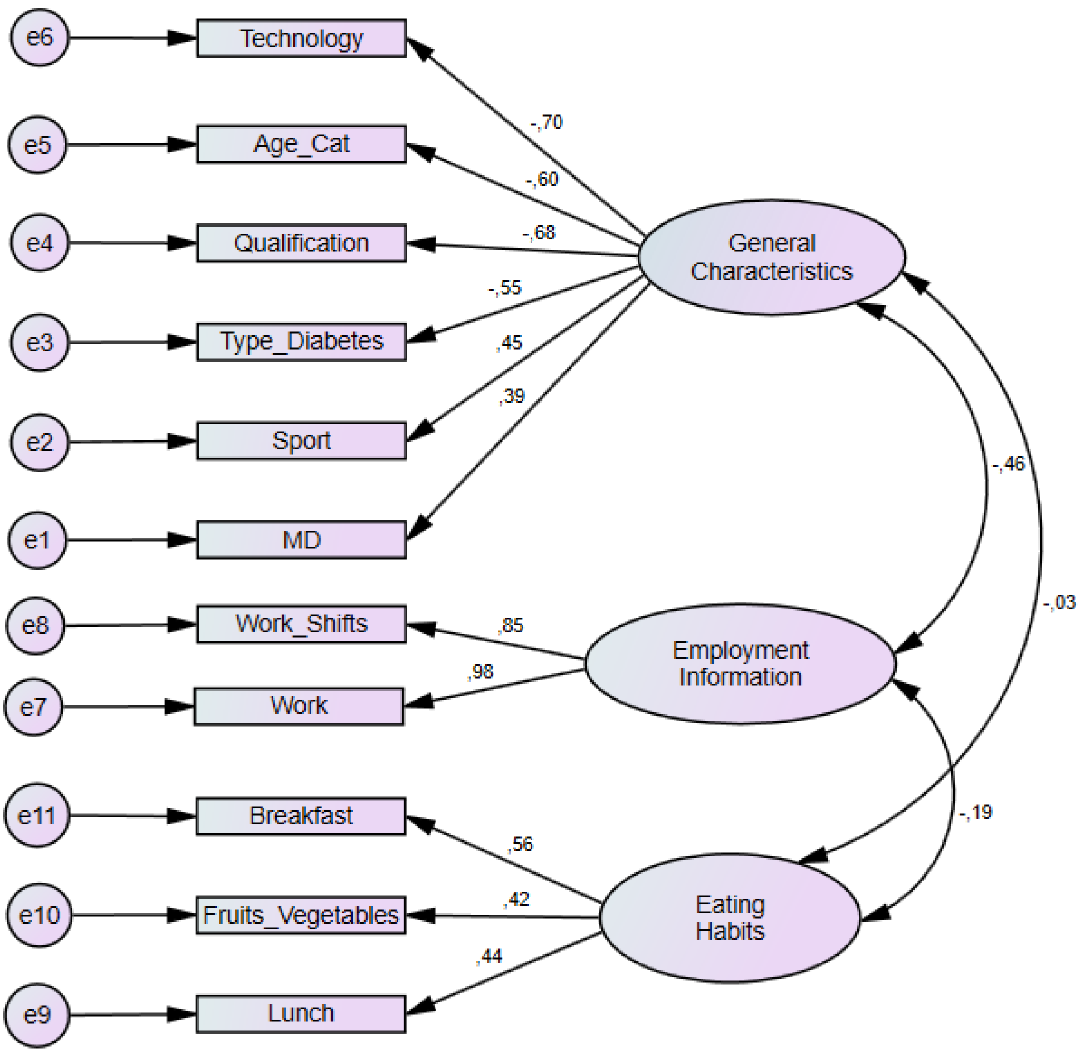

Figure 3. Path diagram with standardized parameters

If we consider only the statistically significant relationships, the number of variables that we have to take into account are much less. In Table 19 we reported only the standardized regression weights and the correlations between factors significant.

Variable		Factor	Estimate	P
Sport	←	General Characteristics	.446	.002
Fruits Vegetables	←	Eating Habits	.425	.028
Breakfast	←	Eating Habits	.561	.040
General Characteristics	←→	Employment Informations	-.462	.003

Table 19. Statistically significant regression weights and correlation

Figure 4 shows the path diagram with colored statistically significant regression weights and correlation.

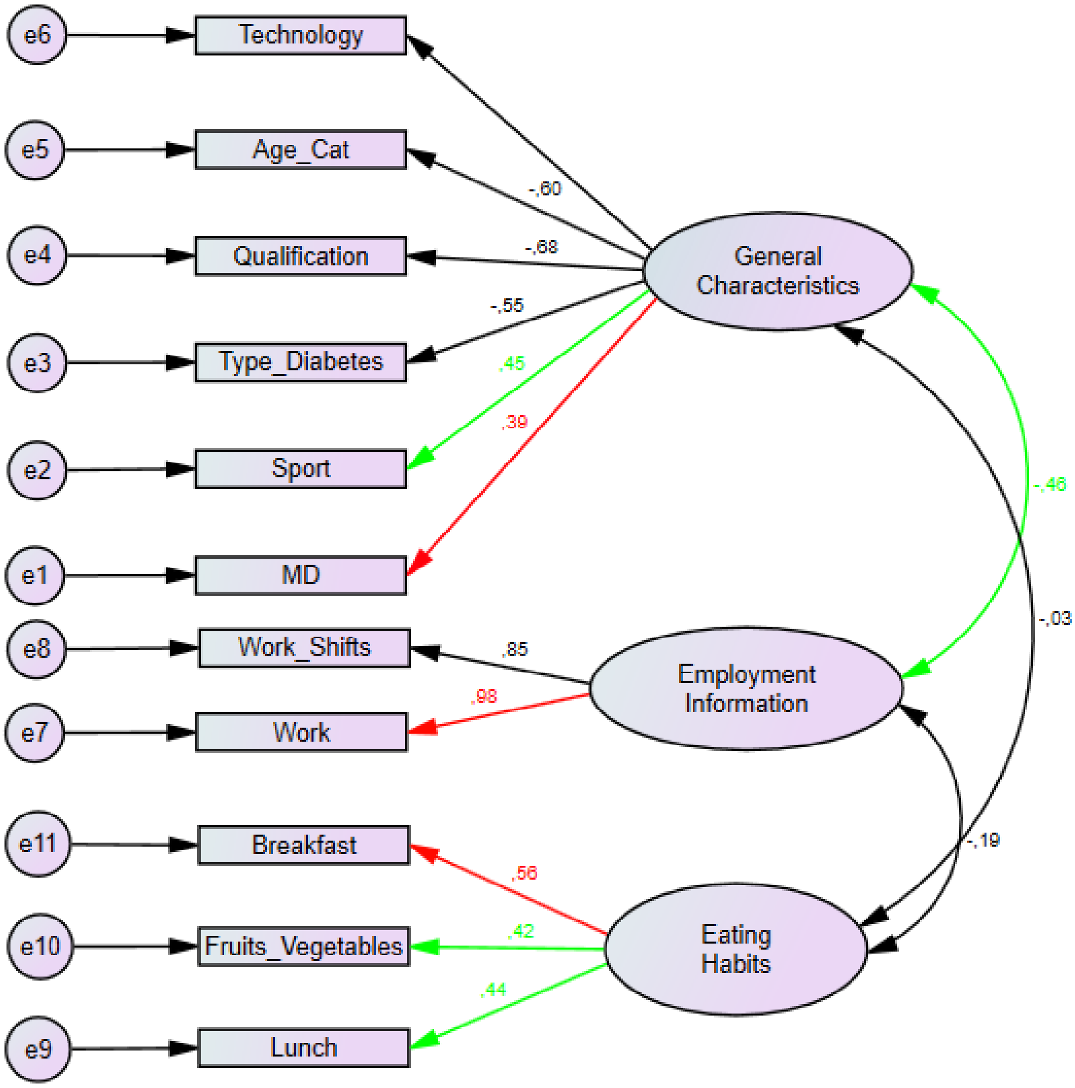

Figure 4. Path diagram of CFA model

Green colored straight arrows are the statistically significant regression weights and the two-headed curved green colored arrow is the correlation between *General Characteristics* and *Eating Habits* latent variables. The red colored straight arrows are the regression weights of observed variables used as constraints to estimate the variance of the latent variables: so that we can't say anything about their statistical significant. From what has been highlighted in the colored path diagram, we can say that two blocks are defined: *General Characteristics* and *Employment Information* together are the first block and *Eating Habits* is the second one.

In the first block there is a statistical significant correlation between the two factors, but the *Employment Information*, despite the high value of factor loadings, doesn't "cause" any observed variables (statistically significant point view). About *General Characteristics* it is interesting that the only statistically significant regression weights is that about *Sport* variable.

The second block shows how eating habits are important to define the characteristics of people with T1D and T2D, independently by medical devices used.

4.2.5 Multiple linear regression results

Multiple linear model was performed to estimate the effects on the costs related to medical devices used. *Cost* was the dependent variable in the model, while as independent variables were considered:

- the four factors results of EFA (*General Characteristics, Employment Informations, Physical Activity, and Eating Habits*);
- non-categorized clinical information about glycaeted hemoglobin (HbA1c), creatinine albumin ratio (ACR), glutamic-pyruvate transaminase (GPT), cardiac anomaly (CA), body mass index (BMI) and diabetic retinopathy (ORD);
- type of diabetes, coded one for T1D and two for T2D;
- cholesterol and other medication intake, coded zero if patient didn't intake, one if they did.

All variables were included into the analysis with stepwise method (criteria probability of F to enter $\leq .05$ and probability of F to remove $\geq .01$).

The analysis was performed on 98 cases, or 73.1% of the observations (see 4.2.1). The variable *Cost* has a mean of 613.4 € $\pm$ 1458.5 €.

Two models were estimated: Model 1 with only *General Characteristics* and Model 2 with *General Characteristics* and *Eating Habits* as variables.

These models explained a significant portion of the variability of the data (see Table 20).

ANOVA						
Model		SS	df	MQ	F	p
1	Regression	57526642.402	1	57526642.402	37.111	.000[b]
	Residual	148811262.744	96	1550117.320		
	Total	206337905.146	97			
2	Regression	65862875.655	2	32931437.827	22.271	.000[c]
	Residual	140475029.491	95	1478684.521		
	Total	206337905.146	97			

a. Dependent variable: Cost
b. Predctors: (constant), General Charateristics
c. Predictors: (constant), General Charateristics, Eating Habits

Table 20. ANOVA table: fit of regression models

Table 21 shows the estimates of the coefficients. The β_i column describes the estimation not standardized of linear model parameters; the SE column provides an estimate of the relative standard error; the Sign column shows the *p-value*.

Coefficients				
	Variable	**β_i**	**SE**	**Sign**
Model 1	*General Characteristics*	-910.67	149.49	.000
	Constant	626.16	125.79	.000
Model 2	*General Characteristics*	-933.96	146.33	.000
	Eating Habits	408.7	171.87	.020
	Constant	616.43	122.92	.000

Table 21. Coefficients and significant value of multiple linear regression models

We conducted a further linear regression analysis were the dependent variable was *Cost* and the only independent variable was the non-categorized clinical information about glycaeted hemoglobin (HbA1c), but in spite of what reported in literature, the model was statistically not significant (F=.329; p=.567).

4.3 Patient's Profile

Considering the path diagram by CFA analysis we defined the profile of patients with type 1 and 2 diabetes in insulin treatment that used MDI (group one) and CSII (group two) starting by count of each PLDI questionnaire's item.

The only thing that we could do was to show the substantial differences between patients that use the two different MD, for the three factors and observed variables of CFA (see 4.2.4). The main differences between MDI and CSII groups were in the frequency of use technology devices and their applications (pc, smartphone, internet, videogames, etc.), in the qualification, in the type of diabetes, in the work and its shift. Table 22 shows the percentage of response for each item by the two different MD used by patients, with highlighted colour for the significant differences among two groups for each observed variables related at latent variable.

We can highlight that:

- 76% of CSII users make use of technology more than once a week versus 29% of MDI users;
- 69% of CSII group have at least a secondary school degree versus 28% of MDI group;
- patients who use CSII technology are mostly T1D patients (94%) differently from patients who use MDI technology that are almost similarly distributed: this is in accordance with international guidelines that recommend the use of CSII in people with T1D diabetes (ADA, 2014; NICE, 2010);
- patients which use CSII technology have every week the same work shifts (31%) versus MDI users that they decide their work shifts or they don't work (both 26%);
- patients which use CSII technology are likewise employees or unemployed (both cases 38%), while most of MDI users don't work (52%);
- equal percentage of responses in the two groups of patients have been counted about age, sport and eating habits in general, although in some cases the percentage value is very different.

		MDI	CSII	Answer	p-value
General Characteristics	Technology	3%	13%	Use technology device every day	.065
		25%	63%	Use technology device more than once a week	**.0019**
		32%	12%	Use technology device once a week	.101
		37%	12%	Use technology device less than once a week	**.048**
		3%	0%	Never	.483
	Age_cat	10%	19%	≤ 30 years old	.286
		22%	37%	31 ≤ years old ≤ 50	.189
		68%	44%	51 ≤ years old ≤ 70	.060
	Qualification	6%	31%	University Degree, Phd	**.001**
		22%	38%	High school	.162
		53%	19%	Secondary School	**.010**
		16%	12%	Primary School	.679
		3%	0%	None	.483
	Type Diabetes	49%	94%	T1D	**.001**
		51%	6%	T2D	**.001**
	Sport	83%	69%	Don't do sport	.181
		17%	31%	Do sport	.181
Employment Information	Work Shifts	24%	31%	Every week have the same work shifts	.545
		5%	6%	Every week have different work shifts	.866
		19%	19%	Every day they know when I start, but not when I'll finish	1
		26%	25%	I decide my work shifts	.932
		26%	19%	Don't work	.547
	Work	28%	38%	Employees	.412
		3%	13%	Contributors	.065
		17%	6%	Self-employees	.257
		0%	5%	Students	**.019**
		52%	38%	Don't work	.295
Eating Habits	Breakfast	2%	25%	Eat also fruits and drink	**.001**
		67%	44%	Drink but don't eat	.073
		25%	31%	Eat and drink	.608
		3%	0%	Eat but don't drink	.483
		3%	0%	No breakfast	.483
	Fruits Vegetables	47%	50%	Eat them more than once a day	.822
		26%	19%	Eat them once a day	.547
		20%	25%	Eat them more than once a week	.645
		5%	6%	Eat them less than once a week	.866
		2%	0%	Don't eat them	.568
	Lunch	94%	94%	At home	1
		2%	6%	At canteen, trattoria, restaurant, hot table	.340
		0%	0%	At the bar	1
		3%	0%	During work	.483
		1%	0%	Don't have lunch	.688

Table 22. Profiles for MDI and CSII patients considering factor resulted by CFA with p-value in dark bold when p<.05

Conclusions

This thesis investigates the profiles of patients with T1D and T2D in treatment with Multiple Daily Injection (MDI) or Continuous Subcutaneous Insulin Infusion (CSII) medical devices. Both MDI and CSII are forms of intensified insulin treatment, but CSII mimics a physiological situation better (Jeitler, et al., 2008). Moreover, the number of patients with T1D and T2D that use CSII increased by 396% in the period 2005-2013 (Bruttomesso, et al., 2015). International associations recommend CSII for patients who attempt to achieve target haemoglobin levels following high levels of HbA1c (8.5% or above) with MDI despite carefully managing their diabetes (NICE, 2008). This study was conducted with the aim of researching the differences between patients who use MDI and CSII, not necessary clinical, to identify the patients eligible for the use of CSII.

Firstly, we developed a questionnaire to study the way of life of patients with diabetes in insulin-treatment that we called *Patients' Lifestyle with Diabetes Insulin-treated* (PLDI) questionnaire to investigate patients' lifestyle. The PLDI questionnaire was validated during a pilot study and contains questions about perception of health, satisfaction of medical device and patient's lifestyle.

Secondly, we conducted an Exploratory Factor Analysis (EFA) of the questionnaire responses and demographic information (age, medical device and type of diabetes) to further understand and identify the factors that describe the characteristics of people with T1D and T2D in insulin treatment. Three factors were lastly extracted: "General Characteristics" (with variables *Technology*, *Age*, *Qualification*, *Type Diabetes*, *Sport* and *MD*), "Employment Information" (with variables *Work Shifts* and *Work*) and "Eating Habits" (with variables *Breakfast*, *Fruits Vegetables* and *Lunch*).

Thirdly, we tested the EFA model result by using Confirmatory Factor Analysis (CFA) and we found two blocks: *General Characteristics* and *Employment Information* together are the first block and *Eating Habits* is the second one. In the first block there is a statistical significant correlation between the two factors, and the second block shows how eating habits are important to define the characteristics of people with T1D and T2D, independently by medical devices used.

Then, we performed a multiple linear regression model to estimate the effects on the costs related to medical devices used. Also in this case, two models were estimated: Model 1 with only *General Characteristics* and Model 2 with *General Characteristics* and *Eating Habits* as independent variables.

Finally, we studied the meaningfulness of percentage differences between patients that use MDI or CSII related to the three-factor model. That is, we can safely say those have CSII for insulin treatment compared to those have MDI:

- are used to using technology much more often;
- have a higher education;
- are affected by T1D;
- can be students;
- have a more balanced breakfast.

The added value of this work is that we studied the lifestyle of patients with diabetes in insulin treatment related to the medical devices that they use. We found interesting differences between the two groups that can be useful for reducing healthcare costs related to diabetic pathology.

These results, which can represent the straightness of our study, provide supporting evidence that there are many, not only clinical, characteristics of patients with diabetes useful to the appropriate choice of medical device for insulin treatment. These characteristics are: familiarity with technology, qualification, type of diabetes, job and breakfast habits. It is obvious that the percentage of HbA1c has not resulted the core solution for the choice of medical device, as literature reports.

On the other hand, this study is not devoid of limitations. The main is based on the sample and its composition: it is not too consistent and is not representative of the general diabetic population for the selection bias of the choice of diabetic center, which limits the generalizability of results. Therefore, the next development is to carry on a multicenters study and make the results more generalizable in order that they can be used by policy makers in healthcare for a better management of resources and the best appropriateness of patients' eligibility at the use of CSII technology.

Appendix A

CONSENSO INFORMATO
Dichiarazione da parte dell'Assistito di età ≥ 18 anni di ricevuta informazione e consenso all'utilizzo dei dati

PROGETTO
"DIABETE E DISPOSITIVI MEDICI: QUALE DISPOSITIVO PER QUALE PAZIENTE?"

Il/la sottoscritto/a ______________________________ nato/a a ______________________ il ______________________

Dichiara di:

- ✓ essere stato adeguatamente informato dal proprio medico Diabetologo del Servizio di Diabetologia Dott. ______________________________ su obiettivi e modalità del progetto di ricerca "Diabete e Dispositivi Medici: quale dispositivo per quale paziente?";
- ✓ di aver preso atto che il proprio medico Diabetologo ha aderito al progetto di ricerca "Diabete e Dispositivi Medici: quale dispositivo per quale paziente?" per la tesi di Dottorato in Sanità Pubblica (Scuola di Dottorato in Scienze Biomediche dell'Università degli Studi di Sassari);
- ✓ di essere stato informato dal mio medico Diabetologo di quali dati clinici presenti nella propria cartella clinica saranno utilizzati nell'ambito di tale progetto;
- ✓ di essere stato informato dal mio medico Diabetologo di dover essere sottoposto ad un questionario sotto forma di intervista nell'ambito di tale progetto;
- ✓ di essere consapevole che tale progetto non interferisce in alcun modo sul mio processo di cura;
- ✓ di essere a conoscenza che i dati forniti mediante la cartella clinica e mediante il questionario saranno utilizzati ai soli fini di ricerca e di valutazione epidemiologica, che tali valutazioni avverranno garantendo il rispetto dell'anonimato, con procedure a tutela della privacy e con la diffusione dei risultati esclusivamente in forma aggregata senza poter risalire in qualsiasi modo a me;

Autorizzo:

- ✓ il mio medico Diabetologo all'utilizzo dei dati personali, sopra riportati, contenuti nella cartella clinica per i fini sopra riportati all'interno del progetto di ricerca "Diabete e Dispositivi Medici: quale dispositivo per quale paziente?";
- ✓ alla diffusione e pubblicazione dei risultati dello studio, completi o parziali, in forma aggregata;

Luogo e Data	Firma (estesa e leggibile)
______________________	______________________

Appendix B

Data rilevazione:	
Codice paziente:	

DISPOSITIVO MEDICO TECNOLOGIA MDI

ESAMI CLINICI DEL SANGUE (ULTIMA RILEVAZIONE)		
Data	**Esame**	**Risultato**
	Creatinina (mg/ml)	
	ACR (mg/mmol)	
	GPT (UI/L)	
	Colesterolo (mg/dl)	
	Colesterolo HDL (mg/dl)	
	Trigliceridi (mg/dl)	
	Colesterolo LDL (calc) (mg/dl)	
	Emoglobina glicata HbA1c (%)	

ALTRI ESAMI		
Data	**Esame**	**Risultato**
	Peso (kg)	
	Altezza (cm)	
	BMI (m/kg^2)	
	Pressione Sistolica (mmHg)	
	Pressione Diastolica (mmHg)	

ESAMI OCULISTICI (ULTIMA RILEVAZIONE)			
Data	**Esame**	**Risultato**	
	Retinopatia diabetica	□ Si	□ No

ESAME CARDIOLOGICO ECG (ULTIMA RILEVAZIONE)			
Data	**Esame**	**Risultato**	
	Anomalie Cardiache	□ Si, ____________________	□ No

FARMACI ASSUNTI (ULTIMA RILEVAZIONE)			
Data	**Esame**	**Risultato**	
	Ipocolesterolemizzanti	□ Si, __________________	□ No
	Antiaggreganti	□ Si, __________________	□ No
	Antipertensivi	□ Si, __________________	□ No

TERAPIA INSULINICA (ULTIMA RILEVAZIONE)		
Data	**Terapia**	**Quantità**
	Basal Bolus	

DISPOSITIVO MEDICO TECNOLOGIA CSII

ESAMI CLINICI DEL SANGUE		
Ultima rilevazione MDI		
Data	**Esame**	**Risultato**
	Creatinina (mg/ml)	
	ACR (mg/mmol)	
	GPT (UI/L)	
	Colesterolo (mg/dl)	
	Colesterolo HDL (mg/dl)	
	Trigliceridi (mg/dl)	
	Colesterolo LDL (calc) (mg/dl)	
	Emoglobina glicata HbA1c (%)	
Ultima rilevazione CSII		
Data	**Esame**	**Risultato**
	Creatinina (mg/ml)	
	ACR (mg/mmol)	
	GPT (UI/L)	
	Colesterolo (mg/dl)	
	Colesterolo HDL (mg/dl)	
	Trigliceridi (mg/dl)	
	Colesterolo LDL (calc) (mg/dl)	
	Emoglobina glicata HbA1c (%)	

ALTRI ESAMI		
Ultima rilevazione MDI		
Data	**Esame**	**Risultato**
	Peso (kg)	
	Altezza (cm)	
	BMI (m/kg^2)	
	Pressione Sistolica (mmHg)	
	Pressione Diastolica (mmHg)	
Ultima rilevazione CSII		
Data	**Esame**	**Risultato**
	Peso (kg)	
	Altezza (cm)	
	BMI (m/kg^2)	
	Pressione Sistolica (mmHg)	
	Pressione Diastolica (mmHg)	

ESAME OCULISTICO			
Ultima rilevazione MDI			
Data	**Esame**	**Risultato**	
	Retinopatia diabetic	□ Si	□ No
Ultima rilevazione CSII			
Data	**Esame**	**Risultato**	
	Retinopatia diabetic	□ Si	□ No

ESAME CARDIOLOGICO ECG			
Ultima rilevazione MDI			
Data	**Esame**	**Risultato**	
	Anomalie Cardiache	□ Si	□ No
	Se si, quali: ___		
Ultima rilevazione CSII			
Data	**Esame**	**Risultato**	
	Anomalie Cardiache	□ Si	□ No
	Se si, quali: ___		

FARMACI ASSUNTI			
Ultima rilevazione MDI			
Data	**Esame**	**Risultato**	
	Ipocolesterolemizzanti	□ Si	□ No
	Se si, quali: ___		
	Antiaggreganti	□ Si	□ No
	Se si, quali: ___		
	Antipertensivi	□ Si	□ No
	Se si, quali: ___		
Ultima rilevazione CSII			
Data	**Esame**	**Risultato**	
	Ipocolesterolemizzanti	□ Si	□ No
	Se si, quali: ___		
	Antiaggreganti	□ Si	□ No
	Se si, quali: ___		
	Antipertensivi	□ Si	□ No
	Se si, quali: ___		

TERAPIA INSULINICA		
Ultima rilevazione MDI		
Data	**Terapia**	**Quantità insulina**
	Basal Bolus	
Ultima rilevazione CSII		
Data	**Terapia**	**Quantità insulina**
	Infusione continua	

Appendix C

Data Rilevazione:					
Codice paziente:					
INFORMAZIONI GENERALI (devono essere rilevate il giorno in cui è somministrato il questionario)					
I	**Marca e modello del Dispositivo Medico attualmente utilizzato per l'insulina:**				
II	**Da quanti anni sta utilizzando l'attuale Dispositivo Medico per l'insulina?**				
III	**Per quale motivo utilizza l'attuale Dispositivo Medico per l'insulina?**				
	□ Me lo ha proposto il medico	□ Me lo ha proposto il medico per motivi clinici	□ L'ho proposto io al medico perché è il migliore Dispositivo	□ L'ho proposto io al medico perché me lo hanno consigliato altri pazienti o amici	□ Non ne conosco altri
IV	**Quanti Dispositivi Medici per l'insulina ha utilizzato in precedenza dal momento in cui è stato diagnosticato il Diabete?**				
V	**Quanto è soddisfatto di utilizzare l'attuale Dispositivo Medico per l'insulina?**				
	□ Molto	□ Abbastanza	□ Mediamente	□ Poco	□ Per niente
VI	**(SOLO SE PAZIENTE ADULTO E SESSO F) Quante gravidanze a termine ha avuto:**				

1	**Come va in generale la sua salute?**				
	□ Molto bene	□ Bene	□ Né bene né male	□ Male	□ Molto male
2	**Controlla il suo peso regolarmente?**				
	□ Sì, tutti i giorni	□ Sì, almeno una volta alla settimana	□ Sì, almeno una volta al mese	□ Sì, qualche volta durante l'anno	□ No
3	**Qual è il suo pasto principale?**				
	□ Prima Colazione	□ Pranzo	□ Cena		
4	**Ha l'abitudine di fare la prima colazione?**				
	□ Sì, bevo bevande come the, caffè, caffelatte, cappuccino e mangio qualcosa come biscotti, fette biscottate, pane; inoltre mangio anche la frutta	□ Sì, bevo bevande come the, caffè, caffelatte, cappuccino e mangio qualcosa come biscotti, fette biscottate, pane.	□ Sì, bevo bevande come the, caffè, caffelatte, cappuccino senza mangiare niente	□ Sì, mangio qualcosa come biscotti, fette biscottate, pane, senza bere nulla	□ Non faccio colazione
5	**Dove pranza abitualmente nei giorni NON festivi (di scuola o di lavoro)?**				
	□ A casa propria o di genitori o parenti	□ In una mensa, ristorante, trattoria o tavola calda	□ In un bar	□ Sul posto di lavoro	□ Non pranzo

6	**Con che frequenza consuma i seguenti gruppi di alimenti?**				
Pane, pasta, riso	□ Più di una volta al giorno	□ Una volta al giorno	□ Qualche volta a settimana	□ Meno di una volta a settimana	□ Mai
Salumi	□ Più di una volta al giorno	□ Una volta al giorno	□ Qualche volta a settimana	□ Meno di una volta a settimana	□ Mai
Carne di pollo o tacchino o coniglio o vitello o bovino o maiale (escluso salumi)	□ Più di una volta al giorno	□ Una volta al giorno	□ Qualche volta a settimana	□ Meno di una volta a settimana	□ Mai
Latte	□ Più di una volta al giorno	□ Una volta al giorno	□ Qualche volta a settimana	□ Meno di una volta a settimana	□ Mai
Formaggi, latticini	□ Più di una volta al giorno	□ Una volta al giorno	□ Qualche volta a settimana	□ Meno di una volta a settimana	□ Mai
Uova	□ Più di una volta al giorno	□ Una volta al giorno	□ Qualche volta a settimana	□ Meno di una volta a settimana	□ Mai
Pesce	□ Più di una volta al giorno	□ Una volta al giorno	□ Qualche volta a settimana	□ Meno di una volta a settimana	□ Mai
Verdure crude o cotte	□ Più di una volta al giorno	□ Una volta al giorno	□ Qualche volta a settimana	□ Meno di una volta a settimana	□ Mai
Frutta	□ Più di una volta al giorno	□ Una volta al giorno	□ Qualche volta a settimana	□ Meno di una volta a settimana	□ Mai
Legumi secchi o in scatola	□ Più di una volta al giorno	□ Una volta al giorno	□ Qualche volta a settimana	□ Meno di una volta a settimana	□ Mai
Patate	□ Più di una volta al giorno	□ Una volta al giorno	□ Qualche volta a settimana	□ Meno di una volta a settimana	□ Mai
Snack salati (patatine, pop-corn, salatini, olive)	□ Più di una volta al giorno	□ Una volta al giorno	□ Qualche volta a settimana	□ Meno di una volta a settimana	□ Mai
Dolci (torte farcite, merendine, gelati, ecc.)	□ Più di una volta al giorno	□ Una volta al giorno	□ Qualche volta a settimana	□ Meno di una volta a settimana	□ Mai
7	**In quale quantità consuma abitualmente le bevande seguenti?**				
Acqua naturale o frizzante	□ Oltre 1 litro al giorno	□ da ½ litro al litro al giorno	□ 1-2 bicchieri al giorno (meno di ½ litro al giorno)	□ Raramente	□ Mai

Bibite gasate (esclusa l'acqua frizzante)	□ Oltre 1 litro al giorno	□ da ½ litro al litro al giorno	□ 1-2 bicchieri al giorno (meno di ½ litro al giorno)	□ Raramente	□ Mai
Birra	□ Oltre 1 litro al giorno	□ da ½ litro al litro al giorno	□ 1-2 bicchieri al giorno (meno di ½ litro al giorno)	□ Raramente	□ Mai
Vino	□ Oltre 1 litro al giorno	□ da ½ litro al litro al giorno	□ 1-2 bicchieri al giorno (meno di ½ litro al giorno)	□ Raramente	□ Mai
Altri alcolici	□ Oltre 1 litro al giorno	□ da ½ litro al litro al giorno	□ 1-2 bicchieri al giorno (meno di ½ litro al giorno)	□ Raramente	□ Mai
Caffè compresa la colazione (numero)					
Come lo consuma	□ Amaro	□ Con dolcificante	□ Con zucchero		
8	**Lei attualmente fuma?**				
	□ No, non ho mai fumato	□ No, ma ho fumato in passato (ex-fumatore)	□ Si, occasionalmente	□ Si, almeno una volta alla settimana	□ Si, tutti i giorni
9	**Con che frequenza svolge le seguenti attività?**				
Ascoltare la radio	□ Ogni giorno	□ Più di una volta alla settimana	□ Una volta alla settimana	□ Qualche volta all'anno	□ Mai
Guardare la TV	□ Ogni giorno	□ Più di una volta alla settimana	□ Una volta alla settimana	□ Qualche volta all'anno	□ Mai
Guardare DVD o videocassette	□ Ogni giorno	□ Più di una volta alla settimana	□ Una volta alla settimana	□ Qualche volta all'anno	□ Mai
Giocare ai videogiochi	□ Ogni giorno	□ Più di una volta alla settimana	□ Una volta alla settimana	□ Qualche volta all'anno	□ Mai
Navigare in internet	□ Ogni giorno	□ Più di una volta alla settimana	□ Una volta alla settimana	□ Qualche volta all'anno	□ Mai
Usare il Computer (non per navigare in internet)	□ Ogni giorno	□ Più di una volta alla settimana	□ Una volta alla settimana	□ Qualche volta all'anno	□ Mai
Usare il telefono cellulare	□ Ogni giorno	□ Più di una volta alla settimana	□ Una volta alla settimana	□ Qualche volta all'anno	□ Mai
Leggere libri, quotidiani e riviste	□ Ogni giorno	□ Più di una volta alla settimana	□ Una volta alla settimana	□ Qualche volta all'anno	□ Mai
Andare a teatro, cinema o spettacoli vari	□ Ogni giorno	□ Più di una volta alla settimana	□ Una volta alla settimana	□ Qualche volta all'anno	□ Mai
Partecipazione ad attività in circoli ricreativi o sociali	□ Ogni giorno	□ Più di una volta alla settimana	□ Una volta alla settimana	□ Qualche volta all'anno	□ Mai
Fare la spesa	□ Ogni giorno	□ Più di una volta alla settimana	□ Una volta alla settimana	□ Qualche volta all'anno	□ Mai
Fare una passeggiata	□ Ogni giorno	□ Più di una volta alla settimana	□ Una volta alla settimana	□ Qualche volta all'anno	□ Mai
Prendere mezzi di trasporto (autobus, metro) all'interno di un comune	□ Ogni giorno	□ Più di una volta alla settimana	□ Una volta alla settimana	□ Qualche volta all'anno	□ Mai
10	**Titolo di studio più alto conseguito?**				
	□ Diploma di Laurea (5 anni di studio), master di II livello, Dottorato, Scuola di Alta Formazione	□ Diploma di maturità (scuola superiore)	□ Licenza media o diploma di qualifica professionale (2-3 anni di studio che non permette l'accesso all'università)	□ Licenza elementare	□ Nessun titolo
11	**Stato civile attuale**				
	□ Celibe o nubile	□ Coniugato/a coabitante col coniuge	□ Coniugato/a non coabitante col coniuge (separato/a di fatto)	□ Separato/a o divorziato/a legalmente	□ Vedovo/a
12	**Nel suo tempo libero pratica qualche sport?**				
	□ Si, pratico con continuità più di uno sport	□ Si, pratico con continuità uno sport	□ Si, pratico saltuariamente uno sport	□ In passato ho praticato uno o più sport ma oggi non ne pratico nessuno	□ No, non ho mai praticato nessuno sport
13	**Dove svolge attualmente attività sportiva?**				
	□ In una Società sportiva, o in un centro sportivo, o palestra, ecc.	□ In un'Associazione scolastica, o in un centro culturale o in un centro universitario	□ In altre strutture diverse dalle precedenti	□ Svolgo attività sportiva autonomamente	□ Non pratico nessuno sport

14	**Con quale frequenza svolge attività fisica?**				
	□ Cinque o più volte a settimana	□ Tre o quattro volte a settimana	□ Una o due volte a settimana	□ Qualche volta al mese (meno di 4 volte)	□ Non pratico nessuna attività sportiva
15	**Quali sono i motivi che le impediscono di praticare attività fisica o di svolgerne di più di quella che già pratica?**				
	□ Impegni di lavoro o di studio	□ Impegni familiari	□ Motivi economici	□ Motivi di salute	□ Altro (specificare quali) ________
16	**Facendo riferimento all'unico o alla principale attività lavorativa, lei svolge?**				
	□ Un lavoro alle dipendenze	□ Un lavoro di collaborazione coordinata continuativa (con o senza progetto) o prestazione d'opera occasionale	□ Un lavoro autonomo come: imprenditore, libero/a professionista, lavoratore/lavoratrice in proprio	□ Sono uno studente	□ Non lavoro
17	**Come è organizzata solitamente la sua attività lavorativa in ore?**				
	□ Ho sempre lo stesso orario	□ Ogni settimana ho un orario diverso	□ So quando inizio, ma non so quando finisco	□ Decido io come organizzarmi il lavoro	□ Non lavoro
18	**Nel tempo libero, in cui non lavora o non studia, cosa preferisce fare o svolge con maggiore frequenza? (solo una risposta)**				
	□ Sport o attività fisica	□ Lavori o pulizie in casa	□ Una passeggiata	□ Andare in circoli ricreativi, bar, o da amici	□ Guardare la TV, navigare in internet, utilizzare il computer, ascoltare musica
19	**(SOLO SE PAZIENTE ADULTO) Quanto ritiene che il dispositivo medico da lei utilizzato influisca nel suo rapporto di coppia?**				
	□ Molto, in termini positivi	□ Poco, in termini positivi	□ Non influisce	□ Poco, in termini negativi	□ Molto, in termini negativi

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