The Simple Lifestyle Indicator Questionnaire and its association with health-related quality of life and well-being.

By

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Abstract

A person's lifestyle may be related to their quality of life and well-being. This cross-sectional survey examined the association between the Simple Lifestyle Indicator Questionnaire, a measure of lifestyle, and health-related quality of life and well-being among a sample of 100 adults living in St John's, Newfoundland & Labrador. Lifestyle was significantly, positively correlated with well-being ($r=0.47$, $p<0.01$), self-perceived health ($r=0.59$, $p<0.01$) and mental health-related quality of life ($r=0.41$, $p<0.01$), but not physical health-related quality of life ($r=0.13$, $p=0.19$). This study benefitted from the use of validated questionnaires but the generalizability of these results is limited by a sample population that was younger, more educated and of higher household income than the general population. Lifestyle appears to be related to well-being and quality of life, and lifestyle factors may predict quality of life in populations similar to the population in this study.

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List of Abbreviations and Symbols

ANOVA - Analysis of variance

BMI - Body mass index

CLAS – Computerized Lifestyle Assessment Scale

EQ5D – EuroQoL EQ-5D questionnaire

EQ5D VAS - EuroQoL EQ-5D visual analogue scale

HRQoL - Health-related quality of life

MCID – Minimal clinically important difference

NL – Newfoundland & Labrador, Canada

PGWB - Psychological General Well-being questionnaire

PGWB-I - Psychological General Well-being Index score

SD - Standard deviation

SF-12 - Short form 12 Questionnaire

SF-36 – Short form 36 Questionnaire

SF-12 MCS - Short form 12 – Mental component score

SF-12 PCS - Short form 12 – Physical component score

SLIQ - Simple Lifestyle Indicator Questionnaire

SPSS - Statistical Package for the Social Sciences

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1.0 Introduction and Overview

1.1 Context

Health is "a state of complete physical, mental and social well-being,"[1] and there is general consensus that a positive health state cannot be limited simply to the absence of disease[1,2]. A variety of factors contribute to an individual's health and their risk of illness, including environment, economic and social circumstances, and a person's characteristics and behaviours[2]. In the latter category, behaviours and habits such as smoking, diet, and physical activity[3] contribute to a construct known as lifestyle, which can significantly affect health. The increasing prevalence of chronic diseases has brought attention to the role that lifestyle factors play in a person's disease risk. Many lifestyle habits can contribute to a person's risk of developing a disease or illness, including tobacco use[4], alcohol consumption[5], physical inactivity[6], an unhealthy diet[7], and psychological stress[8].

Health-related quality of life (HRQoL) was first described in the 1970s as a measure of how an individual's physical and mental health affects their day-to-day functioning[9, 10]. In contrast to many clinical measures of health and disease, HRQoL is a patient-reported outcome with roots in the social sciences that focuses on health, well-being and the way a person's health affects their life from the patient's perspective[11]. For many patients quality of life can be among the most important indicators of their own health[12]. Studies suggest that although HRQoL is subjective, and patients with the same illness may differ in their HRQoL[13], the measure is generally sensitive to clinically-relevant changes in health[11].

There is evidence that lifestyle may also affect a person's current quality of life. Patients recovering from serious illnesses, such as cancer, or living with chronic conditions, such as cardiovascular disease, have a higher quality of life if they have more healthful lifestyle habits[14, 15, 16, 17]. More recently there has been an interest in measuring differences in HRQoL that may be attributed to lifestyle factors among an otherwise healthy population, which shall be discussed in further detail.

1.2 Health-related quality of life

There is a significant body of literature on the value of HRQoL as a measured outcome in a variety of clinical research settings[9, 10, 11]. HRQoL narrows the general concept of quality of life, which may include components such as socioeconomic status and environment, to the components specifically pertaining to health[13]. Including this measure as an outcome in clinical study acknowledges two important realities: that physiologic clinical indicators are not always the most important outcomes for patients; and that patient-reported outcomes are of interest to clinicians, policymakers and researchers as well[11,13,18].

Measures of HRQoL are divided into categories of general instruments, which provide a measure of HRQoL for a general population, and specific instruments, which measure HRQoL in a disease-specific manner[13]. General instruments measure dimensions or domains of quality of life, such as the ability to care for oneself, satisfaction with one's physical or emotional role, or feelings of anxiety or depression[13]. Specific instruments incorporate additional domains relevant to the subpopulation of interest; for example, there a number of instruments designed to measure HRQoL in people with diabetes which

include components of treatment satisfaction, stress related to blood glucose, and food-related problems alongside the generic measures of mobility, well-being and social role fulfillment[19].

There are a number of widely used, validated questionnaires that measure general HRQoL. Some questionnaires, including the Short Form 36 (SF-36), the Nottingham Health Profile and the Dartmouth COOP Charts, are based upon a health profile that produces individual scores for a number of dimensions[20]. The SF-36, for example, measures HRQoL based on 36 likert scale questions which generate scores in the domains: physical functioning, role-physical, bodily pain, general health, vitality, social functioning, role-emotional, and mental health[20, 21]. The Nottingham Health Profile measures energy level, emotional reactions, physical mobility, pain, social isolation, and sleep based on participants' responses of yes or no to 38 questions[20]. Alternatively, HRQoL can be measured using questionnaires built upon preference-based measures that generate single scores to represent an individual's HRQoL, often based on scoring algorithms that combine a number of dimensions[20]. Examples of preference-based questionnaires include the EuroQoL EQ5D, which measures mobility, self-care, usual activity, pain and discomfort and anxiety and depression, and the Quality of Well-Being Scale, which measures of mobility, physical activity, social activity, and symptoms/problems[20].

When choosing a generic measure of HRQoL, researchers must consider carefully the differences between validated instruments. For example, the Nottingham Health Profile is a generic measure of HRQoL with reasonable validity but few reliability studies have

been carried out and it is a fairly lengthy questionnaire; in contrast, the EQ5D, with comparable levels of validity and better reliability, is designed to be completed in approximately five minutes to reduce participant burden[20].

The SF-36 is a commonly used measure of HRQoL that underwent extensive psychometric testing and has proven to be reliable and valid[20]. In addition to the previously mentioned eight dimensional scores, the SF-36 can be scored to generate a general physical component score (PCS) and mental component score (MCS) based upon the four physical and mental domains of HRQoL to allow the testing of hypotheses related to HRQoL with fewer outcome measures[22]. The SF-36 questions were based on questions in established questionnaires, and both the criterion validity and construct validity of this instrument have been evaluated, as has the reliability and sensitivity to change [23, 24]. A comparison between a number of generic measures of HRQoL found that the SF-36 was most efficient at distinguishing between patients with differences in their illness severity[20]. A shorter version of the SF-36, known as the SF-12, was developed to provide a generic measure of HRQoL that was comparable to the SF-36 but with fewer questions to reduce the burden on participants. Completion of the SF-36 takes approximately twelve minutes, while the SF-12 can be completed in under 2 minutes[21]. The SF-12 provides scores based on the same eight domains as the SF-36 but reduces the number of likert scale questions to 12. Scores on the SF-12 are comparable to, although less precise than, the SF-36[25], but the benefits of the shorter instrument may outweigh the drawbacks of reduced precision, particularly if participants must complete a number of

questionnaires[13, 25]. The SF-36, and later the SF-12, was adapted for use in a Canadian population and psychometrically tested to ensure the preservation of its validity[26,27.]

The EQ5D was designed to be a simple, generic measure of HRQoL that was short enough to be administered with other questionnaires[20,28]. As with the SF-36, the EQ5D gathers information on a participant's HRQoL using likert scale questions about five dimensions of quality of life and a visual analogue scale (EQ5D VAS)[20, 28]. The likert scale, which is used to generate five component scores and one summary score, can be either a three-point (EQ5D 3L) or five-point (EQ5D 5L) scale, with the latter reducing the observed ceiling effect of the former[29,30]. The EQ5D VAS measures a participant's self-rated health by asking participants how they would rate their health on a scale of zero to 100, with zero being the worst health they can imagine and 100 being the best health they can imagine[28]. The summary measure of HRQoL provided by the five questions on the EQ5D and the VAS are comparable but not identical measures[31], and studies may use either or both as outcomes[20, 31]. The EQ-5D was tested against the SF-12 to examine its construct validity, and correlations between summary scores of the SF-12 and EQ-5D correlated in the range of 0.41 to 0.55, although it was noted that the EQ-5D was less sensitive than the SF-12 with respect to differentiating between patients of varying severities of illness[20, 25]. The validity of the EQ5D has been studied in a Canadian population[32], and population norms have been described[27]. The EQ5D is a popular measure for studies that include a health economics component, as the preference-based summary score can be more readily integrated into cost-utility analyses[20], but it also has wide use as a general measure of HRQoL[31,27].

Shorter scales measuring HRQoL may improve response rates due to reduced participant burden[20,25]. Shorter instruments also provide an opportunity to use more than one instrument, which may provide valuable information on additional outcomes[13]. Investigators have administered both EQ5D and SF-12 instruments to study participants[25, 31, 27], and investigators note that, "combining the EQ5D and SF-12 instruments provides a broad coverage of health dimensions."[27]

1.3 Well-being

Well-being is a broad concept that evaluates a person's perception of how well their life is going[33]. Well-being and HRQoL are both holistic measures that incorporate physical and mental components of health[33], both are patient-reported outcome measures, and instruments used to quantify them may include common dimensions such as vitality or general health[20,34]. Well-being and HRQoL can be considered related and overlapping constructs, and both serve as valid measures of a patient's experience of their individual health state. Commonalities between domains included in some validated questionnaires that measure both HRQoL and well-being are demonstrated in Figure 1.

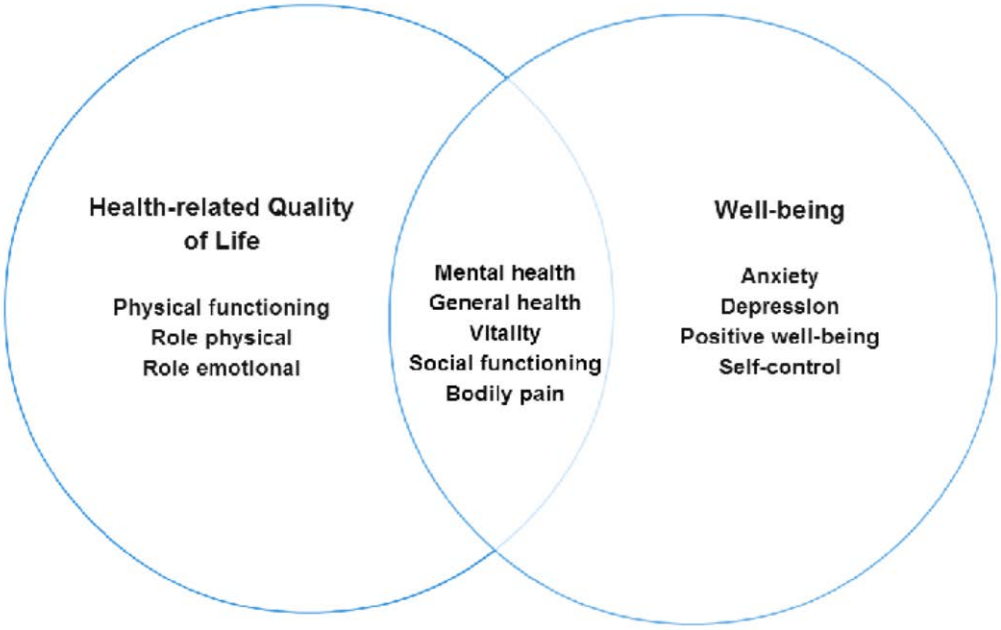

Figure 1 Venn diagram demonstrating domains unique to and shared by measures of health-related quality of life and well-being.

As with HRQoL, a number of questionnaires have been developed to measure well-being. Major population-based studies such as the US National Health Interview Survey have used measures such as the Quality of Well-being scale[33], which measures mobility, social activity, and physical activity[35], while the US National Health and Nutrition Examination Survey uses the General Well-Being Schedule[33], which includes dimensions such as positive well-being, vitality, anxiety and self-control[36].

The Psychological General Well-Being Index (PGWB) is a validated tool used to quantify well-being. Based upon the General Well-Being Schedule, the PGWB was been in relatively wide use since the 1990s and is used to measure well-being in clinical research[37]. The PGWB consists of 22 likert scale questions, the answers to which are used

to calculate scores in the domains of anxiety, depression, positive well-being, general health, vitality, self-control, as well as an overall index score (PGWB-I)[37]. Psychometric testing, which included comparison with SF-36 scores to evaluate convergent validity and evaluations of variation in PGWB scores with different health states to evaluate criterion validity[38], and the PGWB has been shown to be a reliable measure of well-being that has subsequently gained wider use in population-based studies[34,37,39].

1.4 Lifestyle and the Simple Lifestyle Indicator Questionnaire

Lifestyle is a broad concept that includes behaviours such as diet, exercise, alcohol consumption, tobacco use and psychosocial factors[3-7,40]. Researchers choose which lifestyle risk factors to include in their analyses based upon the subpopulation they are studying; for example, occupational exposure to chemical substances or environmental exposure to pollution may be included alongside diet, tobacco use and alcohol consumption in an analysis of the lifestyle risk factors for chronic obstructive pulmonary disease[41], while physical activity, sedentary behaviours, and consumption of salty foods or confectionaries may be of greater interest to researchers investigating adolescent obesity[42,43].

There are a large number of instruments and methods that can be used to quantify lifestyle behaviours. For the category of diet alone there are food frequency questionnaires[44], 24-hour dietary recall interviews[45], and self-reported questionnaires such as the Mini Nutritional Assessment[46]. As with measures of HRQoL, each tools has benefits and limitations; 24-hour dietary recalls are commonly-used and validated, but they require a skilled interviewer[45] and may be prone to bias[47], while food frequency

questionnaires, also widely-used and validated, are long and can be intimidating to study participants. Researchers must consider the participant burden – and potential decreased response rate – when they used multiple questionnaires to measure multiple lifestyle[20,25,48,49].

An alternative is to use a generic questionnaire that includes multiple dimensions of lifestyle. An Australian study generated an improvised lifestyle assessment tool based on dimensions of diet, physical activity, alcohol consumption and BMI[50,51]. Participants were evaluated to see if lifestyle behaviours predicted mortality in healthy older men and older men with vascular disease. Despite finding that the improvised lifestyle assessment tool significantly predicted mortality in both healthy and unhealthy men,[51] there is no evidence that psychometric testing was pursued. The Computerized Lifestyle Assessment Scale (CLAS) is another generic, multi-factorial tool intended to identify potential lifestyle issues in order to discuss them further with their healthcare practitioner[52]. Completed electronically via computer, the CLAS was designed for used in family practices and is a more clinically-oriented tool with a goal of stimulating discussion about a patient's risk[52].

The Simple Lifestyle Indicator Questionnaire (SLIQ) was developed as a short, self-administered questionnaire to evaluate the dimensions of diet, exercise, alcohol consumption, tobacco use and psychosocial stress, and provide a single summary score. Two family physicians and a nutritionist developed the SLIQ with the intention of creating a reliable, valid summary measure of lifestyle that would allow researchers and, eventually, clinicians to quantify lifestyle[53]. The first iteration of the SLIQ consisted of

25 questions, including nine for the dimension of diet. Feedback from health professionals with experience in lifestyle assessment, including family physicians, nutritionists and nurses, was used in conjunction with factor analysis to reduce the number of items in the SLIQ to 12[53].

Initial psychometric testing on a group of family practice patients in a small city in Ontario was undertaken to compare scores on the SLIQ to subjective lifestyle assessments by a family physician, a nurse practitioner and a nutritionist, and to evaluate test-retest reliability. The questionnaire was judged to have reasonable content validity, with strong correlation ($r = 0.77$, $p<0.001$) between SLIQ scores and the blinded assessments by health professionals and test-retest reliability that ranged from 0.63 to 0.97 for the dimensions[53]. Further testing of the concurrent and convergent validity of the SLIQ was carried out in a population of adults living in St. John's, Newfoundland & Labrador (NL), where scores on the SLIQ were compared with objective measures of lifestyle such as the Diet History Questionnaire, the Social Readjustment Rating Scale, the SF-36, and physical activity levels measured by pedometer[54]. The SLIQ was found to correlate well with these validated measures (Table 1), with the exception of the Stress scale which did not correlate well with the Social Readjustment Rating Scale, and the authors suggest that the SLIQ offers researchers a short, relatively simple method of assessing lifestyle in study participants[54]. Further psychometric testing and the generation of population norms are ongoing, but the SLIQ has been shown to be a reliable measurement of lifestyle behaviours.

Table 1 Correlation between SLIQ scores and validated measures of lifestyle. Adapted from Godwin et al. [54]

Dimension	Validated questionnaire	R	P
Diet	Dietary Health Questionnaire (vegetables, fruits, grains)	0.679	0.001
Physical Activity	Pedometer (steps/day)	0.455	0.002
Alcohol	Dietary Health Questionnaire (alcohol)	0.665	0.001
Stress	Social Readjustment Rating Scale	-0.264	0.001
SLIQ lifestyle score	Eight-question scale developed by Spencer et al.	0.475	0.002

1.5 Relationship between lifestyle and health-related quality of life

The relationship between individual lifestyle risk factors and HRQoL has been described fairly extensively in the literature. Physical activity and exercise are consistently linked to improved HRQoL and well-being in a variety of populations[55,56,57]. There are also a number of studies supporting the link between a healthier diet and improved HRQoL[58,59]. For some lifestyle behaviours the relationship with HRQoL is less clear. Some large studies have shown that people who smoke have a reduced quality of life[60, 61], but other studies suggest that the relationship between smoking and lower HRQoL is rendered nonsignificant when regression models control for potential confounders such as BMI and depression[62]. Alcohol consumption, a risk factor for some chronic diseases[63, 64], seems to predominantly have a negative impact on HRQoL among heavy, rather than moderate, consumers of alcohol[65]. People with high levels of psychosocial stress also seem to have reduced HRQoL[66,67]. The majority of studies tend to look at one or two individual

lifestyle risk factors and how they affect HRQoL, but comparatively fewer examine lifestyle comprehensively as a multi-dimensional variable that may affect HRQoL and well-being[68].

A large cross-sectional study was carried out to evaluate lifestyle risk factors among Chinese civil servants and the effects of those lifestyle factors on HRQoL[69]. Of the 15,000 eligible participants employed in the civil service in five regions of China who were at least 18 years of age, over 14,000 agreed to participate. The researchers measured lifestyle factors including tobacco smoking, alcohol consumption, physical activity, amount of sedentary time, and regular consumption of breakfast using an unvalidated questionnaire and compared lifestyle with HRQoL as measured by the SF-36. Using multivariate analysis, sleep duration (+3.743, $p<0.01$), consumption of breakfast (+2.491, $p<0.01$), physical activity (+1.200, $p<0.01$), alcohol consumption (+0.691, $p<0.01$) and smoking (-0.682, $p=0.027$) were significant coefficients for SF-36 PCS while consumption of breakfast (+3.842, $p<0.01$), sleep duration (+3.565, $p<0.01$), and physical activity (+1.271, $p<0.01$) were significant coefficients for SF-36 MCS. The large sample size and the high response rate add strength to this cross-sectional study, although the use of unvalidated instruments to measure lifestyle is a limitation. These results also may not be generalizable to the general population, as the civil servants were overwhelmingly married (82.06%) with at least a college education (92.12%); the degree to which the civil service is representative of China's population is unclear. It must also be noted that while a number of lifestyle factors were statistically significant predictors of outcome scores in the multivariate analysis, they may be of limited clinical significance. For example, the

difference in MCS scores between categories of sleep duration was just 3.565 points, which is only a 3.5% difference.

A prospective cohort in eastern Finland evaluated the association between an unhealthy lifestyle and reduced quality of life among a cohort of 560 adults[68]. The lifestyle risk factors of nutrition, tobacco smoking, alcohol use and exercise were measured using a series of structured questions, while HRQoL was measured using the 15D, a validated questionnaire. The questions were based upon Finnish national guidelines for health, and included questions of alcohol and tobacco consumption alongside items querying types of cooking fats used; vegetable, berry and fruit intake; typical beverage consumed with meals; and habit of adding salt to food. Lifestyle scores were calculated based on the responses to each item (-1 for unhealthy choice, 0 for intermediate choice, +1 for healthy choice), and the points were summed to generate an overall lifestyle score. Additional factors such as BMI, waist circumferences and blood pressure were measured and included as additional comparisons between lifestyle groups. The researchers separated participants by lifestyle score into tertiles, which they categorized as healthy, neutral and unhealthy and compared the differences in 15D scores using total scores and ANOVA. Participants with a healthier lifestyle were significantly more likely to be female (p trend = 0.001) and with a higher level of education (p trend <0.001), while those with an unhealthier lifestyle were more likely to be living alone (p trend = 0.032). Certain lifestyle factors clearly demonstrated trends with respect to the tertiles, but others failed to show a clear trend; for example, only the healthy tertile had positive scores for all four dietary items, which contrasts with the alcohol category where all three tertiles showed a

positive score. Overall there was a significant difference in HRQoL as measured by the 15D when comparing the highest and lowest lifestyle tertiles. Categorizing participant lifestyle by tertile makes it more difficult to compare these results to other studies; the unhealthiest tertile in this Finnish population may not be comparable to the unhealthiest tertile in another city in Finland, let alone another country. The use of unvalidated set questions to measure lifestyle also limits the strength of the study; without psychometric testing it is impossible to judge the validity of the measures upon which these results rely.

A prospective cohort study examined the effect of lifestyle behaviours on healthy aging over a 16-year period[70]. Using data from an established British cohort study of over 10,000 civil servants, the researchers included participants who were over the age of 60 at the time of follow-up with no history of serious diseases such as stroke, cancer or heart attack, which resulted in a cohort of 5100 participants. Lifestyle behaviours were measured through a series of questions focusing on the domains of tobacco smoking, alcohol consumption, exercise, and diet, while healthy aging was defined as participants with "no history of cancer, coronary artery disease, stroke or diabetes; good cognitive, physical, respiratory and cardiovascular functioning, and the absence of disability; and good mental health," as assessed through clinical data, physiologic measurements and validated questionnaires such as the SF-36. Some aspects of healthy aging are considered measures of HRQoL, including the MCS from the SF-36 and the measures of the ability to carry out activities of daily living. Participants were classified as healthy aging, normal aging, or dead at the time of follow-up. Approximately one fifth of the participants fell into the category of healthy aging, and these participants were younger and more likely to

be university-educated and married than their counterparts in the normal aging group. Participants were significantly more likely to be in the healthy aging category if they never smoked (OR 1.29), consumed alcohol in moderate quantities (OR 1.31), were physically active (OR 1.45) and consumed daily servings of fruits and vegetables (OR 1.35) after adjusting for age, sex, level of education and marital status. The researchers noted a positive, significant trend of healthy behaviours on the adjusted OR of good mental health as judged by the SF-36 MCS (p trend < 0.001). Also of note was the conclusions that the authors drew, that "although individual healthy behaviours are moderately associated with successful aging, their combined impact is quite substantial." In contrast to many studies of lifestyle, the binary classification of lifestyle risk factors precludes delving further into their potential effects on HRQoL; for example, physical activity is divided into the categories of >2.5 hours of moderate or >1 hour vigorous physical activity per week versus no physical activity, but it is probable that the range of physical activity is more nuanced and detail is lost when these behaviours are recorded as merely present or absent. As with the study of Chinese civil servants, this cohort of British civil servants may not be representative of the wider British population, and likely has a higher socioeconomic status, which may limit the generalizability of the results.

A cross-sectional survey examined potential clustering between healthy and unhealthy lifestyle behaviours and how those clusters are associated with self-rated health and quality of life[71]. The data analyzed were part of the Survey of Lifestyle, Attitudes and Nutrition 2007 conducted in Ireland. Lifestyle was measured through individual questions about behaviours of interest, such as smoking, and questionnaires such as the

International Physical Activity Questionnaire, the Alcohol Use Disorders Identification Test – Consumption, and a Food Frequency Questionnaire combined with the Dietary Approach to Stop Hypertension guidelines. HRQoL was quantified using the WHO's Quality of Life Survey and mental health was assessed using two subscales of the SF-36. A total of 7,350 study participants were included from a total sample of 10,364 eligible adult participants; participants were excluded if they did not complete the Food Frequency Questionnaire or if their International Physical Activity Questionnaire scores were too extreme, the latter judgement made based on the questionnaire's validated scoring algorithm. Cluster analysis identified six common groupings of lifestyle behaviours, including a healthy lifestyle cluster (physically active, never smokers, nutritious diet), temperate cluster (moderately active, never smokers, moderate alcohol consumption), and multiple risk factor cluster (moderate physical activity, current smokers). Some clusters had significantly different levels of quality of life when compared to the healthy lifestyle cluster, such as the multiple risk factor cluster and the physically inactive cluster. The researchers included common confounders such as age, sex and social class in their analysis, and their overall conclusion was that there are trends in lifestyle behaviours that are related to lower HRQoL. Cluster analysis of this type provides insights into patterns of lifestyle clustering and variability, but as with the Finnish cohort it makes direct comparison with other studies more difficult. Strengths of this study include the use of validated questionnaires to assess lifestyle, and a relatively large, representative sample size.

These four examples are generally representative of the present consensus of the relationship between lifestyle and HRQoL and well-being, and details of additional studies[72, 73, 74] can be found in Appendix 1. A consistent limitation seen throughout this area of the literature is the use of unvalidated measures of lifestyle. Validated questionnaires are extensively tested and evaluated to ensure that they quantify values of interest accurately[75], but an additional benefit is comparability across different studies and population groups; six studies that evaluate HRQoL using the SF-12 are easier to compare than six studies using a variety of different measures. Additionally knowledge of the relationship between lifestyle and HRQoL is based upon relatively few studies of specific subpopulations, and would benefit from additional studies in more diverse populations. Further investigation of the associations between a multi-dimensional construct of lifestyle and HRQoL and well-being using validated questionnaires is warranted as this time.

2.0 Objectives and Research Questions

The objective of this study is to examine the relationship between lifestyle behaviours and an individual's current health-related quality of life and psychological well-being. Healthy and unhealthy lifestyles can have a positive or negative relationship, respectively, with a person's risk of developing a chronic disease, but it is less clear to what degree lifestyle is associated with current HRQoL and well-being in a healthy population and whether lifestyle is predictive of HRQoL. This study examines the relationship between lifestyle and HRQoL and well-being.

Primary question

Is a healthy lifestyle associated with higher HRQoL and well-being? Specifically, is there a significant, positive correlation between lifestyle, as measured by the SLIQ, and HRQoL and well-being, as measured by the SF-12, the EQ5D and the PGWB, in adults living in St. John's, Newfoundland & Labrador?

Secondary questions

Is there a significant, positive correlation between the five dimensions of lifestyle measured by the SLIQ and health status, health-related quality of life and well-being?

Do the people whose lifestyles are rated as healthy, intermediate, or unhealthy by the SLIQ represent distinct populations when comparing their health-related quality of life and well-being?

Does age, sex, household income or level of education affect the relationship between scores on the SLIQ and scores on the EQ5D, SF-12 or PGWB questionnaires?

3.0 Methods

3.1 Study design

This study was designed as a cross-sectional survey to assess the relationship between lifestyle, as measured by the SLIQ, and current health-related quality of life and well-being. The study protocol and all survey instruments were reviewed and approved by the Human Research Ethics Authority for Newfoundland & Labrador, protocol #13.140 (see Appendix 2).

3.2 Pilot study

A pilot study was conducted prior to starting data collection to identify common questions or concerns that participants may have and to determine the time commitment for participants. Ten participants were recruited for the pilot study, and the time taken to read all study documentation and complete the questionnaires was recorded. Pilot surveys were examined for completeness, but were neither scored nor included in the final sample.

Based on the pilot study, common questions that participants had were identified and standard answers were generated. For example, some pilot study participants asked if they could indicate between choices on the likert scale questions; participants recruited for the study were informed that they must choose the one best answer.

3.3 Study population

The target population was adults between the ages of 18 and 65 living in St John's, NL. Inclusion and exclusion criteria (Table 2) were chosen to include as broad a sample as possible while excluding participants likely to have experienced a significant change in

their lifestyle or quality of life in the past year, such as women who are pregnant or people diagnosed with a serious disease.

Table 2 Inclusion and exclusion criteria used to determine eligibility to participate in research project.

Criteria	Rationale
Inclusion	
Age 18-65 years	Surveys validated for use in adults.
Living in St. John's, NL	Population of interest is adults living in St. John's, NL.
Able to understand study information sheet, questionnaires	Must be informed in order to participate, must be able to complete questionnaires.
Exclusion	
Currently pregnant or pregnant within last year	Excluding participants who may have undergone significant lifestyle or HRQoL changes in the past year.
Serious health condition or issue within past 12 months (e.g. heart attack, stroke, cancer)	

3.4 Sample size calculations

The study was powered to detect a correlation of at least 0.30 (low-moderate relationship strength)[76, 77]. Although 0.3 is a relatively low correlational strength, that value was chosen to adequately power the study to detect correlations of 0.3 or higher. Using α=0.05 and β=0.20, and based on the sample size calculations for two-tailed tests[78], a sample size of 84 was required. To account for incomplete responses and missing data, 100 participants were recruited.

3.5 Sampling strategy and recruitment procedures

Recruitment locations were chosen in an effort to enroll participants with diverse lifestyle habits. Participants were recruited from a shopping mall, waiting rooms in family medicine clinics, and through the Faculty of Medicine at Memorial University.

Potential participants were verbally given the criteria for inclusion in the study (Table 2) and asked whether they met the criteria; those who stated that they met the criteria were included in the study. The researcher did not ask for details on any medical conditions to respect participants' privacy. A consent form was not required, as the Human Research Ethics Authority deemed completion of the surveys as implied consent; in its place, a study information sheet was provided to all participants outlining the purpose of the study alongside the benefits and risks of participating. Participants were provided with both a study information sheet (Appendix 2) and a questionnaire package (Appendix 3). Participants were encouraged to ask questions, and based on the pilot study, standard answers to common questions were used by the researcher to ensure consistency of information.

Policies at different locations meant that the recruitment process varied slightly, but all participants were provided with the same information and questionnaires. Detailed descriptions of the recruiting procedures that vary by location are described in greater detail below.

3.5.1 Recruitment at shopping mall

Participants at the largest shopping mall in St. John's, NL were recruited at a small table set up in a foyer. Mall policy required that people must approach the table prior to being greeted. Participants were informed of the purpose of the study and the inclusion criteria and were provided with a survey package as outlined in Section 3.5. Participants had the option to sit at the table to complete the questionnaires, or to take the study package along with a postage-paid envelope to complete at a later time and return by mail. Participants

who took the study package to complete at a later time were given telephone and email contact information in case they had questions; participants completing the survey in person were encouraged to ask for clarification if needed.

3.5.2 Recruitment in family physician waiting rooms

Participants were recruited from the waiting rooms of family medicine clinics associated with the Discipline of Family Medicine at Memorial University. In these clinics, the researcher was allowed to politely approach patients and invite them to participate. Participants were informed of the purpose of the study and the inclusion criteria and were provided with a survey package as outlined in Section 3.5. Participants had the option to complete the survey in the waiting room with a clipboard, or they could take the study package along with a postage-paid envelope to complete at a later time and return by mail. Participants who chose to take the study package to complete at a later time were given both telephone and email contact information in case of further questions; participants completing the survey in person were encouraged to ask for clarification if they had any questions.

3.5.3 Recruitment at Faculty of Medicine

While obtaining permission from staff and clinicians to recruit from family medicine clinics, these staff and clinicians were informed of the study via email. Some staff and clinicians volunteered to participate. Participants were informed of the purpose of the study and the inclusion criteria and were provided with a survey package as outlined in Section 3.5. These participants returned the survey packages as scanned email attachments or through interdepartmental mail.

3.5.4 Other

Participants were also recruited opportunistically through events such as a graduate student seminar series. Participants were informed of the purpose of the study and the inclusion criteria and were provided with a survey package as outlined in Section 3.5. Participants had the option to complete the questionnaires right away, or to take the study package along with a postage-paid envelope to complete at a later time and return by mail. Participants who chose to take the study package to complete at a later time were given both telephone and email contact information in case of further questions; participants completing the survey in person were encouraged to ask for clarification if they had any questions.

3.6 Instruments and variables

The study package included four surveys and a demographic information sheet (Appendix 3). The SLIQ was used to measure of lifestyle. HRQoL was measured with the SF-12 (version 2) and the EQ5D (version 5L). Well-being was measured using the PGWB. The demographic information sheet asked participants to report their age, sex, total household income and level of education. All responses were anonymous. A full list of variables is shown in Table 3.

Demographic and socioeconomic information was collected using a demographic form that has been previously used in the validation of the SLIQ. Participants indicate their age in years; whether they are male or female; their household income (<$25,000; $25,001-$35,000; $35,001-$50,000; $50,001-$75,000; $75,001-$100,000; $100,001-$150,000; $150,001-$200,000; $200,001+; prefer not to say); and their level of education (did not

complete high school; completed high school; some college or university studies; completed college diploma or university degree; some postgraduate or professional training; completed postgraduate or professional training).

All questionnaires were administered in full, regardless of the outcomes being measured, to preserve the validity of the instruments[75].

3.6.1 Measuring lifestyle

For lifestyle, the independent or explanatory variables were the overall SLIQ score, which is provided on a scale of one to ten; overall SLIQ category scores; and dimensional scores, which measure diet, exercise, alcohol consumption, smoking status, and stress.

The SLIQ was scored according to the scoring template (Appendix 4) that has been used in previous validation studies[53, 54]. When scoring the SLIQ, a raw score is calculated for each lifestyle dimension; for example, in the alcohol category the raw score is the number of units of alcohol consumed per week. For all dimensions except alcohol consumption, a higher raw score indicates healthier behavior. The raw scores are converted into category scores from zero to two based on the scoring guide, with 0 indicating a poor score in that dimension, one indicating an intermediate score in that dimension and 2 indicating a healthy score in that dimension. The category scores are summed to determine the overall score on a scale of zero to ten, which is also classified into overall categories of unhealthy (score 0-4), intermediate (score 5-7) and healthy (score 8-10).

3.6.2 Measuring HRQoL

For HRQoL, the PCS and MCS from the SF-12, and the VAS from the EQ5D were used. The SF-12 and the EQ5D provide ten and six scores, respectively. The PCS and MCS scores from the SF-12 were chosen for their broad coverage of physical and mental health components. The EQ5D VAS provides a measure of the patient's self-assessed health, and has been used independently of the other five EQ5D scores in other studies[20, 31]. For all three measures, the score is given as a continuous point on a scale of 0 to 100, with a higher score indicating a higher HRQoL.

To calculate the PCS and the MCS for the SF-12, QualityMetric scoring software using normalizing T-scores was used[79], with data adjusted for a mean of 50 (SD 10). Such normalization is generally not desirable when comparing population means, but the goal of this study is to evaluate the directionality and strength of the relation between lifestyle and HRQoL, so the normalization did not affect the analysis.

3.6.3 Measuring well-being

Well-being was measured with the PGWB-I. The PGWB-I is the summary measure of the PGWB, and was selected as a general measure of well-being that is generated based on the scores of the six dimensions of the questionnaire (anxiety, depressed mood, positive well-being, self-control, general health, and vitality). The PGWB was scored based on the validated scoring scheme. The PGWB-I is a continuous score given on a scale of 0 to 100, with a higher score indicating a higher level of well-being.

Table 3 List of variables and the questionnaires and components used to measure them.

Variable type	Variable	Measurement tool(s)	Type
Independent	Demographics	Age Sex Education level Household income	Continuous Dichotomous Ordinal Ordinal
	Lifestyle	Simple Lifestyle Indicator Questionnaire Overall score 5 dimensions (diet, exercise, alcohol, smoking, stress) Overall score category	 Continuous Continuous Ordinal
Dependent	Health Related Quality of Life	EuroQol EQ5D Visual analogue scale (VAS) SF-12 v2 Physical component score (PCS) Mental component score (MCS)	Continuous
	Well-being	Psychological General Wellbeing Index Index score (PGWB-I)	Continuous

3.7 Data entry and cleaning

When participants completed their surveys, the date was recorded on the study package. For surveys taken and returned by mail, the date of receipt was noted. Surveys were entered into a Microsoft Access database in batches of at least 10. Upon entry, the paper copies were given an identification number and marked with the date of entry. All surveys were stored in a locked filing cabinet.

3.7.1 Missing data

Eleven missing data points were identified out of 5800, a rate of 0.19%. Given the small number of missing data points, sensitivity analysis was not conducted prior to imputation. For the three participants who did not list an age, the median age of participants recruited from the same location was used. A computer randomly generated either male or female for two participants who did not indicate their sex. Missing values on the SF-12 were generated using the overall sample median for that question. One participant indicated on the SLIQ that they were not a current smoker, but did not indicate whether they had ever smoked; as 75% of current non-smoking participants were never smokers, that is the value that was imputed. One participant did not indicate their level of light exercise on the SLIQ, so the median value for that item was used.

3.8 Data analysis

The data were transferred to IBM Statistical Package for the Social Sciences (SPSS, version 20) for scoring and analysis.

Descriptive statistics were used to describe the sample population. To compare the demographic characteristics of this sample population against the general population, census data for both the city of St. John's and the province of NL were obtained from provincial and federal statistics agencies[80] and plotted against study demographic data.

All questionnaires were scored according to the validated scoring procedures and established normalizing algorithms. Normality assumptions for parametric tests were evaluated using histograms. Pearson correlation coefficients were calculated to determine the direction, strength, and significance of the relationship between the explanatory and

outcome variables[81]. The strength of each correlation was interpreted using two published statistical references; although there is some variability in the literature, a value of less than 0.3 is considered weakly or negligibly positive, values between 0.3 and 0.5 are considered moderately positive, values between 0.5 and 0.8 are considered strongly positive, an values above 0.8 are considered very strongly positive[76, 77], with a corresponding scale for negative correlations.

Analysis of variance (ANOVA) was used to determine whether the three categories of SLIQ scores represent distinct populations with respect to the outcome measures, with *post hoc* comparisons using Bonferroni correction.

To examine the effect of age, sex, education, income and lifestyle have on the outcomes of interest, multiple variable linear regression was performed. The ordinal variables of household income and education were coded as dummy variables for the regression with the lowest categories were used as reference values; for household income the category of < $25,000 was used and for level of education the category 'finished high school' was used as there were no participants who had not finished high school. This study was not powered for bivariate multiple variable linear regression, and all measured variables, regardless of their significance, are shown.

4.0 Results

4.1 Response rate

A total of 177 people were asked to take part in the study, of whom 117(66.1%) agreed to be part of the study. People who declined to participate were not asked the reason they declined. One hundred of those participants met the eligibility criteria, for an overall response rate of 56.5%. Eighty-one participants completed a survey at the time of recruitment. Thirty-six participants took a survey to return by mail, of whom 19 (52.8%) returned the completed survey package. Survey packages returned by mail did not include location information, which precluded analysis by recruitment location.

4.2 Descriptive statistics

Of the 100 participants who completed the survey, 60 were female and the average age was 37.5 years (SD 13.1 years) (Table 4). Fifty-three (53%) of the participants had household incomes of $75,000 or greater. All participants had completed high school, and 93 (93%) had at least some post-secondary education, with 20 (20%) completing post-graduate or professional training. When compared to the general population of the city of St. John's and the province of NL, this sample population was younger, with a higher proportion of participants in the higher categories of household income and education (Figures 2-4). Note that the census data had fewer categories for level of education, and the study data were collapsed into the appropriate categories to facilitate comparisons.

The average score on the SLIQ was 7.29 (SD 1.5) out of ten. On the SF-12, the mean scores for the MCS and PCS were 50.93 (SD 11.3) and 53.59 (SD 8.2), respectively, out of 100. The EQ5D VAS had a mean score of 78.96 (SD 13.7) out of 100 and the mean

score on the PGWB-I was 73.15 (SD 16.5) out of 100 (Table 5). The primary explanatory and outcome variables showed negative skew in their distributions (Figures 5 and 6). Using the categories for overall SLIQ scores, there were three, 46, and 51 participants with unhealthy, intermediate and healthy lifestyles, respectively.

Table 4 Description of the socio-demographic characteristics of the study population (n=100).

Characteristic	n
Age mean (SD)	37.5 (13.1)
Female	60
Income	
$25,000 or less	19
$25,001-$35,000	5
$35,001-$50,000	9
$50,001-$75,000	14
$75,001-$100,000	18
$100,001-$150,000	15
$150,001-$200,000	10
$200,001+	6
Prefer not to say	4
Education level	
Completed highschool	7
Some college or university	16
Completed college or university	39
Some postgraduate or professional training	19
Completed postgraduate or professional training	19
Recruitment	
Completed in person	81
Received by mail	19

Note: there were 100 participants recruited, thus the n is equal to the %, and only the former is shown.

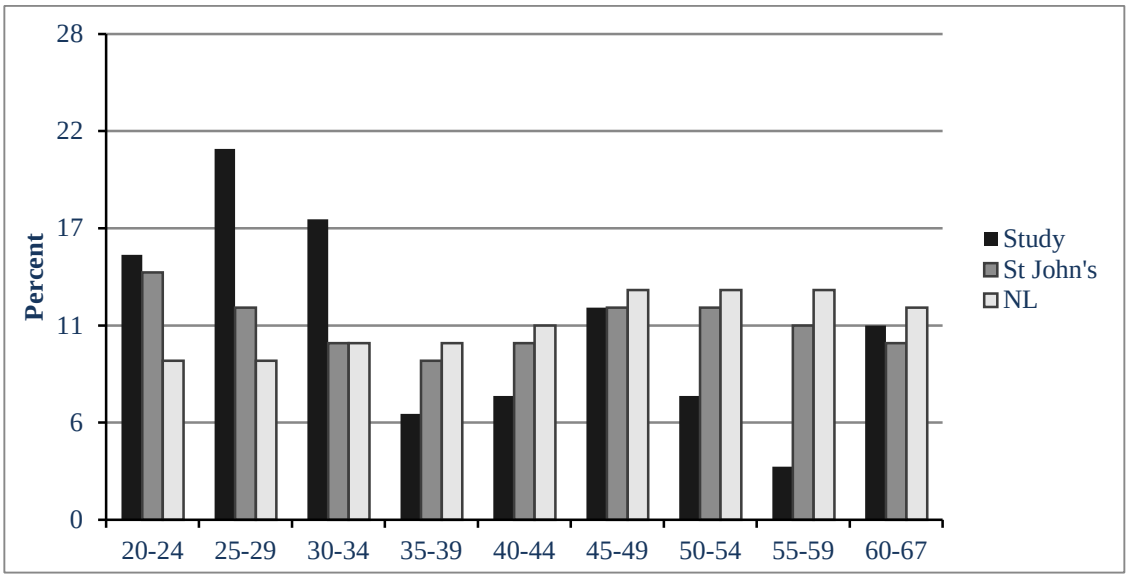

Figure 2 Percent of the population between the ages of 20 and 65 by 5-year age increments for study population, the St John's metropolitan area and the province of Newfoundland & Labrador.

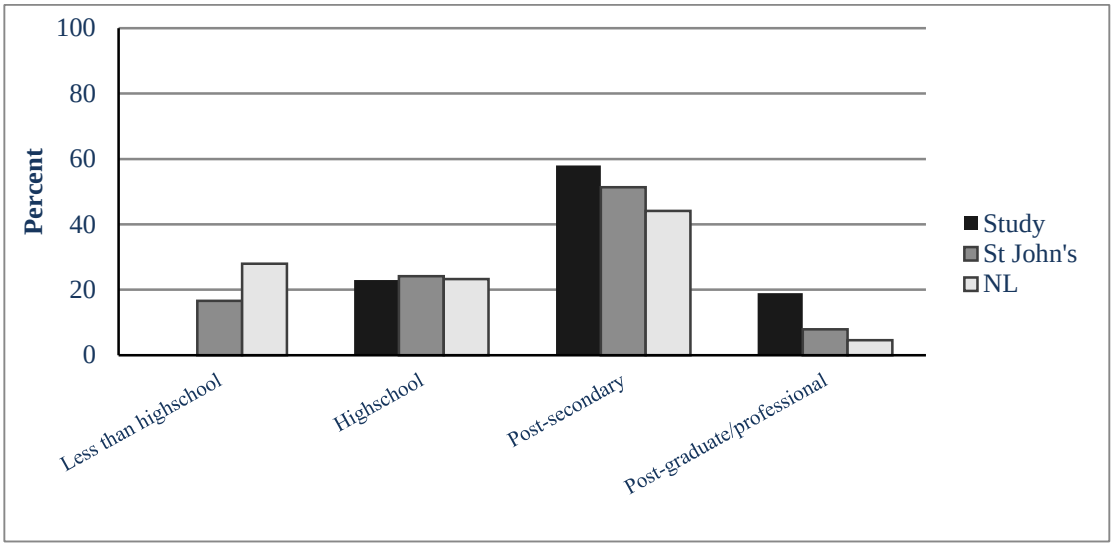

Figure 3 Percentage of individuals achieving stated levels of education for study population, the St John's metropolitan area and the province of Newfoundland & Labrador.

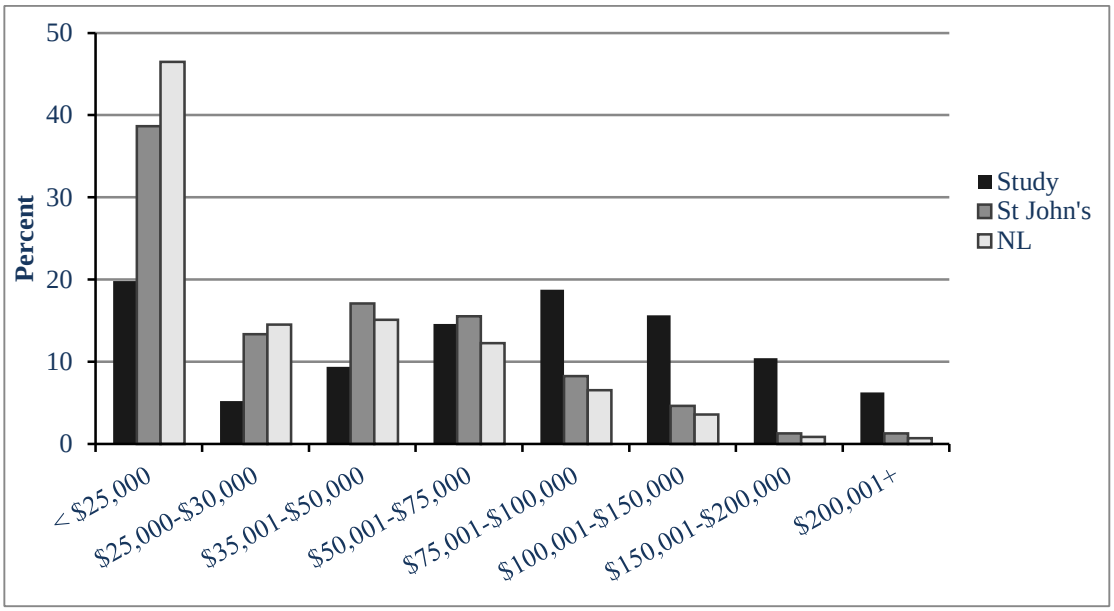

Figure 4 Percentage of individuals from household income levels for study population, the St John's metropolitan area and the province of Newfoundland & Labrador

Table 5 Measures of central tendency and variability for questionnaires

Variable	Mean (SD)	Median	Observed range	Possible range
SLIQ overall score	7.29 (1.5)	8.00	4-10	0-10
SLIQ Diet raw score	8.48 (3.5)	8.00	0-15	0-15
SLIQ Exercise raw score	11.85 (5.3)	13.00	2-24	0-24
SLIQ Alcohol raw score	3.13 (3.3)	2.00	0-12	0 - ∞*
SLIQ Smoking category score	1.64 (0.6)	2.00	0-2	0-2
SLIQ Stress raw score	3.80 (1.3)	4.00	1-6	1-6
SF-12 PCS	53.59 (8.2)	55.94	23.50-69.70	0-100
SF 12 MCS	50.93 (11.3)	53.24	7.19-68.22	0-100
EQ5D VAS	78.96 (13.7)	80.00	20-100	0-100
PGWB-I	73.15 (16.5)	76.82	17-99	0-100

**Note: There is no upper limit for the alcohol raw score as participants report the number of drinks consumed per week. SLIQ scoring documentation lists the top category as "14 or more."*

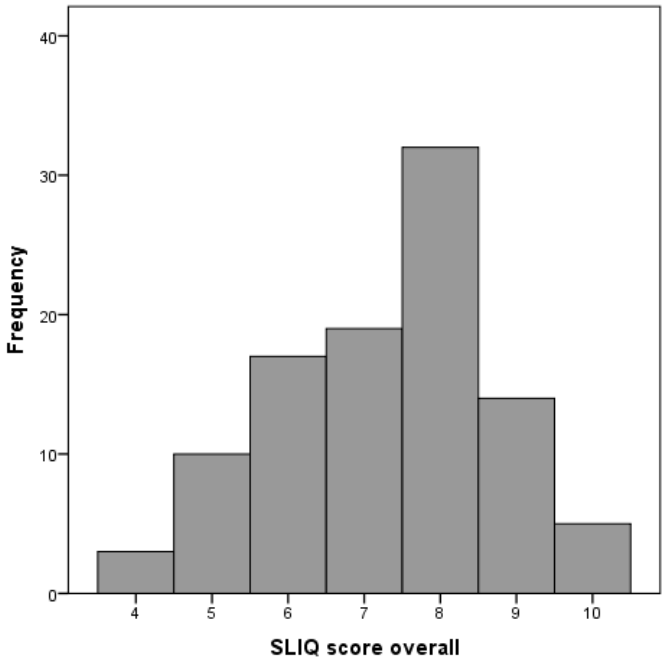

Figure 5 Histogram displaying the distribution of overall SLIQ scores.

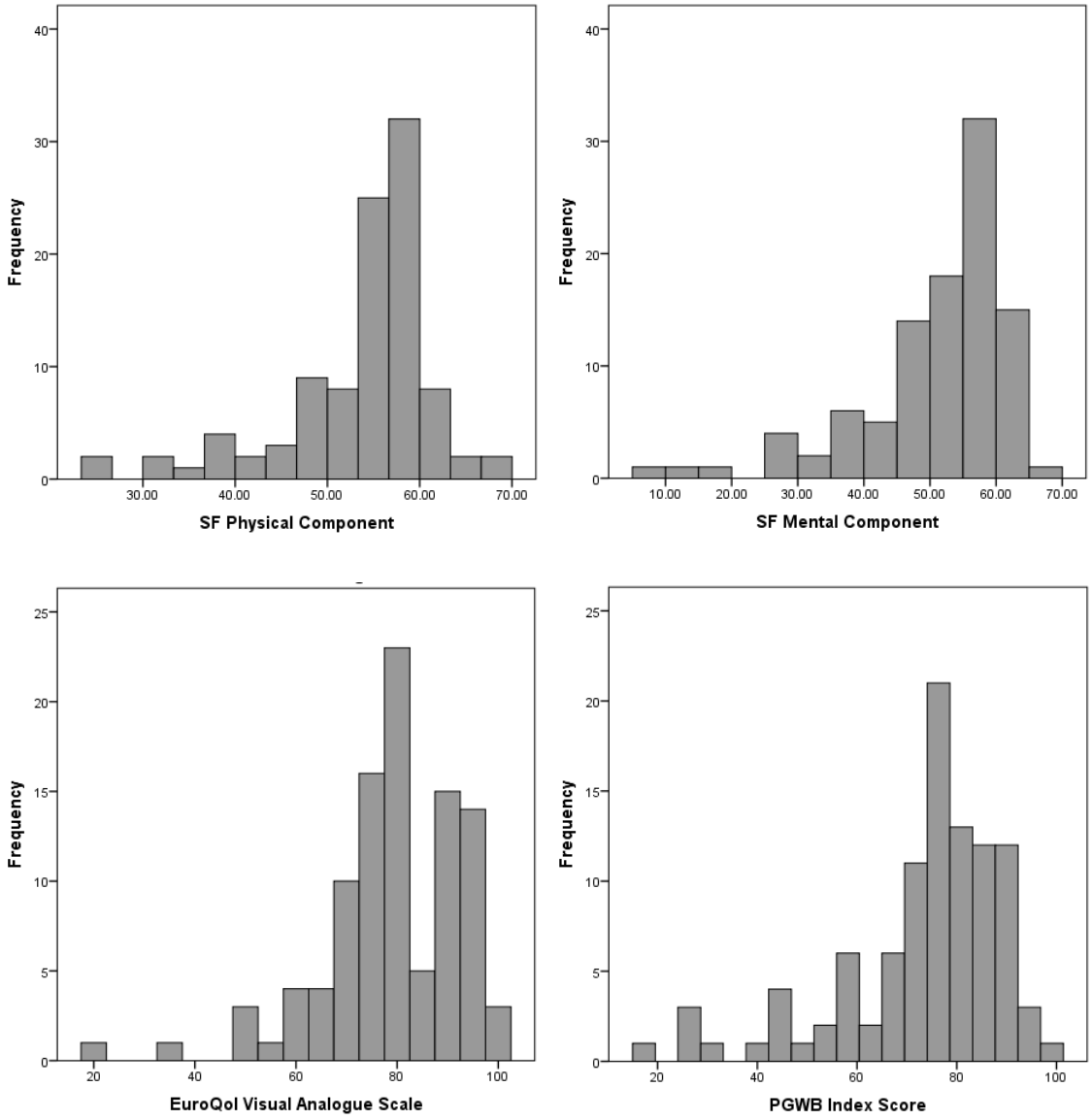

Figure 6 Histogram displaying the distribution of (clockwise from top left) the SF-12 PCS, SF-12 MCS, PGWB-I and EQ5D VAS.

4.3 Correlation between overall SLIQ score and measures of HRQoL and well-being

Given the skew distribution of the outcome measures, the use of non-parametric correlation techniques (e.g. Spearman rank correlation) was considered, as were geometric transformations of the data to achieve a more normal distribution. In tests of

transformed data and when using non-parametric measures the results were similar in the direction and strength of the relationship and the significance, so parametric tests were used on untransformed data.

Figure 7 and table 6 show the strength and directionality of the Pearson correlation between the overall score on the SLIQ and the outcome measures. The correlation between the overall score on the SLIQ was statistically significant and positive for the outcomes of SF-12 MCS ($r=0.41$, $p<0.01$), EQ5D VAS ($r=0.59$, $p<0.01$) and the PGWB-I ($r=0.47$, $p<0.01$). There was no significant correlation between the overall SLIQ score and the PCS ($r=0.13$, $p=0.19$).

Table 6 Pearson correlation coefficient between lifestyle as measured by the SLIQ and the outcome measures for HRQoL and well-being.

Outcome	Pearson's R	P value
SF-12 MCS	+ 0.41	< 0.01*
SF-12 PCS	+ 0.13	0.19
EQ5D VAS	+ 0.59	< 0.01*
PGWB-I	+ 0.47	< 0.01*

Note: values denoted with an asterisk (*) are statistically significant at $p < 0.05$

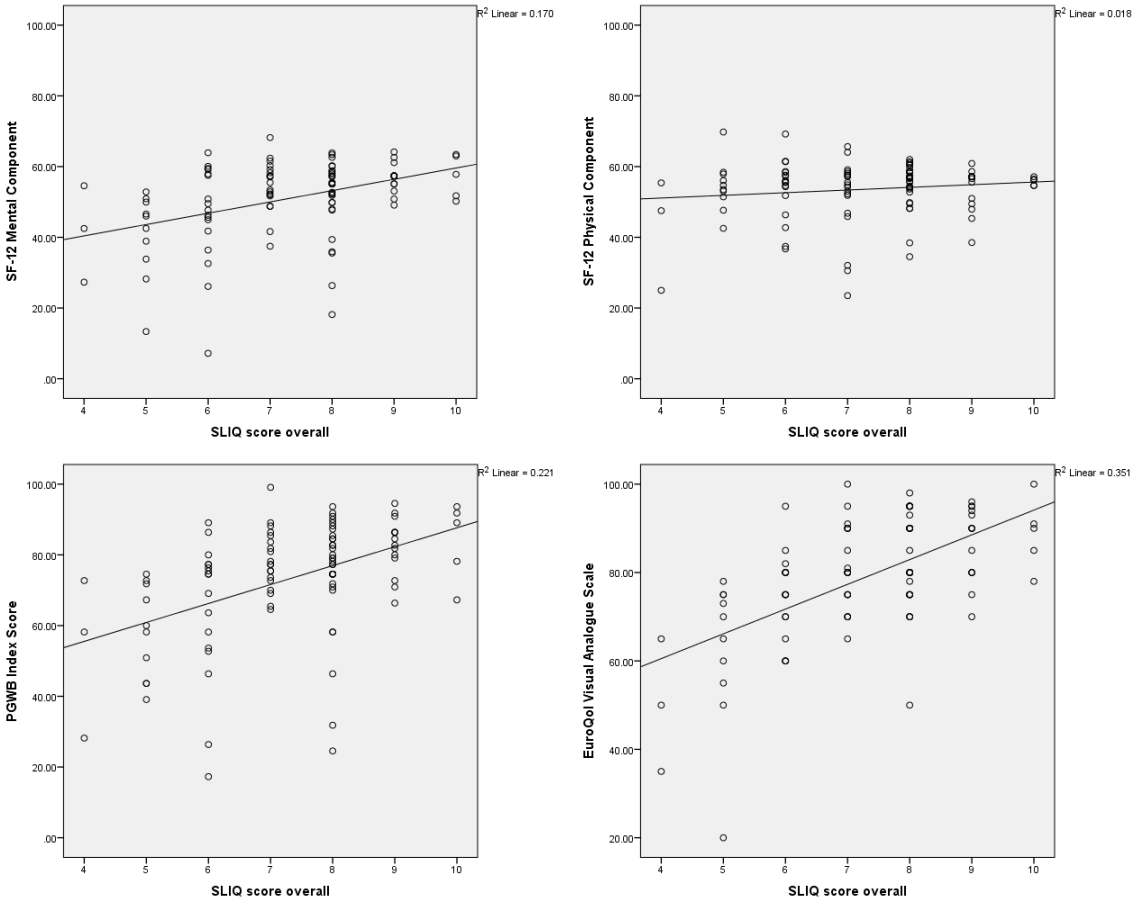

Figure 7 Correlation of overall SLIQ scores with outcomes (clockwise from top left) of the SF-12 MCS, SF-12 PCS, EQ5D VAS, and PGWB-I.

4.4 Correlation between the raw and category scores of the five SLIQ dimensions and measures of HRQoL and well-being

Pearson correlations were calculated between the SLIQ's individual lifestyle dimensions and the outcomes of interest (Table 7). For all SLIQ dimensions the raw score was used except for smoking, for which there is only a category score. The SLIQ raw score for diet correlated significantly and positively with the SF-12 MCS and EQ5D VAS outcome measures. The exercise raw score and the smoking category score were positively correlated with the SF-12 PCS and the EQ5D VAS. The alcohol category was not

significantly correlated with any of the outcome measures. The stress category correlated significantly positively with the SF-12 MCS and PGWB-I and negatively with the SF-12 PCS.

Table 7 Pearson correlation coefficient for the relationship between lifestyle dimensions of the SLIQ and the outcome measures for health-related quality of life and well-being.

	SF-12-MCS	SF-12 PCS	EQ5D VAS	PGWB-I
Diet	0.25* (p=0.01)	0.043 (p=0.67)	0.45* (p<0.01)	0.26* (p=0.01)
Exercise	-0.02 (p=0.85)	0.32* (p=0.01)	0.43* (p<0.01)	0.09 (p=0.37)
Alcohol	-0.06 (p=0.56)	0.17 (p=0.10)	0.05 (p=0.61)	-0.02 (p=0.85)
Smoking	-0.06 (p=0.53)	0.33* (p=0.01)	0.23* (p=0.02)	0.05 (p=0.60)
Stress	0.64* (p<0.01)	-0.25* (p=0.01)	0.15 (p=0.14)	0.62* (p<0.01)

Note: values denoted with an asterisk (*) are statistically significant at $p < 0.05$

4.5 Overall SLIQ score categories as distinct populations

Analysis was conducted to examine mean differences in scores on the HRQoL and well-being questionnaires between the three categories of the overall SLIQ scores. There were few participants with a SLIQ score in the unhealthy category (Table 8), which limited the statistical power of the analysis of this group.

Mean scores for the three categories were calculated for each outcome measure (Table 8). ANOVA was used to determine whether the healthy, intermediate and unhealthy categories of SLIQ scores had significantly different mean scores on the HRQoL and well-being questionnaires (Table 9). There was a significant difference between the categories for the SF-12 PCS, the SF-12 MCS, the EQ5D VAS, and the PGWB-I. Using Bonferroni *post hoc* testing, it was found that for the EQ5D VAS, the differences between all three categories were significant, whereas the PGWB-I and the SF-12 PCS showed significant differences between only some groups (Table 10). For the SF-12 MCS, the Bonferroni *post hoc* testing, which is more conservative than some other *post hoc* tests, failed to detect significant differences in group means.

Table 8 Mean and standard deviation of the outcome measures of health-related quality of life and well-being separated by overall SLIQ category.

SLIQ category	N	MCS	PCS	EQ5D	PGWB
		Mean (SD)			
Unhealthy	3	41.46 (13.67)	42.64 (15.77)	49.19 (13.63)	47.59 (13.60)
Intermediate	46	48.39 (12.57)	53.01 (9.46)	51.76 (9.39)	51.30 (7.86)
Healthy	51	53.78 (9.01)	54.74 (5.84)	54.28 (7.35)	53.64 (6.57)

Table 9 Analysis of variance (ANOVA) of mean score on surveys for three categories of SLIQ score

Outcome	Sum of Squares	Degrees of freedom	Mean Square	F stat.	P value
SF-12 MCS					
Between Groups	980.64	2	490.32	4.12*	0.02
Within groups	11544.26	97	119.01		
Total	12524.90	99			
SF-12 PCS					
Between Groups	444.34	2	222.17	3.46*	0.04
Within groups	6229.49	97	64.22		
Total	6673.83	99			
EQ5D VAS					
Between Groups	5042.61	2	2521.31	18.02*	<0.01
Within groups	13571.23	97	139.91		
Total	18613.84	99			
PGWB Index score					
Between Groups	3255.60	2	1627.80	6.64*	<0.01
Within groups	23778.21	97	245.14		
Total	27033.81	99			

Note: values denoted with an asterisk (*) are statistically significant at $p < 0.05$

Table 10 Post hoc tests of differences in mean variance for SLIQ categories using Bonferroni correction

	Category A	Category B	Mean Difference	P value	95% confidence interval	
SF-12 MCS	Unhealthy	Intermediate	-6.93	0.87	-22.77	8.90
		Healthy	-12.32	0.18	-28.11	3.47
	Intermediate	Unhealthy	6.93	0.87	-8.90	22.77
		Healthy	-5.39	0.05	-10.80	0.013
	Healthy	Unhealthy	12.32	0.18	-3.47	28.11
		Intermediate	5.39	0.05	-0.02	10.80
SF-12 PCS	Unhealthy	Intermediate	-10.37	0.10	-22.00	1.26
		Healthy	-12.11*	0.04	-23.71	-0.52
	Intermediate	Unhealthy	10.37	0.10	-1.26	22.00
		Healthy	-1.74	0.86	-5.71	2.23
	Healthy	Unhealthy	12.11*	0.04	0.52	23.71
		Intermediate	1.74	0.86	-2.23	5.71
EQ5D VAS	Unhealthy	Intermediate	-24.57*	<0.01	-41.74	-7.39
		Healthy	-34.63*	<0.01	-51.75	-17.51
	Intermediate	Unhealthy	24.57*	<0.01	7.39	41.74
		Healthy	-10.06*	<0.01	-15.92	-4.20
	Healthy	Unhealthy	34.63*	<0.01	17.51	51.75
		Intermediate	10.06*	<0.01	4.20	15.92
PGWB Index score	Unhealthy	Intermediate	-15.96	0.27	-38.69	6.77
		Healthy	-25.06*	0.03	-47.72	-2.40
	Intermediate	Unhealthy	15.96	0.27	-6.77	38.69
		Healthy	-9.10*	0.02	-16.86	-1.34
	Healthy	Unhealthy	25.06*	0.03	2.40	47.72
		Intermediate	9.10*	.016	1.34	16.86

Note: values denoted with an asterisk (*) are statistically significant at $p < 0.05$

4.6 Multiple variable linear regression model of HRQoL and well-being outcomes

In order to determine the association between the explanatory variables of SLIQ score and sociodemographic characteristics and the outcome variables of HRQoL and well-being, multiple variable linear regression was performed (Table 11). Variables included age, sex, household income, level of education, and overall SLIQ score. For every outcome measure except the SF-12 PCS, the SLIQ score was a statistically significant variable in the regression. For every outcome except the EQ5D VAS, age was a significant variable. The only other sociodemographic characteristic that was significantly predictive was level of education for the PGWB-I (completed high school versus completed post-graduate or professional training) and SF-12 PCS (completed high school versus completed college/university or completed post-graduate/professional). The amount of variation in outcome measures explained by the regression variables (R^2) ranged from a low of 31% for the SF-12 PCS to a high of 44% for the EQ5D VAS (Table 11).

Table 11 Multiple variable linear regressions for the outcomes of HRQoL and well-being using lifestyle and sociodemographic variables.

Outcome	Variable	B coefficient	P value	R^2
SF-12 MCS	Constant	23.03 *	< 0.01	0.34
	SLIQ score	2.93 *	< 0.01	
	Age	0.27 *	< 0.01	
	Sex	0.63	0.77	
	Education *(reference: Completed high school)*			
	Some college/university	-5.69	0.25	
	Completed college / university	-8.21	0.07	
	Some post-graduate / professional	-1.60	0.74	
	Completed post-graduate / professional	-9.66	0.05	
	Household income (*reference: < $25,000)*			
	$25,001-$35,000	5.70	0.26	
	$35,001-$50,000	-4.29	0.32	
	$50,000-$75,000	4.198	0.24	
	$75,01-$100,000	4.640	0.17	
	$100,001-$150,000	4.312	0.24	
	$150,001-$200,000	-3.132	0.44	
	$200,001+	-.882	0.85	
SF-12 PCS	Constant	50.33 *	< 0.01	0.31
	SLIQ score	0.72	0.20	
	Age	-0.22 *	< 0.01	
	Sex	-1.01	0.53	
	Education *(reference: Completed high school)*			
	Some college/university	4.00	0.27	
	Completed college / university	9.69 *	< 0.01	
	Some post-graduate / professional	5.86	0.10	
	Completed post-graduate / professional	7.96 *	0.03	
	Household income (*reference: < $25,000)*			
	$25,001-$35,000	-7.07	0.06	
	$35,001-$50,000	5.324	0.10	
	$50,000-$75,000	2.267	0.39	
	$75,01-$100,000	-3.482	0.16	
	$100,001-$150,000	3.627	0.19	
	$150,001-$200,000	2.962	0.32	
	$200,001+	4.895	0.17	

Outcome	Variable	B coefficient	P value	R^2
EQ5D VAS	Constant	37.68 *	< 0.01	0.44
	SLIQ score	5.67 *	< 0.01	
	Age	.061	0.53	
	Sex	-0.96	0.69	
	Education *(reference: Completed high school)*			
	Some college/university	-1.79	0.74	
	Completed college / university	-2.53	0.61	
	Some post-graduate / professional	0.61	0.91	
	Completed post-graduate / professional	-5.70	0.30	
	Household income (*reference: < $25,000)*			
	$25,001-$35,000	5.02	0.37	
	$35,001-$50,000	1.84	0.70	
	$50,000-$75,000	5.05	0.21	
	$75,01-$100,000	-2.52	0.50	
	$100,001-$150,000	5.19	0.21	
	$150,001-$200,000	-4.59	0.31	
	$200,001+	7.53	0.16	
PGWB Index	Constant	30.5 *	0.01	0.35
	SLIQ score	5.25 *	< 0.01	
	Age	0.29 *	0.02	
	Sex	0.83	0.79	
	Education *(reference: Completed high school)*			
	Some college/university	-8.08	0.26	
	Completed college / university	-11.71	0.07	
	Some post-graduate / professional	-4.61	0.51	
	Completed post-graduate / professional	-16.91 *	0.02	
	Household income (*reference: < $25,000)*			
	$25,001-$35,000	4.17	0.57	
	$35,001-$50,000	-1.44	0.82	
	$50,000-$75,000	4.64	0.37	
	$75,01-$100,000	3.48	0.48	
	$100,001-$150,000	7.83	0.15	
	$150,001-$200,000	-3.43	0.56	
	$200,001+	-1.34	0.85	

Note: values denoted with an asterisk (*) are statistically significant at $p < 0.05$

5.0 Discussion

The results indicate that there is a significant relationship between lifestyle and some measures of HRQoL and well-being, and that lifestyle as measured by the SLIQ may be associated with HRQoL and well-being. The positive correlation between lifestyle and HRQoL, as measured by the EQ5D VAS, is considered moderate, with a value above 0.5. The correlation between lifestyle and the SF-12 MCS and the PGWB-I were also positive, moderate in strength and statistically significant. A significant correlation between lifestyle and the SF-12 PCS was not detected. With respect to the dimensions of the SLIQ, there were significant, positive associations between diet and the SF-12 MCS, the EQ5D VAS and the PGWB-I; exercise and the SF-12 PCS and EQ5D VAS; smoking status and the SF-12 PCS and the EQ5D VAS; and stress levels and the PGWB-I. There was a significant, negative association between stress and scores on the SF-12 PCS. There were too few participants with an unhealthy lifestyle to explore that category adequately, but significant differences in the mean scores of the intermediate and healthy groups were observed for EQ5D VAS and the PGWB-I. In multivariable linear regression models age was a significant factor for the SF-12 MCS, SF-12 PCS and PGWB-I, and level of education was a significant factor for PGWB-I and SF-12 PCS; all other sociodemographic variables were not statistically significant. These results are generally in line with the literature; despite variability in the definition of lifestyle and measures of HRQOL the correlation between the two has been shown significant in diverse populations[68, 70, 74].

Lifestyle was particularly well correlated with HRQoL, specifically self-perceived health, as illustrated by the EQ5D VAS. There is a moderate, significant correlation between the overall lifestyle score, the dimensions of diet and exercise, and the EQ5D VAS, and participants in the intermediate and healthy SLIQ categories had significantly different mean VAS scores. This suggests that, in this sample population, lifestyle is predictive of a person's self-perceived health. There is general agreement with these findings in the literature, including a study using Statistics Canada's National Population Health Survey data, with the finding that lifestyle habits are significant determinants of self-perceived health[82]. The National Population Health Survey is a representative survey of Canadians living across the country, although people living in remote communities and on First Nations reserves are not included. That study indicates that physical activity and smoking status are among the strongest predictors of self-perceived health.

The relationship between lifestyle and the physical and mental components of the SF-12 are less clear. The SF-12 physical component was not significantly correlated with the overall SLIQ score, although significant correlations were detected for the dimensions of exercise (positive, weak/moderate relationship strength, statistically significant), smoking (positive, weak/moderate relationship strength, statistically significant), and stress (negative, weak/moderate relationship strength, statistically significant). The mental component of the SF-12 was significantly correlated with the overall SLIQ score, as well as the scores for diet (positive, weak/moderate relationship strength, statistically significant) and stress (positive, moderate/strong relationship, statistically significant). This indicates that individual lifestyle dimensions correlate differently with physical and

mental HRQoL, and the degree and strength of those relationships affects how an overall lifestyle score correlates with the measures of HRQoL.

The PGWB-I correlates quite well with the stress dimension of the SLIQ, with a strong, significant correlation observed in this sample. This suggests that a 6-point self-reported scale of stress strongly correlates with a score generated through a 22-item questionnaire; the latter is a simpler measure, and may be helpful in situations where researchers or clinicians wish to generate a general measure of well-being relatively quickly. There was a significant difference of just over 10 points in PGWB-I scores between individuals categorized as intermediate and healthy by the SLIQ, indicating a significant difference in well-being for these groups. Other studies have suggested an independent link between psychosocial stressors and poor lifestyle, which is then further associated with reduced quality of life[73], and additional investigation of these three related factors might be useful.

The only SLIQ dimension that was not significantly associated with of any outcome measures was alcohol consumption. Correlation coefficients were weak and not statistically significant. Participant self-reports ranged from 0-12 drinks per week, with an average of about two drinks per week and a strong positive skew in distribution. Concerns about the validity of self-reported alcohol consumption have been raised in the literature[83,84], and inaccurate reporting, which may have precluded the detection of a relationship between alcohol consumption and the outcomes of interest, must be considered. Mild to moderate alcohol consumption is relatively benign, but high consumption of alcohol is associated with increased risk of developing some chronic diseases[5]. With respect to HRQoL, one study found that among a cohort of men followed

from middle- to old-age, HRQoL was negatively affected in those who reported consuming three or more drinks per day[85]. Similar results were seen in a cross-sectional study, which found a significant decrease in HRQoL among drinkers with DSM-IV-classified alcohol dependence[86]. Participants in this study reported consuming an average of two drinks per week, so it is not surprising that no significant decrease in quality of life related to alcohol consumption was found.

There was no significant correlation between overall SLIQ scores and the SF-12 PCS. This is somewhat at odds with the literature, which has generally shown significant positive relationships between physical activity, physical fitness and quality of life[87, 88]. The exercise category score on the SLIQ did correlated significantly with the SF-12 PCS as well as the EQ5D VAS, which is more in line with the published literature in suggesting an association between physical activity and dimensions of HRQoL[56,89]. One possible explanation for this disparity is in the way the PCS is calculated. On the SF-12, physical health is assessed through questions asking about how a participant's health affects their ability to carry out "moderate activities such as moving a table, pushing a vacuum cleaner, bowling, or playing golf", their ability to "climb several flights of stairs", whether they accomplished less or were limited in the kinds of activities they could do, whether they experienced pain, and whether their physical health affected their social activities. The sample population was generally healthy, community-dwelling adults, and the strong central tendency of the PCS scores suggests that the SF-12 may not have adequate sensitivity in this population. In contrast, the SLIQ measures mild, moderate and intense physical activity, and scores in the study population showed a much

wider range of values. A more detailed evaluation of physical activity or physical fitness than is used in the SF-12 and EQ5D may be needed to differentiate between the physical function of healthy, community-dwelling adults.

Although a statistically significant association between lifestyle and HRQoL and well-being was observed, the relevance to physicians, patients, and the general population is less clear. The minimal clinically important difference (MCID) for measures of HRQoL and well-being is around 10%[90], although there is some variance depending on the health of the population and whether an improvement or decline is observed[91]. It has been suggested that defining an MCID is difficult because patients may not always understand the context of their improvement or decline, and MCID will vary depending upon the general health of the population being observed[92]. For the EQ5D VAS studies have suggested that the MCID, defined as the mean difference in scores associated with a transition between the instrument's health classification system, is 10 points[93, 94]. For the SF-12, a difference of 5 points on either the MCS or PCS is considered minimally important[93]. There seems to be some consensus that a difference in 10 percent in an instrument's scoring range reaches the threshold of MCID, although this will vary by population and health status[93,95]. The coefficients in the linear regression models indicate that lifestyle may affect some measures of HRQoL and well-being in a clinically important way. In the regression of both the PGWB-I and the EQ5D VAS, a difference in SLIQ scores of two points would yield a difference of just over ten percent, while the difference in SLIQ scores required to see a MCID on the SF-12 MCS is four points. The weak, nonsignificant association between the overall SLIQ score and the SF-12 PCS does

not permit the determination of a threshold for MCID. These results indicate that a change in lifestyle that resulted in two to four point difference in SLIQ scores would result in a clinically meaningful change in HRQoL and well-being in this population. A combination of lifestyle changes would yield that magnitude of change in SLIQ, including quitting smoking (+ 1 point), reducing alcohol consumption from fourteen drinks per week to fewer than seven (+ 2 points), adding vigorous exercise to one's lifestyle habits (+ 1 or 2 points, depending on previous exercise), and consuming two or more servings of leafy greens, fruit and high-fibre carbohydrates to the diet (+ 1 or 2 points). Physicians counselling patients on making lifestyle changes and people considering changing their lifestyle should be aware that it may take a number of moderate changes or a one or two large changes to their lifestyle before they notice a difference in their quality of life.

Sociodemographic characteristics varied in the significance of their association with HRQoL and well-being. The results of this study suggest that some sociodemographic characteristics, specifically age and education level, are significantly associated with HRQoL and well-being. Age was a significant predictor of SF-12 MCS, PCS, and PGWB-I, although the directionality of the coefficients varied; older participants had lower values for PCS scores but higher values for MCS and PGWB-I; this is similar to a large Canadian study of people with chronic diseases, which found that advancing age was associated with lower PCS scores but higher MCS scores[96]. Some studies have suggested that overall HRQoL declines with age in certain populations[97], particularly for physical domains in those with underlying health issues[98, 99]. Higher levels of income and

education, which have been independently associated with increased quality of life[68,100, 101], may ameliorate the effects of age in certain studies as well; at least one study reported lower HRQoL among older participants, but noted that participants in the oldest age category who were more educated and with higher household income actually had a higher HRQoL than younger participants in the lowest categories of education and household income[102]. Household income was not significantly associated with any of the outcomes, and education was only associated with the PCS and PGWB-I in a few categories. As a secondary outcome, this study was not statistically powered to evaluate relationships between sociodemographic factors and the outcomes of interest, and a large sample of this population may have yielded results more in line with the literature.

One significant limitation of this study relates to the study population and the ways in which it differs from the general population in the city of St John's and the province of NL. This study population was younger and with a higher proportion of people who are highly educated and with high household incomes than is representative of either the St John's metropolitan area or the province as a whole. Recruitment locations were selected strategically to recruit people of different backgrounds in areas of varying socioeconomic status. Despite these efforts, the study population differed from the general population both in the city and the province, which reduces the generalizability of these results. To some degree this may be expected, as exclusion criteria restricted the sample population to people who had been free of serious disease or illness in the past year; the sample was compared to the general population of the city of St. John's and the province of NL, not to healthy adults within those areas. Loosening those exclusion criteria still may not have

yielded a representative sample; researchers may distribute surveys to a random sample of their target population, but the people who agree to participate and complete the survey may not be representative of the population as a whole[103]. Recruiting more diverse participants, particularly having greater representation of individuals with lower levels of education or household income, may have added diversity to the observed lifestyle scores, as studies in the literature suggest that these characteristics are associated[68, 100, 101]. The exclusion criteria, as well, may have prevented some people with unhealthy lifestyles from participating, but the population of interest for this study was otherwise healthy adults so excluding people who had experienced a major health crisis in the last year was reasonable.

The strong central tendencies and skew of the distribution of lifestyle, HRQoL and well-being variables may violate normality assumptions required for correlational and linear regression analysis. This possibility was investigated by comparing parametric and non-parametric tests, which produced correlation and regression coefficients of the same direction, magnitude, and significance as the parametric tests. Statistical references suggest using Pearson correlation and other parametric tests when the data are generally normally distributed, stating that the effect on results is minimal as long as the data are independent[104,105].

A number of variables that could have affected the results of this study were not measured. A person's lifestyle, HRQoL and well-being may be affected by medical conditions such as arthritis or depression, medications they are currently taking, and physiologic characteristics such as BMI. Social and personal events, such as a family

member's illness, a divorce, or lost job may also affect lifestyle and HRQoL. Participants who had experienced a serious health issue or pregnancy within the last year were excluded, but attempting to screen for and measure or exclude all possible confounders would have been impractical. The sociodemographic factors included in the study are similar to those in the literature, but future studies in this area should consider including a wider range of factors that may be confounders or effects modifiers in their analysis.

The necessary variability in recruitment techniques and study procedures may have introduced some bias into the results. For example, any potential participant could be directly approached in family medicine clinic waiting rooms, while participants at the shopping mall had to approach a table and inquire about the study before they could be recruited. Also, some participants completed their questionnaire packages at the time of recruitment while others took the questionnaire packages to complete at a later time and return by mail. This variability was largely unavoidable, as study procedures had to comply with the regulations in the venues at which participants were recruited; the shopping mall provided access to a diverse population of potential participants but had firm rules that participants must approach the table. As well, the Human Research Ethics Authority required that participants have the option to complete the questionnaires privately and at their own pace, so the choice to take the surveys and return them by mail was provided. The study procedures attempted to reduce this variability by developing standard language for recruiting participants, and standard answers to common questions were identified during the pilot study phase. All participants were recruited by the same

person (the candidate), which ensured consistency of information given and helped reduce further variability.

The validated questionnaires used in this study used different time periods as frames of reference for questions. The SLIQ, for example, asks participants to consider their lifestyle habits over the last year, the EQ5D asks about a person's HRQoL on the day it is filled out, the SF-12 asks about quality of life in the past four weeks, and the PGWB does not give a time period, instead asking how things have been going. It would be preferable for all instruments to evaluate the same period of time, but questionnaires are validated with specific wording and cannot be modified[75]. By querying lifestyle over the last 12 months, the SLIQ avoids some of the seasonal sensitivity and general variability that may affect shorter time periods; people may be less physically active during the winter months, for example, or may experience short periods of time during which their lifestyle habits depart from normal, such as a vacation or holiday season. In contrast, the measures of HRQoL and well-being seek the evaluate individuals on a much shorter timescale. Although HRQoL and well-being are, no doubt, subject to variation throughout the year and based on life events, the surveys are designed to give a snapshot of how an individual's quality of life is around the time they are surveyed.

As a cross-sectional survey, this study cannot provide evidence for causation or order of events, but it can provide evidence for associations. This study cannot determine whether people who have a good HRQoL and well-being are better able to lead a healthy, active lifestyle, or if a healthy, active lifestyle improves a person's quality of life; likely it is some combination of both. This study is also unable to determine whether changes in

lifestyle consistently result in changes to HRQoL and well-being, as this sample population was measured at just a single time point.

Studies in the literature use a number of measures to quantify lifestyle, and this variability precludes making comparisons between studies. Just as quality of life research benefitted greatly from the wider use of validated tools, so would the study of lifestyle risk factors benefit from more consistent definitions and measurement tools. Validated instruments such as the SLIQ provide consistent, comparable measurements of lifestyle, and researchers should consider the use of such tools in place of the improvised assessment measures that are often used at present.

Further understanding of the relationship between lifestyle and HRQoL and well-being would benefit greatly from additional studies in more generalizable populations using validated questionnaires.

6.0 Conclusions

In a sample of community-dwelling adults in St John's, NL, there were significant associations between lifestyle, as measured by the SLIQ, and some measures of HRQoL and well-being. This study also found significant associations between certain dimensions of lifestyle, especially diet, exercise and stress as measured by the SLIQ, and some measures of quality of life. The three categories of overall SLIQ scores represent populations with significantly different mean scores for the measures of HRQoL and well-being. The SLIQ seems to have at least moderately associated with HRQoL and well-being, which is a conclusion in line with previously-published literature on the subject.

This study is strengthened by the use of validated questionnaires, which add reliability to the results. The generalizability of these results may be limited by a sample population that was younger, more educated and with higher household income than the general population of adults in St. John's, NL, and the province of NL as a whole. A paucity of participants with a lifestyle categorized as unhealthy meant that some analyses were underpowered.

These results indicate that there is a significant association between lifestyle and the outcomes of HRQoL and well-being. Further study in this area is needed to assess whether similar associations are present in more diverse populations, and to promote the understanding of lifestyle as a source of disparity in both quality of life and well-being in healthy, community-dwelling populations.

7.0 References

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Appendix 1 – Overview of studies evaluated during literature search

Table 12 Examples of the literature examining the association between lifestyle and HRQoL and well-being evaluated in the literature review.

Author, year	Purpose	Study type Population	Exposure variable	Outcome variable	Limitations	Results & conclusions
Conry, 2011	To explore clusters of lifestyle behaviours and determine effect on health, mental health and HRQoL	•Cross-sectional survey •Nationally-representative sample of adults. Republic of Ireland (n=7350)	•Lifestyle - diet, exercise, alcohol consumption, tobacco use. •Demographic information – age, sex, social class	•HRQoL. •Self-rated health •Mental health	•Clustering analysis makes comparisons difficult	•In this population there are identifiable clusters of lifestyle behaviours, both positive and negative. •Multi-factorial interventions may be required to address clusters of poor lifestyle behaviours in certain populations.
Savolainen, 2014	Examine the association between lifestyle and HRQoL	•Cross-sectional survey (baseline data from cohort) •Community-dwelling adults in eastern Finland (n=560)	•Lifestyle – nutrition, alcohol consumption, tobacco use, exercise •Demographic information : age, sex, marital status, education	•HRQoL.	•Country-specific, unvalidated instrument for lifestyle •Analysis based on tertiles, making comparisons difficult	•Participants in the healthiest lifestyle tertile were significantly more likely to have better HRQoL. •"People who are expected to strive most to change their lifestyle have the lowest quality of life and psychological welfare, which should be taken into account in both clinical work and health promotion"

Xu, 2012	To evaluate lifestyle and HRQoL among civil servants in China	•Cross-sectional study •Adults working in the Chinese civil service (n=14,021)	•Lifestyle – tobacco smoking, alcohol consumption, physical activity, sedentary time, sleep duration, breakfast habits. •Demographic information – martial status, level of education	•HRQoL	• Sample may not represent wider population – high levels of university education • No validated instruments to measure lifestyle	•Smoking, alcohol consumption, decreased physical activity, short sleep duration, and high sedentariness were associated ($p<0.05$) with lower PCS and MCS scores •Lifestyle factors and behaviours affect HRQoL
Pisinger, 2009	To determine if an intervention to improve lifestyle leads to an improvement of HRQoL	•Interventional study with 5-year follow-up •Stratified random sample of adults aged 30-60 years from Copenhagen, Denmark (n=7719)	•Lifestyle •Medical health assessment •Cardiovascular risk assessment •Demographic information - age, sex, nationality, employment status, education, •Disease history - myocardial infarction and diabetes	•HRQoL	•Lifestyle measures at 3- and 5-year followup not reported. •No validated instruments to measure lifestyle	•Interventions to improve lifestyle may also result in changes to HRQoL.
Seib, 2014	To examine lifestyle, stress and quality of life among older women	•Cross-sectional study •Random sample of women aged 60-70 years living in	•Lifestyle – weight, physical activity, alcohol and tobacco use, fruit and vegetable consumption, sleep	•HRQoL •Presence of chronic illness	•No validated instruments to measure lifestyle	• Women with history of personal trauma have poorer lifestyle. Poorer lifestyle is associated with poorer outcomes such as HRQoL and chronic disease.

	who have (or have not) experienced life stressors.	Australia (n=181)	quality •Demographic information – age, marital status, area of residence, country of birth, education level, income, employment •History of stressful life events			•This suggests that lifestyle, life experiences and health are interrelated - life stressors contribute to unhealthy lifestyle behaviours, which in turn negatively affect health.
Myint, 2011[66]	Evaluation of the relationship between lifestyle and quality-adjusted life years	•Cross-sectional study • Healthy adults recruited as part of the Norfolk site of the Eur. Prospective Investigation into Cancer (n=13,358)	•Lifestyle – tobacco use, alcohol consumption, fruit and vegetable consumption, physical inactivity •Demogaphics – age, BMI, education, social class	•HRQoL (converted to generate QALYs)	•No validated instruments to measure lifestyle	•People with extremely poor lifestyles were 6.5 times more likely to die during follow-up period (mean follow-up 11.4 yrs). •Healthier lifestyle behaviours are associated with higher QALYs
Sabia, 2012 [64]	To evaluate the relationship between lifestyle and healthy aging	•Cross-sectional study participants in the Whitehall II cohort study ≥60 years of age at the time of the study (n=5100)	•Lifestyle – history of tobacco use, physical activity levels, consumption of fruits and vegetables, consumption of alcohol •Age, sex, marital status, education	•HRQoL •Disability •Healthy aging –no serious illnesses, good physical functioning,	•Unrepresentative sample – high levels of university education •Binary measures of lifestyle limits detailed analysis	•Lifestyle behaviours have a dose-response relationship with some aspects of healthy aging. •Suggests that combination of healthy lifestyle behaviours may confer more benefit than individual behaviours.

Appendix 2 – Human Research Ethics Authority approval and study information sheet:

Ethics Office
Suite 200, Eastern Trust Building
95 Bonaventure Avenue
St. John's, NL
A1B 2X5

July 12, 2013

Ms. Jacqueline Fortier
Primary Healthcare Research Unit
Janeway Hostel
Room 420
Health Science Centre

Dear Ms. Fortier:

Reference #13.140

RE: **The simple lifestyle indicator questionnaire and its predictive validity for Health status and well being**

This will acknowledge receipt of your correspondence dated July 12, 2013.

This correspondence has been reviewed by the Chair under the direction of the Board. ***Full board approval*** of this research study is granted for one year effective **June 27, 2013.**

This is to confirm that the Health Research Ethics Board reviewed and approved or acknowledged the following documents (as indicated):

- Application, approved
- Letter of information dated June 17, 2013, approved
- SF-12 questionnaire, approved
- EuroQol EP-5D-5L, questionnaire, approved
- Psychological General Well-Being Index (PGWB-I), approved
- Simple Lifestyle Indication Questionnaire (SLIQ), approved

MARK THE DATE

This approval will lapse on **June 26, 2014**. It is your responsibility to ensure that the Ethics Renewal form is forwarded to the HREB office prior to the renewal date. ***The information provided in this form must be current to the time of submission and submitted to HREB not less than 30 nor more than 45 days of the anniversary of your approval date.*** The Ethics Renewal form can be downloaded from the HREB website http://www.hrea.ca.

The Health Research Ethics Board advises THAT IF YOU DO NOT return the completed Ethics Renewal form prior to date of renewal:

email: info@hrea.ca Phone: 777-8949 FAX: 777-8776

- *Your ethics approval will lapse*
- *You will be required to stop research activity immediately*
- *You may not be permitted to restart the study until you reapply for and receive approval to undertake the study again*

Lapse in ethics approval may result in interruption or termination of funding

It is <u>your responsibility to seek the necessary approval from the Regional Health Authority or other organization as appropriate.</u>

Modifications of the protocol/consent are not permitted without prior approval from the Health Research Ethics Board. Implementing changes in the protocol/consent without HREB approval may result in the approval of your research study being revoked, necessitating cessation of all related research activity. Request for modification to the protocol/consent must be outlined on an amendment form (available on the HREB website) and submitted to the HREB for review.

This research ethics board (the HREB) has reviewed and approved the research protocol and documentation as noted above for the study which is to be conducted by you as the qualified investigator named above at the specified site. This approval and the views of this Research Ethics Board have been documented in writing. In addition, please be advised that the Health Research Ethics Board currently operates according to *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*; *ICH Guidance E6: Good Clinical Practice* and applicable laws and regulations. The membership of this research ethics board is constituted in compliance with the membership requirements for research ethics boards as defined by *Health Canada Food and Drug Regulations Division 5; Part C*.

Notwithstanding the approval of the HREB, the primary responsibility for the ethical conduct of the investigation remains with you.

We wish you every success with your study.

Sincerely,

Dr. Fern Brunger
Chair, Non-Clinical Trials
Health Research Ethics Board

C C VP Research c/o Office of Research, MUN
VP Research c/o Patient Research Centre, Eastern Health
HREB meeting date: July 25, 2013

email: info@hrea.ca Phone: 777-8949 FAX: 777-8776

Primary Healthcare Research Unit
Janeway Hostel, 4th Floor
Health Sciences Centre
300 Prince Philip Dr
St. John's NL A1B 3V6
Web: www.med.mun.ca/phru

Letter of Information

TITLE: **The Simple Lifestyle Indicator Questionnaire and its Predictive Validity for Health Status and Well-Being**

INVESTIGATOR(S): Jacqueline Fortier (MSc. candidate) and Dr. Marshall Godwin (supervisor)

You have been invited to take part in a research study. Taking part in this study is voluntary. It is up to you to decide whether to be in the study or not. You can decide not to take part in the study. If you decide to take part, you are free to leave at any time. This will not affect your usual care.

Before you decide, you need to understand what the study is for, what risks you might take and what benefits you might receive. This form explains the study.

Please read this carefully. Take as much time as you like. If you like, take it home to think about for a while. Mark anything you do not understand, or want explained better. After you have read it, please ask questions about anything that is not clear.

The researchers will:

- discuss the study with you
- answer your questions
- keep confidential any information which could identify you personally
- be available during the study to deal with problems and answer questions

1. Introduction/Background:

We are trying to learn more about lifestyle habits and a person's health and well-being. We know that some lifestyle habits increase your risk of getting a chronic disease. We want to know whether those same lifestyle habits affect how you feel right now. We are interested in how a person's diet, exercise, tobacco use, stress, and alcohol consumption affect their health.

This study will help us learn more about the link between lifestyle and health. We hope it will help us understand how current habits can affect the way people feel.

2. Purpose of study:

The purpose of our study is to measure the lifestyle, health status and well-being of adults. We will use these measurements to see whether lifestyle is connected to health or well-being.

3. Description of the study procedures:

People who choose to participate in this study will provide some information about themselves, including their age and sex. They will then complete four short surveys. The researcher will help answer any questions that might come up.

4. Length of time:

Participation in this study will take between ten and twenty minutes, depending on the time it takes to complete the questionnaires.

5. Possible risks and discomforts:

- Some participants may feel uncomfortable answering questions about their emotional or physical health and well-being.

6. Benefits:

It is not known whether this study will benefit you.

7. Liability statement:

Completing our study questionnaires gives us your consent to be in this study. It tells us that you understand the information about the research study. When you complete the study questionnaires, you do not give up your legal rights. Researchers or agencies involved in this research study still have their legal and professional responsibilities.

8. What about my privacy and confidentiality?

Protecting your privacy is an important part of this study. Every effort to protect your privacy will be made. However it cannot be guaranteed. For example we may be required by law to allow access to research records.

When you complete the questionnaires you give us permission to

- Collect information from you
- Share information with the people conducting the study
- Share information with the people responsible for protecting your safety

<u>Access to records</u>

The members of the research team will see study records, but they will not identify you by name.

Other people may need to <u>look</u> at the study record, but those records will not identify you by name. This might include the research ethics board.

<u>Use of your study information</u>

The research team will collect and use only the information they need for this research study.

This information will include your

- date of birth
- sex
- level of education
- household income
- your general health in the last year
- information from study interviews and questionnaires

Your name and contact information will not be collected. Your name will not appear in any report or article published as a result of this study.

Information collected for this study will kept for five years.

If you decide to withdraw from the study, the information collected up to that time will continue to be used by the research team. It may not be removed. This information will only be used for the purposes of this study.

Information collected and used by the research team will be stored as encrypted files on servers at the Primary Healthcare Research Unit. Jacqueline Fortier is the person responsible for keeping it secure.

Your access to records

You may ask the researcher to see the information that has been collected about you.

9. Questions or problems:

If you have any questions about taking part in this study, you can meet with the investigator who is in charge of the study at this institution. That person is:

Jacqueline Fortier
709-777-2942
Jacqueline.fortier@med.mun.ca

Or you can talk to someone who is not involved with the study at all, but can advise you on your rights as a participant in a research study. This person can be reached through:

Ethics Office

Health Research Ethics Authority

709-777-6974 or by email at info@hrea.ca

Appendix 3 – Study package provided to participants

PARTICIPANT DEMOGRAPHIC SHEET

GENDER: [ ] Male [ ] Female

AGE: _____

TOTAL HOUSEHOLD INCOME:

- ☐ $25,000 or less
- ☐ $25,001 to $35,000
- ☐ $35,001 to $50,000
- ☐ $50,001 to $75,000
- ☐ $75,001 to $100,000
- ☐ $100,001 to $150,000
- ☐ $150,001 to $200,000
- ☐ $200,001 plus
- ☐ Prefer not to respond

Educational Level

- ☐ Did not complete high school
- ☐ Completed high school
- ☐ Some college or university studies
- ☐ Completed college diploma or university degree
- ☐ Some postgraduate or professional training
- ☐ Completed postgraduate or professional training.

Simple Lifestyle Indicator Questionnaire

Diet: To answer these questions, think about your eating habits in the past year. Indicate how often you eat the following foods. Please include all meals, snacks and eating out

1. Lettuce or green leafy salad, with or without other vegetables

[ ] less than 1/week [ ] 1/week [ ] 2-3x/week [ ] 4-6x/week [ ] once/day [ ] 2+/day

2. Fruit: include fresh, canned or frozen, but do not include juices

[ ] less than 1/week [ ] 1/week [ ] 2-3x/week [ ] 4-6x/week [ ] once/day [ ] 2+/day

3. High fiber cereals or whole grain breads: this includes cereal such as Raisin bran, Fruit and Fiber, cooked oatmeal, and breads which are whole wheat, multigrain, rye or pumpernickel

[ ] less than 1/week [ ] 1/week [ ] 2-3x/week [ ] 4-6x/week [ ] once/day [ ] 2+/day

Exercise: To answer the following questions please indicate how many times per week you take part in the following activities for a duration of at least 30 minutes or more at a time:

I. Light exercise, such as:

- light gardening and light housework (dusting, sweeping, vacuuming)
- leisurely walking (walking your dog)
- bowling, fishing, carpentry, playing a musical instrument
- volunteer work

[ ] 0/week [ ] 1-3x/week [ ] 4-7x/week [ ] 8 and more/week

II. Moderate exercise, for example:

- brisk walk
- bicycling, skating, swimming, curling
- gardening (raking, weeding, spading)
- dancing, Tai Chi or moderate exercise classes

[ ] 0/week [ ] 1-3x/week [ ] 4-7x/week [ ] 8 and more/week

III. Vigorous exercise, for example:

- running, bicycling, x-country skiing, lap swimming, aerobics
- heavy yard work
- weight training
- soccer, basketball or other league sports

[ ] 0/week [ ] 1-3x/week [ ] 4-7x/week [ ] 8 and more/week

Alcohol: Please indicate how many drinks of the following types of alcohol you consume in an average week:

- ✓ Wine: _____ drinks (3-5 oz.)
- ✓ Beer: _____ drinks (10-12 oz or 1 bottle)
- ✓ Spirits: ____ drinks (1-1 ½ oz.)

Smoking: Please indicate your smoking habits below:

Are you a smoker? [ ] Yes [ ] No

If yes, how long have you been smoking? _____ years

If no, did you ever smoke? [ ] Yes [ ] No

If yes, how many years ago did you quit? _____ years

Life Stress: To answer this question please circle the number which you feel best corresponds to the level of stress in your everyday life

1 2 3 4 5 6

Not at all stressful Very stressful

EuroQoL EQ-5D-5L

Under each heading, please tick the ONE box that best describes your health TODAY

MOBILITY

I have no problems in walking about ❑
I have slight problems in walking about ❑
I have moderate problems in walking about ❑
I have severe problems in walking about ❑
I am unable to walk about ❑

SELF-CARE

I have no problems washing or dressing myself ❑
I have slight problems washing or dressing myself ❑
I have moderate problems washing or dressing myself ❑
I have severe problems washing or dressing myself ❑
I am unable to wash or dress myself ❑

USUAL ACTIVITIES *(e.g. work, study, housework, family or leisure activities)*

I have no problems doing my usual activities ❑
I have slight problems doing my usual activities ❑
I have moderate problems doing my usual activities ❑
I have severe problems doing my usual activities ❑
I am unable to do my usual activities ❑

PAIN / DISCOMFORT

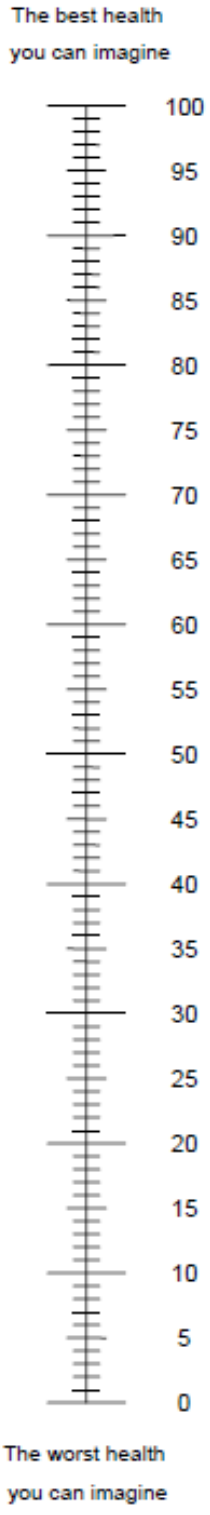
I have no pain or discomfort ❑
I have slight pain or discomfort ❑
I have moderate pain or discomfort ❑
I have severe pain or discomfort ❑
I have extreme pain or discomfort ❑

ANXIETY / DEPRESSION

I am not anxious or depressed ❑
I am slightly anxious or depressed ❑
I am moderately anxious or depressed ❑
I am severely anxious or depressed ❑
I am extremely anxious or depressed ❑

- We would like to know how good or bad your health is TODAY.
- This scale is numbered from 0 to 100.
- 100 means the best health you can imagine.
  0 means the worst health you can imagine.
- Mark an X on the scale to indicate how your health is TODAY.
- Now, please write the number you marked on the scale in the box below.

YOUR HEALTH TODAY = ☐



Your Health and Well-Being

This survey asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities.
Thank you for completing this survey!

For each of the following questions, please mark an ☒ in the one box that best describes your answer.

1. **In general, would you say your health is:**

Excellent	Very good	Good	Fair	Poor
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

2. **The following questions are about activities you might do during a typical day. Does <u>your health now limit you</u> in these activities? If so, how much?**

	Yes, limited a lot	Yes, limited a little	No, not limited at all
a. <u>Moderate activities</u>, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	☐ 1	☐ 2	☐ 3
b. Climbing <u>several</u> flights of stairs	☐ 1	☐ 2	☐ 3

3. During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a. Accomplished less than you would like	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
b. Were limited in the kind of work or other activities	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

4. During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a. Accomplished less than you would like	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
b. Did work or other activities less carefully than usual	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

5. During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?

Not at all	A little bit	Moderately	Quite a bit	Extremely
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

6. **These questions are about how you feel and how things have been with you <u>during the past 4 weeks</u>. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the <u>past 4 weeks</u>…**

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a. Have you felt calm and peaceful?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
b. Did you have a lot of energy?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
c. Have you felt downhearted and depressed?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

7. **During the <u>past 4 weeks</u>, how much of the time has your <u>physical health or emotional problems</u> interfered with your social activities (like visiting with friends, relatives, etc.)?**

All of the time	Most of the time	Some of the time	A little of the time	None of the time
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

Thank you for completing these questions!

Psychological General Well-Being Index

READ: This section of the examination contains questions about how you feel and how things have been going with you. For each question check [ ] the answer which best applies to you.

1. How have you been feeling in general during the past month?
(Check one box)

In excellent spirits	☐ 5
In very good spirits	☐ 4
In good spirits mostly	☐ 3
I have been up and down in spirits a lot	☐ 2
In low spirits mostly	☐ 1
In very low spirits	☐ 0

2. How often were you bothered by any illness, bodily disorder, aches or pains during the past month?
(Check one box)

Every day	☐ 0
Almost every day	☐ 1
About half of the time	☐ 2
Now and then, but less than half the time	☐ 3
Rarely	☐ 4
None of the time	☐ 5

3. Did you feel depressed during the past month?
(Check one box)

Yes - to the point that I felt like taking my life	☐ 0
Yes - to the point that I did not care about anything	☐ 1
Yes - very depressed almost every day	☐ 2
Yes - quite depressed several times	☐ 3
Yes - a little depressed now and then	☐ 4
No - never felt depressed at all	☐ 5

4. Have you been in firm control of your behavior, thoughts, emotions or feelings during the past month?
(Check one box)

Yes, definitely so	☐ 5
Yes, for the most part	☐ 4
Generally so	☐ 3
Not too well	☐ 2
No, and I am somewhat disturbed	☐ 1
No, and I am very disturbed	☐ 0

5. Have you been bothered by nervousness or your "nerves" during the past month?
(Check one box)

Extremely so - to the point where I could not work or take care of things	☐ 0
Very much so	☐ 1
Quite a bit	☐ 2
Some - enough to bother me	☐ 3
A little	☐ 4
Not at all	☐ 5

6. How much energy, pep, or vitality did you have or feel during the past month?
(Check one box)

Very full of energy - lots of pep	☐ 5
Fairly energetic most of the time	☐ 4
My energy level varied quite a bit	☐ 3
Generally low in energy or pep	☐ 2
Very low in energy or pep most of the time	☐ 1
No energy or pep at all - I felt drained, sapped	☐ 0

7. I felt downhearted and blue during the past month.
(Check one box)

None of the time	☐ 5
A little of the time	☐ 4
Some of the time	☐ 3
A good bit of the time	☐ 2
Most of the time	☐ 1
All of the time	☐ 0

8. Were you generally tense or did you feel any tension during the past month?
(Check one box)

Yes - extremely tense, most or all of the time	☐ 0
Yes - very tense most of the time	☐ 1
Not generally tense, but did feel fairly tense several times	☐ 2
I felt a little tense a few times	☐ 3
My general tension level was quite low	☐ 4
I never felt tense or any tension at all	☐ 5

9. How happy, satisfied, or pleased have you been with your personal life during the past month?
(Check one box)

Extremely happy - could not have been more satisfied or pleased	☐ 5
Very happy most of the time	☐ 4
Generally satisfied - pleased	☐ 3
Sometimes fairly happy, sometimes fairly unhappy	☐ 2
Generally dissatisfied or unhappy	☐ 1
Very dissatisfied or unhappy most or all the time	☐ 0

10. Did you feel healthy enough to carry out the things you like to do or had to do during the past month?
(Check one box)

Yes - definitely so	☐ 5
For the most part	☐ 4
Health problems limited me in some important ways	☐ 3
I was only healthy enough to take care of myself	☐ 2
I needed some help in taking care of myself	☐ 1
I needed someone to help me with most or all of the things I had to do	☐ 0

11. Have you felt so sad, discouraged, hopeless, or had so many problems that you wondered if anything was worthwhile during the past month?
(Check one box)

Extremely so - to the point that I have just about given up	☐ 0
Very much so	☐ 1
Quite a bit	☐ 2
Some - enough to bother me	☐ 3
A little bit	☐ 4
Not at all	☐ 5

12. I woke up feeling fresh and rested during the past month.
(Check one box)

None of the time	☐ 0
A little of the time	☐ 1
Some of the time	☐ 2
A good bit of the time	☐ 3
Most of the time	☐ 4
All of the time	☐ 5

13. Have you been concerned, worried, or had any fears about your health during the past month?
(Check one box)

Extremely so	☐ 0
Very much so	☐ 1
Quite a bit	☐ 2
Some, but not a lot	☐ 3
Practically never	☐ 4
Not at all	☐ 5

14. Have you had any reason to wonder if you were losing your mind, or losing control over the way you act, talk, think, feel or of your memory during the past month?
(Check one box)

Not at all	☐ 5
Only a little	☐ 4
Some - but not enough to be concerned or worried about	☐ 3
Some and I have been a little concerned	☐ 2
Some and I am quite concerned	☐ 1
Yes, very much so and I am very concerned	☐ 0

15. My daily life was full of things that were interesting to me during the past month.
Check one box)

None of the time	☐ 0
A little of the time	☐ 1
Some of the time	☐ 2
A good bit of the time	☐ 3
Most of the time	☐ 4
All of the time	☐ 5

16. Did you feel active, vigorous, or dull, sluggish during the past month?
(Check one box)

Very active, vigorous every day	☐ 5
Mostly active, vigorous - never really dull, sluggish	☐ 4
Fairly active, vigorous - seldom dull, sluggish	☐ 3
Fairly dull, sluggish - seldom active, vigorous	☐ 2
Mostly dull, sluggish - never really active, vigorous	☐ 1
Very dull, sluggish every day	☐ 0

17. Have you been anxious, worried, or upset during the past month?
(Check one box)

Extremely so - to the point of being sick or almost sick	☐ 0
Very much so	☐ 1
Quite a bit	☐ 2
Some - enough to bother me	☐ 3
A little bit	☐ 4
Not at all	☐ 5

18. I was emotionally stable and sure of myself during the past month.
(Check one box)

None of the time	☐ 0
A little of the time	☐ 1
Some of the time	☐ 2
A good bit of the time	☐ 3
Most of the time	☐ 4
All of the time	☐ 5

19. Did you feel relaxed, at ease or high strung, tight, or keyed-up during the past month?
(Check one box)

Felt relaxed and at ease the whole month	☐ 5
Felt relaxed and at ease most of the time	☐ 4
Generally felt relaxed but at times felt fairly high strung	☐ 3
Generally felt high strung but at times felt fairly relaxed	☐ 2
Felt high strung, tight, or keyed-up most of the time	☐ 1
Felt high strung, tight, or keyed-up the whole month	☐ 0

20. I felt cheerful, lighthearted during the past month.
(Check one box)

None of the time	☐ 0
A little of the time	☐ 1
Some of the time	☐ 2
A good bit of the time	☐ 3
Most of the time	☐ 4
All of the time	☐ 5

21. I felt tired, worn out, used up, or exhausted during the past month.
(Check one box)

None of the time	☐ 5
A little of the time	☐ 4
Some of the time	☐ 3
A good bit of the time	☐ 2
Most of the time	☐ 1
All of the time	☐ 0

22. Have you been under or felt you were under any strain, stress, or pressure during the past month?
(Check one box)

Yes - almost more than I could bear or stand	☐ 0
Yes - quite a bit of pressure	☐ 1
Yes, some - more than usual	☐ 2
Yes, some - but about usual	☐ 3
Yes - a little	☐ 4
Not at all	☐ 5

Appendix 4 – Scoring template for the Simple Lifestyle Indicator Questionnaire

Scoring the Simple Lifestyle Indicator Questionnaire

Diet:

1. Lettuce or green leafy salad, with or without other vegetables

☐less than 1/week ☐ 1/week ☐ 2-3x/week ☐ 4-6x/week ☐ once/day ☐2+/day
0 1 2 3 4 5

2. Fruit: include fresh, canned or frozen, but do not include juices

☐less than 1/week ☐1/week ☐2-3x/week ☐ 4-6x/week ☐once/day ☐ 2+/day
0 1 2 3 4 5

3. High fiber cereals or whole grain breads: this includes cereal such as Raisin bran, Fruit and Fiber, cooked oatmeal and breads which are whole wheat, rye or pumpernickel

☐less than 1/week ☐ 1/week ☐2-3x/week ☐ 4-6x/week ☐ once/day ☐2+/day
0 1 2 3 4 5

DietRawScore = _____
Q1+Q2+Q3

DietCategoryScore = _____
0 If DietScore 0-5
1 If DietScore 6-10
2 If DietScore 11-15

Exercise:

1. Light exercise, such as:
   - light gardening and light housework (dusting, sweeping, vacuuming)
   - leisurely walking (walking your dog)
   - bowling, fishing, carpentry, playing a musical instrument
   - volunteer work

☐0/week ☐1-3x/week ☐4-7x/week ☐8 and more/week
0 2 3 4

2. Moderate exercise, for example:
   - brisk walk
   - bicycling, skating, swimming, curling
   - gardening (raking, weeding, spading)
   - dancing, Tai Chi or moderate exercise classes

☐0/week ☐1-3x/week ☐4-7x/week ☐8 and more/week
0 4 6 8

3. Vigorous exercise, for example:
   - running, bicycling, x-country skiing, lap swimming, aerobics
   - heavy yard work
   - weight training
   - soccer, basketball or other league sports

☐0/week ☐1-3x/week ☐4-7x/week ☐8 and more/week
0 6 9 12

ActivityRawScore = _____
Q1+Q2+Q3

ActivityCategoryScore = ____
0 If Light Exercise Only
1 If Any Moderate Activity
2 If Any Vigorous Activity

Alcohol: (per week)

- ✓ Wine: _____ drinks (3-5 oz.)
- ✓ Beer: _____ drinks (10-12 oz or 1 bottle)
- ✓ Spirits: ____ drinks (1-1 ½ oz.)

AlcoholRawScore _____
Wine + Beer + Spirits

AlcoholCategoryScore _____

0 If Alcohol Score 14 or more
1 If Alcohol Score 8-13
2 If Alcohol Score 0-7

Smoking:

Are you a smoker?
☐Yes ☐No
0

If no, did you ever smoke?
☐Yes ☐No
1 **2**

SmokingRawScore _____
(0,1, or 2)
SmokingCategory Score_____
(Same as Smoking Score)

Life Stress:

6 5 4 3 2 1

Not at all stressful Very stressful

StressRawScore = _____
As indicated on Line

StressCategoryScore _____
O If Life Stress 1 or 2
1 If Life Stress 3 or 4
2 If Life Stress 5 or 6

SLIQScore = DietCategory + ActivityCategory + AlcoholCategory + SmokingCategory + StressCategory