HAW Hamburg University of Applied Sciences

Faculty of Life Sciences

Master of Health Sciences

Effect of Health Care Access on General Health Related Quality of Life (HRQoL) among Diabetics in the Southern Cone of Latin America

Master Thesis

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Submitted by:	Nadja Kartschmit
Enrollment Number:	[redacted]
Examination Supervisor:	Prof. Dr. Joachim Westenhöfer
Secondary Supervisor:	Prof. Dr. Zita Schillmöller

Abstract

Background: Health related quality of life (HRQoL) is an important health outcome measure in diabetics and is influenced by socioeconomic, demographic and disease related factors. Additionally, health care access could affect HRQoL in diabetics. The effect of access to care on HRQoL could be more prominent in people with diabetes than in people without diabetes. However, these associations have been rarely investigated. Especially in the Southern Cone of Latin America, were diabetes is increasing and access to care may be impeded, there is a lack of research regarding this topic. Hence, the aim of this thesis was to enhance knowledge on the effect of health care access in diabetics HRQoL in the Southern Cone of Latin America.

Methods: Data of 1025 diabetics and 6064 non-diabetics of the CESCAS I study were analyzed. The physical component summary (PCS-12) and the mental component summary (MCS-12) of the SF-12, a generic instrument to measure HRQoL, were used to determine HRQoL. 4 groups were compared 1) Insured people without barriers to realized access (no problems in accessing health care), 2) Uninsured people without barriers to realized access (no potential, but realized access), 3) Insured people with barriers to realized access (no realized, but potential access) 4) Uninsured people with barriers to realized access (no potential and no realized access).

Group differences among diabetics' characteristics and HRQoL as well as between diabetics and non-diabetics were analyzed using Chi Square test, One Way ANOVA, unadjusted and adjusted two-factorial univariate ANOVA, Welch test, Tukey, Bonfferoni and Games Howell as post hoc tests, when appropriate. The association between HRQoL in the diabetic sample and health care access was adjusted for important covariates using multivariate linear regression. Reasons for barriers to realized access were analyzed descriptively.

Results: In diabetics, HRQoL was lowest in the fourth group for both component summary scales and highest in the first group followed by the second and the third group. (p-value < 0.001). In adjusted analyses, HRQoL was associated with a decrease of 2 points for the PCS-12 in the second (p-value 0.014), 4.75 points in the third (p-value 0.007) and 6.13 points in the fourth group (p-value < 0.001) compared to the first group. For the MCS-12, the decrease was 4.82 points for the second (p-value 0.032) and 5.6 points in the fourth group (p-value 0.001) compared to the first group. The decrease of 0.62 points in the second group was not significant (p-value 0.553). Reasons for barriers to realized care includ-

ed long appointment waiting times and compulsory copayments. Diabetes and access to care significantly predicted lower HRQoL regarding the PCS-12 (p-value < 0.001). The MCS-12 was significantly predicted by access to care (p-value < 0.001), but not by diabetes (p-value 0.349). Diabetes and access to care were not interacting in predicting HRQoL in neither the PCS-12 (p-value 0.853), nor the MCS-12 (p-value 0.425).

Discussion and Conclusion: In the Southern Cone of Latin America, impeded health care access is common among diabetics and non-diabetics. Realized health care access seems to play a more important role than health insurance status in determining the physical and mental component of HRQoL in both, diabetic and non-diabetic patients. Diabetes seems to negatively affect the physical, but not the mental component of HRQoL. Interventions should be implemented to overcome especially the barriers to realized health care access in order to enhance HRQoL among diabetics.

Keywords: HRQoL, diabetes, health care access, Southern Cone of Latin America

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Abbreviations

IDF	International Diabetes Federation
HRQoL	Health Related Quality of Life
CDC	Centers for Disease Control and Prevention
CVD	Cardiovascular disease
SES	Socioeconomic status
CESCAS	Centro de Excelenica en Salud Cardiovascular - Centre of Excellence in Cardiovascular Health
IECS	Instituto de Efectividad Clinica y Sanitaria - Institute for Clinical Effectiveness and Health Policy
HbA1c	Glycosylated Hemoglobin Type A1C
WHO	World Health Organization
ADDQoL	Audit of Diabetes-Dependent Quality of life
DSQOLS	Diabetes-Specific Quality-of-life Scale
SF	Short Form
PCS	Physical component summary
MCS	Mental component summary
HDL-C	High-density lipoprotein cholesterol
LDL-C	Low-density lipoprotein cholesterol
OR	Odds Ratio
MOH	Ministry of Health
OS	Obras Sociales - Social Security

INSSJyP/ PAMI	Instituto Nacional de Servicios Sociales para Jubilados y Pensionados/ Programa de Atención Médica Integral - National Institute for Social Services for the Retired/ Program for Integrated Medical Assistance Argentina
EMP	Empresas de Medicina Prepaga - Medical Prepaid Companies
IAMC	Instituciones de Asistencia Médica Colectiva - Institutions of Community Health Care Uruguay
OECD	Organization for Economic Cooperation and Development
FONASA	Fondo Nacional de Salud - National Health Fund
ISAPRE	Instituciones de Salud Previsional - Private Previsional Health Institutions
AUGE	Plan de Accesso Universal con Guarantías Explícitas - Universal Health Care Plan with Explicit Guarantees
FNR	Fondo Nacional de Recursos - National Resources Fund
ASSE	Atención de Servicios de Salud del Estado - Statutory Health Care
PIAS	Plan Integral de Atención a la Salud – Holistic Health Care Plan
LILACS	Literatura Latino-Americana e do Caribe em Ciências da Saúde - Latin American and Caribbean Literature on Health Sciences
IPAC	International Physical Activity Questionnaire
FFkA	Freiburger Questionnaire for physcial activity
MVPA	Moderate-vigorous physcial activity
PedsQoL	Pediatric Quality of Life Inventory
BACS	Barrier to Care Scale
HCHS/SOL	Hispanic Community Health Study/ Study of Latinos

1. Introduction

According to the International Diabetes Federation (IDF), approximately 415 million people worldwide are affected by diabetes and this number is expected to increase to 642 million people by the year 2040 (cf. IDF 2015). In the Southern Cone of Latin America, the prevalence of diabetes is 14 % (cf. Shen, Kondal et al. 2016: 63). According to the Global Burden of Diseases, Injuries, and Risk Factors Study, diabetes is the sixth leading cause of years lived with disability worldwide and the seventh and eighth leading cause in Chile, Argentina and Uruguay, respectively (cf. Vos, Allen et al. 2016: 1585).

Health related quality of life (HRQoL) is an important health outcome measure and can be seen as a supplement to the common public health measures mortality and morbidity (cf. CDC 2016). Due to the specific characteristics of the disease, the assessment of HRQoL in diabetic patients is essential in order to plan processes, to decide on interventions and to enhance patients' outcomes (cf. Luscombe 2000: 15f.).

Currently, there is an increasing interest in evaluating HRQoL in people with diabetes in epidemiological studies as well as in clinical trials (cf. Ose, Wensing et al. 2009).

HRQoL of people with diabetes is worse compared to people without diabetes (cf. Daniele, Bruin et al. 2013: 47; Schunk, Reitmeir et al. 2012: 646). Several factors negatively influence the HRQoL in people with diabetes for example: longer diabetes duration, existent diabetic complications and comorbidities (cf. O'Shea, Teeling et al. 2015: 623f.; Al Hayek, Robert et al. 2014: 224f.; Maddigan, Feeny et al. 2006: 1652; Wändell 2005: 72), such as chronic kidney disease (cf. Campbell, Huang et al. 2013) and cardiovascular disease (CVD) (cf. Tan, Ng et al. 2014), poor glycemic control (cf. Al-Shehri 2014: 228), physical inactivity (cf. Thiel, Al Sayah et al. 2016; Bennett, Ouyang et al. 2008), obesity, insulin-therapy (cf. Schunk, Reitmeir et al. 2015: 207; Vidal-Peracho, Lucha-López et al. 2014: 10), being female (cf. Sepúlveda, Poínhos et al. 2015: 221ff.; Urzúa, Chirino et al. 2011: 316) and having a low socioeconomic status (SES) (cf. Nejhad, Vardanjani et al. 2013).

Additionally, barriers for accessing health care could affect HRQoL in people with diabetes (cf. Brown, Ettner et al. 2004: 64). However, in most studies on HRQoL in diabetics, barriers to health care access have not been taken into account. Only few studies have examined the association between barriers to health care and HRQoL in particular and found significant associations between barriers to health care and poor HRQoL (cf. Maliski,

Connor et al. 2011; Hoffmann, Rohrer et al. 2008; Seid, Varni et al. 2006). However, few studies focused on people with diabetes in particular regarding this association.

With knowing whether there is a negative association between health care access, diabetes and HRQoL, adequate interventions could be implemented in order to be able to reduce health inequalities and to improve HRQoL in patients with diabetes. Most research on diabetics HRQoL was conducted in developed countries and very little is known on diabetics HRQoL and its determining factors in developing countries and especially concerning the association with barriers to health care access. Above all in South America there is a lack of research regarding this topic. Given that the burden of diabetes and the impact on barriers to health care access could even be more prominent in developing countries than in developed countries (cf. Safita, Islam et al. 2016: 6), research is implicitly needed in countries of the Global South.

The overall aim of the thesis was to enhance knowledge on the effect of health care access in diabetics HRQoL in the Southern Cone of Latin America. The specific aims were 1) to examine the association between general HRQoL and access to health care and common determinants of HRQoL in diabetics, 2) to determine self-perceived barriers to health care access among diabetics and 3) to examine the association of diabetes and health care access on general HRQoL.

This thesis consists of nine chapters. The main topics of the thesis - namely diabetes, HRQoL and health care access - are described in the theoretical background. Conceptual models of HRQoL and health care access are presented, which provide the framework for the research. The next chapter deals with epidemiological and health policy aspects of diabetes as well as with aspects of health care access in the Southern Cone of Latin America. Then, the current state of the art is presented concerning a) the association of HRQoL and diabetes, b) determining factors in HRQoL among diabetics and c) the association of HRQoL and barriers to health care access. The next chapter consists of the research questions and hypotheses, followed by a description of the methods used in order to answer the research questions. In the following chapters, results of the study are given and discussed. Finally, in chapter nine, a conclusion of the research is drawn with stating the public health relevance of this topic.

2. Theoretical background

This chapter provides brief information on the definition, diagnosis and treatment of diabetes mellitus.

Additionally, conceptual models of HRQoL and health care access are presented. Conceptual models can be used in order to better understand a phenomenon like HRQoL and access to health care. These models are schematic portrayals of a theory and represent interrelationships among different concepts. The term conceptual model can be used as a synonym for theoretically based conceptual model, theoretical model and conceptual framework (cf. Roop, Payne et al. 2011: 45ff.).

2.1 Diabetes mellitus

According to the World Health Organization (WHO), diabetes is a metabolic disease, which is characterized by increased levels of blood glucose. Over time, increased blood glucose leads to micro- and macrovascular damages, affecting the heart, nerves, kidneys and eyes. In type 2 diabetes, the body becomes resistant to insulin and/ or the pancreas does not produce enough insulin in order to keep blood glucose levels in a range that is not harmful to organs and organ systems. Type 2 diabetes is the most common type of diabetes. In type 1 diabetes, little or no insulin is produced by the pancreas (cf. WHO 2017). The diagnostic criteria for diabetes are fasting plasma glucose that is equal or above 7.0 mmol/l (126 mg/dl) or plasma glucose that is equal or above 11.1 mmol/l (200 mg/dl) 2 hours after 75 g oral glucose load, measured ideally from venous plasma (cf. IDF 2012: 9ff.).

In order to minimize the development of complications, people with diabetes should maintain a target level of the Glycosylated Hemoglobin Type A1C (HbA1c) below 7.0 % / 53 mmol/mol (cf. IDF 2012: 38ff.).

Treatment of diabetes primary consists of lifestyle interventions, such as healthy nutrition and physical activity. When these interventions alone are unable to maintain the target blood glucose level, oral glucose lowering medications should be considered. Treatment with insulin should only be started, if oral agent options are not or no longer effective in order to keep blood glucose at the target values (cf. IDF 2012: 55ff.).

2.2 Common Health Related Quality of Life (HRQoL) conceptual models used in research

Commonly, HRQoL is perceived as subjective, dynamic and multidimensional. The dimensions imply physical, mental, spiritual and social aspects related to people's health (cf. Haas 1999: 728ff.).

The term HRQoL varies across health conditions and many different HRQoL models exist for certain diseases, life stages, and among individuals and communities. According to Bakas, McLennon et al. (2012), the most frequently used models for HRQoL in research are the models from Wilson and Cleary, Ferrans, Zerwic et al. and the WHO (cf. Bakas, McLennon et al. 2012: 7). The HRQOL model by Wilson and Cleary (1995) consists of five levels, namely biological and physiological factors, symptoms, functioning, general health perception and overall quality of life (Figure 1).

Biological and physiological factors focus on the function of organ systems, organs and cells and include the diagnosis of a disease, laboratory values and measures of physiological function and physical examination findings. Wilson and Cleary (1995) define symptoms as "a patient's perception of an abnormal physical, emotional, or cognitive state" (Wilson and Cleary 1995: 61). Functioning, the next level in the model is determined by symptom status and by social and economic support, personality and motivation. This level measures the ability to perform certain tasks and includes minimally the four domains physical function, social function, role function, and physiological function. The following level in the model is the general health perception. General health perception integrates all previous concepts, but also includes other health related aspects such as mental health. This level is associated with physiological and biological factors, and is also related to individual and environmental characteristics and is subjective by its definition. All the prior levels should influence the overall quality of life, which means the general satisfaction or happiness with life (cf. Wilson and Cleary 1995: 61f.). However, "lower general measures of life satisfaction or happiness are not as strongly related to objective life circumstances as might be anticipated, lower levels of functional status are not necessarily related to lower levels of satisfaction […]" (Wilson and Cleary 1995: 62). Hence, questions about the satisfaction according to certain aspects of one's health may be more delicate for obtaining a clearer picture of overall quality of life.

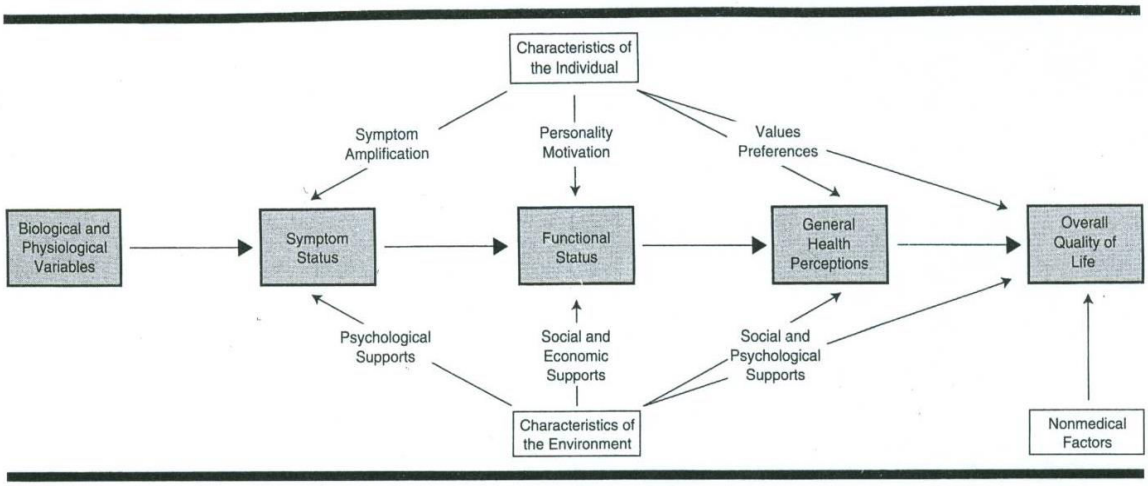

Figure 1: HRQoL model by Wilson and Cleary

Source: Wilson & Cleary (1995): 60.

Ferrans, Zerwic et al. (2005) revised the HRQoL model by Wilson and Cleary. In their model, the five major levels of the model by Wilson and Cleary were maintained (cf. Ferrans, Zerwic et al. 2005). Ferrans, Zerwic et al. (2005) define the individual and environmental characteristics in-depth, and they simplify the representation of the model by eliminating non-medical factors and the labels on the arrows in the figure. Additionally, further theoretical backgrounds about the model's main concepts and examples of instruments in order to improve measurement are provided. Despite the causal relationships represented in the model, reciprocity between the different aspects is implied. Understanding the relationships among the aspects will allow for designing effective and adequate interventions (cf. Ferrans, Zerwic et al. 2005). The revised model is applicable to any health care discipline. Comparing the different models, the model by Ferrans, Zerwic et al. provides completer and clearer operational definitions of the concepts and the relationships among each other than the model by Wilson and Cleary (cf. Bakas, McLennon et al. 2012: 10).

The International Classification of Functioning, Disability, and Health by the WHO (WHO ICF) provides depiction of health and health states using a standard language that is applicable to different disciplines and cultures. In the model by the WHO, HRQoL is conceptualized as the perception of health and health-related aspects of well-being by an individual (cf. WHO 2001). Within the model, health and health-related aspects are furthermore con-

ceptualized concerning functioning. The model consists of two main parts. The first part deals with functioning and disability, for example body functioning and participation, whereas the second part focuses on environmental and personal factors. Unlike the two previously described models by Wilson and Cleary and Ferrans, Zerwic et al. the model by the WHO is not a particular model for HRQOL. However, the categories described under functioning can provide the fundament for operationalizing HRQoL and hence serve as a classification and mapping framework for generating hypothesis concerning the concept of HRQoL. The model could be applied to specific HRQoL studies, for example to studies of educational nature as well as among different cultures (cf. Bakas, McLennon et al. 2012: 10).

Bakas, McLennon et al. (2012) criticize that "most existing models focus on the influence of symptoms rather than on management related to the condition. For example, for those with diabetes, both symptoms (such as hypoglycemia) and management (such as frequent checking of glucose levels) are important influential factors for HRQoL" (Bakas, McLennon et al. 2012: 9). A variety of different models were applied in studies on HRQoL and yet no coherent body of evidence exists for guiding further research and practice (Bakas, McLennon et al. 2012). However, there is consensus on the main concept of HRQoL. Dimensions of general health, mental health, physical functioning, role functioning, social functioning, vitality and pain are included in the majority of HRQoL conceptualizations (Ware 1987; Fries 1991)

The revised model of Wilson and Cleary (1995) provided by Ferrans, Zerwic et al. (2005) is used as theoretical framework for the study at hand, as it provides plain definitions, clarifies relationships among different concepts and includes the most common dimensions of HRQoL. Unlike the WHO model, the model by Ferrans, Zerwic et al. (2005) is specific to HRQoL and provides a clearer depiction of the concept than the model of Wilson and Cleary and hence is appropriate in guiding research and practice.

2.3 Common HRQoL measurement instruments used in diabetes research

In order to measure HRQoL, instruments have been developed using conceptual frameworks such as the ones mentioned above. Common studies on HRQoL and diabetes used mainly two types of generic instruments in order to measure HRQoL that are described briefly in Table 1, namely the SF-36 and the SF-12, respectively and the EuroQol. The SF-

36/ SF-12 have eight dimensions, namely physical function, role limitations due to physical problems (role-physical), role limitations due to emotional problems (role-emotional), vitality, bodily pain, social function, mental health, and general health as well as two summary scores: physical component summary (PCS), mental component summary (MCS) (cf. Bennett, Ouyang et al. 2008: 2f.). The EuroQol consists of the EQ-5D with five dimensions, namely mobility, self-care, usual activities, pain/discomfort, and anxiety/ depression and a Visual Analog Scale for general health status (EQ-VAS) (Javanbakht, Abolhasani et al. 2012: 2f). Additionally, there is a variety of diabetes-specific instruments available in order to determine HRQoL, for example the Audit of Diabetes-Dependent Quality of Life (ADDQoL) or the Diabetes-Specific Quality-of-life Scale (DSQOLS) (Watkins and Connell 2004). These instruments are more sensitive to capture factors of HRQoL that are of particular interest in people with diabetes when compared to generic instruments. The combined use of both, one generic and one specific HRQoL instrument appears to be the most appropriate way for evaluating HRQoL among diabetic patients (Aguiar, Vieira et al. 2008).

Table 1: Common general HRQoL measurement instruments

	Dimensions	Items	Range	Strengths and limitations
Short Form 36 (SF-36) and Short Form 12 (SF-12) **Quality of Life questionnaire derived from the Medical Outcome Study**	8 dimensions: physical function, role limitations due to physical problems (role-physical), role limitations due to emotional problems (role-emotional), vitality, bodily pain, social function, mental health, and general health 2 summary scores: physical component summary (PCS), mental component summary (MCS)	SF-36: 36 items SF-12: 12 items	0 – 100 (higher values indicate better HRQoL)	Good reliability, construct validity and internal consistency; tested in different population and for different diseases More sensitive than EQ-5D in order to detect health changes
EuroQoL **Questionnaire developed by an inter-disciplinary five-country group**	EQ-5D: 5 dimensions: mobility, self-care, usual activities, pain/discomfort, and anxiety/ depression EQ-VAS: health status	EQ-5D: 5, one single question for one dimension, three response levels EQ-VAS: 1	EQ-5D: -0,171 to 1 (1 best health status, 0 death, below 0 health status worse than death EQ-VAS: 0 – 100 (higher values indicate better health	Easy to use, not time-consuming Not sensitive enough to detect small health changes

Source: Own illustration based on: Javanbakht, Abolhasani et al. 2012 ; Bennett, Ouyang et al. 2008 ; Norris 2005 ; Luscombe 2000; Pakpour, Nourozi et al. 2011

2.4 Health care access conceptual models

Historically, health insurance coverage was considered the main concept of access to care with the underlying assumption that the removal of barriers to coverage would lead to similar utilization rates across subpopulations once adjusted for need. However, other organizational, financial, structural and personal requirements of the health care delivery systems need to be considered when conceptualizing access to care (cf. Gold 1998: 627f.).

According to Aday and Andersen (1981) access to health care can be divided into potential and realized access (cf. Aday and Andersen 1981: 6).

Potential access imbeds predisposing factors, for example social structure, health beliefs and needs of the population at risk and the organization and availability of health services, which enable the access to care. Indicators for potential access are for example insurance status, a particular provider or a regular source of care. Realized access reflects satisfaction and utilization of health care services and is influenced by waiting times for appointments, specialty referrals, adjacency to health care facilities, waiting time at the health care facility and compulsory copayments, among others (cf. Brown, Ettner et al. 2004: 6; Gold 1998: 633; Andersen, McCutcheon et al. 1983: 51).

Andersen, McCutcheon et al. (1983) stated that "the potential of individual entry to the health care system is influenced by structural characteristics of the delivery system itself and the nature of the wants, resources, and needs that potential consumers may bring to the care-seeking process. The realization of entry is reflected in a population's reported rates of utilization and in subjective descriptions of the care eventually obtained […]. Access may be defined as those dimensions which describe the potential and actual entry of a given population group to the health care delivery system." (Andersen, McCutcheon et al. 1983: 50ff.).

Figure 2 shows the indicators of potential and realized access. The complexity of the health care access concept necessitates evaluating the various indicators separately, despite their interrelations. In order to facilitate the assessment of potential and realized access for health policy issues, a single or a limited number of indicators can be evaluated (Andersen, McCutcheon et al. 1983: 53).

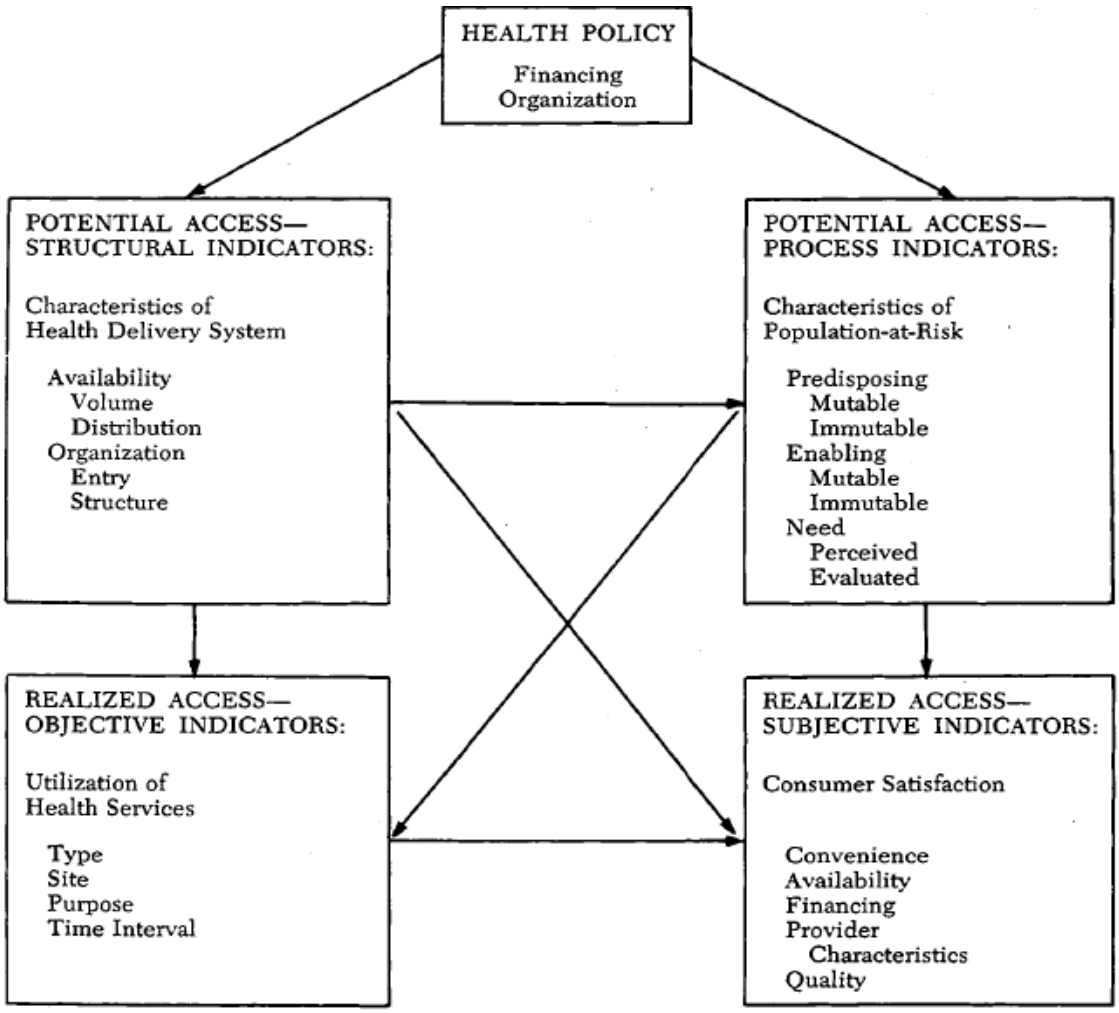

Figure 2: Access to health care framework by Aday and Andersen

Source: Aday & Andersen (1981); cit. in Gold (1998): 634.

The framework on access to care of the Institute of Medicine's Committee on Monitoring Access to Personal Health Services (1993, cit. in Gold 1998: 643) put emphasizes on effectiveness and efficiency in measuring health care access and connects access-related structural, financial, and personal barriers with outcome measures. Appropriateness of care, quality of providers, and patient adherence are seen as moderators of outcomes and were included in the model (Figure 3). The emphasis on health outcomes as measures of access highlights the interrelationships among the concepts in order to assess the health care system. This model shows that access to care influences well-being and functioning, which are important concepts in HRQoL (cf. Gold 1998: 632).

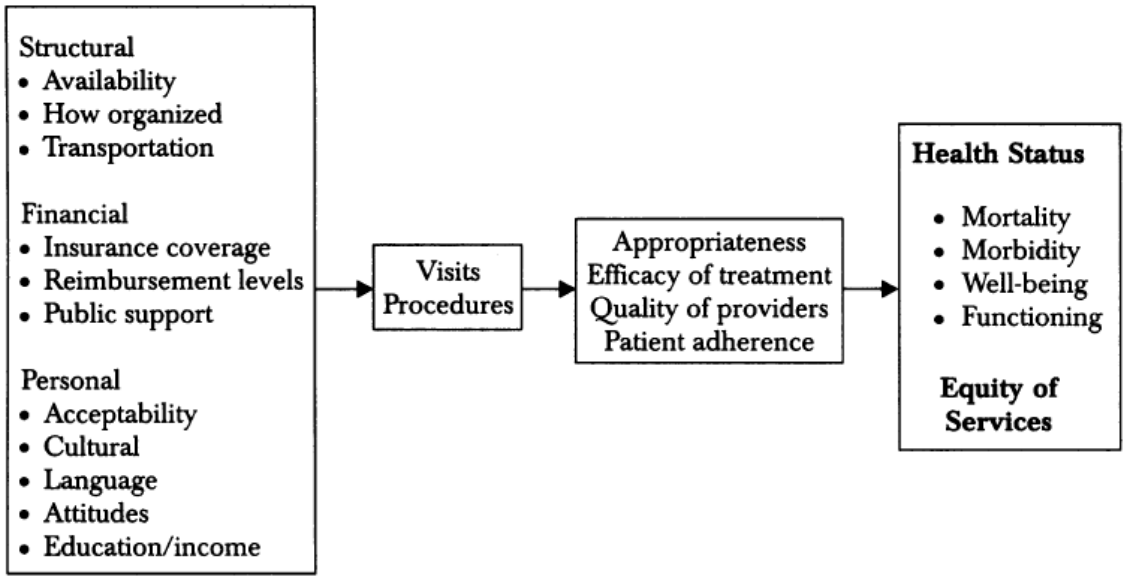

Figure 3: Access to health care framework by the Institute of Medicine's Committee on Monitoring Access to Personal Health Services

Source: Gold (1998): 635

Both concepts include individual factors, organization, availability and insurance coverage in their models. While the model of Aday and Andersen (1981) includes the concept of realized access, the model of the Institute of Medicine's Committee on Monitoring Access to Personal Health Services contains health outcomes, such as HRQoL as indirect measures of access to care.

However, both conceptual models fail to encompass the complexity of different healthcare systems. Hence, when measuring and evaluating health care access the special features of the health care system and current health policies need to be taken into account (cf. Gold 1998: 647ff.). Since both frameworks represent an important approach in measuring access to care by taking into account different dimensions and a variety of influencing factors and complement each other, they are both considered as theoretical frameworks for this study.

3. Diabetes and access to care in the Southern Cone of Latin America

This chapter provides an overview of the situation in the Southern Cone of Latin America concerning epidemiological and health policy aspects of diabetes. Additionally, characteristics of the health care systems in each of the three countries belonging to the Southern Cone of Latin America are described.

3.1 Epidemiological aspects of diabetes in the Southern Cone of Latin America

Because of urbanization, aging, increasing obesity and physical inactivity, the prevalence of diabetes is raising worldwide. Argentina, Chile and Uruguay are countries of middle income and almost 80 % of all people suffering from diabetes live in low- and middle-income countries. Additionally, the highest increase in the prevalence of diabetes is expected in these countries (cf. IDF 2015).

In the Southern Cone of Latin America, 14 % of the population are affected by diabetes, 17.8 % by pre-diabetes and 31.8 % by dysglycemia (cf. Shen, Kondal et al. 2016: 63).

Age and gender play an important role in the epidemiology of diabetes in this region. Regarding age, the prevalence of pre-diabetes increases sharply at 35 to 44 years and for the prevalence of diabetes the highest increase is observed at the age of 45 to 54 years. According to the prevalence of diabetes there is a gradual increase with higher age. Diabetes prevalence is highest among those older than 65 years (cf. Shen, Kondal et al. 2016: 64; Figure 4).

Compared to women, men have higher prevalence of pre-diabetes at every age group. However, according the prevalence of diabetes, there is only a slightly difference between men and women in the Southern Cone of Latin America (cf. Shen, Kondal et al. 2016: 64; Figure 4).

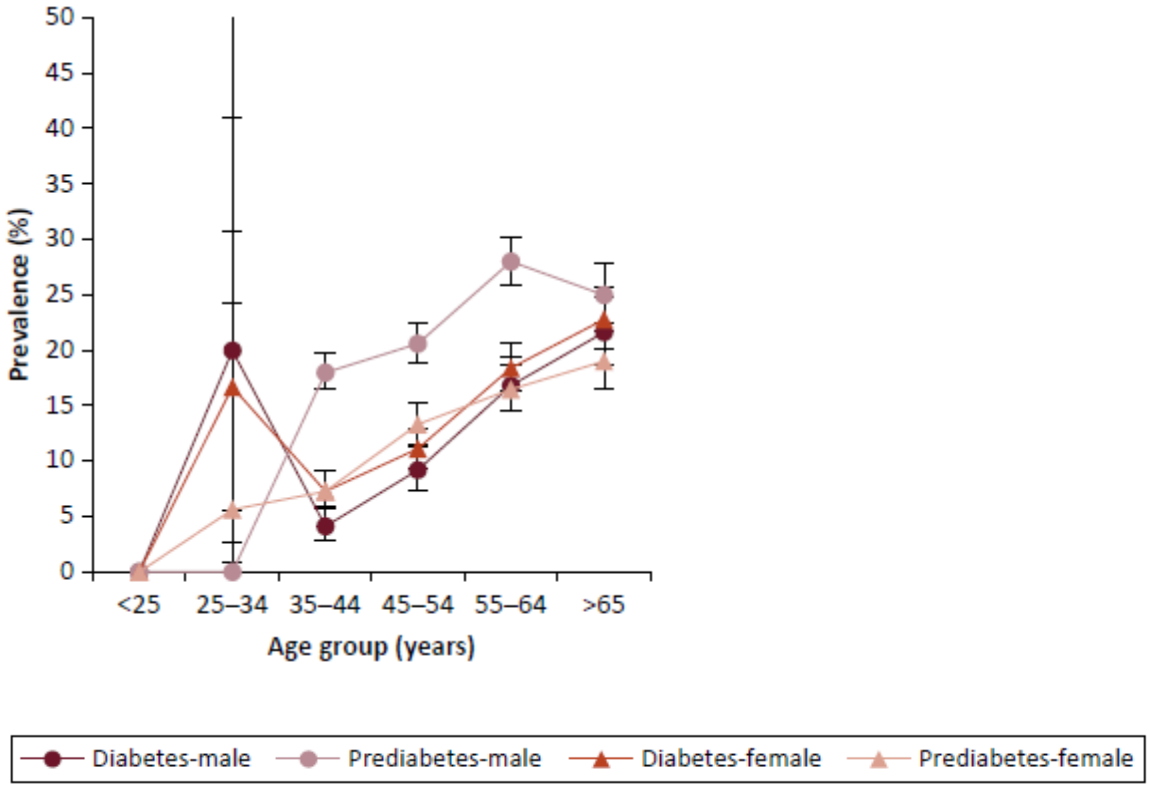

Figure 4: Age- and sex specific prevalence of diabetes and pre-diabetes in the Southern Cone of Latin America

Source : Shen et al. (2016): 64

People in the Southern Cone of Latin America that suffer from diabetes are usually older, have lower high-density lipoprotein cholesterol (HDL-C), higher triglycerides, systolic and diastolic blood pressure, low-density lipoprotein cholesterol (LDL-C), waist circumference and BMI than those with normal fasting glucose (cf. Shen, Kondal et al. 2016: 67).

Compared to other common risk factors of diabetes, hypertriglyceridemia and hypertension are associated with the highest odds of having diabetes in the diabetic population in Argentina, Chile and Uruguay with an Odds Ratio (OR) of 2.04 (95 % CI: 1.75 – 2.38) for hypertriglyceridemia and an OR of 1.91 (95 % CI: 1.62 – 2.24) for hypertension. Higher age, being male, higher BMI, abdominal obesity, waist to height ratio greater or equal 0.5 and low HDL-C also increase the odds of having diabetes. However, being a smoker and having hypercholesterolemia are associated with decreased odds of having diabetes in the population in the Southern Cone of Latin America (OR 0.80 (95 % CI: 0.67 – 0.96) and OR 0.68 (95 % CI: 0.59 – 0.80, respectively) (cf. Shen, Kondal et al. 2016: 67).

Table 2 shows the risk factors associated with diabetes in the Southern Cone of Latin America. The OR is adjusted for all other risk factors in the table.

Table 2: Risk factors associated with diabetes in the Southern Cone of Latin America

Risk Factor	OR (95 % CI)
Age (per 10-year increment)	1.04 (1.04 – 1.05)
Male	1.03 (0.89 – 1.20)
Current smoking	0.80 (0.67 – 0.96)
Obesity (BMI >= 25 kg/m2)	1.65 (1.29 – 2.17)
Abdominal obesity	1.75 (1.19 – 2.60)
Waist to height ratio >= 0.5	1.33 (0.81 – 2.19)
Hypertension	1.91 (1.62 – 2.24)
Hypercholesterolemia	0.68 (0.59 – 0.80)
Hypertriglyceridemia	2.04 (1.75 – 2.38)
Low HDL-C	1.34 (1.15 – 1.57)

Source: Adopted from: Shen et al. (2016): 67

Roughly 80 % of the diabetics living in the Southern Cone of Latin America are aware of their disease. Among them, about 75 % receive treatment and half of all treated diabetics in this area are able to attain diabetic control, with keeping fasting plasma glucose below 130 mg/dl (cf. Shen, Kondal et al. 2016: 67f.).

Overall, the majority of the risk factors of diabetes in this region are modifiable. Though, diabetes is an epidemic in the Southern Cone of Latin America. Additionally, not all diabetics are aware of their disease, receive treatment or are able to control blood glucose levels. The numbers show, that diabetes is a public health concern in Latin America. Research and practice should focus on this group of people in order to be able to enhance health outcomes, such as HRQoL in this population.

3.2 Health policy aspects of diabetes in the Southern Cone of Latin America

Through the ministerial resolution Nº 301/99, the Ministry of Health (MOH) of Argentina has approved a National Program of the Prevention and Control of Diabetes (in Spanish:

"Programa Nacional de Prevención y Control de Diabetes Mellitus). The aim of this program is to improve HRQoL among diabetics, to prevent and mitigate diabetic complications and hence to reduce direct and indirect costs associated with diabetes. One of the functions of this program is to facilitate the access to information about diabetes prevention and control for the general population (cf. MOH Argentina 2009)

Additionally, the Argentine MOH and the National Academy of Medicine of Argentina elaborated a national and clinical practice guideline on the prevention, diagnosis and treatment of diabetes for primary care providers. One of the main purposes of this guideline is again the improvement of HRQoL among diabetics. The guideline generates recommendations based on high scientific evidence according prevention, early detection, diagnosis, treatment, control and surveillance of diabetes taking into consideration the available resources in the Argentine health care system (cf. MOH Argentina 2009).

The MOH of Chile has implemented a national strategy concerning diabetes in order to comply with the health objectives for the years 2011 – 2020. The overall objective of the strategy is to increase the percentage of diabetics with good glycemic control. Good glycemic control is considered as keeping a target value of HbA1C of 7 % or below. The program evaluates the quality of care through a national database. 136 493 people with diabetes were registered in this database in 2014. Access to care is not evaluated in this program (cf. MOH Chile 2015).

In order to combat diabetes and its complications, the MOH of Uruguay created specialized services for diabetics in the primary care units. According to Article 3° of the Uruguayan law N°14.032, the diagnosis of diabetes is not associated with any costs for the patient. However, dependent of their economic situation, people with diabetes have to pay up to 50 % of their diabetes treatment out of pocket (cf. Diabetic Association of Uruguay n.d.).

The MOH in Argentina, Chile and Uruguay seem to be aware of the diabetes epidemic in their countries and reacted with certain health policies, laws and national programs in order to combat the disease and its complications. However, only the MOH in Argentina explicitly emphasizes the importance of improving HRQoL among diabetics as an overall objective in their national health policy.

3.3 Overview of the health care systems in the Southern Cone of Latin America

3.3.1 Overview of the health care system in Argentina

According to the Argentine MOH, the priority of health policy makers is to ascertain that all habitants of the nation have access to health care, including services of health promotion, prevention, assistance and rehabilitation (cf. MOH Argentina 2009).

The health care system in Argentina consists of three sectors: the public, the obligatory social security (Obras Sociales: OS) and the private sector (cf. Belló and Becerril-Montekio 2011: 97).

The public sector is integrated in the provincial and national structures and consists of public hospitals and primary care units providing health care to the uninsured and poor population, and hence to approximately 14.6 million people in 2008. This sector is financed by national, provincial and municipal resources (cf. Belló and Becerril-Montekio 2011: 98f.).

The social security sector is built up of the OS, which cover all workers of the formal economy and their families according to their occupational sector. Additionally, for every province there is an OS for all public officials. The National Institute for Social Services for the Retired/ the Program for Integrated Medical Assistance (INSSJyP – PAMI) provides coverage for all retired people and their spouses. Funding is provided by contributions of employers and employees as well as by provincial and national resources (cf. Belló and Becerril-Montekio 2011: 98f.).

Finally, the private sector includes professionals that provide independent services to certain patients with special OS or private hospitals with prepaid services as well as hospitals and clinics that have contracts with the OS. Recipients of the public sector are private insurance entities, the majority belonging to the so-called Medical Prepaid Companies, in Spanish Empresas de Medicina Prepaga (EMP) and are financed by payments made by individuals or companies (cf. Belló and Becerril-Montekio 2011: 99f.).

The OS and the EMP are obliged to participate in the Medical Program of the National MOH. The program covers about 95 % of all ambulatory consultants, as well as surgical and dental services, mental health care, palliative care and rehabilitation. However, the program does not apply to the provincial OS, private insurances not belonging to the EMP

and the public sector. The provincial OS offer mutual services in each province and the public sector offers the most basic services defined by the certain provincial ministries (cf. Belló and Becerril-Montekio 2011: 100f.).

About 60 % of the hospitals in Argentina are private, 38 % public and 2 % have contracts with the OS. In these hospitals, there are 4.1 beds per 1000 habitants, which is slightly higher than the average in countries belonging to the Organization for Economic Cooperation and Development (OECD). 44.4 % of the ambulatory services are public (cf. Belló and Becerril-Montekio 2011: 102f.).

Argentina is one of the countries with the highest amount of physicians. In 2005, there were 3.2 physicians per 1000 habitants. However, there are differences among the different provinces. In Buenos Aires, for example the number of physicians is seven times higher than in Misiones or Formosa. Per 1000 habitants there are 0.5 nurses, which is a very low number when compared to OECD countries, where there are 8.9 nurses per 1000 habitants (cf. Belló and Becerril-Montekio 2011: 102f.).

During the economic crisis in 2001, the private and public provision of pharmaceuticals and basic medical care was strongly impeded. In order to confront this situation of emergency the National Policy of Pharmaceuticals was approved in 2002, which consists of three parts: 1) Prescription of pharmaceuticals not with the brand name but with the name of the active pharmaceutical ingredient 2) Priority of providing essential pharmaceuticals in sectors that need them the most, basically primary care units and 3) Modification of the Medical Program of the National MOH (cf. Belló and Becerril-Montekio 2011: 103).

3.3.2 Overview of the health care system in Chile

The health care system in Chile consists of two sectors, the public and the private sector. The public sector covers about 80 % of the population. Of these, 70 % are covered by the National Health Fund (Fondo Nacional de Salud, FONASA), 3 % belong to the Military, and are covered by the Military Fund and 7 % are self-employed without contributions paid to FONASA. The private sector covers about 17.5 % of the population and is built up of Private Previsional Health Institutions (Instituciones de Salud Previsional, ISAPRE). The ISAPRE provides services for the private and public sector. The private sector includes 2.5 % of the population with high income that pays directly out of their pocket for receiving health care (cf. Becerril-Montekio, Reyes et al. 2011: 133ff.).

In 2005, the health care system was reformed with the creation of a plan for universal access for beneficiaries of the FONASA and the ISAPRE using public health care services (in Spanish: Plan de Acceso Universal con Garantías Explícitas; AUGE). This plan consists of four guarantees according to currently 80 health problems, including type 1 and type 2 diabetes:

1) Guarantee to access: Individuals are able to attain nearby health care services; 2) Guarantee to opportunity: There is a maximum waiting time for getting health care attendance depending on the disease and health status; 3) Guarantee to quality: Services are based on medical evidence and 4) Guarantee to coverage: The maximum copayment is 20 % of the obtained service and depending on the income of the beneficiary (cf. Bastías and Valdivia 2007: 53; MOH Chile 2017; MOH Chile 2007).

Every beneficiary of the FONASA can attend private health care providers by paying the difference between the fix price of the private provider and the fix contribution provided by the FONASA. Commonly people with middle income make use of this possibility. People with high income use the services of the ISAPRE without paying the difference, but rather pay the whole amount of the services out of pocket (cf. Becerril-Montekio, Reyes et al. 2011: 135ff.).

The ISAPRE offers diverse health planes, depending on the health status and the health risk of the insurees. However, by law the offers by the ISAPRE have to comply with at least the following conditions a) to cover preventive diagnostics b) to compensate for the loss of income of the insuree in case of illness c) to cover minimum interventions for pregnant women and children less than 6 years (cf. Becerril-Montekio, Reyes et al. 2011: 136).

In 2003, Chile had 2177 hospitals and primary care units, mostly public ones, 1.09 physicians per 1000 habitants and 10000 nurses. There were 2.3 hospital beds per 1000 habitants in 2009 (cf. Becerril-Montekio, Reyes et al. 2011: 137f.).

3.3.3 Overview of the health care system in Uruguay

The Health Care System in Uruguay has, alike the system in Chile two components, the public and the private sector (cf. Aran & Laca 2011: 265).

The public sector is funded by obligatory contributions of employers and employees as well as general taxes. These resources open out into the National Health Fund (FONASA) and the National Resources Fund (FNR). The FSR assures coverage in case of catastro-

phes. There are also other funds for special groups, for example the military and the police, which cover 5 % of the population. The households fund the private insurances and realize out-of-pocket payments (cf. Aran & Laca 2011: 266).

The primary providers of health care are the Institutions of Community Health Care (Asistencia Médica Colectiva, IAMC, especially "Unión de la Mutualidad del Uruguay", UMU), which are financed by the FONASA. These institutions are non-profit associations of health care professionals providing care to the social security beneficiaries, which represent 56 % of the Uruguayan population. The public sector also includes public hospitals and University hospitals funded by the FONASA. These hospitals are assigned to the Statutory Health Care (Services de Salud del Estado, ASSE). The public hospitals and University hospitals provide care to 37 % of the population, mainly the uninsured and people with low resources. The ASSE and the IAMC receive payments from the FONASA per capita depending on the risk of the insured population and the objectives of the MOH (cf. Aran and Laca 2011: 268ff).

The private sector consists of private, profit-oriented insurances, which cover about 2 % of the population. This sector also includes private hospitals, which are funded by out-of-pocket payments and payments by private insurances. The ASSE, the IAMC and some private insurance companies provide a package of services, the so-called Holistic Health Care Plan (Integral de Atención a la Salud, PIAS). Independent of the chosen provider, the services included are identical, consisting for example in services according to conventional ambulatory service, family medicine, surgery, and gynecology. The private sector offers diverse services depending on the certain contract (cf. Aran and Laca 2011: 269).

Uruguay has 105 hospitals, among them 56 public and 48 private ones and one University hospital. In 2008, there were 11132 hospital beds in Uruguay. 8.1 % of the occupied population is working as health professionals, among them are 20031 physicians and 10168 nurses. There are 3.9 physicians and 1.02 nurses per 1000 habitants (cf. Aran and Laca 2011: 270f.).

3.3.4 Health care systems in the Southern Cone of Latin America - Conclusion

Generally, the health care system in the Southern Cone of Latin America can be divided into the public, (the public and the social security sector in Argentina, respectively) and the private sector (Table 3).

The public sector provides health care to the poor and uninsured population. Besides, the public sector (in Argentina the social security sector) covers as well all workers of the formal economy and their families. The private sector covers individuals paying premiums to private insurances or realizing out-of-pocket payments.

Theoretically, all people in the Southern Cone of Latin America, insured and uninsured people can attend medical care for free. However, not all services are covered, especially for the uninsured, which account for 56.2 % of all people living in the Southern Cone of Latin America. This results in compulsory copayments, which could impede health care access for uninsured, but as well for the insured population (cf. Rubinstein, Irazola et al. 2015: 84).

Even though all three countries have a high amount of physicians per habitant, the distribution of these is not equally across cities and provinces. Additionally, compared to the amount of people using public providers, the supply of public providers may not be sufficient. Hence, waiting times for appointments, specialty referrals and waiting time at the health care facility due to a lack of health care providers could be an issue in this region. Adjacency to health care facilities could play a role in rural areas in the Southern Cone of Latin America (cf. Aday and Andersen 1981: 9).

Table 3: Health care systems in the Southern Cone of Latin America

	Argentina			Chile		Uruguay	
Sector	**Public**	**Social Security**	**Private**	**Public**	**Private**	**Public**	**Private**
Funding	National resources Provincial resources Municipal resources	Employers contributions Employees contributions National and provincial resources	Individuals Companies	National and municipal taxes Copayments Obligatory contributions	Additional obligatory contributions Copayments Out-of-pocket payments Companies	General taxes Employers contribution Employers contribution	Households
Recipient	MOH	National and provincial OS INSSJyP	EMP	FONASA	ISAPRE	FONASA	Private insurances Out-of pocket payments
Providers	Public hospitals Public primary care centers	Professionals providing independent services Private, OS contracted hospitals	Professionals providing independent services Private hospitals (with or without OS contract)	Public hospitals Public primary care centers	Private health care providers	ASSE IAMC	Private hospitals Private primary care units
Users	Uninsured population	Workers of the formal economy Public officials Retired people	Population able to pay	Primary people with low income	People with middle income (affiliated to ISAPRE) and high income	People with low income (ASSE) and working population (IAMC)	Population able to pay

Source: Own illustration based on Becerril-Montekio, Reyes et al. 2011, Aran and Laca 201, Belló and Becerril-Montekio 2011.

4. State of the Art – HRQoL among diabetics

This chapter provides information on current epidemiological research on HRQoL among diabetics when compared to non-diabetics and on factors determining HRQoL in people with diabetes as well as on the effect of barrier to health care on HRQoL.

A systematic literature research was conducted in order to obtain information on HRQoL among people with diabetes and when compared to people without diabetes as well as on the association on HRQoL and access to health care in diabetics and in people with other conditions. The online databases PubMed, Google Scholar and LILACS were searched for English, German and Spanish articles. The literature review was restricted on studies investigating determinants of HRQoL and were included if they implied a link between HRQoL as an outcome and keywords such as “diabetes”, “predictor” “determinant” “access to care” “care provider”, “realized care” and “insurance status”.

Search was conducted with synonyms and translation of the keywords in German and in Spanish. The number of items found by each search string can be found in the appendices.

Studies on children and adolescents, studies on gestational diabetes, validation of HRQoL instruments, clinical trials as well as studies published before 2005 were excluded. Scientific quality and the relevance for the aim of the thesis were essential criteria for inclusion. There was no restriction on certain HRQoL instruments used in the studies.

465 titles of studies were screened and in the end 56 studies were included that served as theoretical background for the conduction of the study at hand. Only one study was found that investigated the association of access to care on HRQoL in diabetics in particular. In order to provide broader evidence on the association of HRQoL and access to care, 12 studies were included that investigated this association in conditions other than diabetes (Figure 5).

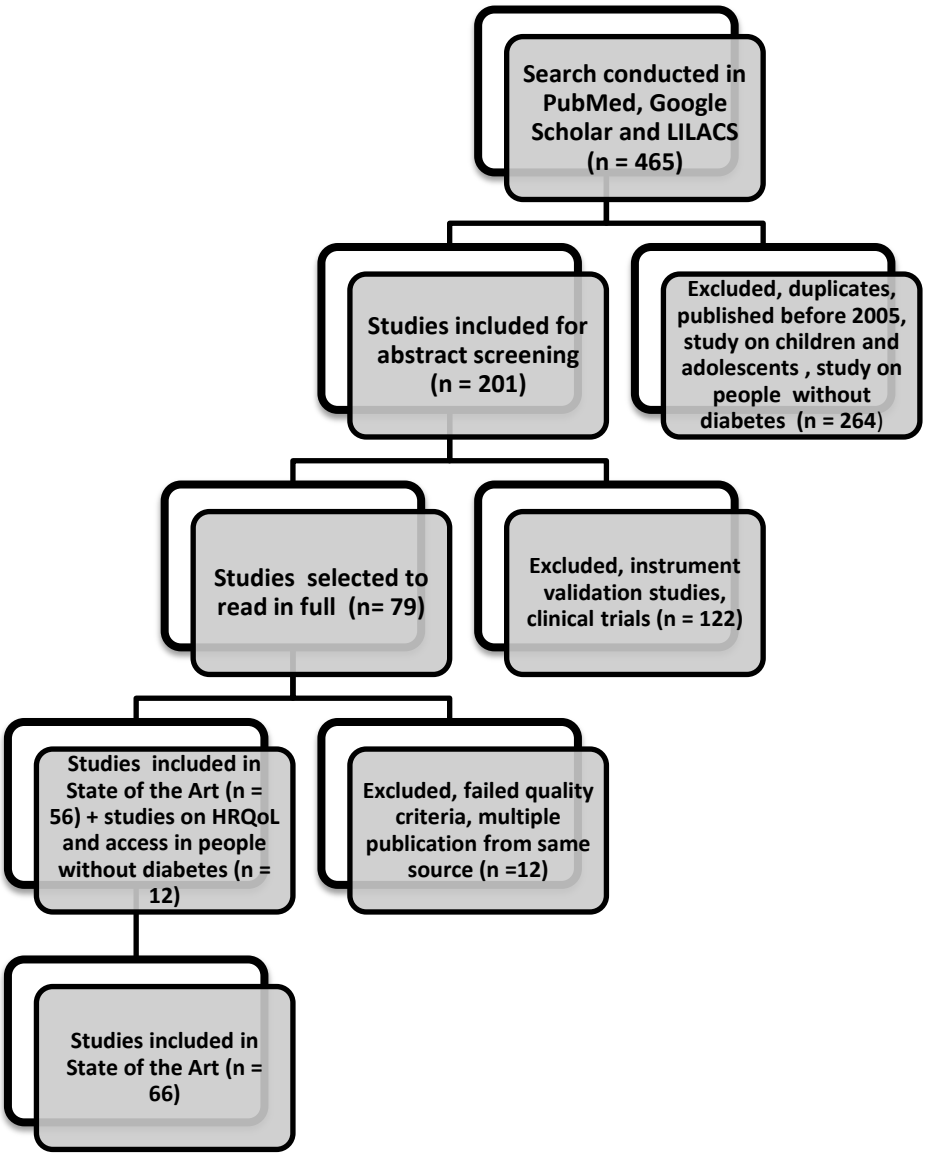

Figure 5: Flow diagram of literature research

The majority of the studies was conducted in high income countries and used the SF-36 or the SF-12 questionnaire, followed by the EQ-5D questionnaire in order to assess HRQoL. One study used both, a generic and a diabetes-specific HRQoL instrument (cf. Sundaram, Kavookjian et al. 2007). Few studies used a diabetes-specific instrument, mainly the ADDQoL (cf. Urzúa, Chirino et al. 2011). Two studies were conducted in Latin America, one in Chile (cf. Urzúa, Chirino et al. 2011) and one in Brazil (cf. Daniele, Bruin et al. 2013).

4.1 HRQoL in diabetics compared to non-diabetics

Current studies indicate that HRQoL of people with diabetes is worse compared to people without diabetes. From these studies, the majority used the SF-36 or the SF-12 instrument to assess HRQoL (cf. Bennett, Ouyang et al. 2008; Yan, Hong, et al. 2016; Schunk, Reitmeir et al. 2012, Bolarinwa, Ameen et al. 2016; Nielsen, Ovesen et al. 2016).

Bennett, Ouyang et al. (2008) investigated the association of obesity, fitness and HRQoL among diabetics and compared HRQoL between people with and without type 2 diabetes in the United States. Adjusted for race, age and sex, people with diabetes had significantly lower HRQOL for the SF-36 scores physical component summary (mean difference -2.99), role physical (mean difference -8.61), vitality (mean difference -5.48) and general health (mean difference -12.84) compared to people without diabetes (cf. Bennett, Ouyang et al. 2008: 4). These results are of importance when considering that decreases of more than 2 points on a scale from 0 – 100 can be considered as clinically meaningful (cf. Sprangers, de Regt et al. 2000: 899). The associations were mitigated by higher fitness rather than reduced obesity (cf. Bennett, Ouyang et al. 2008: 4f.). After adjustment for obesity and fitness, only the association between diabetes and general health remained significant. Concerning the mental component summary, there were no significant differences between diabetics and non-diabetics. This may be due to the sample size of only 217 participants which may have decreased power in order to detect this difference. The study only included participants with good diabetic control and less complicated disease status. Nevertheless, HRQoL detriments were found in diabetics when compared to non-diabetics. This indicates, that diabetes itself could represent an independent risk factor for decreasing HRQoL (cf. Bennett, Ouyang et al. 2008: 5f).

A study by Choi, Lee et al. (2011) investigated the association between diabetes and HRQoL in Korean adults and found that “diabetes was clearly associated with impaired

HRQoL compared with the non-diabetic population […]" (Choi, Lee et al. 2011: 587). After controlling for comorbidities, sociodemographic and psychosocial factors, HRQoL was still significantly lower in diabetes compared to participants without diabetes with mean scores EQ-5D: 0.94; EQ-VAS: 77.40 vs. EQ-5D: 0.87; EQ-VAS: 71.94 (cf. Choi, Lee et al. 2011: 587). However, diminution of HRQoL was smaller than those for other chronic conditions, such as chronic kidney disease and cardiovascular disease. Strength of the study was that data were derived from a nationwide cohort study with high response rates that represented the Korean population well. Uncontrolled diabetic complications were not taken into account, although they could have affected HRQoL in diabetic patients. However, comorbidities were assessed that incorporate macro- and microvascular complications in diabetics (cf. Choi, Lee et al. 2011: 591ff.).

In Germany, a study by Schunk, Reitmeir et al. (2012) assessed HRQoL with the SF-12 questionnaire in participants with and without type 2 diabetes using pooled data from five large population-based survey studies. There was a significant difference by 4.1 points for the physical component summary in diabetics compared to participants without diabetes. The association of diabetes and lower scores in the mental component summary was only significant in women. This could be due the exclusion of participants older than 75 years. There is evidence that the scores of the mental component summary decrease in people older than 74 years (cf. Schunk, Reitmeir et al 2012: 651). Although the study used standardized definitions of variables and an unselected large sample, it needs to be considered that the range of available variables was limited and hence the effect could not be controlled for the impact of comorbidities. Additionally, the included studies were not perfectly comparable regarding the way variables were assessed, for example one study used face-to-face interviews to assess HRQoL. Nevertheless, data was consistent among the studies (cf. Schunk, Reitmeir et al. 2012: 652).

Shah and Deshpande (2014) investigated HRQoL and its relationship with diabetes among people with coronary artery disease hospitalized at a cardiac intensive care unit in an Indian tertiary care hospital. HRQoL was assessed at one year follow up after full recovery was made. Results of this study showed, that people with diabetes reported more problems than participants without diabetes for all dimensions of the EQ-5D questionnaire except for self-care (mobility: 12.3% vs. 4.1%; usual activities: 56.9% vs. 41.3%; pain/discomfort: 50.8% vs. 17.8%; anxiety/depression: 33.8% vs.14.9%). The mean scores of the EQ-VAS and EQ-5D were lower in diabetic patients when compared to non-diabetic patients (mean

scores 0.75 +/- 0.15 vs. 0.83 +/-0.15 and 67.8 +/- 8.8 vs. 73.6 +/- 5.4) (cf. Shah and Deshpande 2014: 67). However, diabetes control and diabetes duration and other factors that could influence HRQoL in diabetics were not taken into account. Additionally, the diagnosis of diabetes was based on secondary data and a misclassification of undiagnosed diabetic cases cannot be precluded. Because the sample was constricted to patients with coronary artery disease, results are not generalizable to the general Indian population (cf. Shah and Deshpande 2014: 69).

One study from Denmark by Nielsen, Ovesen et al. (2016) investigated HRQoL in type 1 diabetics compared to the general population adjusted for age and sex and indicated that HRQoL was lower in people with type 1 diabetes compared to people without this disease. Mean differences ranged from -3.4 to -7.5 points in the certain scales of the SF-12. The association between lower HRQoL and type 1 diabetes was more prominent in older participants and in women (cf. Nielsen, Ovesen et al. 2016: 65f). A possible selection bias in the diabetic sample needs to be considered when interpreting the results. Participants were recruited in a hospital, where usually people get treated with higher educational levels and higher socioeconomic status. Furthermore, selection of participants was restricted to people with type 1 diabetes and results are not generalizable to type 2 diabetics (cf. Nielsen, Ovesen et al. 2016: 66).

In Bangladesh, Safita, Islam et al. (2016) investigated HRQoL in diabetics and non-diabetic controls as well as influencing factors of HRQoL in diabetics. Diabetics had lower HRQoL than non-diabetics (mean difference of the EQ-VAS: -11.5) and reported more often problems in all EQ-5D dimensions with largest effects observed for self-care (OR = 5.9; 95 %-CI: 2.9, 11.8) and mobility (OR = 4.5; 95 %-CI: 3.0, −6.6) (cf. Safita, Islam et al. 2016: 4ff.). According to Safita, Islam et al. (2016) the effect of diabetes on HRQoL in this sample was stronger compared to western populations. The authors hypothesize that this could be due to differences in the health care systems and high obligatory copayments and simultaneously economic burden in Bangladesh. However, the association between access to care and HRQoL was not investigated (cf. Safita, Islam et al. 2016: 6).

A study investigating HRQoL in participants with and without diabetes living in a rural area in China found out, that according to SF-36 scores, participants older than 60 years with diabetes had significantly lower physical component scores (mean 67.6 +/- 22.8 vs. 76.0 +/- 20.6; p-value: 0,015), higher physical (mean 47.7 +/- 50.3 vs. 70.2 +/- 45.8; p-value <

0.001) and emotional limitations (mean 76.9 +/- 42.5 vs. 89.7 +/- 30.5; p-value: 0.006) and more bodily pain (mean 79.7 +/- 18.4 vs. 84.9 +/- 16.8; p-value: 0.021) compared to participants without diabetes. Compared to participants without diabetes, residents aged between 40 – 59 years reported lower general health (mean 61.9 +/- 23.8 vs. 69.2 +/- 20.6; p-value: 0.029) and emotional limitations (mean 80.3 +/- 40.1 vs. 89.5 +/- 30.7; p-value: 0.035) (cf. Yan, Hong et al. 2016: 175). However, this association was not controlled for covariates and hence diabetes may not be the driving force in predicting HRQoL in the certain age groups (cf. Yan, Hong et al. 2016: 170). Additionally the sample consisted of induced migrants in a province of Northern China and is not generalizable to the general population (cf. Yan, Hong et al. 2016: 174).

Bolarinwa, Ameen et al. (2016) examined HRQoL among participants with diabetes, hypertension and both diseases in Nigeria. Lowest HRQoL was observed among participants with both diseases, while participants with diabetes had the lowest scores in the mental component summary compared to the other groups. Though, only slightly differences between the groups were observed (PCS-12: 47.2 vs. 46.1 vs. 45.6; MCS-12: 39.5 vs. 40.3 vs. 40.6) (cf. Bolarinwa, Ameen et al. 2016: 184). Overall, the authors conclude that HRQoL among diabetics is suboptimal in Nigeria when compared to the HRQoL of general western populations (cf. Bolarinwa, Ameen et al. 2016: 187).

A study conducted in Brazil examined associations of HRQoL, comorbidities, physical activity and diabetes. With regards to the SF-36 subscales, physical function (mean 54.0 +/- 31.6 vs. 85.8 +/- 17.4), pain (mean 55.2 +/- 30.8 vs. 74.9 +/- 25.0), physical limitation (mean 46.0 +/- 44.5 vs. 86.0 +/- 29.5) and general health (mean 45.0 +/- 22.8 vs. 61.3 +/- 17.6) were worse in patients with diabetic (cf. Daniele, Bruin et al. 2013: 47). However, these associations were not controlled for potential confounders of HRQoL (cf. Daniele, Bruin et al. 2013: 46).

Thommasen and Zhang (2006) found a negative association between diabetes and all HRQoL dimension of the SF-36 questionnaire in a population living in the United States, of which about half of the participants were of aboriginal descent. The highest difference was observed for role physical (mean 43.1 vs. 70.5) (cf. Thommasen and Zhang 2006: 275). The sample size included in total 675 participants and generalizability of the results, especially for sub-groups analyses should be acted with caution (cf. Thommasen and Zhang 2006: 277).

All studies used a generic HRQoL instrument and none of these studies included a diabetic specific questionnaire in order to assess HRQoL. Using a generic instrument allowed for direct comparison of participants with and without diabetes. However, generic instruments are less sensitive to diabetes-specific aspects of life and symptoms. Including both, a generic and a diabetes-specific instrument would have been the most appropriate way in assessing HRQoL in such studies (cf. Huang, Hwang et al. 2008: 450).

The studies mentioned above are not irreproachably comparable because different HRQoL instruments and methods to gather and analyze the data were used. Additionally the studies were conducted in different countries with different living conditions and healthcare systems and not all studies took important confounders of HRQoL into account. Furthermore, some studies examined only type 1 or type 2 diabetes and some did not distinguish between these two diseases. Additionally, some studies relied on self-reported data concerning diabetes (cf. Choi, Lee et al. 2011; Yan, Hong et al. 2016). Despite of these differences and some limitations of the studies, all studies found a link between lower HRQoL in diabetics when compared to people without diabetes. Hence, overall current research indicates that diabetes diminishes HRQoL across different populations.

4.2 Determinants of HRQoL in diabetics

Several factors negatively influence the HRQoL in people with diabetes and should be taken into account as important covariates when investigating diabetics HRQoL. In the following, the most important determinants of HRQoL in diabetics are described, which were derived from the review of the current literature.

4.2.1 Age as determinant of HRQoL in diabetics

Studies conducted in Greece (cf. Papazafiropoulou, Bakomitrou et al. 2015) and in Bangladesh (cf. Saleh, Ara et al. 2015) indicate that older age is associated with decreased diabetes-specific and general HRQoL with an OR of 0.94; 95 % CI: 0.91–1.98 in the Greek study (cf. Papazafiropoulou, Bakomitrou et al. 2015: 1) and B: -0.007+/- 0.002 in the study from Bangladesh (cf. Saleh, Ara et al. 2015: 7). However, in diabetics with comorbid chronic kidney disease, younger age was associated with lower HRQoL in the mental component summary of the SF-36 in multivariate analysis in an Australian study with B: 0.1; 95 % CI: 0.02 - 0.3 (cf. Zimbudzi, Lo et al. 2016: 7). A possible explanation would be that younger people could be more afraid of the impact of their disease in the future and

hence certain anxiety and uncertainty could diminish HRQoL (cf. Papazafiropoulou, Bakomitrou et al. 2015: 3) Additionally, "patients of advanced age as well as patients suffering from chronic conditions over a long period of time may become used to their health status and might downscale their expectations" (Kamradt, Krisam et al. 2017: 10).

According to Al Hayek, Robert et al. (2014) general HRQoL of people older than 50 years of age was significantly lower concerning the SF-36 scales physical functioning (63.2 +/- 19.2 vs. 45.5 +/- 17.5), role emotional (67.2 +/- 26.8 vs. 47.9 +/- 38.7) and energy (56.4 +/- 11.2 vs. 34.5 +/- 13.5) compared to people younger than 50 years. However, adjusted for sex, economic status, and diabetes-specific measures, age was not an independent risk factor for lower HRQoL (cf. Al Hayek, Robert et al. 2014: 224). This is in line with the results by Al-Sherhri (2014) and Kamradt, Krisam et al. (2017), where no significant association was found between age and diabetes-specific HRQoL (cf. Al-Shehri 2014: 227; Kamradt, Krisam et al 2017: 8)

Although the association between older age and lower HRQoL seemed to be well established in the past, findings in the current literature regarding this relationship are inconsistent and the effect of age on HRQoL seems to be rather weak (cf. Papazafiropoulou, Bakomitrou et al. 2015: 3).

4.2.2 Being female as determinant of HRQoL in diabetics

According to Al Hayek, Robert et al. (2014), being female was associated with significant (p-values < 0.001) decreases between 31.5 and 9.72 points in all SF-36 subscales of HRQoL except for role emotional. These decreases were controlled for age, economic status and disease-specific measures (cf. Al Hayek, Robert et al. 2014: 226). In line with these results, females had significantly lower diabetes-specific HRQoL than males in a study conducted in Malaysia with mean difference of -2.8 points on the ADDQoL, p-value: 0.036 (cf. Goh, Rusli et al. 2015: 1677) and in Chile with means of 30.16 +/- 8.99 vs. 34.12 +/- 9.50 on the ADDQoL (cf. Urzúa, Chirino et al. 2011: 316ff) as well as significantly lower HRQoL in the majority of EQ-5D dimensions in a study conducted in Saudi Arabia with mean EQ-5D scores: 0.58 +/- 0.23 vs 0.74 +/- 0.20 (cf. AL-Aboudi, Hassali et al. 2015: 1), and in studies conducted in Iran, were the OR of reporting problems in EQ-5D dimensions that ranged from 1.69 to 3.04 for the different scales (cf. Javanbakht, Abolhasani et al. 2012: 6) in Germany (r = -0.0494; p-value: 0.0261; cf. Kamradt, Krisam et al. 2017: 1), and in Bangladesh. In the studies from Bangladesh, the OR of reporting

problems in EQ-D5 dimensions ranged from 1.640 to 1.332 for the different scales (cf. Saleh, Ara et al. 2015: 6) and mean scores of the WHO quality of life questionnaire significantly decreased by -4.2 points in females when compared to males (cf. Safita, Islam et al. 2016: 5). In all studies, the effect was controlled for sociodemographic and socioeconomic factors, as well as for comorbidities and disease-specific measures, except or the studies assessing diabetes-specific HRQoL. According to AL-Aboudi, Hassali et al. (2015), it seems that the effect of gender on HRQoL is stronger in Arabic countries compared to Western populations. This could be due to differences according lifestyle behavior and the role of the women in the different countries (cf. AL-Aboudi, Hassali et al. 2015: 4). However, findings on the association of being female and having lower HRQoL compared to men were consistent in all studies. Hence, gender disparities among diabetics need taken into account when assessing HRQoL.

4.2.3 Diabetes duration as determinant of HRQoL

Al Hayek, Robert et al. (2014) did not found a significant association between diabetes duration and most SF-36 scales (p-values > 0.05) (cf. Al Hayek, Robert et al. 2014: 226). This is consistent with finding from Bourdel-Marchasson, Druet et al. (2013) and Al-Aboudi, Hassali et al. (2015) who found no effect of diabetes duration on HRQoL in adjusted analyses (cf. Bourdel-Marchasson, Druet et al. 2013: 231; AL-Aboudi, Hassali et al. 2015: 3ff.)

However, due to the sample sizes, which ranged between 75 and 283 participants in the certain studies, no sufficient statistical power could have been reached in order to detect significant differences (cf. AL-Aboudi, Hassali et al. 2015: 5; Bourdel-Marchasson, Druet et al. 2013: 233)

Among women, diabetes duration of more than 10 years decreased overall quality of life by almost 4 point on the HRQoL questionnaire of the WHO in a study conducted in Iran when compared to women living less than 10 years with the disease (p-value: 0.023). This association was controlled for age, economic status and comorbidities. The authors conclude that the association between lower HRQoL and higher diabetes duration is due to the rise of the incidence of diabetes complications rises with increased duration (cf. Didarloo and Alizadeh 2016: 5f.)

Participants with longer diabetes duration were more likely to report ‘‘some or extreme problems’’ in most dimensions in HRQoL measured with the EQ-5D in another study con-

ducted in Iran. OR ranged from 1.5 and 2.1 for diabetics with disease duration of more than 10 years when compared to diabetics who lived less than 5 years with the diagnosis. However, this association was not controlled for diabetic complications (cf. Javanbakht, Abolhasani et al. 2012: 7f.)

Thommasen and Zhang (2006) also found associations between longer diabetes duration and decreased HRQoL for physical functioning, role physical and general health controlled for age. Decreases of the mean ranged from 9.9 to 16.6 points on the SF-36 comparing people with less than 4 years to people with more than 9 years of duration (cf. Thommasen and Zhang 2006: 4). According to a study by Safita, Islam et al. (2016) diabetes duration of more than 10 years was one of the driving forces in predicting lower HRQoL in diabetics in Bangladesh with decreases of 6.3 points on the EQ-VAS score (p-value < 0.001) (cf. Safita, Islam et al. 2016: 5).

Despite some limitations of the studies, the results indicate that longer diabetes duration determines lower HRQoL among diabetics.

4.2.4 Complications and comorbidities as determinants of HRQoL in diabetics

In a study conducted in Canada, comorbidities, especially stroke, had the strongest effect on HRQoL as measured with the Health Utility Index, taking social and environmental factors into account (B: -0.11; 95% CI: –0.17, −0.06, considering B > 0.03 as a clinically meaningful effect) (cf. Maddigan, Feeny et al. 2006: 1650ff). This is in contrast to a study from Bangladesh, where complications (except for diabetic food ulcer) and comorbidities were not associated with poor HRQoL (p-values > 0.05). However, when interpreting this result, it needs to be taken into account, that comorbidities and complications were self-reported and various different conditions were summarized into few categories. Hence, the effect of certain conditions could have been disguised (cf. Safita, Islam et al. 2016: 5f.).

Less studies have been conducted on certain microvascular complications such as retinopathy (cf. Alcubierre, Rubinat et al. 2014), and on lower limp amputation as a result of diabetic foot ulcers (cf. Abdelgadir, Shebeika et al. 2009) and its association with HRQoL. In absence of other major complications, retinopathy was found to be significantly associated with poorer HRQoL when compared to diabetics without this complication with an average weighted impact score of −0.35 (95% CI:0.78-0.06) compared to −0.88 (95% CI:1.76-0.38) (cf. Alcubierre, Rubinat et al. 2014: 6). Lower limp amputation was associated with poor HRQoL in Sudanese diabetics, with highest decreases observed for the SF-12 dimen-

sion role physical (mean 11.9+/- 18.5 vs. 74.0 +/- 29.4) (cf. Abdelgadir, Shebeika et al. 2009: 47).

A study conducted in the United States examined determinants of HRQoL in diabetics with comorbid chronic kidney disease. After adjustment for sociodemographic, disease-specific measures and cardiovascular disease, chronic kidney disease was not associated with significantly lower HRQoL (p-value > 0.05), suggesting that cardiovascular complications account for impaired HRQoL rather than chronic kidney disease (cf. Campbell, Huang et al. 2013: 6). However, in a study conducted by Shamshirgaran, Ataei et al. (2016) renal disease was the most important predictor in overall HRQoL, taking into account cardiovascular diseases as well as other comorbidities and diabetic complications in an Iranian sample. Renal disease decreased the mean WHOQOL score by 9.829 points in adjusted analysis (p-value 0.004). (cf. Shamshirgaran, Ataei et al. 2016: 248).

A strong association between CVD and poor HRQoL measured with the 15D instrument among diabetics was shown by a study by Tan, Ng et al. (2014) were the presence of CVD was associated with an OR for impaired HRQoL of 11.746 (95% CI 4.898–28.167) (cf. Tan, Ng et al. 2014: 209).

According to a study conducted in Singapore, diabetics with macrovascular complications had "significantly lower EQ-5D index (-0.062), EQ-VAS (-9.2), SF-12 PCS (-5.0), and MCS (-2.1) after controlling for differences in sociodemographics, smoking status, diabetes severity, and comorbidities (all P < 0.001)" when compared to diabetics without these complications (cf. Fu, Qiu et al. 2011: 825).

This result is consistent with results from reviews conducted for Scandinavia and Iran. A review of research conducted in the Nordic countries found that macrovascular diseases, especially coronary heart disease, were the most important predictors according HRQoL among diabetics (cf. Wändell 2005). Similarly, a review about research conducted in Iran showed that comorbidities and complications were associated with lower HRQoL in diabetics in all studies included (cf. Kiadaliri, Najafi et al. 2013).

O'Shea, Teeling et al. (2015) found, that HRQoL as measured with the EQ-5D and adjusted for age and sex, declined with a higher number of comorbidities in an outpatient population in Ireland (B: -0,16; SE: 0.05; p-value 0.001) (cf. O'Shea, Teeling et al. 2015: 627).

Neuropathy was found to decrease HRQoL among type 1 and type 2 diabetics in a study conducted in Norway. OR ranged from 4.61 (95 % CI: 1.05 - 20.21) and 27.13 (95 % CI: 3.13 -235.07) for reporting problems in certain EQ-5D dimensions (cf. Solli, Stavem et al. 2010: 5).

Current literature provides a broad body of evidence on the detrimental effect of comorbidities and diabetic complications on HRQoL among diabetics.

4.2.5 Diabetic control as determinant of HRQoL

Diabetic control is commonly measured with the HbA1C. According to Al-Shehri (2014) diabetes-specific HRQoL is worse in poorly controlled diabetics (HbA1C > 11 %) compared to diabetics with excellent control (HbA1C < 7 %) with mean ADDQoL scores of −1.57 + 1.68 compared to −3.98 + 2.73 (cf. Al-Shehri 2014: 228). In a study by Vidal-Peracho, Lucha-López et al. (2014) high HbA1C values were one of the main predictors of HRQoL in adjusted analysis (summary index score of the COOP WONCA, a functional, subjective health assessment questionnaire: 16.8 +/- 3 vs. 20.2 +/- 4.3) (cf. Vidal-Peracho, Lucha-López et al. 2014: 10)

Co, Tan et al. (2015) found a relationship between decreased diabetes-specific HRQoL and increasing HbA1C among diabetics from Singapore. However, when adjusted for psychological distress, the association between these two variables was no longer significant (p-value 0.197) (cf. Co, Tan et al. 2015: 381).

A study conducted in France found a weak association between HbA1c values ranging from 8.1–10.0% with decreases by 1.88 points in the mental component of the SF-12 when compared to values below or equal 6.5 % (p-value: 0.01). No significant associations were found for the physical component (p-value: 0.4368).. However, values above 10 % were associated with significant decreases of almost 7 points for the mental (p-value < 0.001) and almost 4 points (p-value: 0.009) for the physical component in adjusted analysis (cf. Bourdel-Marchasson, Druet et al. 2013: 229f.).

According to studies conducted in Germany (Kamradt, Krisam et al 2017) and the USA (Sundaram, Kavookjian et al. 2007), no association was found between HRQoL and HbA1C levels (p-values 0.35 and 0.294, respectively) (cf. Sundaram, Kavookjian et al. 2007: 174, Kamradt, Krisam et al. 2017: 8).

Findings of the effect of diabetic control on HRQoL are inconsistent. However, HbA1C values of above 10 % seem to decrease HRQoL sustainably. Additionally, poorly controlled diabetes leads to complications, which also impact HRQoL (see 4.2.4).

4.2.6 Body Mass Index (BMI) as determinant of HRQoL in diabetics

Current research found significant associations between increased BMI and decreased diabetes-specific and general HRQoL among people with diabetes in Germany (r = -0.0047; p-value: 0.045) (cf. Kamradt, Krisam et al. 2017: 1) in the United States (ß: -0.164; p-value 0.007 for the PCS-12) (cf. Sundaram, Kavookjian et al. 2007: 174) and in Spain (summary index score of COOP/WONCA: 16 +/- 1.7 for BMI: 25.0-26.9 vs. 19.6 +/- 4.6 for BMI: ⩾ 50) (cf. Vidal-Peracho, Lucha-López et al. 2014: 10). This association was also found in diabetics with comorbid chronic kidney disease (B: -0.8; 95 % CI: -3.8,2.2 for the PCS-12 and B:-1.9; 95 % CI: -4.9,1.0 for the MCS-12 comparing people with a BMI of 18.5 – 24.9 to a BMI of > 30; p-value < 0.05) (cf. Zimbudzi, Lo et al. 2016: 7). The results of Kamradt, Krisam et al. (2017) and Sundaram, Kavookjian et al. (2007) were controlled for sociodemographic factors and other chronic conditions and complications. Additionally, Sundaram, Kavookjian et al. (2007) controlled for insurance status. Results from the research show, that BMI should be taken into account as one determinant of HRQoL, although overall the effect appears to be rather weak when compared to other determinants, for example comorbidities and complications (see 4.2.4). Some studies used self-reported data for BMI, which could have biased the results (cf. Maddigan, Feeny et al. 2006: 1654).

4.2.7 Physical activity as determinant of HRQoL in diabetics

Compared to physically active people with diabetes, sedentary diabetics had worse HRQoL in all SF-36 dimensions in a study conducted in Brazil. Highest differences were observed for functional capacity (40.5 +/-3.5 vs. 69.6 +/-4.3). In analysis adjusted for age, BMI and gender, only the functional capacity domain remained significant (p-value < 0.001). In order to assess physical activity, the International Physical Activity Questionnaire (IPAQ) was used (cf. Daniele, Bruin et al. 2013: 44ff.).

A study conducted in Canada showed that active people had higher HRQoL scores as measured with the Health Utility Index compared to physical inactive people (B: 0.06, considering B > 0.03 as clinically meaningful), adjusted for several covariates, including socioeconomic and sociodemographic factors and comorbidities. The levels of physical ac-

tivity (active, moderate and inactive) were derived from 47 questions regarding activity participation (cf. Maddigan, Feeny et al. 2006: 1650ff.).

A study conducted in Germany examined the association between physical activity (measured with the Freiburger Questionnaire for Physical Activity; FFkA) and HRQoL (measured with the SF-36) and found that physical activity was "a significant predictor of physical composite summary (B = 0.09; β = 0.11; P , 0.05), physical function (B = 0.10; β = 0.13; P < 0.01), mental composite summary (B = 0.13; β = 0.20; P < 0.001), vitality (B = 0.15; β = 0.24; P < 0.001), and psychological well-being (B = 0.11; β = 0.18; P < 0.01) when controlling for age, sex, and BMI" (Eckert 2012: 303). However, the authors admit that the selected questionnaire for measuring physical activity could have been inappropriate for the sample and misclassification of activity levels could have occurred (cf. Eckert 2012: 308).

Thiel, Al Sayah et al. (2017) examined the association of weekly moderate-vigorous physical activity (MVPA) as measured with the Godin Leisure Time Physical Activity Questionnaire, and HRQL as measured with the SF-12 and EQ-5D. People with 150 minutes of MVPA per week had higher HRQoL scores compared to those with less than 150 minutes of MVPA per week. According to Thiel, Al Sayah et al. (2017), "those who met physical activity recommendations reported higher scores on physical functioning (b=9.58; p<0.001); role-physical (b=8.87; p=0.001); bodily pain (b=5.12; p=0.001); general health (b=6.66; p<0.001); vitality (b=9.05; p<0.001); social functioning (b=3.32; p=0.040); and role-emotional (b=3.08; p=0.010); physical component summary (b=3.31; p<0.001); mental component summary (b=1.43; p=0.001) and EQ-5D-5L index score (b=0.022; p=0.005) compared to those not meeting recommendations" (Thiel, Al Sayah et al. 2017: 58).

Although the studies are not perfectly comparable because different instrument have been used to measure physical activity, the findings of the current research indicate that low physical activity is an important predictor of lower HRQoL among diabetics.

4.2.8 Insulin therapy as determinant of HRQoL in diabetics

A study conducted in Germany revealed that treatment type was significantly associated with lower SF-12 scores regarding the physical component summary with lowest values for insulin treatment (p-value 0.006). There was a decrease of the mean PCS-score by 4.44 points compared to oral treatment and 4.41 points compared to combination therapy. According to the mental component summary, women undergoing oral therapy and combina-

tion of insulin and oral medication treatment had lower scores compared to men with mean difference of –4.25 for oral therapy and of –6.99 for combination therapy, respectively (p-value: 0.012) (cf. Schunk, Reitmeir et al. 2015: 206ff).

According to Sepúlveda, Poínhos et al. (2015) insulin therapy had detrimental effects of lower physical functioning (mean difference -11.3 SD: 27.3; p-value 0.016) and vitality (mean difference -9.4 SD: 23.6; p-value 0.012) compared to participants without insulin therapy adjusted for age (cf. Sepúlveda, Poínhos et al. 2015: 223).

In the study by Al Hayek, Robert et al. (2014) participants treated with combined therapy of insulin and oral medication indicated better HRQoL compared to participants with insulin therapy alone. However, in multivariate analysis treatment type and HRQoL were not significantly associated with each other (p-values < 0.05) (cf. Al Hayek, Robert et al. 2014:227).

This is consistent with finding from Bourdel-Marchasson, Druet et al. (2013) and AL-Aboudi, Hassali et al. (2015) where adjusted analyses revealed no significant differences in HRQoL according treatment type (p-values < 0.05). However, these results could be due to insufficient statistical power (cf. Bourdel-Marchasson, Druet et al. 2013: 232; AL-Aboudi, Hassali et al. 2015: 5).

Compared to people without insulin use, people with insulin treatment had lower physical functioning scores (means: 70.0 vs. 66.4), more bodily pain (means: 56.9 vs. 48.2), as well as poorer general health (means: 55.0 vs. 45.3) and social functioning scores (means: 72.2 vs. 62.5) in a study conducted in the United States. Though, no adjustment for comorbidities or diabetic complications was performed (cf. Thommasen and Zhang 2006: 275).

Current research suggests that insulin therapy negatively affects HRQoL among diabetics when compared to diabetics without insulin therapy. Combination therapy seems to increase HRQoL when compared to insulin treatment alone.

4.2.9 Socioeconomic status as determinant of HRQoL in diabetics

Socioeconomic status commonly consists of income, educational level and occupational status (cf. Al Hayek, Robert et al. 2014: 221). Compared to participants with low income, participants with middle and high income had significantly higher HRQoL in all subscales in a study by Al Hayek, Robert et al. (2014) conducted in Saudi Arabia. The sex, age and disease-specific adjusted differences showed significant and clinically relevant findings for

all SF-36 scales except for energy with increases of HRQoL between 3.2 and 16.4 points in people with middle and high socioeconomic status compared to people with low economic status (all p-values < 0.05). However, educational level was not associated with significant differences in adjusted analysis (p-value > 0.05) (cf. Al Hayek, Robert et al. 2014: 224ff.). Consistent with this finding, Al-Sherhi (2014) found no association between HRQoL measured with a disease-specific instrument and educational level in Saudi Arabian diabetics (p-value: 0.718) (cf. Al-Shehri 2014: 227).

Though, Didarloo and Alizadeh (2016) found that educational level and household income independently determined HRQoL among women in Iran. According overall HRQoL high educational level was associated with an increase of 4.790 points and household income with an increase of 14.044 points for the HRQoL questionnaire of the WHO (all p-values < 0.001) (cf. Didarloo and Alizadeh 2016: 5). This is in line with other studies conducted in Iran, were unemployment and low educational level decreased HRQoL significantly (all p-values < 0.001) (cf. Javanbakht, Abolhasani et al. 2012; Shamshirgaran, Ataei et al. 2016).

Low educational level of nine years or less also showed a decrease in general HRQoL in diabetics in Germany (r = -0.0609; p-value 0.0006) (cf. Kamradt, Krisam et al. 2017: 1).

A study conducted in France demonstrated that low income was an independent risk factor for poor HRQoL in the mental and physical component as measured with the SF-12 when compared to people with middle and high income with decreases between -11.31 and -3.51 points for the certain dimensions of the SF-12 (all p-values < 0.001) (cf. Bourdel-Marchasson, Druet et al. 2013: 229). Unemployment was associated with a decrease of almost 9 points in the EQ-VAS scale in a study conducted in Iran (p-value < 0.001) (cf. Nejhad, Vardanjani et al. 2013: 189).

A positive association was found for increasing HRQoL and having the highest education level (ß = +6.4; 95 % CI 1.5 - 11.4; p-value 0.0113), as well as for belonging to the highest income quartile (ß = +5.75 95 % CI: 1.3 - 10.1; p-value: 0.0113) in a study conducted in Bangladesh. Hence, low socioeconomic status was associated with lower HRQoL. The authors hypothesize that “it might be possible that the high out of pockets costs for diabetes medications and time resources spend for the management of the disease put individuals under financial pressure, resulting in psychologic and physical stress that translates into lower perceived HRQL” (Safita, Islam et al. 2016: 6).

Findings from the current literature are consistent concerning the negative impact of socio-economic status on HRQoL among diabetics. However, results according the effect of educational level are inconsistent, indicating that income could be a more important predictor of HRQoL than education among diabetics.

4.2.10 Other determinants of HRQoL in diabetics

Less studies were conducted for other factors that indicate to determine HRQoL in diabetic patients, for example self-management behavior, social support and disease acceptance (cf. Misra and Lager 2008), sleep (cf. Chasens, Sereika et al. 2014), diabetes-related distress (cf. Chew, Mohd-Sidik et al. 2015), ethnicity (cf. Laiteerapong, Karter et al. 2013), personality traits (cf. Imayama, Plotnikoff et al. 2011), spiritual well-being (cf. Jafari, Farajzadegan et al. 2014), diabetes-related hospitalization in the past year (cf. Javanbakht, Abolhasani et al. 2012) and health literacy (Al Sayah, Qiu et al. 2016). These determinants represent possible confounders of HRQoL in diabetics when not taking into account in predicting HRQoL.

4.3 HRQoL and its association with access to health care

The relationship between HRQoL and access to health care was rarely investigated among diabetics. Sundaram, Kavookjian et al. (2007) found no association between health insurance status, namely private, governmental and not insured and generic and diabetes-specific HRQoL among diabetics in the United States with p-values above 0.05 (cf. Sundaram, Kavookjian et al. 2007: 174). However, the authors did not discuss possible explanations for this finding.

In a study by Fu, Qui et al. from Singapore (2011) diabetic participants were more often uninsured (10.2 % vs. 18.2 %) less often private insured (21.6 % vs. 30.2 %) and had lower HRQoL (mean EQ-VAS score 66.6 vs. 80.8) compared to people without diabetes. Though, associations between these factors were not further investigated (cf. Fu, Qiu et al. 2011: 829).

Maddigon, Feeny et al. (2006) found a significant and clinically meaningful decrease of B:-0.08 in HRQoL as measured with the Health Utility Index for diabetics with self-perceived unmet healthcare needs. Self-perceived unmet healthcare need was one important predictors of HRQoL among diabetics in this study, considering $B > 0.03$ as clini-

cally meaningful. However, the study used imputed data and this may limit the generalizability of the results (cf. Maddigan, Feeny et al. 2006: 1653ff.).

Only one study examined the effect of health care access measures on HRQoL among diabetics in particular. Konerding, Bowen et al. (2017) examined the effects of travel distance and travel time to the primary diabetes care provider and waiting time in the provider´s practice on HRQoL. Data from participants with type 2 diabetes were analyzed from six regions in Europe, namely England, Finland, Germany, Greece, the Netherlands, and Spain. Associations of 4 EQ-5D indices with travel distance, travel time, and waiting time in the practice were investigated and adjusted for region, gender, age, educational level, diabetes duration, thoroughness of communication between patient and provider. EQ-5D-3L indices decreased with increasing travel and waiting time. Decreases ranged from -0.0007 (0.095) and -0.0015 (0.107) points for the EQ-5D (all p-values < 0.001) (cf. Konerding, Bowen et al. 2017: 20f.). The samples were very different and the fact that no interactions between region and other variables were determined could be due to the rather small sample sizes of the certain regions. Additionally, the unstandardized regression coefficients concerning travel and waiting time were very small. However, when considering that the EQ-5D ranged between 0 and 1 and travel and waiting time were measured in minutes, the effect seems to be considerable (cf. Konerding, Bowen et al. 2017: 22f).

The studies mentioned above indicate that impaired access to care could negatively influence HRQoL in diabetics. Studies conducted on this association in conditions other than diabetes provide further evidence on this relationship. In the following these studies are briefly described. Some studies focused on self-reported perceptions on health care access, (cf. Seid, Varni et al. 2006; Baran, Mulcahy et al. 2014) while others examined health insurance status as measure for access to care (cf. Alghnam, Schneider et al. 2016; Bharmal and Thomas 2005).

In a two-year prospective cohort study, Seid et al. (2006) found a significant decrease in HRQoL in children reported by parents and children with unmet healthcare needs. This decrease remained clinically relevant even after adjustment for baseline HRQoL, demographics, chronic health condition status and the presence of a regular physician. Self-reported forgone care and problems getting care were associated with significant decreases of 3.5 and 4.5 points for parent proxy-report Pediatric Quality of Life Inventory (PedsQL) and with decreases of 3.2 and 4.4 points for child self-report PedsQL, respectively (all p-

values < 0.001) (cf. Seid, Varni et al. 2006: 357f). However, the authors admit that selection bias could have been occurred. Families who dropped out of the study over time, might be systematically different compared to families that stayed in the study concerning factors, that were not controlled for (cf. Seid, Varni et al. 2006: 359).

Results from Seid, Varni et al. (2006) are consistent with findings reported among the HRQoL of people with HIV/AIDS experiencing barriers to care in studies by Baran, Mulcahy et al. (2014). The authors found that HRQoL as measured with the AIDS Clinical Trials Group (ACTG) Health Status Assessment instrument was significantly lower for people experiencing barriers to care as measured with the Barrier to Care Scale (BACS) ($p < 0.0001$). However, no information on effect size is given (cf. Baran, Mulcahy et al. 2014).

Hoffmann et al. (2008) examined barriers to realized health care such as ‘‘long waiting time in provider’s office,’’ ‘‘someone had to miss work,’’ ‘‘cost of care too much‘‘, ‘‘long wait for an appointment’’ and ‘‘lack of transportation’’ and their association with HRQoL in adult asthmatics. Met medical care needs and self-reported access to local health care services were significantly associated with higher HRQoL as measured with the HRQoL questionnaire of the WHO in this sample ($r = 0.59$; p-value < 0.001) (cf. Hoffmann, Rohrer et al. 2008: 174ff.).

A longitudinal study using pooled data from the Medical Expenditure Panel Survey of the years 2000 to 2006 examined HRQoL among participants with or without injuries and their insurance status taking into account sociodemographic and socioeconomic factors as well as comorbidities. Public insured injured individuals had lower PCS-12 (-8.5 points), MCS-12 (-4.9 points) EQ-5D (-0.25 points) and VAS scores (-11.4 points) than injured individuals with private insurance. Additionally, uninsured individuals without injuries had lower EQ-5D (-0.12 points), VAS (-7.2 points), PCS-12 (-2.6 points) and MCS-12 (-4.1 points) than privately insured controls (all p-value < 0.05) (cf. Alghnam, Schneider et al. 2016: 990f.). The relationship between insurance status and HRQoL was also seen for the whole sample using data from the year 2000 of the Medical Expenditure Panel Survey data. Adjusted analysis revealed lower mean PCS-12 (-5.8 points) and MCS-12 scores (-1.1) for uninsured people when compared to insured participants (all p-value <0.05) (cf. Bharmal and Thomas 2005: 643ff.).

A systematic review by Maliski et al. (2011) explored links between HRQoL and the access to care for men with prostate cancer. The studies included in the review mainly examined insurance status, education, income and race/ethnicity disparities as related factors to health care access. They concluded that "socioeconomic factors contribute to accessibility and HRQoL, but not consistently, suggesting that there is still much work to be done in identifying factors and relationships that connect access to care and HRQoL for underserved men with prostate cancer" (Maliski, Connor et al. 2011: 267). In the studies included in the review, the realized access to care was often not taken into account as a factor related to health care access and could explain the inconsistencies in the findings (Maliski, Connor et al. 2011: 275).

4.4 Conclusion of the literature review and rationale for the study

There is sustainable evidence that HRQoL is lower in people with diabetes when compared to people without diabetes. However, less evidence is available on this association in the Southern Cone of Latin America. The association between diabetes and poor HRQoL could not exclusively be explained by the common determinants presented in the current literature. Impaired access to health care could also contribute to this association. Newsworthy research indicates a link between impaired access to care and lower HRQoL among different populations and in people with different diseases. Though, less evidence is available on this association in diabetic patients, especially in low-and middle income countries.

Diabetes is a threatening condition and associated with various complications and good health care access is required in order to be able to guarantee preferable health outcomes (Rhee, Cook et al. 2005, Zhang, Bullard et al. 2012). When access to care is impaired in these patients, this could lead to considerable decreases in HRQoL. Hence, the aim of this thesis was to determine the association between HRQoL and access to care among diabetics and compare this association to non-diabetics living in the Southern Cone of Latin America. In the following, research questions and hypotheses are described in order to comply with this aim.

5. Research questions and hypotheses

The study aimed to answer five major research questions. The first questions focused solely on patients with diabetes:

- *Research Question 1: Is limited access to health care associated with lower HRQoL in diabetics in the Southern Cone of Latin America?*
- Hypothesis 1: Limited access to care is associated with lower HRQoL in diabetics in the Southern Cone of Latin America.

For this question, the specific research questions and hypotheses were:

  - *Specific research question 1.1: Are barriers to potential access associated with lower HRQoL among diabetics?*
  - Specific hypothesis 1.1: Having barriers to potential access is associated with lower HRQoL among diabetics.
  - *Specific research question 1.2: Are barriers to realized health care access associated with lower HRQoL among diabetics?*
  - Specific hypothesis 1.2: Having barriers to realized health care access is associated with lower HRQoL among diabetics.
  - *Specific research question 1.3: Are barriers to realized and potential access together associated with lower HRQoL among diabetics?*
  - Specific hypothesis 1.3: Having barriers to potential and realized access together are associated with lower HRQoL among diabetics.

Additionally, self-perceived barriers to realized health care access were determined among diabetics using the following questions:

- *Research question 2: What factors are mentioned by diabetic people as barriers to realized health care access?*
- *Research question 2.1: How are these factors distributed?*

The two research questions above are of descriptive nature and answer possibilities were preset by the questionnaire used in CESCAS I without certain hypothesis *a priori* according the distribution of the mentioned factors.

The following research question focused on the association of HRQoL and health care access among people with diabetes when compared to people without diabetes. The following research questions and hypotheses were determined:

- *Research question 3: Is limited health care access associated with lower HRQoL among diabetics when compared to people without diabetes in the Southern Cone of Latin America?*
- Hypothesis 3: Limited health care access is associated with lower HRQoL among diabetics when compared to people without diabetes.

Specific research questions and hypotheses for research question and hypothesis 4 included:

  - *Specific research question 3.1: Are barriers to potential access associated with lower HRQoL in people with diabetes when compared to people without diabetes?*
  - Specific hypothesis 3.1: Barriers to potential access are associated with lower HRQoL in diabetics when compared to people without diabetes.
  - *Specific research question 3.2: Are barriers to realized health care access associated with lower HRQoL in people with diabetes when compared to people without diabetes.*
  - Specific hypothesis 3.2: Barriers to realized health care access is associated with lower HRQoL in people with diabetes when compared to people without diabetes.
  - *Specific research question 3.3: Are barriers to potential and realized access together associated with lower HRQoL in people without diabetes when compared to people without diabetes?*
  - Specific hypothesis 3.3: Having barriers to potential and realized access together are associated with lower HRQoL in people with diabetes when compared in people without diabetes.
  - *Research question 3.4: Is there an interacting effect of diabetes and impeded access to care in predicting lower HRQoL*?
  - Hypothesis 3.4: There is an interacting effect of diabetes and impeded access to care in predicting lower HRQoL.

6. Methods

6.1 Study design and sample

Research was conducted in the South American Centre of Excellence in Cardiovascular Health (CESCAS), which belongs to the Institute for Clinical Effectives and Health Policy (IECS) located in Buenos Aires, Argentina. The main study of CESCAS is the 'Study of Cardiovascular Disease and Risk Factors detection and follow-up' with data on a population sample of 7524 adults aged 35-74 years in 4 mid-sized cities, two located in Argentina (Bariloche and Marcos Paz), one in Chile (Temuco) and one in Uruguay (Canelones). Baseline data was obtained between February 2010 and December 2011. Follow-up data was collected twice since the start of the study. The aims of the CESCAS study are to: 1) estimate the prevalence and the trend of major CVD and risk factors in the Southern Cone of Latin America, 2) determine the association between CVD risk factors and CVD incidence; 3) investigate the burden of CVD (cf. Rubinstein, Irazola et al. 2011: 2).

The study at hand is a cross-sectional analysis of the association between HRQoL and health care access of data derived from the baseline data of CESCAS I Study.

Sampling of the CESCAS I study was stratified following four stages in order to gain a representative sample from each location. In the first stage, randomly sampling census radii from each location were conducted with stratification by socio-economic level. The second stage consisted of a random selection of a number of blocks commensurate with the radius size. In the third stage, households from each block were sampled systematically. If selected houses were not permanent residences (for example offices and weekend residences), these houses were replaced with other houses. All members aged between 35 and 74 years were recorded in the selected households. The fourth stage consisted of the randomly selection of one recorded member in each household, resulting in a final sampling frame of one subject per household, stratified by age category (35-44, 45-54, 55-64 and 65-74 years old) and gender (50% women and 50% men) (cf. Rubinstein, Irazola et al. 2011: 2).

A total of 2000 subjects per site were recruited meeting the following inclusion criteria: being a permanent resident at the location for at least 6 months per year, willingness to sign a consent form for participating, not having the intention to move away from the location in

the next 2 years, and being able to answer the questionnaires autonomously. Selected subjects who refused to participate or were not able to be located were not replaced (cf. Rubinstein, Irazola et al. 2011: 2f).

Baseline data collection was conducted at home and in health centers. First, participants were surveyed at home by trained researchers regarding participant characteristics including sociodemographic and socioeconomic factors as well as information on healthcare utilization, family and personal CVD history, CVD risk factors, current non-pharmacological and pharmacological treatment and health behavior. Once the survey was completed, fasting blood samples, electrocardiography and physical measurements were obtained for each subject in health centers (cf. Rubinstein, Irazola et al. 2011: 3).

The final sample consisted of 7524 men and women, aged 35 to 74 years (Rubinstein, Irazola et al. 2011) (Rubinstein, Irazola et al. 2015). From the sample, 1061 participants had either a self-reported previous diagnosis of diabetes or a value of fasting blood glucose above 126 mg/dl and were hence identified as diabetics (cf. Rubinstein, Irazola et al. 2011: 3f.). 6463 participants had levels of fasting blood glucose below 126 mg/dl and no diagnosis of diabetes. Self-reported as well as newly diagnosed diabetic cases were included in the analyses. Cases with missing data regarding HRQoL or in health care access were excluded, resulting in a final sample of 1025 participants for the diabetes groups and 6064 participants for the group without diabetes. Figure 6 shows how the sample was selected.

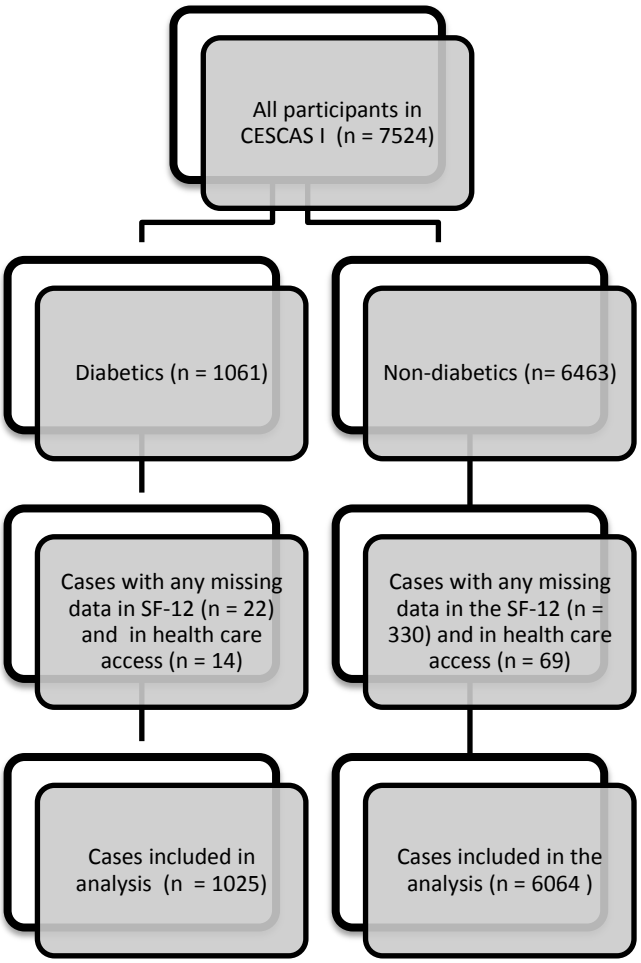

Figure 6: Sample selection flow chart

6.2 Measures for dependent and independent variables

6.2.1 Measurement of diabetes

Diabetes was either self-reported or determined in the study with a fasting blood glucose value equal to or above 126 mg/dl (cf. IDF 2012: 9ff). The variable was binary with the characteristic diabetes: yes/ no.

6.2.2 Short Form 12 (SF-12) instrument as measurement of HRQoL

The Medical Outcomes Study developed a range of functioning and well-being measures and addressed methodological and conceptual issues concerning the measurement of health status concepts (Stewart 1992). From this study, a questionnaire for measuring HRQoL, the Short Form 36 questionnaire (SF-36) was developed representing the most frequently health concepts derived from surveys and empirical studies, (cf. Ware Jr and Sherbourne

1992) which are also comprised in the HRQoL conceptualizations of Ferrans, Zweric et al. (2005) and Wilson and Cleary 1995 (cf. 3.1). The Short Form 12 (SF-12) questionnaire is a self-administered questionnaire derived from the Medical Outcome Study SF-36 questionnaire. The SF-12 consists of 12 items and 8 scales, namely general health, mental health, physical function, role limitations due to physical problems (role physical), role limitations due to emotional problems (role emotional), bodily pain, vitality and social function (cf. Stewart 1992; Ware Jr and Sherbourne 1992).

In the CESCAS I study, HRQoL was assessed using the Spanish version of the SF-12 questionnaire and the EQ-5D (see appendices). The SF-12 is more sensitive than EQ-5D in order to detect health changes and hence, this instrument was used in order to assess HRQoL in the study at hand (cf. Javanbakht, Abolhasani et al. 2012; Norris 2005; Luscombe 2000; Pakpour, Nourozi et al. 2011).

For each of the 8 scales of the SF-12, t-scores were calculated. The scales are scored from 0 to 100 with higher scores indicating higher HRQoL. The SF-12 contains a physical and a mental component summary, the PCS-12 and the MCS-12, respectively. For the summary scores PCS-12 and MCS-12, factor weights from the general population of the United States were adopted to the 8 sub-dimensions to compare with a standard deviation of 10 and a mean of 50 for the general population. Scores of the PCS-12 and the MCS-12 also range from 0 to 100, with higher scores indicating higher HRQoL (cf. Ware and Kosinski 2001; Ware Jr, Snow et al. 1993).

The scores of the SF-12 were used as continuous outcome variable as well as dependent variable for comparing participants with and without diabetes.

6.2.3 Measurement of health care access

In the CESCAS I study, information on health care utilization was obtained using questionnaire forms of the Hispanic Community Health Study/Study of Latinos (HCHS/SOL) with adoptions made for the population living in the Southern Cone of Latin America regarding health insurance status (cf. Rubinstein, Irazola et al. 2011: 4; SOL 2017).

The HCHS/ SOL study is an epidemiological study in the Hispanic and Latino population in four major cities in the United States that aims to assess the impact of acculturation regarding the prevalence and incidence of diseases, and to identify risk factors and protective factors associated with certain health outcomes in this population (cf. SOL 2017a).

The questionnaire on health care utilization contains for example questions on the presence of a regular physician, hospitalization in the last 12 month or the visit of traditional healing practitioners or psychic healers (machi). The original questionnaire used in the CESCAS I study can be found in the appendices.

The health care access model of Aday and Andersen (1981) includes the concept of availability as subjective indicator of realized access to health care (cf. Aday and Andersen 1981). This concept was operationalized in the health care utilization questionnaire in CESCAS I using the following question: "In the last 12 month, has there been any moment, where you needed health care services, but were not able to obtain these services?" There was the possibility to answer the question with "yes", "no", and "does not apply/ do not know". The last answer possibility was handled as missing. In the following the foregone question is translated as realized access and used as binary variable that has two characteristics, yes and no. When the question was answered with "yes" this was considered as having barriers to realized access.

When the question according realized access was answered with yes, forwarding to a further question was set up according reasons for barriers to realized access and included following answer possibilities:

a.) I could not communicate with the medical practice by telephone.
b.) I could not obtain an appointment on time.
c.) I could not obtain an appointment for the times I could have had attended.
d.) I had no possibility to get to the practice due to lack of transportation or no accompanying person.
e.) When I got to the appointment, I had to wait too long at the provider's office.
f.) I could not take a day off at work/ I was occupied.
g.) I had to take care of another person and could not leave him/ her alone.
h.) I could not pay for the service.
i.) I did not call for an appointment, because I am not satisfied with the service and quality of care.
j.) I had other reasons, namely (please specify).

The answer possibilities provide indicators of realized access gained from the theoretical framework (cf. Andersen, McCutcheon et al. 1981: 51).

Models of health care access by Aday and Anderson and the Institute of Medicine's Committee on Monitoring Access to Personal Health Services (1998) include insurance coverage as an important concept (Aday and Andersen 1981; Gold 1998). In the model by Aday and Anderson (1981) insurance status is considered as indicator of potential access (Andersen, McCutcheon et al. 1983: 51). Hence, insurance status was considered as variable of potential health care access in the analyses.

Because health care systems differ in Argentina, Chile and Uruguay, three questions were developed in order to obtain comparability among the countries concerning health insurance:

What kind of health insurance or coverage do you have currently? (choose one answer possibility)

a.) I attend public hospitals and public primary health care centers (public hospitals and health care centers in Argentina and Uruguay, hospitals of FONASA in Chile)
b.) I have a social security that is discounted from my income or the income of a family member (Obra Social in Argentina, FONASA or ISAPRE in Chile, Mutualista or ASSE in Uruguay)
c.) I pay out of pocket for a private insurance (EMP in Argentina, ISAPRE in Chile, Mutualista or private insurance in Uruguay)

The last two answer possibilities were considered as being insured and the first answer possibility was considered as being uninsured. Health insurance status was computed as a binary variable “not health insured” and included the two characteristics yes and no.

Self-perceived barriers to realized access and insurance status were considered the most appropriate measures for health care access in the health care utilization questionnaire and hence used for computing a variable in order to be able to compare participants with and without appropriate health care access. The categorical variable as measure of health care access contained four possible characteristics: 1) Insured people without barriers to realized access (no problems in accessing health care), 2) Uninsured people without barriers to realized access (no potential, but realized access), 3) Insured people with barriers to realized access (no realized, but potential access) 4) Uninsured people with barriers to realized access (no potential and no realized access).

In the following, having no potential access is used synonymously with being uninsured including only the uninsured without self-perceived barriers to realized access.

6.2.4 Measurements of covariates of HRQoL in diabetics

Covariates as potential predictors of diabetics HRQoL were derived from the systematically literature review and included socioeconomic, sociodemographic and personal factors as well as comorbidities and disease related factors and the presence of a regular physician. In order to simplify the analysis, the presence of a regular physician was not included in the computation of the health care access variable, although the theoretical frameworks consider a regular physician as indicator to health care access (cf. Andersen, McCutcheon et al. 1983: 51). It was supposed that the presence of a regular physician was a rather weak indicator of health care access when compared to insurance status or perceived barriers to realized access (cf. Seid, Varni et al. 2006: 357; Andersen, McCutcheon et al. 1983: 51ff). However, this variable was included as potential predictor of HRQoL in the analyses. Hospitalization in the last 12 month as an indicator of health status and was considered in the analyses. Table 4 shows all covariates included and gives information on how these variables were defined and measured.

Table 4: Covariates of HRQoL in diabetics in the analyses

Covariate	Definition and level of measurement
Gender	Binary (male or female), self-reported
Age	In years, continuous, self-reported
Occupational status	White collar worker, categorical, self-reported
	Blue collar worker, categorical, self-reported
	Retired, categorical, self-reported
	Unemployed, categorical, self-reported
	Housewife, categorical, self-reported
Low educational level	Less than high school certificate, binary (yes or no), self-reported
BMI	Calculated of weight and height, continuous, anthropometric measures
Physical inactivity	Below b600 MET-minutes/per week, binary (yes or no), measured with IPAQ (International Physical Activity Ques-

	tionnaire), self-reported
Aware of diabetes	Diagnosis of diabetes before begin of the study, binary (yes or no), self-reported
Age of diabetes onset	In years, continuous, self-reported
Insulin therapy	Treatment with insulin, binary (yes or no), self-reported
Glycemic control	Blood sugar in mg/dl, continuous, laboratory tested
Chronic kidney disease	Estimated-glomerular filtration rate < 60 ml/min/ 173 m2, binary (yes or no), laboratory tested
Cardiovascular disease	Cardiovascular disease, binary (yes or no), self-reported
Hospitalization last year	Being at least hospitalized once in past 12 month, binary (yes or no), self-reported
Regular physician	Having a regular physician, binary (yes or no), self-reported

Source: Own illustration based on Rubinstein, Irazola et al. 2011

6.3 Data analyses

All analyses were run using SPSS 20. Since the database was used before, data was prepared, cleaned and checked before the analyses were performed.

In order to answer the first research question, four groups were compared in the analysis: 1) Insured people without barriers to realized access (no problems in accessing health care), 2) Uninsured people without barriers to realized access (not health insured), 3) Insured people with barriers to realized access (no realized access) 4) Uninsured people with barriers to realized access (not health insured and no realized access).

In descriptive statistics, continuous variables are presents as means (M) with standard deviation (SD). Categorical and dichotomous variables are presented as percentages.

Group differences between participants' characteristics and HRQoL were analyzed using Chi Square test and One Way ANOVA with Tukey as post hoc test. In case of heterogeneity of variance across the four groups, the obtained Welch's adjusted F ratio was used with Games Howell test as post hoc test. These tests are robust to heterogeneity of variances and unequal group sizes (cf. Posten 1984; Ramsey 1980; Games and Howell 1976; Havlicek and Peterson 1974). For Chi Square post hoc tests, p-values were estimated with adjusted residual z-scores using Bonferroni correction (cf. Beasley and Schumacker 1995; Kohr and Games 1974).

The association between HRQoL and barriers to health care access was adjusted for important covariates derived from the literature review using multivariate linear regression. Covariates were related to 1) socioeconomic, sociodemographic and personal factors: gender, age, occupational status, educational level, body mass index (BMI), physical inactivity, awareness of diabetes, and 2) disease related factors and comorbidities: age of diabetes onset, insulin therapy, fasting blood glucose, hospitalization in the last year, chronic kidney disease, cardiovascular disease and 3) having a regular physician. Because pp-Plot showed that the assumption of normality could be violated, log10-transformation was performed to confirm the results.

According to the second research question, frequencies of the mentioned reasons for self-perceived barriers to realized health care in diabetics were determined.

In order to answer the third part of research questions, diabetics to non-diabetics were compared using the student's t-tests and Chi Square tests with calculation of Cohen's d effect size r and unadjusted Odds Ratio (OR), respectively with non-diabetics as reference category. Because the student's t-tests is not robust to unequal variances when sample sizes differ, a random sample of non-diabetics (n = 1025) was compared to the whole sample of diabetics (n = 1025) in order to confirm the results (cf. Boneau 1960). Welch test was performed, since variances were heterogeneous. Two-factorial univariate ANOVA was performed to investigate the effect of diabetes and access to health care and an interaction between the two factors on HRQoL with Bonfferoni post hoc test. Additionally, the two-factorial ANOVA was adjusted for socioeconomic and sociodemographic factors, comorbidities and the presence of a regular physician.

Any p-values lower than 0.05 were considered significant. Cases were excluded pairwise.

7. Results

7.1 Sample characteristics among diabetics with differences in health care access

Of 1025 participants with diabetes, 407 were health insured and reported no barrier in realized access to health care. 471 participants were uninsured, but had no barrier in realized access, 44 participants had no realized access, but were health insured and 103 participants had neither health insurance nor realized access.

The majority of the diabetics sample consisted of females, ranging from 58.9 % to 69.8 % in the certain group, with the highest amount of females in the group of people with neither insurance nor realized access and lowest amount of females in the group without any problems in accessing care. Mean age ranged from 56.7 (SD: 9.2) and 61.5 (SD: 9.1) years among the certain groups with highest mean age in the group of people without problems in accessing care and lowest mean age in the group of uninsured people with barriers to realized access.

According to occupational status, the percentage of unemployed people ranged from 3.7 % in the group without problems in access and 9 % in the group of people with neither insurance nor realized access. The percentage of white collar workers ranged from 8.1 % to 11 % and the percentage of blue collar workers ranged from 17.2 % to 23.9 % in the certain groups. The highest percentage of retired people was observed in the group of people without any problems in accessing care (57.6 %) and the lowest percentage in people with neither insurance nor realized access (26.5 %). 68.6 % in the group of people without any problems had low educational status, compared to 76.3% in the uninsured group, 55.6% in the group of people with perceived barriers to realized access and 68.9% in the group of uninsured people with impeded realized access.

Mean BMI ranged from 33 (SD 6.9) and 31.5 (SD 6.2) and physical inactivity ranged from 34 % and 42.2% in the certain groups. Between 76.1 % and 88.9 % were aware of their diabetes among the groups. Mean age of diabetes onset ranged from 46.6 (SD: 12.5) and 51 (SD: 11.9) years. Between 10.2 % and 13.3 % of the diabetics required insulin. Blood sugar ranged from 132.1 (SD: 50) and 154.9 (SD: 68.7) mg/dl. The prevalence of chronic kidney disease ranged from 4.4 % and 7.6 % and the prevalence of cardiovascular disease

ranged from 16.9 % to 26.7 %. Between 9.9 % and 14.2 % were hospitalized in the last 12 month. 69.1 % of the people without any problems in accessing health care had a regular physician, compared to 32.1 % of the uninsured people, 33.3 % of the people experiencing barriers to realized health care and 18.9 % of uninsured population experiencing barriers to realized access to care.

Differences among the groups were significant regarding being retired (χ^2 (3, N = 1003) = 47.07; p-value < 0.001; Cramer's V: 0.22), being a housewife (χ^2 (3, N = 1003) = 34.51; p-value < 0.001; Cramer's V: 0.19), having a regular physician (χ^2 (3, N = 1025) = 167.24; p-value < 0.001; Cramer's V: 0.40) and having a low educational level (χ^2 (3, N = 1035) = 13.07; p-value = 0.004; Cramer's V: 0.11). Post hoc residual analysis showed that all groups contributed to the significance of the results (p-value < 0.006), except for the group of insured people with perceived barriers to realized access (p-values = 0.387; 0.989; 0.999 and 0.038 respectively).

Welch test showed that groups significantly differed regarding age (F (3/164.52) = 10.81; p-value < 0.001; partial eta squared: 0.029). Games Howell post-hoc tests showed that these differences were significant between uninsured people and people without any problems in accessing health care (B: -2.74; SE: 0.65; p-value < 0.001) and between uninsured people reporting barriers to realized health care access and people without any problems in health care access (B: -4.88; SE: 1.01; p-value < 0.001).

Differences for all other covariates were not significant (for unemployed χ^2 (3, N = 1003) = 7.42; p-value = 0.060; for white collar worker χ^2 (3, N = 1003) = 2.07; p-value = 0.557; for blue collar χ^2 (3, N = 1003) = 5.75; p-value = 0.124; for cardiovascular disease χ^2 (3, N = 1035) = 2.89; p-value = 0.409; for chronic kidney disease χ^2 (3, N = 1035) = 1.06; p-value = 0.786; for awareness of diabetes χ^2 (3, N = 1035) = 7.96; p-value = 0.053; for low physical activity χ^2 (3, N = 1035) = 1.39; p-value = 0.720; for hospitalization χ^2 (3, N = 1028) = 4.14 ; p-value = 0.242; for gender χ^2 (3, N = 1035= = 4.44; p-value = 0.217; for insulin therapy χ^2 (3, N = 815) = 6.61; p-value = 0.086; for age of diabetes onset F (3/746) = 2.59; p-value = 0.052; for fasting blood glucose F (3/999) = 2.10; p-value = 0.980 and for BMI (3/1027) = 0.83; p-value = 0.480). Table 5 provides a detailed description of the sample characteristics in each group.

Table 5: Sample characteristics of diabetics regarding access to care

	No problems in accessing health care	No potential, but realized access	No realized, but potential access	No potential and no realized access	p-value
	(n = 407)	(n = 471)	(n = 44)	(n = 103)	
Sociodemographic- economic and personal data					
Female	58.9 %	61.1 %	64.4 %	69.8 %	0.217
Age	61.5 (9.1)	58.8 (SD 10.1)	58 (SD 11.7)	56.7 (9.2)	< 0.001
White collar worker	11%	8.1 %	9.3 %	9.8 %	0.557
Blue collar worker	17.2 %	23.9 %	20.9 %	21.6 %	0.124
Retired	57.6 %	38.7 %	46.5 %	26.5 %	< 0.001
Unemployed	3.7 %	7.2 %	7%	9.8 %	0.060
Housewife	10.5 %	22.1 %	16.3 %	32.4 %	< 0.001
Low educational level	68.6 %	76.3 %	55.6 %	68.9 %	0.004
BMI	31.9 (5.7)	32.2 (SD 6.6)	33 (SD 6.9)	31.5 (SD 6.2)	0.480
Physical inactivity	39.2 %	37.6 %	42.2 %	34%	0.720
Aware of diabetes	82%	76.1 %	88.9 %	76.4 %	0.053
Disease-related factors and comorbidities					
Age of diabetes onset	51 (11.9)	49.5 (SD 13.5)	50.6 (14)	46.6 (SD 12.5)	0.052
Insulin therapy	10.2 %	13.3 %	4.4 %	11.3 %	0.086
Blood sugar in mg/dl	146 (64)	153.6 (SD 69.9)	132.1 (50)	154.9 (SD 68.7)	0.098
Chronic kidney disease	6.3 %	7.6 %	4.4 %	7.5 %	0.786
Cardiovascular disease	18.5 %	16.9 %	26.7 %	19.8 %	0.409
Hospitalization last year	14.1 %	9.9 %	11.1 %	14.2 %	0.242
Regular physician	69.1 %	32.1 %	33.3 %	18.9 %	< 0.001

Age, BMI, age of onset and blood sugar as M (SD)

7.2 Effect of health care access on diabetics HRQoL

The group main effect of health care access on HRQoL among diabetics was significant for the MCS-12 (F (3/1024) = 10.98; p-value < 0.001) and the PCS-12 (F (3/ 158.26) = 6.88; p-value < 0.001).

Because the assumption of homogeneity of variances of the continuous variables across the groups was violated for PCS-12 (Levene's test p-value 0.016), Welch test and Games Howell as post hoc test were used. Table 6 provides the summary of the Welch conducted for the PCS-12 and the ANOVA conducted for MCS-12 among the four groups.

Table 6: ANOVA and Welch Summary tables for MCS-12 and PCS-12

		Sum of Squares	**df**	**Mean Square**	**F**	**p-value**
MCS-12	Between Groups	4789.15	3	1596.38	10.98	< 0.001
	Within Groups	148483.95	1021	145.43		
	Total	153273.10	1024			
		Partial eta sqaured	**Power**			
		0.031	0.999			
		Statistic	**df1**	**df2**		**p-value**
PCS-12	Welch	6.88	3	158.26		< 0.001
		Partial eta squared	**Power**			
		0.023	0.992			

Table 7 shows the mean quality of life for each group. PCS-12 scores were lower compared to MCS-12 scores among all four access groups. Quality of life was lowest in people with neither potential nor realized access and highest in people without problems in access for both summary scales. Insured diabetics without realized access had lower quality of life compared to uninsured diabetics with realized access. For the PCS-12, Games Howell test showed, that differences were significant between diabetics without health insurance and with neither health insurance nor realized access (B: -3.95; SE:1.19; p-value: 0.006) and for people without any access and people with no problems in accessing care (B: -5.05; SE: 1.21; p-value < 0.001). For the MCS-12, Tukey test showed, that differences were significant between diabetics without health insurance and neither health insurance nor realized access (B: -5.77; SE: 1.31; p-value < 0.001), between diabetics without realized access and diabetics without problems in accessing care (B: -6.03; SE: 1.91; p-value: 0.009) and be-

tween diabetics with neither insurance nor realized access and diabetics without problems in accessing care (B: -6.77; SE: 1.33; p-value < 0.001). PCS-12 scores ranged from 8 to 66 and MCS-12 scores ranged from 5 to 78.

Differences for the PCS-12 reached clinical relevance between people without any access and people with no problems in accessing care, when considering the one-half standard deviation benchmark rule. For the MCS-12 clinically relevant differences were obtained between diabetics without realized access and diabetics without problems in accessing care as well as between diabetics with neither insurance nor realized access and diabetics without problems in accessing care. All of these differences complied with the threshold of approximately half a standard deviation of the mean of people without any problems in accessing care and hence achieved a minimal clinically important difference (Norman, Sloan et al. 2003).

Table 7: HRQoL in diabetics with different health care access

	1. No problems in accessing health care	**2. No potential, but realized access**	**3. No realized, but potential access**	**4. No potential and no realized access**	**p-value**
	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	
PCS-12	45.77 (9.97)	44.67 (10)	41.46 (12.34)	40.72 (11.15)	< 0.001
MCS-12	53.43 (11.85)	52.41 (11.92)	47.39 (13.93)	46.65 (12.64)	< 0.001

Figure 7 shows the tendency in HRQoL among the groups, with highest quality of life in the first group, followed by the second group for both, PCS-12 and MCS-12. Compared to the second group, quality of life was lower in the third and lowest in the fourth group for both component summary scores.

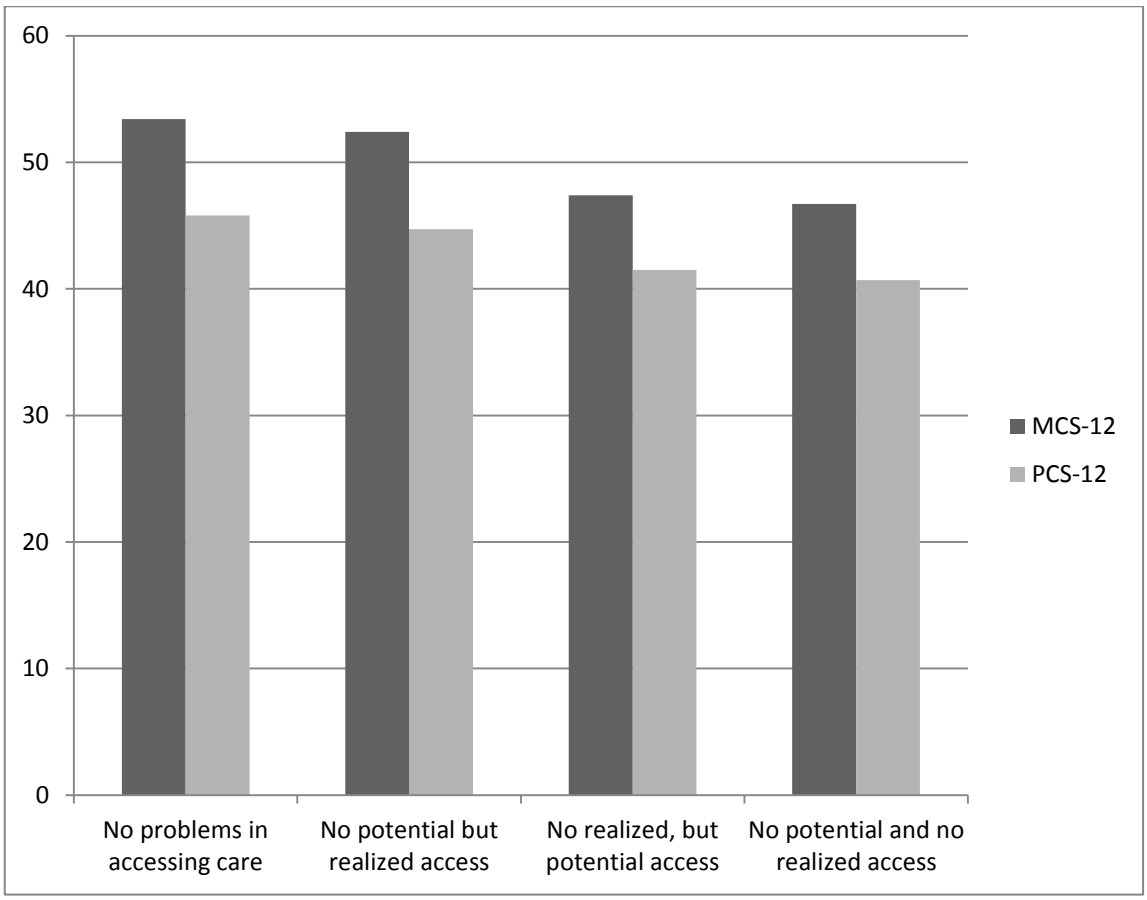

Figure 7: HRQoL in diabetics with different health care access

A linear regression was conducted for each component summary including access to care, sociodemographic, socioeconomic, personal and disease-related factors, comorbidities and the presence of a regular physician as predicting factors of HRQoL.

The linear regression models showed that access to health care significantly predicted HRQoL except for diabetics without health insurance compared to people without problems in accessing care in the mental component summary (Table 8).

The models explained 21 % of the variance of the PCS-12 ($F (20/ 716) = 10.68$; p-value < 0.001). For the MCS-12, the explained variance was 6.8 % ($F (20/ 716) = 3.70$; p-value < 0.001).

The value of the Durbin-Watson was 1.89 for the PCS-12 and 1.82 for the MCS-12, which indicates that residuals were not strongly correlated with each other.

Adjusted and unadjusted R^2 differed from each other (0.231 vs. 0.210 for the PCS-12 and 0.094 vs. 0.068 for the MCS-12). Tolerance levels were above 0.2 and VIF values were below 10 for both regression models, indicating no multicollinarity of the predictors. Fur-

thermore, histogram indicated a normal distribution of the residuals and the scatterplot of the standardized predicted dependent variable and the standardized residual showed a random distribution around the z-Mean 0 for both regression models. However, the pp-Plot indicated that the assumption of normally distributed data could be violated (see appendices) (Mailberg 2003: 442ff.). Hence, log10 transformation was conducted to confirm the results, with pp-Plots indicating a perfect normal distribution after transformation.

The PCS-12 score was decreased by 2 points (SE: 0.81; p-value: 0.014) for people without health insurance, by 4.75 points (SE: 1.75; p-value: 0.007) for people with barriers to realized access and by 6.13 points (SE: 1.29; p-value < 0.001) for people without health insurance and barriers to realized access when compared to insured people without self-perceived barriers to realized health care access. For the MCS-12 score, the decrease for people without health insurance when compared to the reference group was not significant (B: -0.62; SE: 1.04; p-value: 0.553). The MCS-12 score was decreased by 4.82 (SE: 2.24; p-value: 0.032) for people with barriers to realized access and by 5.6 points for people with neither potential nor realized access (SE: 1.64; p-value: 0.001) when compared to insured people without perceived barriers to realized health care access.

Considering a decrease of more than 2 points as clinically meaningful, being insured, but having no realized access as well as having neither insurance nor realized access, reached a minimal clinically important difference for both component summary scores (cf. Sprangers, de Regt et al. 2000: 899).

After log10 transformations, access to health care remained a significant predictor of HRQoL for the PCS-12 (p-values: 0.013 for no potential, but realized access; 0.016 for no realized, but potential access and < 0.001 for no realized and no potential access). For the MCS-12, only no realized and no potential access remained a significant predictor of lower HRQoL (p-value: 0.001). No potential but realized access remained not significant (p-value: 0.637) and having no realized, but potential access was no longer significant (p-value 0.060).

All other significant predictors in the untransformed model remained significant, expect for being retired in the PCS-12 (p-value: 0.067) (see appendices).

7.3 Effect of covariates on diabetics HRQoL

Table 8 shows all determinants of HRQoL in diabetics included in the model. For the PCS-12 important determinants among diabetics included being aware of the disease (B: -2.25;

SE: 0.89; p-value: 0.012), being retired (B: -3.05; SE: 1.43; p- value: 0.033) and being a housewife (B: -3.69; SE: 1.5; p-value: 0.014) when compared to white collar workers, having chronic kidney disease (B: -2.85; SE: 1.38; p-value: 0.039), having cardiovascular disease (B: -3.46; SE: 0.9; p-value < 0.001), being physically inactive (B: -3.95; SE: 0.72; p-value < 0.001) and being hospitalized in the last year (B: -3.36; SE: 1.05; p-value: 0.001). Age, BMI and age of diabetes onset were also significant predictors in the model, but to a lower extent when compared to the predictors mentioned before. Gender, educational level, being a blue collar worker and being unemployed when compared to being a white collar worker, insulin therapy, blood sugar in mg/dl and having a regular physician were not significantly associated with HRQoL. Having no realized access and neither having realized access nor health insurance were associated with the highest decreases in HRQoL for the PCS-12.

Important significant predictors for the MCS-12 were female gender (B:-3.05; SE: 1; p-value: 0.002), being aware of the disease (B: -2.79; SE: 1.14; p-value: 0.015), insulin therapy (B: -3.17; SE: 1.36; p-value: 0.02) and physical inactivity (B: -2.11 SE: 0.92; p-value: 0.021). All other predictors in the model were not significantly associated with lower MCS-12 scores.

The predictors associated with the highest decreases in HRQoL in the MCS-12 were the presence of self-perceived barriers to realized health care access and being uninsured with perceiving barriers to realized health care access.

Table 8: Linear regression model for HRQoL among diabetics

	PCS-12			MCS-12		
	B	Std. Error	p-value	B	Std. Error	p-value
Constant	73.24	3.9	< 0.001	56.21	4.98	< 0.001
Age	-0.18	0.06	0.001	0.1	0.07	0.177
Being female	-0.53	0.79	0.503	-3.05	1	0.002
Low educational level	-0.52	0.79	0.511	1.54	1	0.126
Aware of diabetes	-2.25	0.89	0.012	-2.79	1.14	0.015
White collar worker	Ref.					
Blue collar worker	-1.11	1.38	0.423	-0.65	1.77	0.713
Retired	-3.05	1.43	0.033	0.43	1.83	0.815
Unemployed	-2.19	1.78	0.218	-2.79	2.27	0.220
Housewife	-3.69	1.5	0.014	-0.13	1.91	0.945
Chronic kidney disease	-2.85	1.38	0.039	-1.21	1.76	0.493
Cardiovascular disease	-3.46	0.9	< 0.001	-1.85	1.15	0.108
Physical inactivity	-3.95	0.72	< 0.001	-2.11	0.92	0.021
BMI	-0.27	0.06	< 0.001	0.09	0.07	0.193
Age of diabetes onset	0.13	0.04	< 0.001	-0.03	0.05	0.525
Insulin therapy	-0.43	1.06	0.684	-3.17	1.36	0.020
Blood sugar in mg/dl	-0.003	0.01	0.569	0.01	0.007	0.196
Hospitalization in last year	-3.36	1.05	0.001	-1.32	1.34	0.325
Having regular physician	-1.11	0.78	0.156	0.51	0.99	0.611
Potential and realized access	Ref.					
Not potential, but realized access	-2	0.81	0.014	-0.62	1.04	0.553
No realized, but potential access	-4.75	1.75	0.007	-4.82	2.24	0.032
No realized, no potential access	-6.13	1.29	< 0.001	-5.6	1.64	0.001

7.4 Reasons for barriers to realized health care access among diabetics

Distributions of the certain reasons for barriers to realized health care access mentioned by the people with diabetes are shown in Table 9.

Table 9: Reasons for barriers to realized health care access among diabetics

Reason for barriers to realized health care access	n
I could not communicate with the medical practice by telephone.	17
I could not obtain an appointment on time.	68
I could not obtain an appointment for the times I could have had attended.	18
I had no possibility to get to the practice due to lack of transportation or no accompanying person.	12
When I got to the appointment, I had to wait too long at the provider's office.	20
I could not take a day off at work/ I was occupied.	14
I had to take care of another person and could not leave him/ her alone.	5
I could not pay for the service.	53
I did not call for an appointment, because I am not satisfied with the service and quality of care.	11
I had other reasons.	16
Total	234

Other reasons (n = 16) included that there was no doctor available in the health care facility (n = 4), the patient asked for medical attendance at home, but did not receive it (n = 1), the available doctor did not want to treat the patient (n = 2), the health care facility was closed (n =1), personnel was on strike (n = 1), the providers practice told the patient to wait for a call-back, that the patient did not have received yet (n = 3), the patient did not have any documents (n = 3) and because of weather conditions (n = 1).

7.5 Sample characteristics of people with and without diabetes

Table 10 shows the sample characteristics of the participants with and without diabetes as well as the odds of people with diabetes to have certain characteristics and the effect size r of diabetes on certain characteristics.

People with diabetes were older (mean = 59.6 years SD 9.9) when compared to people without diabetes (mean = 54.4 years SD: 10.6); t (2004.47) = -11.36; p-value < 0.001 and more often females (60.9 % vs. 57.5 %; χ^2 (1, N = 7387) = 4.25; p-value 0.039).

According to occupational status, people with diabetes were less likely to be white and blue collar workers when compared to people without diabetes (χ^2 (1, N = 7045) = 55.58; p-value < 0.001 and χ^2 (1, N = 7045) = 53.77; p-value < 0.001, respectively), while people with diabetes were more often retired (χ^2 (1, N = 7045) = 130.85; p-value < 0.001). Diabetic people were more likely to have a low educational level when compared to people without diabetes (χ^2 (1, N = 7336) = 29.68; p-value < 0.001). There were no significant differences between diabetics and non-diabetics according the unemployment rate (χ^2 (1, N = 7045) = 2.23; p-value: 0.135).

People with diabetes had higher blood glucose (mean = 150 mg/dl, SD = 67.1 vs. mean = 92 mg/dl, SD = 10.4; t (1039.31) = -26.91; p-value < 0.001), higher BMI (mean = 32.1 SD = 6.2 vs. mean = 28.7 SD = 5.3; t (1976.11) = -13.1; p-value < 0.001) and were more likely to be physically inactive (χ^2 (1, N = 7387) = 38.29) than people without diabetes.

Diabetic people were more likely to suffer from chronic kidney disease (χ^2 (1, N = 7387) = 52.27; p-value < 0.001) and from cardiovascular disease (χ^2 (1, N = 7387) = 94.82) when compared to non-diabetic participants.

Additionally, diabetics were more likely to have experienced hospitalization in the last year when compared to people without diabetes (χ^2 (1, N = 7336) = 17.87; p-value < 0.001) and also more likely to have a regular physician (χ^2 (1, N = 7254) = 60.98; p-value < 0.001). People with diabetes were less likely to have no problems in accessing health care compared to non-diabetic participants (χ^2 (1, N = 7202) = 7.54). The odds of diabetics to have no health insurance, but realized access were not significant (χ^2 (1, N = 7202) = 0.005; p-value: 0.943). Though, diabetics were more likely to report barriers to realized access when compared to non-diabetics (χ^2 (1, N = 7202) = 4.12) and to have neither health insurance nor realized access (χ^2 (1, N = 7202) = 13.43; p-value < 0.001).

Table 10: Sample characteristics of participants with and without diabetes

	Diabetes	No diabetes	OR	Effect size r	95 % CI		p-value
	n = 1025	n = 6064			Lower Bound	Upper Bound	
Female	60.9%	57.5%	1.15	-	1.01	1.31	0.039
Age	59.6 (9.9)	54.4 (10.6)	-	0.24	-6.08	-4.29	< 0.001
White collar worker	9.3%	18.9%	0.44	-	0.36	0.55	< 0.001
Blue collar worker	20.9%	32.3%	0.55	-	0.47	0.65	< 0.001
Retired	44.9%	27.2%	2.18	-	1.9	2.49	< 0.001
Unemployed	6.4%	7.7%	0.82	-	0.63	1.07	0.135
Housewife	18.5%	13.8%	1.41	-	1.19	1.68	< 0.001
Low educational level	71.5%	62.9%	4.59	-	4.03	5.23	< 0.001
BMI	32.1 (6.2)	28.7 (5.3)	-	0.28	-3.87	-2.86	< 0.001
Physical inactivity	38.4%	28.9%	1.53	-	1.34	1.75	< 0.001
Blood sugar in mg/dl	150 (67.1)	92 (10.4)	-	0.63	-62.24	-53.77	< 0.001
Chronic kidney disease	6.8%	2.6%	2.75	-	2.07	3.66	< 0.001
Cardiovascular disease	18.4%	8.7%	2.37	-	1.99	2.84	< 0.001
Hospitalization last year	12.4%	8.4%	2.70	-	2.19	3.34	< 0.001
Regular physician	46.3%	33.8%	1.73	-	1.45	2.09	< 0.001
No problems in accessing health care	39.7%	44.3%	0.83	-	0.72	0.95	0.006
No potential, but realized access	45.7%	45.6%	1.00	-	0.88	1.15	0.943
No realized, but potential access	4.3%	3.1%	1.41	-	1.01	1.96	0.042
No potential and no realized access	10.2%	7%	1.51	-	1.21	1.89	< 0.001
PCS-12	44.5 (10.3)	48.3 (8.7)	-	0.16	2.43	4.13	< 0.001
MCS-12	52.1 (12.2)	53.1 (11.4)	-	0.02	-0.23	1.83	0.127

Age, BMI, blood sugar, PCS-12 and MCS-12 as M (SD)

Regarding HRQoL, people with diabetes had significantly lower PCS-12 scores in comparison to people without diabetes (mean = 44.6 SD = 10.3 vs. mean = 48.3 SD = 8.7; t (2001.82) = 7.6; p-value < 0.001). However, there was no significant difference between people with and without diabetes concerning the MCS-12 scores (mean = 52.1 SD = 12.2 vs. mean = 53.1 SD = 11.4; t (2018.19) = 1.53; p-value: 0.127).

7.6 Effect of diabetes and access to care on HRQoL

PCS-12 scores were lower than MCS-12 scores for both, diabetic and non-diabetic participants (Tables 11 and 12).

For the PCS-12, people with diabetes had lower scores across all four access groups when compared to people without diabetes with mean scores of 49.08 vs. 45.77 in the first group, 48.37 vs. 44.67 in the second group, 45.96 vs. 41.46 in the third group and 44.19 vs. 40.72 in the fourth group (F (1/ 7081) = 63.18; p-value < 0.001). In people with and without diabetes combined, lowest PCS-12 scores were observed among people with neither realized nor potential access, followed by people without realized, but potential access and people without health insurance but realized access. Highest PCS-12 scores were observed in people without any problems in health care access (F (3/ 7081) = 32.83; p-value < 0.001). Bonferroni post hoc tests showed that these differences were significant across all groups, except for the difference between people with potential but no realized access and people with neither realized nor potential access. Highest mean differences were observed between people without problems in accessing care and people with neither health insurance nor realized access (B: -4.97; SE: 0.54; p-value < 0.001) (Table 13).

For the MCS-12, diabetic participants had lower scores across all access groups except for the group of people with neither realized access nor health insurance, were scores were higher in the diabetic group with means of 53.7 vs. 53.42 in the first, 53.84 vs. 52.41 in the second, 48.29 vs. 47.39 in the third and 46.31 vs. 46.65 in the fourth group (F (1/ 7081) = 32.83; p-value = 0.349). Alike the PCS-12, in people with and without diabetes, highest MCS-12 scores were observed in people without any problems in health care access followed by uninsured people with realized access and insured people without realized access. People with neither realized access nor health insurance achieved lowest MCS-12 scores (F (3/ 7081) = 44.67; p-value < 0.001). Except for the difference between people with no realized access and people with neither realized access nor health insurance these differences were significant across all groups. Highest mean differences were observed be-

tween people without problems in accessing care and people with neither health insurance nor realized access (B: -7.08; SE: 0.69; p-value < 0.001) (Table 13).

Table 11: PCS-12 for people with and without diabetes with different health care access

PCS-12	No diabetes			Diabetes		
	Mean	**SD**	**N**	**Mean**	**SD**	**N**
No problems in accessing care	**49.08**	8.46	2672	**45.77**	9.97	407
No potential, but realized access	**48.37**	8.27	2774	**44.67**	10	471
No realized, but potential access	**45.96**	9.84	189	**41.46**	12.34	44
No realized + no potential access	**44.19**	10.74	429	**40.72**	11.15	103

Table 12: MCS-12 for people with and without diabetes with different health care access

MCS-12	No diabetes			Diabetes		
	Mean	**SD**	**N**	**Mean**	**SD**	**N**
No problems in accessing care	**53.7**	11.2	2672	**53.42**	11.85	407
No potential, but realized access	**53.84**	10.81	2774	**52.41**	11.92	471
No realized, but potential access	**48.29**	13.83	189	**47.39**	13.93	44
No realized + no potential access	**46.31**	13.13	429	**46.65**	12.64	103

Figure 8 and Figure 9 show the mean scores for the PCS-12 and the MCS-12 in diabetics and non-diabetics across the access groups.

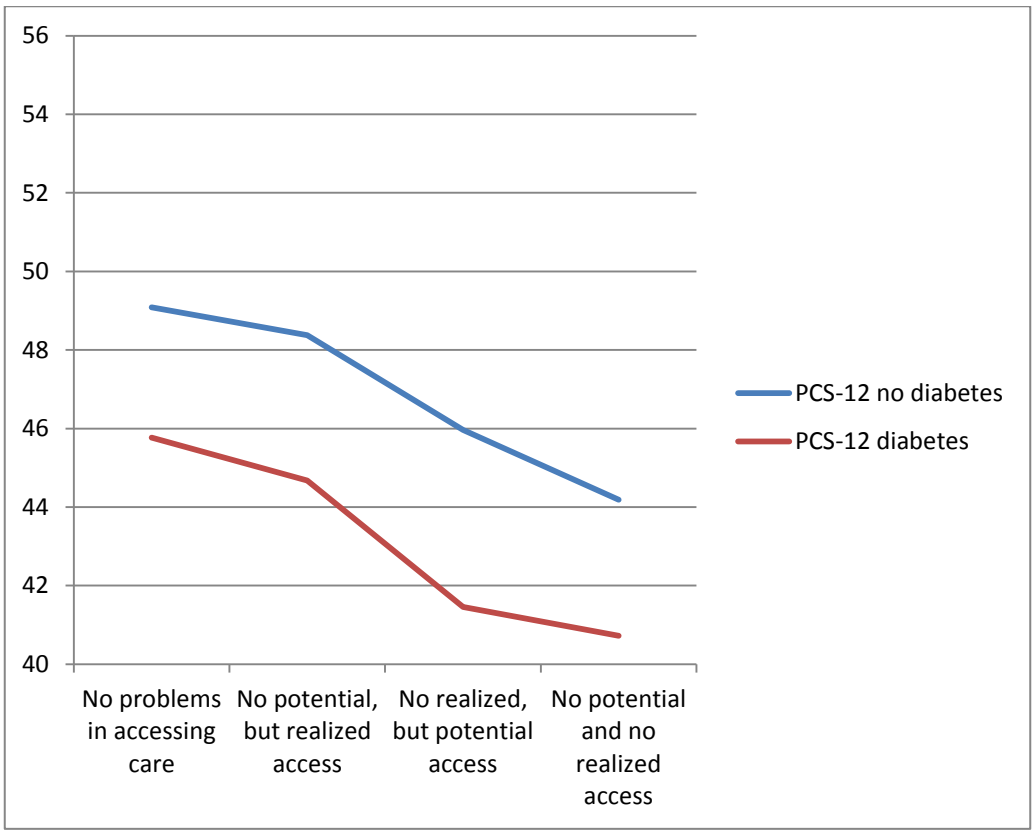

Figure 8: PCS-12 for people with and without diabetes with different health care access

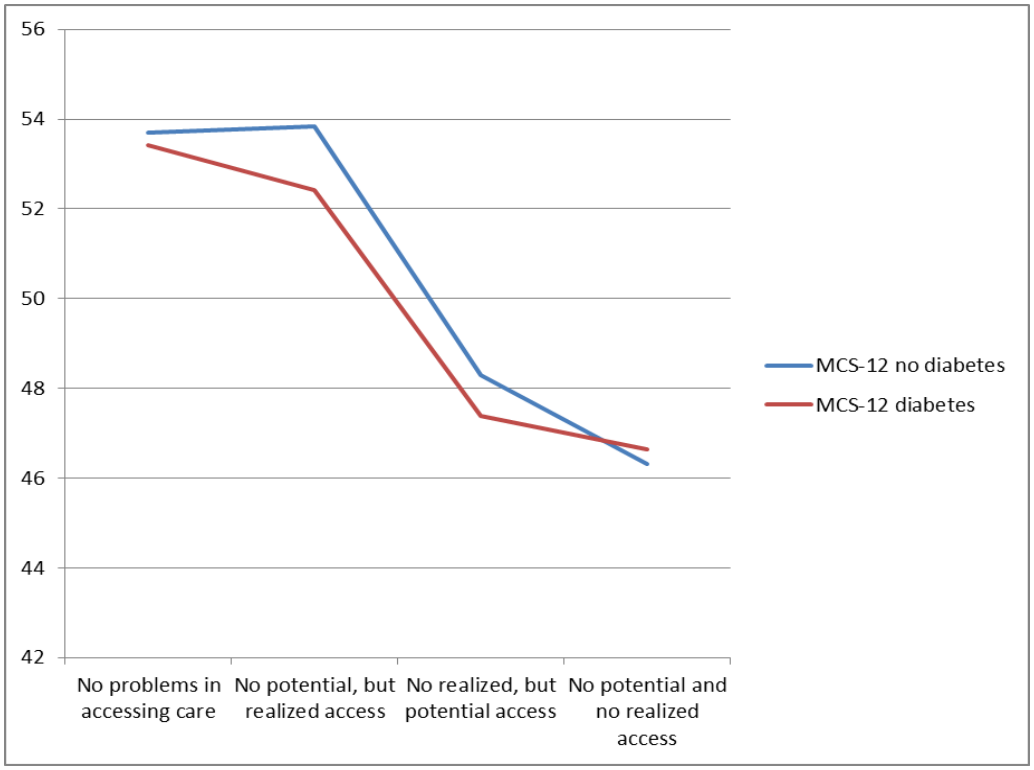

Figure 9: MCS-12 for people with and without diabetes with different health care acces

Table 13: Mean differences across people with different access to health care (diabetics and non-diabetics combined)

		PCS-12			MCS-12		
		Mean Difference	**SE**	**p-value**	**Mean Difference**	**SE**	**p-value**
No problems in accessing care	**No potential, but realized access**	0.9	0.32	0.031	0.43	0.42	0.999
	No realized, but potential access	3.72	0.78	< 0.001	5.72	1	< 0.001
	No potential and no realized access	4.97	0.54	< 0.001	7.08	0.69	< 0.001
No potential, but realized access	**No problems in accessing care**	-0.9	0.32	0.031	-0.43	0.41	0.999
	No realized, but potential access	2.81	0.77	0.002	5.29	0.99	< 0.001
	No potential and no realized access	4.1	0.53	< 0.001	6.65	0.69	< 0.001
No realized, but potential access	**No problems in accessing care**	-3.72	0.78	< 0.001	-5.72	1	< 0.001
	No potential, but realized access	-2.81	0.77	0.002	-5.29	0.99	< 0.001
	No potential and no realized access	1.26	0.89	0.933	1.36	1.14	0.999
No potential and no realized access	**No problems in accessing care**	-4.97	0.54	< 0.001	-7.08	0.69	< 0.001
	No potential, but realized access	-4.07	0.53	< 0.001	-6.65	0.69	< 0.001
	No realized, but potential access	-1.26	0.89	0.933	-1.36	1.14	0.999

Table 14 provides the summary of the 2-factorial ANOVA. Levene's test was significant for the PCS-12 (F (7/ 7081) = 27.25; p-value < 0.001) and for the MCS-12 (F (7/ 7081) = 9.62; p-value < 0.001). For the PCS-12, there was a significant main effect for diabetes (F (1/ 7081) = 63.18; p-value < 0.001) as well as for access to care (F (3/ 7081) = 32.83; p-value < 0.001). However, the interaction between diabetes and access to care was not significant (F (3/ 7081) = 0.26; p-value: 0.853). For the MCS-12, only the main effect of access to care was significant (F (3/ 7081) = 44.67; p-value < 0.001). The effect of diabetes, as well as the interaction of diabetes and access to care was not significant (F (1/ 7081) = 0.88; p-value = 0.349 and F (3/ 7081) = 0.93; p-value = 0.425, respectively).

After adjustment for age, sex, physical inactivity, educational level, occupational status, BMI, blood glucose values, chronic kidney disease, cardiovascular disease, hospitalization in the last year and the presence of a regular physician, for the PCS-12, the significant main effect for diabetes (F (1/ 6560) = 5.38; p-value: 0.020) and access to care (F (3/ 6560) = 39.75; p-value < 0.001) remained significant. The interaction between diabetes and access to care was not significant for the PCS-12 in the adjusted analysis (F (3/ 6560) = 0.53; p-value = 0.660). For the MCS-12, the main effect for access to care also remained significant (F (3/ 6560) = 36.07; p-value < 0.001). The effect for diabetes and the interaction between diabetes and access to care was not significant for the MCS-12 in adjusted analysis (F (1/ 6560) = 2.11; p-value = 0.146; F (3/ 6560) = 0.86; p-value = 0.461). In adjusted analyses, Levene's test was significant for the PCS-12 (7/ 6571) = 20.66; p-value < 0.001) and for the MCS-12 (7/ 6571) = 9.96; p-value < 0.001).

Table 14: 2-factorial ANOVA summary tables for the effect of diabetes and access to care on HRQoL

2-factorial ANOVA summary tables

Tests of Between-Subjects Effects

PCS-12

Source	Type III Sum of Squares	df	Mean Square	F	p-value	Partial Eta Squared	Observed Power
Corrected Model	24779.88	7	3539.98	45.16	< 0.001	0.043	1
Intercept	2859919.76	1	2859919.76	36485.67	< 0.001	0.837	1
Diabetes	4952.39	1	4952.39	63.18	< 0.001	0.009	1
Access to care	7720.69	3	2573.56	32.83	< 0.001	0.014	1
Diabetes * Access to care	61.64	3	20.55	0.26	0.853	0	0.101
Error	555042.38	7081	78.39				
Total	16759582.1	7089					
Corrected Total	579822.27	7088					

R Squared = .043 (Adjusted R Squared = .042)

MCS-12

Source	Type III Sum of Squares	df	Mean Square	F	p-value	Partial Eta Squared	Observed Power
Corrected Model	32412.13	7	4630.3	35.72	< 0.001	0.034	1
Intercept	3561728.25	1	3561728.25	27479.95	< 0.001	0.795	1
Diabetes	113.9	1	113.9	0.88	0.349	0	0.155
Access to care	17367.82	3	5789.27	44.67	< 0.001	0.019	1
Diabetes * Access to care	362.04	3	120.68	0.93	0.425	0	0.257
Error	917781.67	7081	129.61				
Total	20803327	7089					
Corrected Total	950193.8	7088					

R Squared = .034 (Adjusted R Squared = .033)

8. Discussion

8.1 Discussion of the results

This study examined the association between barriers to health care access and general HRQoL in patients with and without diabetes in the Southern Cone of Latin America.

8.1.1 Effect of health care access on diabetics HRQoL

Several clinically relevant new findings are given by this study according to the effect of access to care on HRQoL.

A high amount of the diabetics in this study had barriers to health care access, either they were not insured or they perceived barriers to realized access or both together. Only 407 out of 1025 participants of the total sample were health insured and did not perceive barriers in realized health care access. This is alarming given the fact, that limited health care access in diabetics is associated with negative health outcomes, such as poor glycemic control (cf. Rhee, Cook et al. 2005; Zhang, Bullard et al. 2012), and as indicated in this study, with poorer HRQoL.

Diabetic patients, who had barriers to health care access, had significantly lower quality of life and this remained statistically significant even after controlling for sociodemographic, socioeconomic factors and disease related factors, comorbidities and having a regular physician.

Although there are no clear guidelines for interpreting differences between mean scores as clinically meaningful, a difference between 2 points on a scale from 0 to 100 can be considered as rather small (cf. Sprangers, de Regt et al. 2000: 899). Being uninsured was associated with a significant decrease of 2 points in the PCS-12 and with no significant decrease in the MCS-12. Hence, insurance status seems to play a minor role in determining HRQoL in diabetics. This maybe because, even though people are uninsured, they have the possibility to attend medical service in the public hospitals for free. However, differences in people without realized access, regardless of insurance status could be of clinical relevance when compared to people without problems in accessing care. Being uninsured and having no realized access was associated with a decrease of 6.13 points in the PCS-12 and 5.6 points in the MCS-12. Being insured, but having no realized access was associated with a decrease of 4.75 and 4.8 points in the PCS-12 and MCS-12, respectively. These decreases can be considered as differences of moderate to large magnitude when considering

a threshold of 3 to 5 points as minimal clinically important difference (cf. Schunk, Reitmeir et al. 2012: 208; Sprangers de Regt et al. 2000: 899; Ware Jr, Kosinski et al. 1996: 220ff.; Ware Jr, Snow et al. 1993: 473ff.). However, the decrease in the MCS-12 in the third group was not significant after log10 transformation. Though, the small sample size in this group (n = 44) needs to be considered when interpreting this result. A higher sample size could have detected significant decreases in this group as well after log10 transformation. Overall, barriers to realized health care access as well as having neither realized nor potential access seem to play an important role in the HRQoL among diabetics in the Southern Cone of Latin America. As a matter of fact, access to care was the most important predictor of HRQoL in this population, and associated with higher decreases of HRQoL when compared to other important predictors, such as female gender or physical inactivity.

The results concerning the significant decreases in the mental component are of concern as they indicate, that problems getting health care access could increase the risk for mental problems in diabetics, a population which itself has a higher risk for developing mental disorders compared to non-diabetics (cf. Nicolau and Masmiquel 2013, Hasan, Clavarino et al. 2015; Rotella and Mannucci 2003). Diabetics who experience limited access to care may feel less cared for and could experience more anxiety and uncertainty according disease control and the impact of disease complications on their health. Additionally, obligatory copayments for diabetic treatments paired with unfavorable economic situations may represent a severe burden for diabetics and their families living in the Southern Cone of Latin America. All these factors could contribute to mental health problems in this vulnerable population. However, diabetes itself was not associated with significant decreases in the mental component summary in this population, indicating that access to care plays a more important role in determining the mental component of HRQoL in this population.

Self-perceived barriers to realized access seems also to have negative effects on the physical component. When diabetics need access to care, but are not able to attend health care services, comprehensively physical health will deteriorate due to lack of needed treatment. Additionally, diagnosis and treatment of diabetic complications may be delayed, which would lead to a higher burden of disease for the diabetic patient.

The findings of the detrimental effect of health care access on HRQoL are consistent with previous research on the association of HRQoL and health care access conducted for other chronic diseases.

Self-perceived barriers to health care access was one of the most important predictors for HRQoL among diabetics in this study. This is consistent with results from Maddigon, Feeny et al. (2006) who found that self-perceived unmet healthcare need was also one important predictors of HRQoL among diabetics in Canada (cf. Maddigan, Feeny et al. 2006: 1653f.). as well as from results from studies by Krause, Butler et al. (2013) and Baran, Mulcahy et al. (2014) who found a negative association between self-perceived barriers to health care and lower HRQoL in patients with HIV/ AIDS (cf. Baran, Mulcahy et al. 2014; Krause, Butler et al. 2013). Hoffmann, Rohrer et al. (2008) found that self-reported good access to health care services was associated with higher HRQoL in patients with asthma (cf. Hoffmann, Rohrer et al. 2008).

In this study, realized health care access decreased HRQoL at a clinically relevant level, which is in line with results from Seid, Varni et al (2006), who also found significant decreases in HRQoL of more than 3 points for unmet health care needs in children. Alike this study, the association was controlled for the presence of a regular physician as well as sociodemographic and socioeconomic factors (cf. Seid, Varni et al 2006).

According to the effect of health insurance, the results of this study are inconsistent with previous research. In the study at hand, a significant decrease of 2 points was only observed for the PCS-12. However, the decrease of 2 points can be considered as a rather weak effect. In contrast to this result, a study conducted in the United States found significant and clinically relevant decreases for the PCS-12 (-8.5 points) and the MCS-12 (-4.9 points in uninsured individuals when compared to private insured (cf. Alghnam, Schneider et al. 2016). However, the health care system in the United States is not perfectly comparable to the system in the Southern Cone of Latin America. Insurance status may play a more important role in the United States than in Latin America and the results of the study at hand have to be seen in the light of the situation in the Southern Cone of Latin America. Structural and organizational factors as well as compulsory copayments seem to play a more important role in determining HRQoL among insured and uninsured diabetics in the Southern Cone of Latin America. Furthermore, this study did not distinguish between un-

insured and private insured individuals as the study in the United States did and hence, this could have led to the inconsistent findings between the two studies.

Additionally, the result that realized access may be more important than insurance status could explain the findings of a study by Maliski et al. (2011), who found no consistent relationship between factors contributing to access to care - mainly measured as insurance status - and HRQoL. Realized access to care was often not taken into account as a factor related to health care access and could explain these inconsistencies (cf. Maliski, Connor et al. 2011).

Having a regular physician was not significantly associated with HRQoL (B: -1.11; SE: 0.78; p-value: 0.156; B: 0.51; SE: 0.99; p-value 0.611), indicating that a regular source of care seems to play a minor role as an indicator of health care access in affecting HRQoL in this population. Even though a regular source of care is given, waiting time for appointments, copayments and other barriers of realized access could still be present, impeding access to care.

8.1.2 Effect of covariates on diabetics HRQoL

Besides the access to health care, other determinants of HRQoL among diabetics could have been determined.

In this study, higher age decreased the PCS-12 significantly by -0.19 points (SE: 0.06; p-value: 0.001). However, increasing age was associated with higher MCS-12 scores (B: 0.1; SE: 0.07), but this result was not significant (p-value: 0.177). The decrease in the PCS-12 was rather weak, which is in line with studies conducted in Greece (cf. Papazafiropoulou, Bakomitrou et al. 2015) and in Bangladesh (cf. Saleh, Ara et al. 2015). Anxiety and uncertainty of the diseases impact in the future could affect the mental health of younger diabetics more when compared to older diabetics and this could explain the increase of the mental component with increasing age (cf. Papazafiropoulou, Bakomitrou et al. 2015: 3; Kamradt, Krisam et al. 2017: 10). However, the result was not significant, consistent with the results by Al-Sherhri (2014) and Kamradt, Krisam et al. (2017).

Female gender was only associated with significant and clinically relevant decreases in the MCS-12 (B: -3.05; SE: 1; p-value: 0.002), but not in the PCS-12 (B: -0.53; SE: 0.79, p-value: 0.503). However, the effect of gender was not as strong when compared to Saudi Arabia, were decreases ranged between 9.72 and 31.5 points for the certain SF-36 scales

(cf. Al Hayek, Robert et al. 2014: 226). The decrease in the MCS-12 is rather comparable to results from Chile and Bangladesh, were female gender was associated with a decrease of around 4 points for the ADDQoL and the WHOQOL, respectively (cf. Urzúa, Chirino et al. 2011: 316ff; Safita, Islam et al. 2016: 5). Even though the decrease was only significant in the MCS-12, this finding is consistent with previous research and points out the importance of putting emphasize on women when conducting strategies to improve HRQoL in diabetics.

According to SES, income was not taken into account as covariate in this study due to a high amount of people, who preferred not to answer this question. Previous research showed that income should be taken into account as an important predictor of HRQoL among diabetics (cf. Al Hayek, Robert et al. 2014; Didarloo and Alizadeh 2016: 221; Bourdel-Marchasson, Druet et al. 2013: 229). Educational and occupational statuses were considered as measures of SES in this study. Educational level was associated with a decrease in the PCS-12, but with an increase in the MCS-12. However, these results were not significant (B: -0.52; SE: 0.79; p-value: 0.511 and B: 1.54; SE: 1.01; p-value: 0.126, respectively). This is in line with results from Al Hayek, Robert et al. (2014) and Al-Sherhi (2014) where no association was found between educational level and HRQoL in diabetics. When compared to white collar workers, being retired decreased the PCS-12 by 3.05 points (SE: 1.43; p-value: 0.033) and being a housewife by 3.69 points (SE: 1.5; p-value: 0.014). Being unemployed decreased the PCS-12 by 2.19 points (SE: 1.78). Though, this result was not significant (p-value: 0.218). Results for the MCS-12 according occupational status were not significant (p-values: 0.815; 0.220 and 0.945, respectively). The decrease of HRQoL in unemployed people was not so high when compared to an Iranian population, where unemployment was associated with an almost 9 point decrease in the EQ-VAS scale (cf. Nejhad, Vardanjani et al. 2013: 189). Though, results of the study at hand indicate that being unoccupied, whether because of unemployment, retirement, or household duties, could decrease HRQoL among diabetics in the physical, but not the mental component. Being not able to work could be a result of impaired physical-related quality of life, whether due to the impact of diseases or advanced age of the individual.

Chronic kidney disease and cardiovascular disease significantly decreased the PCS-12 (B: -2.85; SE: 1.38; p-value: 0.039 and B: -3.46; SE: 0.9; p-value < 0.001, respectively), which is consistent with previous research on the association of comorbidities on HRQoL among diabetics (cf. Tan, Ng et al. 2014; Shamshirgaran, Ataei et al. 2016: 248). However,

there was no significant association between comorbidities and MCS-12 scores (p-values: 0.493 and 0.108). Hence, comorbidities seem not to affect diabetics mentally, but rather physically in this population.

Physical inactivity was associated with significant decreases in the PCS-12 and in the MCS-12 (B: -3.95; SE: 0.72; p-value < 0.001 and B: -2.11; SE: 0.92; p-value: 0.021, respectively). This is consistent with previous research (cf. Daniele, Bruin et al. 2013; Maddigan, Feeny et al. 2006: 1652; Eckert 2012:303; Thiel, Al Sayah et al. 2017). This result is not surprisingly when considering that physical activity supports the maintenance of a healthy body, reduces the risk of comorbidities and has positive effects on mental health (cf. WHOa 2017; Penedo and Dahn 2005). Hence, physical inactivity in people with diabetes affects not only the physical, but also the mental component of HRQoL.

Increased BMI was associated with lower HRQoL in the PCS-12 (B:-0.27; SE: 0.06; p-value < 0.001, which is consisted with previous research. Obesity as indicated with high BMI could be the result of physical inactivity and negatively affects physical health status (cf. Sundaram, Kavookjian et al. 2007: 174; Vidal-Peracho, Lucha-López et al. 2014: 10; Zimbudzi, Lo et al. 2016: 7; Maddigan, Feeny et al. 2006: 1654).

Higher age of diabetes onset, indicating fewer years lived with the disease was associated with increases of PCS-12 (B: 0.13; SE: 0.04 p-value < 0.001). This is consistent with previous research (cf. Didarloo and Alizadeh 2016: 6; Javanbakht, Abolhasani et al. 2012: 7 Thommasen and Zhang 2006: 4; Safita, Islam et al. 2016: 5). However, the age of onset in the MCS-12 was not significantly associated with HRQoL (B: -0.03; SE: 0.05; p-value: 0.525). Longer diabetes duration could lead to more complications and participation restrictions, which then has negative effects on the physical component of HRQoL (cf. Saleh, Ara et al. 2015).

Insulin therapy was only associated with significant decreases in the MCS-12 (B: -3.17 SE: 1.36; p-value: 0.020), which is consistent with previous research. However, unlike the results of previous research, no significant decreases were observed for the PCS-12 (B: -0.43; SE: 1.06; p-value: 0.684) (cf. Schunk, Reitmeir et al. 2015; Sepúlveda, Poínhos et al. 2015; Al Hayek, Robert et al. 2014: 227; Bourdel-Marchasson, Druet et al. 2013: 232; AL-Aboudi, Hassali et al. 2015: 5; (Thommasen and Zhang 2006: 275). The negative affect of insulin therapy on the mental component of diabetics HRQoL in the Southern Cone of Latin America could be due to the dependence of insulin paired with the uncertainty and anxi-

ety to be able to constantly receive this drug in the light of impeded health care access and the economic burden of individuals and their families. Insulin therapy seem not to affect the physical component, indicating that other factors, such as comorbidities play a more important role in determining physical-related HRQoL in this population.

Since the HbA1C value was not available, fasting blood glucose was considered as measure of glycemic control in this study. However, no significant association was found between blood sugar and HRQoL (B: -0.003; SE: 0.01; p-value: 0.569 for the PCS-12 and B: 0.01; SE: 0.007; p-value: 0.196 for the MCS-12). The value of fasting blood glucose only represents a snap-shot and may not be a precise reflection of disease control (cf. Sacks 2011). In this population, HRQoL could be determined by HbA1C levels rather than by fasting blood glucose.

Hospitalization was associated with decreases in the PCS-12 (B: -3.36; SE: 1.05; p-value < 0.001), but not with the MCS-12 (B: -1.32; SE: 1.34; p-value: 0.325). Hospitalization could be due to deterioration in physical health and hence affected the domain of physical HRQoL significantly.

8.1.3 Reasons for barriers to realized health care access among diabetics

In this study, some barriers to realized health care access could have been determined. However, the numbers for each different reason were too small for running any analyses concerning the impact of each factor on PCS-12 and MCS-12 scores. Nevertheless, results of this study gave a hint on the factors that could impede realized health care access and revealed structural and organizational shortcomings according health care access. A study by Konerding, Bowen et al. (2017) found that HRQoL decreased with increasing travel and waiting time (cf. Konerding, Bowen et al. 2017: 22f.). Long waiting time in the provider's office was also mentioned by the participants in this study. Other reasons for barriers to realized access mentioned by the participants were long appointment waiting times, commitments at home and at work, required copayments, negative expectations of the healthcare system and a lack of infrastructure and public transport in order to get to health care facilities.

Surprisingly, when taking into account that all three countries range high according the amount of physicians per habitant, 4 participants in the diabetic sample mentioned that they could not obtain health care due to a lack of physicians in the health care facility. However, this could be due to the provinces and sizes of the cities the study was conducted

in. As mentioned earlier, the number of physicians differs among the cities, with more physicians in metropolises when compared to mid-sized cities, were this study was conducted. Additionally, the supply of public providers could be insufficient, when compared to the high amount of people using public providers.

Participants also mentioned long appointment waiting times as barriers to realized health care. In Chile, maximum waiting times are guaranteed by law. For diabetes, treatment after confirmation of the diagnosis is guaranteed within 24 hours in type 1 diabetes and within 45 days for type 2 diabetes. Referrals to specialists are guaranteed within 90 days when required (cf. MOH Chile 2007: 12ff.). Although in Chile guarantees exists on maximum waiting times, it is not known, whether these maximum waiting times are applied in practice. In Argentina and Uruguay, such guarantees do not exist. Diabetic people in all three countries experience waiting times as too long and as a restriction in accessing health care.

8.1.4 Effect of diabetes and health care access on HRQoL

Mean SF-12 scores among diabetics were 44.51 (SD 10.36) for the PCS-12 and 52.07 (SD 12.18) for the MCS-12. Mean PCS-12 scores were 5 points higher when compared to a Nigerian diabetic population, but almost 4 points lower when compared to a diabetic population in the United States (cf. Bennett, Ouyang et al. 2008: 4; Bolarunwa, Ameen et al. 2016: 184). For the MCS-12, mean scores were comparable to populations in the United States (mean: 53.3 SD: 8.8) and in Germany (mean: 53.3 SD: 9.3) (cf. Bennett, Ouyang et al. 2008: 4; Schunk, Reitmeir et al. 2012: 649).

Consistent with previous research, HRQoL among diabetics was lower when compared to participants without this disease. The SF-12 scores of diabetics were 3.75 points lower for the PCS-12 and 1.02 points lower for the MCS-12 when compared to non-diabetics. However, decreases were only significant for the PCS-12. These findings are comparable to results from a German study, were a significant difference by 4.1 points for the PCS-12 in diabetics compared to participants without diabetes was found. A significant difference in the MCS-12 was only found in women (cf. Schunk, Reitmeir et al. 2012: 652). In the study at hand, no sensitivity analysis was performed for gender differences between diabetic and non-diabetics. However, female gender was associated with a significant decrease of more than 3 points in the MCS-12 for the diabetic sample, indicating that females are more affected by impaired mental HRQoL than males. Bennett, Ouyang et al. (2008) reported a significant decrease of the SF-36 PCS-12 of around 3 points in diabetics compared to non-

diabetics, which is slightly lower but still comparable to the decrease of 3.746 points that was found in this study (cf. Bennett, Ouyang et al. 2008).

Diabetes-associated decreases in HRQoL in this study are more comparable to diabetes associated decreases found in western populations rather than in other middle and low income countries. In Bangladesh, a mean difference of -11.5 for the EQ-VAS was found in diabetics when compared to non-diabetics (cf. Safita, Islam et al. 2016: 6). In China the decrease in general health measured with the SF-36 was almost 8.4 points in diabetics (cf. Yan, Hong et al. 2016: 174). Diabetes seems to be a less important predictor of HRQoL in South America when compared to South Asian countries. South Asian countries have lower percentages of diabetics able to control the disease when compared to the diabetic population in the Southern Cone of Latin America and this could contribute to the differences in diabetes-related HRQoL between these populations (Shen, Kondal et al. 2016: 68).

Since not only self-reported diabetics were included, but also diabetics that were identified as diabetics through the study, awareness of diabetes was considered a covariate in the analysis, comparing people who knew about their disease and newly diagnosed diabetics. The SF-12 was filled in before the newly diagnosed diabetics received the diagnosis. Being aware of the disease decreased the PCS-12 by -2.25 points (SE: 0.89; p-value: 0.012) and the MCS-12 by -2.79 points (SE: 1.14; p-value: 0.015). This indicates that the diagnosis of diabetes itself could have a detrimental effect on HRQoL, regardless of disease-related complications, which is consistent with previous research (cf. Bennett, Ouyang et al. 2008).

Diabetics were less likely to have good access to health care, reported more often barriers to realized access and were more likely to have neither potential nor having realized access when compared to people without diabetes. This is concerning when taking into account that diabetics were more likely to have other chronic conditions and complications, such as chronic kidney disease and cardiovascular disease, when compared to non-diabetics. Hence, diabetics rely on good health care access in order to treat these conditions and to prevent other undesirable health outcomes. Surprisingly, even though diabetics were more likely to have a regular physician in comparison to people without this disease, self-reported access to care was more often impeded in diabetics when compared to non-diabetics. Hence, having a regular physician may not facilitate access to care, even though this seemed conclusive. This could be due to the fact, that even though a regular source of

care exists, people could still experience barriers to realized access, such as compulsory copayments.

According to the effect of access to care on HRQoL among diabetics and non-diabetics, quality of life was lower in all access groups in the diabetic sample when compared to the non-diabetic sample, but not consistently with regards to the MCS-12 scores. Results of the 2-factorial ANOVA revealed no significant interaction for access to care and diabetes for both, the PCS-12 and the MCS-12. However, there was a significant main effect of access to care in both summary scores and a significant main effect for diabetes in the PCS-12.

Hence, access to care seems to have a detrimental effect on HRQoL among diabetics, but also among people without diabetics for both, physical and mental components of HRQoL. Additionally, diabetes seems to negatively affect the physical component of HRQoL.

Diabetics depend on good access to care in order to be able to control the disease and to prevent complications. However, the presence of diabetes and poor access to care seem not to interact in predicting lower HRQoL. Nevertheless, this result could be due to some limitations in the methods (see 8.2).

Access to health plays an important role in predicting HRQoL of diabetics, even though this role may not be significantly and clinically more prominent regarding the mental component of HRQoL in comparison to people without diabetes. Diabetes and access to care have detrimental effects on the physical component of HRQoL and even though these factors seem not to interact, access to care in diabetics should be tackled in order to improve HRQoL.

8.2 Discussion of the methods

The study at hand represents some strength and limitations according to the study design and the methods used in order to answer the research questions. In the following, strengths and limitations are discussed.

8.2.1 Limitations of the methods

The cross-sectional nature of the data analyses represents a limitation of the study. Hence, no cause and effect could be determined, but rather associations. However, it can be assumed that rather the access to health care impacts HRQoL and not vice versa.

Another limitation of the study is that there was no distinction between diabetes type 1 and type 2, and hence no differences among these groups could have been determined. Previous research showed that determinants of HRQoL as well as HRQoL may differ between type 1 and type 2 diabetics (cf. Naughton, Joyce et al. 2014). Thus the effect of health care access in the certain group may be under- or overestimated. However, it can be assumed that the majority of the sample has diabetes type 2, since this is the most common type of diabetes worldwide as well as in the Southern Cone of Latin America (cf. WHO 2017).

Furthermore, there was no comparison between countries. Health care systems in the three countries differ according to the amount of copayments, which vary between 20 % and 50 % of the obtained services in the certain countries. Countries could also differ according waiting times for appointments. While the government of Chile implemented a guarantee for maximum waiting times, governments of Argentina and Uruguay do not considered such guarantees in health policy. Hence, the real effect of barriers to health care could be disguised by such differences.

Additionally, no comparison between social security and private insurance was made. Since the effects on HRQoL could differ, whether someone has a social security or a private insurance, distinguishing only between insured and uninsured people could cover up this effect (Bock, Hajek et al. 2017).

In CESCAS I, HRQoL was measured with the SF-12 and the EQ-5D. Because the SF-12 is more sensitive than EQ-5D in order to detect health changes, this instrument was used in the study at hand (cf. Javanbakht, Abolhasani et al. 2012; Bennett, Ouyang et al. 2008; Norris 2005; Luscombe 2000; Pakpour, Nourozi et al. 2011).

The SF-36, from which the SF-12 was derived, as well as the PCS-12 and MCS-12 were successfully validated in South America (cf. Augustovski, Lewin et al. 2008). Due to highly corresponding summary scores, the SF-12 is a practical alternative to the SF-36 with good reliability, construct validity and internal consistency and was tested in different population and for different diseases (Rotella and Munnucci 2013; Pakpour, Nourozi et al. 2011; King Jr, Horowitz et al. 2005). The SF-12 was broadly used in previous studies on HRQoL among diabetics and represents a practical and valid instrument for epidemiological research (cf. Schunk, Reitmeir et al. 2012: 651).

Though, the lack of a disease-specific instrument for measuring HRQoL represents a limitation of the study. Despite the great practicability and the high validity of the SF-12, this

instrument is not sensitive enough to evaluate factors of particular interest for people suffering from diabetes and hence may underestimate the health loss that is associated with this specific disease (cf. Garratt, Schmidt et al. 2002; Speight, Reaney et al. 2009). However, by using a generic instrument, diabetics could be included, that did not know about their disease. Additionally, Huang, Hwang et al. (2008) indicated, that the SF-36, from which the SF-12 was derived, was superior compared to the D-39, a diabetes specific instrument, regarding the discrimination of complication and well-being groups (cf. Huang, Hwang et al. 2008). Most studies on HRQoL in diabetics as well in other chronic conditions used generic instruments, especially the SF-12 and thus the broad use of this questionnaire in previous research allows for better comparing the results of this study with previous research. However, the use of both, a generic and a disease-specific questionnaire would have been the most appropriate way in assessing HRQoL in diabetics (cf. Aguiar, Vieira et al. 2008).

For measuring access to care, questions were derived from the HCHS/ SOL questionnaire. This questionnaire was developed for the Latino population living in the United States and could not be suitable for the Latin population living in the Southern Cone of Latin America. These two populations could face different problems in accessing health care due to different health care systems. Hence, factors considered as important according to health care access could have been not taken into account for the population living in the Southern Cone of Latin America.

Additionally, it was not considered what kind of health care need was not able to be fulfilled and if the unmet needs where associated with diabetes and/or diabetic complications or not. Hence, no conclusions can be drawn whether the unmet health care needs were related to the disease.

The question of unmet health care needs referred to the past 12 month and this time interval could have led to recall bias. Participants may have experienced barriers, but did not remember this. In this studies, people with diabetes reported more often barriers to realized access than participants without the disease. Due to the threatening characteristics of the disease, participants with diabetes could attach more importance to barriers to realized health care access and hence rather remember these barriers than participants without diabetes.

The explained variance of HRQoL, especially in the MCS-12, was quite low (6.8 %), indicating that there are other predictors of HRQoL that are not considered in the model, for

example neuropathy, self-management behavior, social support, personality traits and disease acceptance (cf. Misra and Lager 2008; Solli, Stavem et al. 2010: 5). Psychological and social support as well as motivation and personality are factors that influence HRQoL in the theoretical model by Ferrans, Zerwic et al. (2005). However, these factors were not considered in this study. Factors, that were significantly and clinically relevant associated with decreases in the PCS-12 (for example comorbidities or occupational status), were not associated with the MCS-12, indicating that these factors did not account for the mental component of HRQoL in diabetics in the Southern Cone of Latin America and that other predictors account for the mental component, that were not considered in the model. However, not all important predictors could be taken into account because they were not available in the database or the amount of missing values was so high, that they could not have been considered in the analysis, for example in the case of income as measure of socioeconomic status.

Other confounders of HRQoL include self-management behavior, social support and disease acceptance (cf. Misra and Lager 2008), sleep (cf. Chasens, Sereika et al. 2014), diabetes-related distress (cf. Chew, Mohd-Sidik et al. 2015), ethnicity (cf. Laiteerapong, Karter et al. 2013), personality traits (cf. Imayama, Plotnikoff et al. 2011), spiritual well-being (cf. Jafari, Farajzadegan et al. 2014), diabetes-related hospitalization in the past year (cf. Javanbakht, Abolhasani et al. 2012) and health literacy (Al Sayah, Qiu et al. 2016), which were not taken into account in the analyses as potential predictors and confounders of HRQoL.

Glycemic control was measured with fasting blood glucose. Fasting blood glucose has several disadvantages compared to HbA1C values and may not reflect glycemic control well and represents a limitation of the study (cf. Sacks 2011). HbA1C may be a more important predictor HRQoL among diabetics, but was not considered as predictor in the study at hand (cf. Vidal-Peracho, Lucha-López et al. 2014: 381).

Additionally, not all important indicators of potential and realized access could have been measured in the study, but rather two that were considered as the most important indicators that could have been derived from the available questionnaire used in the CECAS I study. Quality of care was not taken into account, which may have also an important impact on HRQoL and could have also affected perceived barriers to health care access. In the diabetic sample, 11 participants mentioned that they did not obtain health care, although they

needed it, because they were not satisfied with the provided care. According to the health care access framework of the Institute of Medicine's Committee on Monitoring Access to Personal Health Services, appropriateness of care and quality of providers moderate HRQoL and should be included when assessing access to health care and HRQoL (cf. Gold 1998). However, quality of care was not taken into account and represents a limitation of the study.

According to the statistical methods, some limitations need to be considered. In order to compare diabetics and non-diabetics, ORs were calculated. However, there was no adjustment made for covariates, degrading the validity of the results.

The observed power for the 2-factorial ANOVA concerning the interaction of diabetes and health care access was very low for both, the PCS-12 and the MCS-12 (0.101 and 0.155, respectively). Additionally, the power was very low for diabetes for the MCS-12 (0.257). The insufficient power could have led to the non-significant results. With sufficient power, the results could have been significant. Hence, these results should be interpreted with caution.

For the two-factorial ANOVA, the assumption of homogeneity of variances was not met for adjusted and unadjusted analyses (Levene's test < 0.001 for both PCS-12 and MCS-12). Additionally, for the diabetic and non-diabetic sample, sample sizes among the groups were unequal and the number of participants in the group with potential, but no realized health care access was quite low when compared to the other three groups. Overall, generalizability of these results should be taken with caution, because important assumptions for the two-factorial ANOVA were not met.

8.2.2 Strengths of the methods

To the authors' knowledge, this is one of the first studies regarding the association of access to care and HRQoL in diabetics and the first one examining determinants of HRQoL in diabetics in the Southern Cone of Latin America and contributes to the evidence of the association between HRQoL and health care access.

Data was derived from the CESCAS I study, which used multiple stage sampling. Hence, selection bias can be rather precluded due to the sophisticated sampling method used.

Strength of the study include, that the association of HRQoL health care access was controlled for various covariates that are considered important determinants of diabetics´ quality of life in current literature.

Questionnaires were filled in at the homes of the participants by trained researchers and not at health care facilities or with their regular physicians and hence social desirability bias could be minimized. In this study, the insurance status as well as the realized access to care were taken into account. This represents strength of the study as it revealed which of these factors played a more important role in determining HRQoL.

Additionally, misclassification of diabetic cases can be rather precluded due to the inclusion of diabetic cases, which were detected in the study by international diagnostic criteria.

The measurement of included covariates can be considered as being of good quality. For example BMI was not self-reported, but calculated with anthropological measures of weight and height and valid instruments were used for examining health behavior, for example the IPAQ for examining physical activity (Rubinstein, Irazola et al. 2011: 3f.).

Overall, assumptions for the statistical tests in the analyses for answering the first research question were met, and if not, other appropriate tests and corrections were applied, such as Welch correction, contributing to the quality of the analyses and the obtained results. For describing the diabetic sample characteristics, residuals of the continuous variables BMI and fasting blood glucose were not perfectly normally distributed and hence, the assumption of normally distributed data in order to conduct one way ANOVA was violated. However, ANOVA is quite robust to non-normal distributed data and no log10 transformation is needed in order to confirm these results (cf. Schmider, Ziegler et al. 2010).

8.3 Implications for further research

This study indicates that especially barriers to realized health care access negatively affect HRQoL in diabetics. Insurance status seems to play a minor role in determining HRQoL in this population. However, more research is necessary in order to provide broader evidence on these associations. Additionally, the sample was limited on a population in the Southern Cone of Latin America. Further research should determine if such associations also exist in other middle and in low income countries.

Furthermore, research should determine the magnitude of the reasons for barriers to realized health care regarding HRQoL and other health outcomes in diabetic patients in the

Southern Cone of Latin America. With knowing which factors impede the realized access to health care, these factors could be tackled on the health policy level in order to improve not only the access to health care, but also the quality of life among diabetic patients.

Studies should determine the effects of barriers for health care access on important diabetes-related measures other than HRQoL. Previous research showed that about 20 % of the diabetics in the Southern Cone of Latin America are not aware of their disease and that 35 % of all diagnosed diabetics receive no treatment. Additionally, only half of all treated diabetics comply with the target levels of blood glucose (cf. Shen, Kondal et al. 2016: 67). Results of this study showed, that 82 % of diabetics with good access to care were aware of their disease and had mean blood glucose of 146 mg/dl (SD: 64), while only 76.4 % of the uninsured diabetics with barriers to realized access were aware of their disease and had mean blood glucose of 153.6 mg/dl (SD 69.9). However, these results were not significant (p-values: 0.053 and 0.098, respectively), which may be due to the rather small sample size. Hence, whether access to health care contributes to awareness and diabetic control, should be further investigated.

9. Conclusion and public health relevance

Despite some limitations, the study represents also some noteworthy strength and indicates that health care access should be taken into account as an important factor determining the quality of life in patients with diabetes living in the Southern Cone of Latin America.

According to the Argentine MOH, the priority of health policy makers is to ascertain that all habitants of the nation have access to health care. However, this study showed that impeded health care access is a common experience among people with diabetes in this region.

Since improving HRQoL among diabetics is an overall objective in the national health policy in Argentina, and is also important in Chile and Uruguay, access to health care should be taken into account in order to be able to comply with this objective.

Results indicate that realized access to care seems to be more important than insurance status in order to determine HRQoL in diabetics. Because barriers to realized access to health care are associated with such notable decreases in HRQoL in diabetics, even among health insured patients, interventions and policies should be implemented to overcome these barriers and to improve HRQoL in diabetic patients.

An example of a policy could be the implementation of a maximum waiting time in Argentina and Uruguay following the Chilean example. However, implementing such policies is not enough. Such implementations should be evaluated in practice. Compulsory copayments seem to contribute to barriers to realized access and can only be solved with changes on the policy level. However, in order to recommend interventions for improving realized access, more research is necessary in order to explore what factors impede the realized access to health care services and to determine whether there is a social gradient in realized access to care. Hence, made-to-order interventions could be implemented aiming to improve realized access to health care and thereby HRQoL in diabetic patients.

Overall, results of this study indicate that health policy makers should focus on improving the realized access to care for all people rather than to provide general coverage to the population in order to be able to improve HRQoL in diabetics and non-diabetics. However, this does not mean that providing general coverage should be neglected by health policy,

but rather means that improvements of the realized access should be the priority by policy makers in the Southern Cone of Latin America.

Additionally, female gender, insulin therapy, being retired, being a housewife, having cardiovascular disease, being physically inactive and hospitalized in the last year are also important influencing factors on HRQoL in diabetics in this population and should be taken into account when planning interventions to enhance diabetics HRQoL in the Southern Cone of Latin America.

Since there was an effect of the presence of diabetes and an effect of poor access to care for predicting lower physical HRQoL, interventions should focus on diabetics with impeded access to care.

The effect of impeded access to care on lowering HRQoL was not only observed in diabetics, but also in participants without diabetes. Hence, not only people with diabetes would benefit from interventions for improving access to care in the Southern Cone of Latin America, but also people without this disease.

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Appendices

Search results of studies on determinants of HRQoL and diabetes

CESCAS HRQoL questionnaire (SF-12 and EuroQol)

CESCAS health care access questionnaire based on SOL

Linear regression histograms and plots

Linear regression summary tables of log10 transformed PCS-12 and MCS-12 scores

Adjusted 2-factorial ANOVA summary table

DECLARATION OF INDEPENDENT WORK

"I hereby declare that I wrote this thesis without any assistance and used only the aids listed. Any material taken from other works, either as a quote or idea have been indicated under 'References'."

Hamburg, ...

.....

Search results of studies on determinants of HRQoL and diabetes

Search strings	PubMed	LILACS	Google Scholar
“health related quality of life” AND “diabetes” AND “determinant”	Items found: 280	Items found: 5	Items found: 21900
“health related quality of life” AND “diabetes” AND “predictor”	Items found: 631	Items found: 2	Items found: 20900
“health related quality of life” AND “diabetes” AND “access to care”	Items found: 333	Items found: 5	Items found: 4640
“health related quality of life” AND “diabetes” AND “care provider”	Items found: 432	Items found: 1	Items found: 8240
“health related quality of life” AND “diabetes” and “realized access”	Items found: 11	Items found: 0	Items found: 72
“realized quality of life” AND “diabetes” AND “insurance status”	Items found: 79	Items found: 0	Items found: 3330

CESCAS

Calidad de vida

Formulario: CV Versión: 17/09/10

Número identificatorio			-			-				

CV01

Número control			.				.			

(Número de documento) CV02

Instrucciones: Los recuadros en gris contienen frases que usted puede utilizar durante la encuesta. Ingrese la respuesta dada por el participante para cada pregunta.

Ahora quisiera hacerle unas preguntas generales sobre cómo se siente usted habitualmente y sobre algunas cosas que le han sucedido.

1. En general, usted diría que su salud es:

Excelente	1☐
Muy buena	2☐
Buena	3☐
Regular	4☐
Mala	5☐

Cinta de opciones A

CV1

2. Las siguientes preguntas se refieren a actividades o cosas que usted podría hacer en un día normal. Su salud actual, ¿le limita para hacer esas actividades o cosas? Si es así, ¿cuánto?

	Sí, me limita mucho ▼	Sí, me limita un poco ▼	No, no me limita nada ▼
a. Esfuerzos moderados, como mover una mesa, pasar la aspiradora, jugar golf o caminar más de 1 hora. CV2A	1☐	2☐	3☐
b. Subir varios pisos por escalera CV2B	1☐	2☐	3☐

Cinta de opciones B

3. Durante las 4 últimas semanas, ¿con qué frecuencia ha tenido alguno de los siguientes problemas en su trabajo o en sus actividades cotidianas, debido a algún problema físico?

	Siempre ▼	Casi siempre ▼	Algunas veces ▼	Sólo alguna vez ▼	Nunca ▼
a. ¿Hizo menos de lo que hubiera querido hacer? CV3A	1☐	2☐	3☐	4☐	5☐
b. ¿Tuvo que dejar de hacer algunas tareas en su trabajo o en sus actividades cotidianas? CV3B	1☐	2☐	3☐	4☐	5☐

Cinta de opciones C

Número identificatorio			-			-				

Formulario: CV
Versión: 17/09/10

4. Durante las 4 últimas semanas, ¿con qué frecuencia ha tenido alguno de los siguientes problemas en su trabajo o en sus actividades cotidianas, debido a algún problema emocional (como estar triste, deprimido/a, o nervioso/a)?

	Siempre ▼	Casi siempre ▼	Algunas veces ▼	Sólo alguna vez ▼	Nunca ▼
a. ¿Hizo menos de lo que hubiera querido hacer por algún problema emocional? CV4A	1☐	2☐	3☐	4☐	5☐
b. ¿Hizo su trabajo o sus actividades cotidianas menos cuidadosamente que de costumbre por algún problema emocional? CV4B	1☐	2☐	3☐	4☐	5☐

Cinta de opciones C

5. Durante las 4 últimas semanas, ¿hasta qué punto el dolor le ha dificultado su trabajo habitual (incluido el trabajo fuera de casa y las tareas domésticas)?

Nada 1☐
Un poco 2☐
Moderadamente 3☐
Bastante 4☐
Mucho 5☐

Cinta de opciones D

CV5

6. Las siguientes preguntas se refieren a cómo se ha sentido y cómo le han ido las cosas durante las 4 últimas semanas. Para cada pregunta elija la respuesta más cercana a la manera en que se estuvo sintiendo. Durante las últimas 4 semanas ¿con qué frecuencia...

	Siempre ▼	Casi siempre ▼	Algunas veces ▼	Sólo alguna vez ▼	Nunca ▼
a. se sintió tranquilo/a? CV6A	1☐	2☐	3☐	4☐	5☐
b. se sintió lleno/a de energía? CV6B	1☐	2☐	3☐	4☐	5☐
c. Se sintió desanimado/a y/o deprimido/a? CV6C	1☐	2☐	3☐	4☐	5☐

Cinta de opciones C

7. Durante las 4 últimas semanas, ¿con qué frecuencia la salud física o los problemas emocionales le han dificultado sus actividades sociales (como visitar a los amigos o familiares)?

CV7

Siempre 1☐
Casi siempre 2☐
Algunas veces 3☐
Sólo alguna vez 4☐
Nunca 5☐

Cinta de opciones C

Número identificatorio			-			-				

Formulario: CV
Versión: 17/09/10

¿Cuáles de las siguientes afirmaciones describen mejor su estado de salud el día de hoy?

8. **Movilidad** CV8

Cinta de opciones E

No tengo problemas para caminar 1 ☐
Tengo algunos problemas para caminar 2 ☐
Tengo que estar en cama 3 ☐

9. **Cuidado-Personal** CV9

Cinta de opciones F

No tengo problemas con el cuidado personal 1 ☐
Tengo algunos problemas para lavarme o vestirme solo 2 ☐
Soy incapaz de lavarme o vestirme solo 3 ☐

10. **Actividades Cotidianas**
(ej., trabajar, estudiar, hacer tareas domésticas, actividades familiares o actividades recreativas) CV10

Cinta de opciones G

No tengo problemas para realizar mis actividades cotidianas 1 ☐
Tengo algunos problemas para realizar mis actividades cotidianas 2 ☐
Soy incapaz de realizar mis actividades cotidianas 3 ☐

11. **Dolor/Malestar** CV11

Cinta de opciones H

No tengo dolor ni malestar 1 ☐
Tengo un dolor o malestar moderado 2 ☐
Tengo mucho dolor o malestar 3 ☐

12. **Ansiedad/Depresión** CV12

Cinta de opciones I

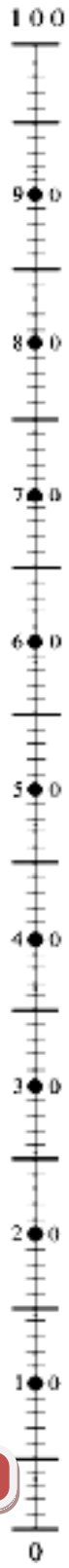
No estoy ansioso ni deprimido 1 ☐
Estoy moderadamente ansioso o deprimido 2 ☐
Estoy muy ansioso o deprimido 3 ☐

13. Estado de salud

Para ayudar a la gente a describir lo bueno o malo que es su estado de salud hemos dibujado una escala parecida a un termómetro en la cual se marca con un 100 el mejor estado de salud que pueda imaginarse y con un 0 el peor estado de salud que pueda imaginarse.

Su estado de salud hoy

Nos gustaría que nos indicara en esta escala, en su opinión, lo bueno o malo que es su estado de salud en el día de hoy. Por favor, **marque el punto que en su opinión indique lo bueno o malo que es su estado de salud en el día de hoy.**



Mejor estado de salud imaginable

Peor estado de salud imaginable

PUNTAJE ☐☐☐ CV13

Número identificatorio			-			-				

Formulario: CV
Versión: 17/09/10

14. Durante las últimas 2 semanas, ¿con qué frecuencia ha tenido molestias por cualquiera de los siguientes problemas?

	No	Varios días	Más de la mitad de los días	Casi todos los días	
a. Poco interés o placer en hacer cosas	1☐	2☐	3☐	4☐	CV14A
b. Sentirse decaído/a, deprimido/a o desesperanzado/a	1☐	2☐	3☐	4☐	CV14B
c. Dificultad para dormirse o para mantener el sueño, o dormir demasiado	1☐	2☐	3☐	4☐	CV14C
d. Sentirse cansado/a o con poca energía	1☐	2☐	3☐	4☐	CV14D
e. Con poco apetito o comer excesivamente	1☐	2☐	3☐	4☐	CV14E
f. Sentirse mal con usted mismo/a o sentir que usted es un fracaso o que le ha fallado a su familia o a sí mismo/a	1☐	2☐	3☐	4☐	CV14F
g. Dificultad para concentrarse en cosas, tales como leer el diario o ver televisión	1☐	2☐	3☐	4☐	CV14G
h. Estar más lento/a que lo habitual para moverse o hablar, o, por el contrario, estar más inquieto/a e intranquilo/a, moviéndose más que lo habitual	1☐	2☐	3☐	4☐	CV14H
i. Pensamientos de que usted estaría mejor muerto/a, o de hacerse daño a sí mismo/a de alguna manera	1☐	2☐	3☐	4☐	CV14I

Cinta de opciones J

15. Si Ud. tuvo molestias por alguno de los problemas mencionados, ¿cuánta dificultad le han causado estos problemas para hacer su trabajo, encargarse de tareas del hogar o llevarse bien con otras personas?

CV15

1☐ Ninguna dificultad 2☐ Un poco de dificultad 3☐ Mucha dificultad 4☐ Extremada dificultad

Cinta de opciones K

16. ¿Ha experimentado alguna de estas situaciones en el último año?

	No	Sí	
a. Separación o divorcio	1☐	2☐	CV16A
b. Pérdida de trabajo	1☐	2☐	CV16B
c. Jubilación	1☐	2☐	CV16C
d. Pérdida de la cosecha / falla de negocios	1☐	2☐	CV16D
e. Violencia	1☐	2☐	CV16E
f. Conflicto familiar importante	1☐	2☐	CV16F
g. Enfermedades o lesiones importantes	1☐	2☐	CV16G
h. Muerte o enfermedad grave de un familiar cercano	1☐	2☐	CV16H
i. Muerte del cónyuge	1☐	2☐	CV16I

Número identificatorio			-			-				

Formulario: CV
Versión: 17/09/10

17. Durante las últimas 4 semanas ¿con qué frecuencia le ha molestado alguno/s de los siguientes problemas?

	Nunca	Varios días	Más de la mitad de los días	
a. Sentirse nervioso/a, ansioso/a, con los nervios de punta o preocuparse mucho por distintas cosas.	1☐	2☐	3☐	CV17A

ENCUESTADOR: SI RESPONDIÓ "NUNCA" FINALICE EL CUESTIONARIO

b. Sentirse inquieto/a de tal forma que le cuesta quedarse quieto/a	1☐	2☐	3☐	CV17B
c. Cansarse con mucha facilidad	1☐	2☐	3☐	CV17C
d. Dolor o tensión muscular	1☐	2☐	3☐	CV17D
e. Problemas para quedarse dormido/a o para seguir durmiendo	1☐	2☐	3☐	CV17E
f. Problemas para concentrarse en algo, como leer un libro o ver la televisión	1☐	2☐	3☐	CV17F
g. Irritarse o enfadarse fácilmente	1☐	2☐	3☐	CV17G

CESCAS

Utilización de Servicios de Salud

Formulario: SS Versión: 17/09/10

Número identificatorio			-			-				

Instrucciones: Los recuadros en gris contienen frases que usted puede utilizar durante la encuesta. Ingrese la respuesta dada por el participante para cada pregunta.

Ahora quisiera hacerle unas preguntas sobre el tipo de cobertura médica que usted tiene, y con qué frecuencia consulta al médico.

1. En los <u>últimos 12 meses</u>, ¿hubo algún momento en el que necesitó atención médica pero no pudo obtenerla?

SS1

No	1 ☐ →	**CONT. EN PREGUNTA 4**
Sí	2 ☐	
No contesta	3 ☐ →	**CONT. EN PREGUNTA 4**
No sabe	9 ☐ →	**CONT. EN PREGUNTA 4**

2. En los <u>últimos 12 meses</u>, ¿por qué razón o razones no recibió usted atención médica cuando la necesitó?

	No	Sí	
a. No pudo comunicarse por teléfono con el consultorio médico	1 ☐	2 ☐	SS2A
b. No pudo obtener una cita lo suficientemente rápido	1 ☐	2 ☐	SS2B
c. No se daban citas los días que usted podía ir	1 ☐	2 ☐	SS2C
d. No tenía medios de transporte o alguien que lo lleve	1 ☐	2 ☐	SS2D
e. Cuando llegó a la cita tuvo que esperar demasiado para ver al doctor	1 ☐	2 ☐	SS2E
f. No podía tomar tiempo libre de su trabajo/no tenía tiempo	1 ☐	2 ☐	SS2F
g. Estaba cuidando a alguien y no podía dejarlo solo(a)	1 ☐	2 ☐	SS2G
h. No podía pagarlo	1 ☐	2 ☐	SS2H
i. No pidió cita porque nunca lo atienden bien	1 ☐	2 ☐	SS2I
j. Otra:	1 ☐	2 ☐	SS2J

j.1 especifique _____ SS2J1

Número identificatorio			-			-				

Formulario: SS
Versión: 17/09/10

SI RESPONDE "Sí"A 2h → 3. Durante los <u>últimos 12 meses</u>, ¿necesitó usted algo de lo siguiente, pero no lo obtuvo porque no podía pagarlo?

	No	Sí	
a. Medicamentos con receta médica	1 ☐	2 ☐	SS3A
b. Ir a ver a un doctor	1 ☐	2 ☐	SS3B
c. Cuidado o consulta de salud mental	1 ☐	2 ☐	SS3C
d. Cuidado dental	1 ☐	2 ☐	SS3D
e. Anteojos	1 ☐	2 ☐	SS3E

4. Durante los <u>últimos 12 meses</u>, ¿cuántas veces consultó a un doctor u otro profesional de salud? Si la respuesta es "Nunca", ingrese "00". Si no sabe o no recuerda escriba "99".

☐☐ Número de veces SS4

SI LA RESPUESTA A LA PREGUNTA 4 ES "00" → CONTINÚA EN LA PREGUNTA 9

5. ¿De qué especialidad eran él o los profesionales consultados? *(puede marcar más de una opción)*

	No	Sí	
a. Clínico/Médico General/Médico de familia	1 ☐	2 ☐	SS5A
b. Gineco-Obstetra	1 ☐	2 ☐	SS5B
c. Cirujano general	1 ☐	2 ☐	SS5C
d. Enfermera	1 ☐	2 ☐	SS5D
e. Médico especialista	1 ☐	2 ☐	
f. Otro:	1 ☐	2 ☐	SS5F

f.1 especifique: _____ SS5F1

6. ¿Cómo fueron estas consultas? *(puede marcar más de una opción)*

	No	Sí	
a. Con turno en el consultorio del médico *(centro de salud, hospital o consultorio privado)*	1 ☐	2 ☐	SS6A
b. Sin turno en un centro de atención primaria	1 ☐	2 ☐	SS6B
c. Sin turno en la Guardia o en Emergencias	1 ☐	2 ☐	SS6C
d. Otra:	1 ☐	2 ☐	SS6D

d.1 especifique_____ SS6D1

7. Durante los <u>últimos 12 meses</u>, ¿con qué frecuencia el <u>personal</u> del consultorio médico o de una clínica…

	Nunca	Algunas veces	Usualmente	Siempre	
a. lo(a) trató con cortesía y respeto?	1 ☐	2 ☐	3 ☐	4 ☐	SS7A
b. lo(a) ayudó tanto como usted pensó que deberían ayudarlo(a)?	1 ☐	2 ☐	3 ☐	4 ☐	SS7B

Número identificatorio			-			-				

Formulario: SS
Versión: 17/09/10

8. Durante los <u>últimos 12 meses</u>, ¿con qué frecuencia los doctores u otros profesionales de la salud…

	Nunca	Algunas veces	Usualmente	Siempre	
a. le escucharon con atención?	1 ☐	2 ☐	3 ☐	4 ☐	SS8A
b. le explicaron las cosas de manera que usted pudiera entender?	1 ☐	2 ☐	3 ☐	4 ☐	SS8B
c. demostraron respeto a lo que usted tenía que decir?	1 ☐	2 ☐	3 ☐	4 ☐	SS8C
d. le dedicaron tiempo suficiente?	1 ☐	2 ☐	3 ☐	4 ☐	SS8D

9. En los <u>últimos 12 meses</u>, ¿se realizó usted algún análisis de laboratorio (por ejemplo de sangre, orina, etc.)?

No 1☐
Sí 2☐
No sabe/No contesta 9☐

SS9

10. En los <u>últimos 12 meses</u>, ¿se realizó usted algún estudio diagnóstico como radiografías, ecografías, electrocardiograma u otros?

No 1☐
Sí 2☐
No sabe/No contesta 9☐

SS10

11. En los <u>últimos 12 meses</u>, ¿ha estado internado/hospitalizado al menos una vez?

No 1 ☐ → **CONT. EN LA PREGUNTA 13**
Sí 2 ☐

SS11

12. ¿Alguna de estas internaciones/hospitalizaciones fue por alguno de los siguientes motivos? *(puede marcar más de una opción)*

	No	Sí	
a. infarto, preinfarto o ataque cardíaco	1 ☐	2 ☐	SS12A
b. accidente cerebrovascular o ataque cerebral	1 ☐	2 ☐	SS12B
c. problema pulmonar	1 ☐	2 ☐	SS12C
d. parto-cesárea	1 ☐	2 ☐	SS12D
e. cirugía	1 ☐	2 ☐	SS12E
f. otro	1 ☐	2 ☐	SS12F

13. Un médico de cabecera o personal es el profesional de la salud que mejor lo/la conoce. Puede ser un médico de familia o general, un médico clínico, o un especialista. ¿Tiene usted un médico de cabecera o personal?

No 1☐
Sí 2☐
No sabe/No contesta 9☐

SS13

14. En los <u>últimos 12 meses</u>, ¿ha consultado usted a un curandero, santero, espiritista (machi) u otro tipo de medicina no convencional para tratar cualquier problema de salud emocional o física?

No 1 ☐
Sí 2 ☐
No contesta 3 ☐
No sabe 9 ☐

SS14

15. ¿Qué tipo de cobertura médica o seguro tiene usted en la actualidad?

	No	Sí	
a. Me atiendo en hospitales o centros del sistema público *(hospitales públicos y centros de salud en Argentina y Uruguay; hospitales del FONASA en Chile)*	1 ☐	2 ☐	SS15A
b. Tengo un seguro por el que me descuentan de mi sueldo o del de un familiar (*Obra Social en Argentina; FONASA o ISAPRE en Chile; Mutualista o ASSE en Uruguay*)	1 ☐	2 ☐	SS15B
c. Pago de mi bolsillo por un seguro privado (prepaga en Argentina, ISAPRE en Chile, *Mutualista o seguro privado en Uruguay*)	1 ☐	2 ☐	SS15C

16. ¿Podría indicarnos cuál es el monto que pagó de su bolsillo por la atención médica de los miembros de su hogar el mes pasado?

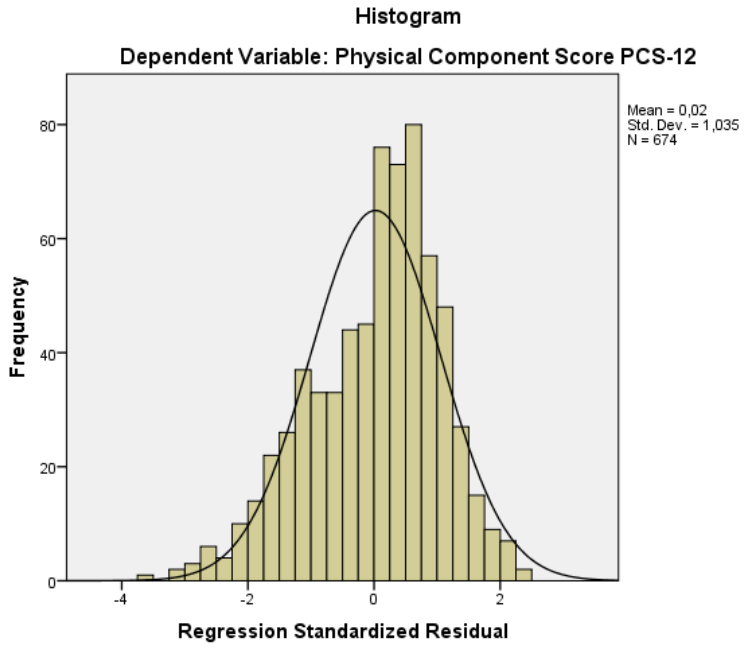
a- ☐☐☐.☐☐☐.☐☐☐ SS16A

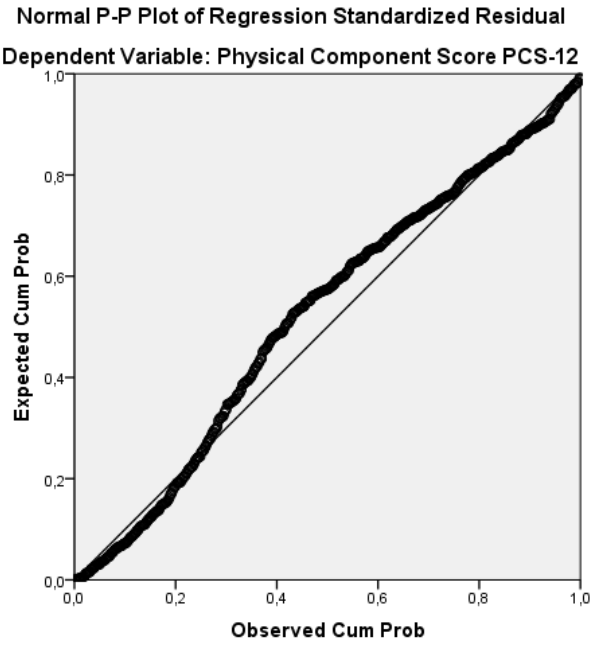
b- Pesos Argentinos 1 ☐
Pesos Chilenos 2 ☐
Pesos Uruguayos 3 ☐ SS16B

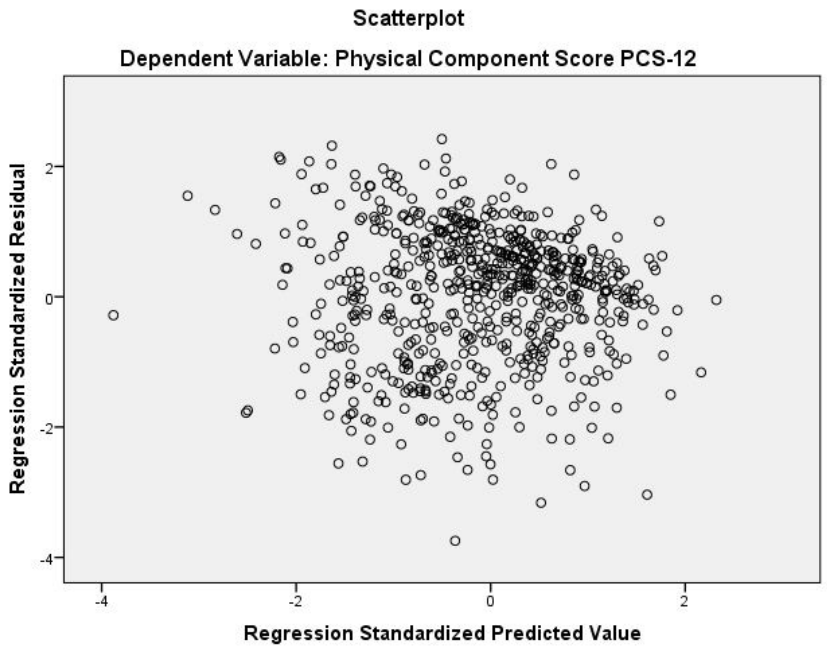
c- No sabe/no contesta ☐ SS16C

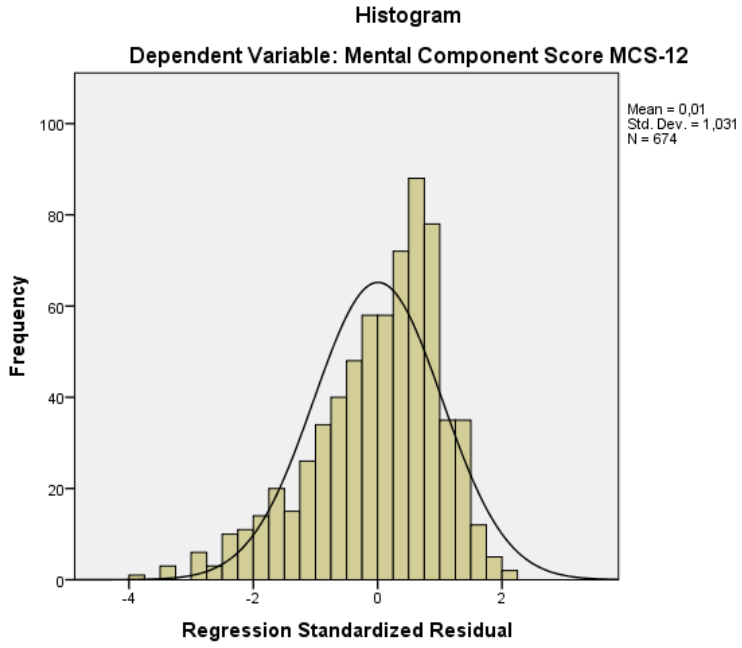
Linear Regression Histograms and Plots

All histograms and plots were produced by SPSS 20 (IBM)






Scatterplot
Dependent Variable: Physical Component Score PCS-12
Regression Standardized Residual
Regression Standardized Predicted Value
2
0
-2
-4
-4
-2
0
2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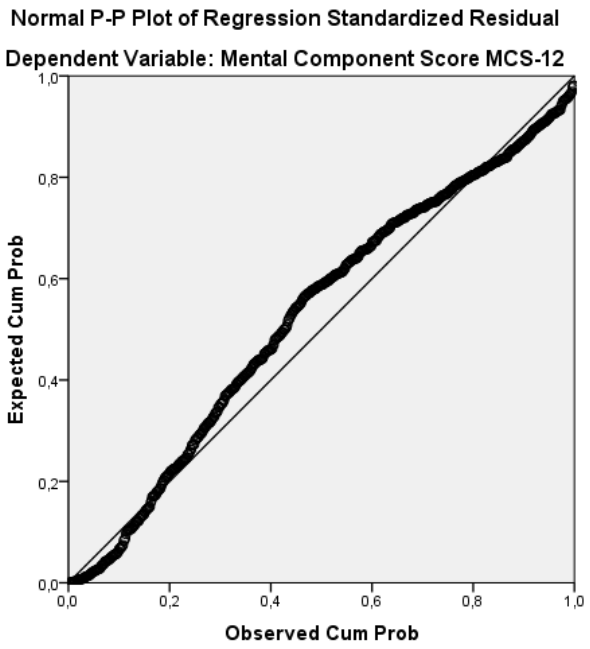
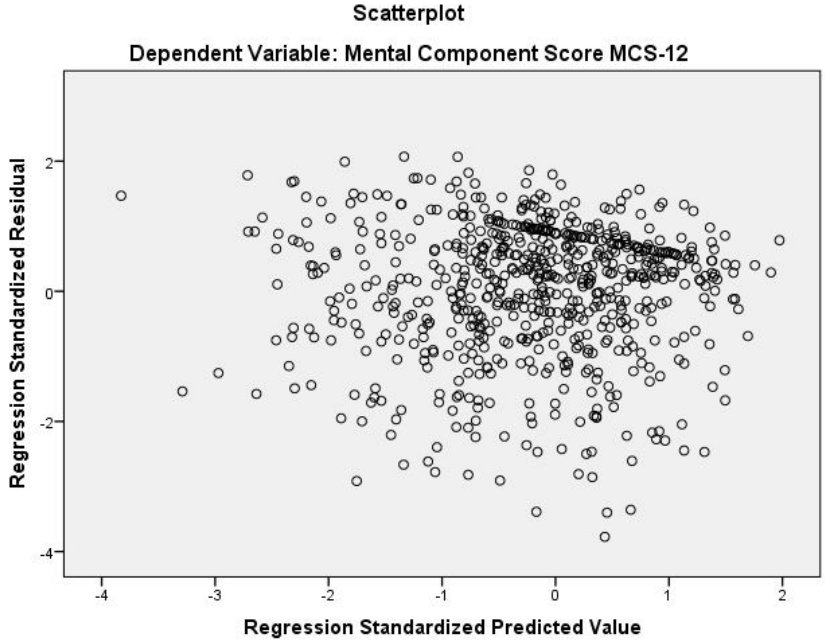
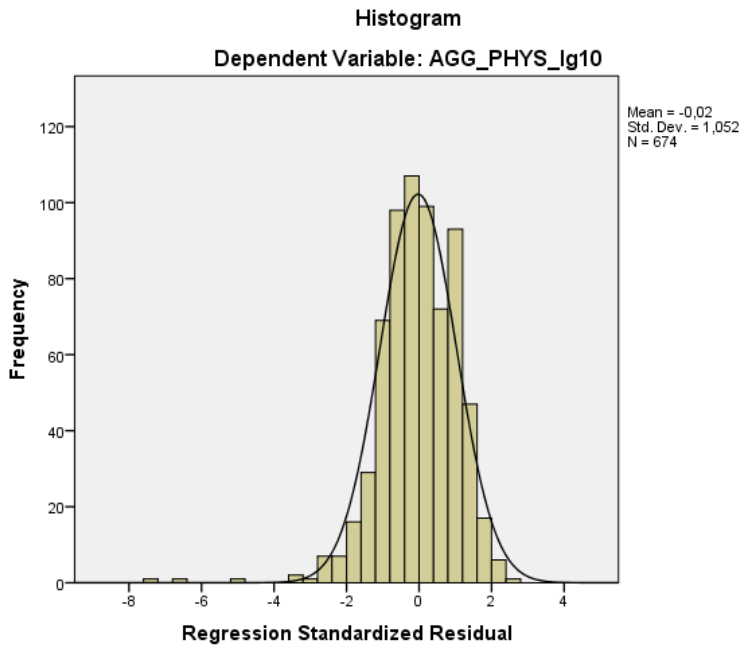
Dependent Variable: Mental Component Score MCS-12
Mean = 0,01
Std. Dev. = 1,031
N = 674
Frequency
Regression Standardized Residual
100
80
60
40
20
0
-4
-2
0
2


Normal P-P Plot of Regression Standardized Residual
Dependent Variable: Mental Component Score MCS-12
Expected Cum Prob
Observed Cum Prob
0,0
0,2
0,4
0,6
0,8
1,0


Scatterplot
Dependent Variable: Mental Component Score MCS-12
Regression Standardized Residual
Regression Standardized Predicted Value
2
0
-2
-4
-3
-1
1


Histogram
Dependent Variable: AGG_PHYS_lg10
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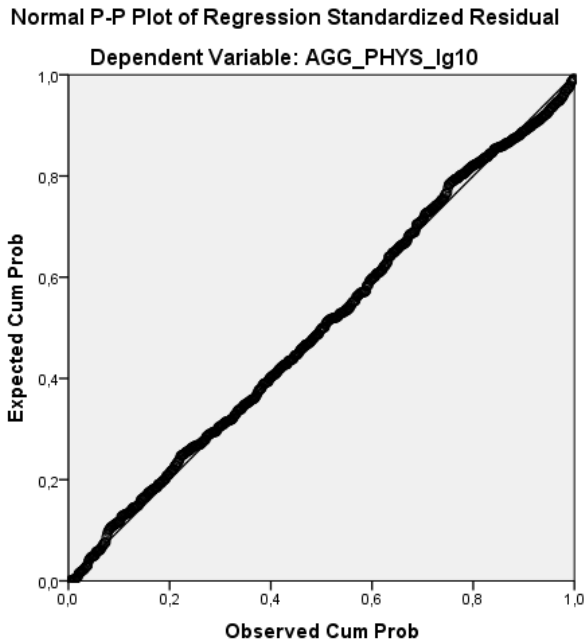
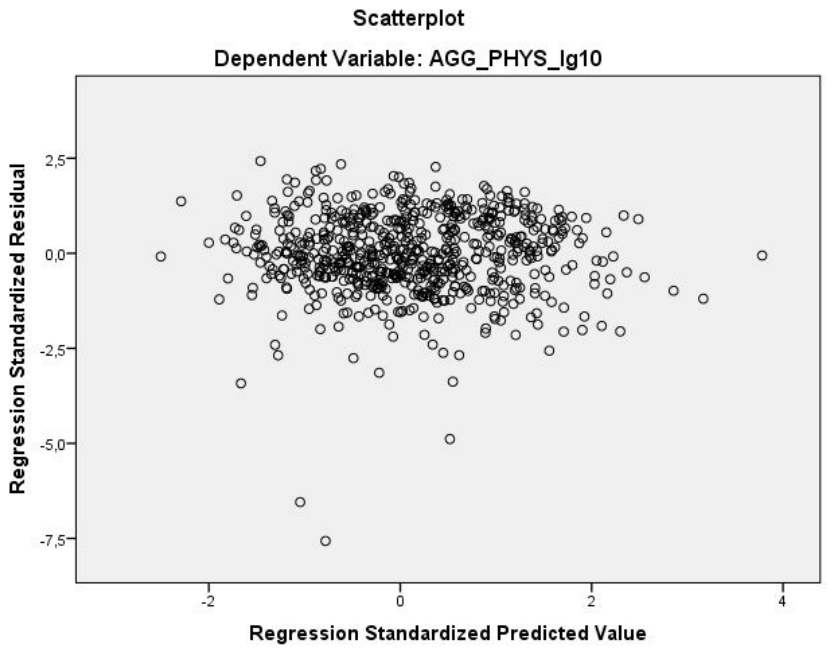
Std. Dev. = 1,052
N = 674
Frequency
Regression Standardized Residual


Normal P-P Plot of Regression Standardized Residual
Dependent Variable: AGG_PHYS_lg10
Expected Cum Prob
Observed Cum Prob


Scatterplot
Dependent Variable: AGG_PHYS_lg10
Regression Standardized Residual
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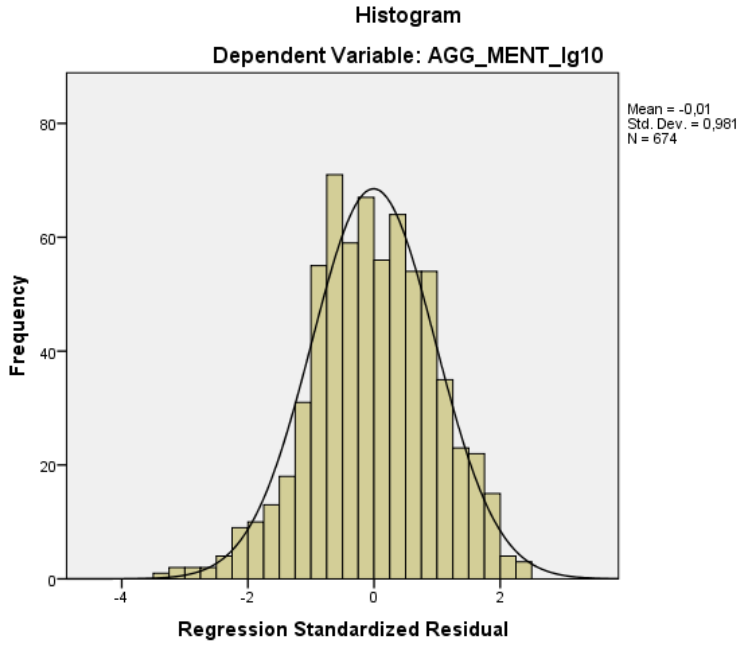
-2,5
-5,0
-7,5
-2
0
2
4
Regression Standardized Predicted Value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Dependent Variable: AGG_MENT_lg10
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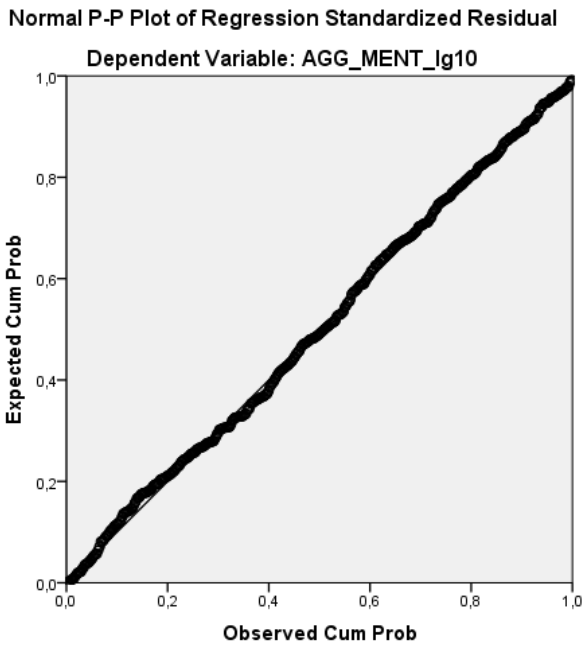
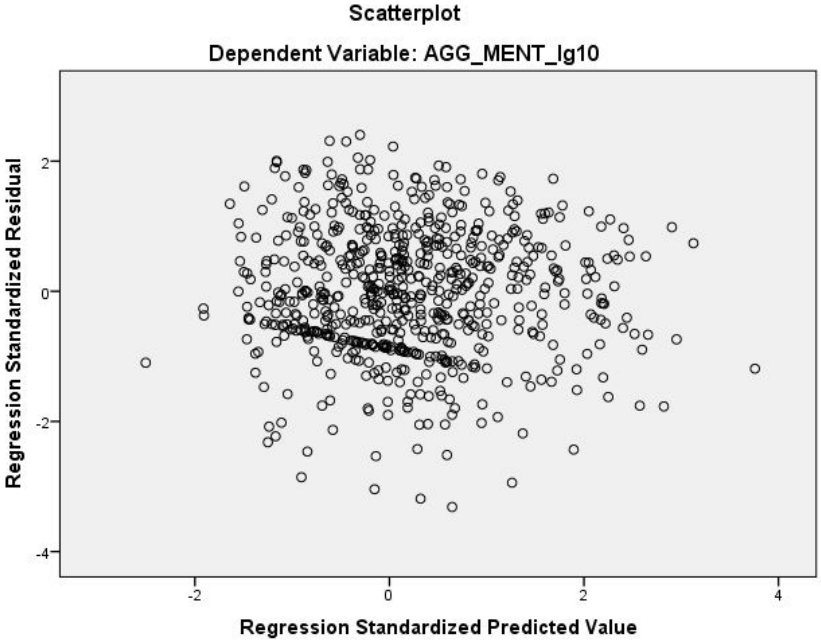
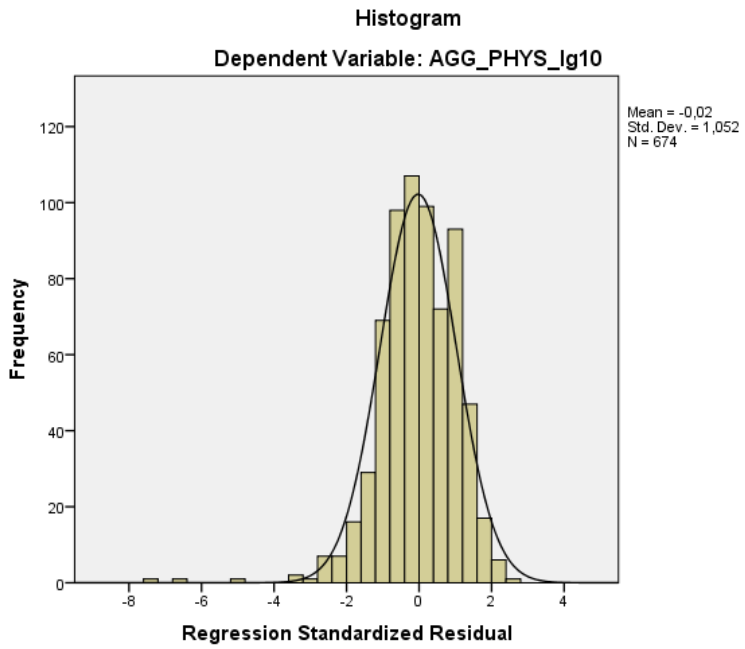
Std. Dev. = 0,981
N = 674
Frequency
80
60
40
20
0
-4
-2
0
2
Regression Standardized Residual


Normal P-P Plot of Regression Standardized Residual
Dependent Variable: AGG_MENT_lg10
Expected Cum Prob
Observed Cum Prob
0,0
0,2
0,4
0,6
0,8
1,0


Scatterplot
Dependent Variable: AGG_MENT_lg10
Regression Standardized Residual
Regression Standardized Predicted Value
2
0
-2
-4
-2
0
2
4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Dependent Variable: AGG_PHYS_lg10
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Std. Dev. = 1,052
N = 674
Frequency
120
100
80
60
40
20
0
-8
-6
-4
-2
0
2
4
Regression Standardized Residual

Linear Regression Summary tables of log10 transformed PCS-12 and MCS-12 scores

Model Summary PCS-12 log10				
R	R Square	Adjusted R Square	Std. Error of the Estimate	Durbin-Watson
0.448	0.201	0.178	0.18888	1.916

ANOVA PCS-12 log10					
	Sum of Squares	df	Mean Square	F	p-value
Regression	6.416	20	0.321	8.992	< 0.001
Residual	25.544	716	0.036		
Total	31.961	736			

PCS-12	B	Std. Error	p-value
(Constant)	0.782	0.08	< 0.001
Age	0.004	0.001	0.002
Being female	0.014	0.016	0.38
Low educational level	0.026	0.016	0.113
Awareness of diabetes	0.043	0.018	0.019
White collar worker	Ref.		
Blue collar worker	0.017	0.028	0.553
Retired	0.054	0.029	0.067
Unemployed	0.035	0.036	0.332
Housewife	0.065	0.031	0.035
Chronic kidney disease	0.055	0.028	0.051
Cardiovascular disease	0.057	0.018	0.002
Physical inactivity	0.077	0.015	< 0.001
BMI	0.005	0.001	< 0.001
Age of diabetes onset	-0.003	0.001	< 0.001
Insulin therapy	-0.002	0.022	0.938
Blood sugar in mg/dl	7.82E-05	0	0.487
Hospitalization	0.059	0.022	0.006
Regular physician	0.013	0.016	0.431
No problems in accessing care	Ref.		
No potential, but realized access	0.041	0.017	0.013
No realized, but potential access	0.086	0.036	0.016
No realized, no potential access	0.113	0.026	< 0.001

Model Summary MCS-12 log10				
R	R Square	Adjusted R Square	Std. Error of the Estimate	Durbin-Watson
0.298	0.089	0.063	0.19823	1.851

ANOVA MCS-12 log10					
	Sum of Squares	df	Mean Square	F	p-value
Regression	2.744	20	0.137	3.492	< 0.001
Residual	2.134	716	0.039		
Total	30.879	736			

MCS-12	B	Std. Error	p-value
(Constant)	1,379	0.084	< 0.001
Age	-0.002	0.001	0.103
Being female	0.048	0.017	0.004
Low educational level	-0.024	0.017	0.166
Awareness of diabetes	0.044	0.019	0.022
White collar worker	Ref.		
Blue collar worker	0.024	0.03	0.414
Retired	0.006	0.031	0.841
Unemployed	0.054	0.038	0.161
Housewife	0.016	0.032	0.61
Chronic kidney disease	0.018	0.03	0.534
Cardiovascular disease	0.023	0.019	0.243
Physical inactivity	0.034	0.015	0.028
BMI	-0.003	0.001	0.026
Age of diabetes onset	0.001	0.001	0.29
Insulin therapy	0.053	0.023	0.02
Blood sugar in mg/dl	0	0	0.121
Hospitalization	0.011	0.023	0.627
Regular physician	-0.014	0.017	0.388
No problems in accessing care	Ref.		
No potential, but realized access	0.008	0.017	0.637
No realized, but potential access	0.071	0.038	0.06
No realized, no potential access	0.091	0.028	0.001

ANOVA summary table - Tests of Between-Subjects Effects

PCS-12

Source	Type III Sum of Squares	df	Mean Square	F	p-value	Partial Eta Squared	Noncent. Parameter	Observed Power
Corrected Model	87871.46	18	4881.75	71.73	< 0.001	0.164	1291.2	1
Intercept	269401.32	1	269401.32	3958.63	< 0.001	0.376	3958.64	1
Gender	28.05	1	28.05	0.41	< 0.001	< 0.001	0.41	0.098
Age	5408.53	1	5408.53	79.47	< 0.001	0.012	79.47	1
Hospitalization	4705.57	1	4705.57	69.15	< 0.001	0.01	69.15	1
Regular physician	2308.73	1	2308.73	33.93	< 0.001	0.005	33.93	1
Low educational level	1258.5	1	1258.5	18.49	< 0.001	0.003	18.49	0.99
Physcial inactivity	8813.94	1	8813.94	129.51	< 0.001	0.019	129.51	1
Cardiovascular disease	7719.14	1	7719.14	113.43	< 0.001	0.017	113.43	1
Chronic kidney disease	484.04	1	484.04	7.11	0.008	0.001	7.11	0.76
Occupational status	4758.88	1	4758.88	69.93	< 0.001	0.011	69.93	1
Blood glucose	0.002	1	0,002	0	0.996	< 0.001	< 0.001	0.05
BMI	5227.78	1	5227.78	76.82	< 0.001	0,012	76.82	1
Diabetes	366.2	1	366.2	5.38	0.02	0.001	5.38	0.64
Access to care	8114.6	3	2704.86	39.75	< 0.001	0.018	119.24	1
Diabetes * access to care	108.61	3	36.2	0.53	0.66	< 0.001	1.6	0.16
Error	446434.7	6560	68.05					
Total	15555391.6	6579						
Corrected Total	534306.07	6578						

R Squared = 0.164 (Adjusted R Squared = 0.162)

ANOVA summary table - Tests of Between-Subjects Effects

MCS-12

Source	Type III Sum of Squares	df	Mean Square	F	p-value	Partial Eta Squared	Noncent. Parameter	Observed Power
Corrected Model	59719.6	18	3317.76	26.51	< 0.001	0.068	477.14	1
Intercept	160636.46	1	160636.46	1283.44	< 0.001	0.164	1283.44	1
Gender	13969.84	1	13969.84	111.61	< 0.001	0.017	111.62	1
Age	1314.27	1	1314.27	10.5	0.001	0.002	10.5	0.9
Hospitalization	1227.29	1	1227.29	9.81	0.002	0.001	9.81	0.879
Regular physician	17.43	1	17.42	0.14	0.709	0	0.14	0.066
Low educational level	1656.52	1	1656.52	13.24	< 0.001	0.002	13.24	0.953
Physcial inactivity	2378.61	1	2378.61	19.004	< 0.001	0.003	19.004	0.992
Cardiovascular disease	3108.05	1	3108.05	24.83	< 0.001	0.004	24.83	0.999
Chronic kidney disease	15.52	1	15.51	0.12	0.725	0	0.12	0.064
Occupational status	5.62	1	5.61	0.05	0.832	0	0.05	0.055
Blood glucose	878.26	1	878.26	7.02	0.008	0.001	7.02	0.754
BMI	2212.89	1	2212.89	17.68	< 0.001	0.003	17.68	0.988
Diabetes	264.31	1	264.31	2.11	0.146	0	2.11	0.306
Access to care	13541.94	3	4513.98	36.07	< 0.001	0.016	108.11	1
Diabetes * access to care	322.64	3	107.55	0.86	0.46	0	2.58	0.239
Error	821054.07	6560	125.16					
Total	19377837.1	6579						
Corrected Total	880773.67	6578						

R Squared = 0.068 (Adjusted R Squared = 0.065)