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# Effects of a Formal Educational Class on the Quality of Life in Patients Diagnosed with Hypothyroidism

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 $Popal, DNP, BSN, MSN, FNP-C, T. (2018). Effects of a Formal Educational Class on the Quality of Life in Patients Diagnosed with Hypothyroidism., (). Retrieved from https://hsrc.himmelfarb.gwu.edu/son_dnp/39$ 

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Effects of a Formal Educational Class on the Quality of Life in Patients Diagnosed with

Hypothyroidism

Presented to the Faculty of the School of Nursing

The George Washington University

In partial fulfillment of the requirements for the degree of Doctor of Nursing Practice

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Date of final approved DNP Project: Spring 2018



**Background:** Hypothyroidism is a chronic disease that requires self-care skills such as healthy diet, exercise, and a daily medication regimen where timing of food intake is essential. Adequate education is essential for patients with hypothyroidism to be able to manage their disease, and to live with the best quality of life possible. Many studies have been conducted to assess the perceived health status of patients with hypothyroidism, but few have examined the effects of a formal educational program on the quality of life.

**Objectives:** The purpose of this study is to determine if a formal hypothyroidism educational class will improve the ThyPRO-39us quality of life survey among patients diagnosed with hypothyroidism.

**Methods:** In this prospective pretest-posttest design study, 12 patients diagnosed with hypothyroidism recruited from a private endocrinology practice in Fairfax, Virginia completed the ThyPRO-39us quality of life survey at baseline and then again 4 weeks after the formal educational class. SPSS23 was used for statistical analysis and Wilcoxon Signed Rank Tests were performed to determine any significant changes in the ThyPRO-39us composite and subscale scores on quality of life.

**Results:** The educational class demonstrated a statistically significant change in the ThyPRO-39us composite score which is comprised of seven subscales and the goiter, hyper and hypo subscales. There was no statistically significant change in the eyes and appearance/cosmetics subscales.

**Conclusions:** The education class improved the quality of life of patients with hypothyroidism. I suggest implementing educational programs in clinical management of such patients.



# Effects of a Formal Educational Class on the Quality of Life in Patients Diagnosed with Hypothyroidism

The thyroid gland is regulated by the thyroid-stimulating hormone (TSH) which is secreted by the anterior pituitary and is responsible for metabolic homeostasis through secretion of two hormones, thyroxine (T4) and triiodothyronine (T3). Hypothyroidism is the under secretion of the two hormones (Rugge, Bougatsos, & Chou, 2014). A person's energy level, mood, weight and body temperature regulation are affected by T3 and T4 hormones (Center for Disease Control and Prevention, 2014).

Thyroid disease is a chronic illness affecting about 200 million people around the world and about 30 million Americans (McCormick, 2015). More women are diagnosed with hypothyroidism than men in the United States (Rugge et al., 2014). There is an annual incidence of 4.1 per 1000 in women and 0.6 per 1000 in men according to the Whickham survey (Chakera, Pearce, & Vaidya, 2012).

When hypothyroidism is left untreated, it can lead to hypertension, dyslipidemia, infertility, cognitive impairment, and neuromuscular dysfunction (David, Gaitonde, Kevin, Rowley, Lori, & Sweeney, 2012). Treatment for hypothyroidism is reasonably straightforward in that it requires taking only one medication, levothyroxine, once a day. There are many barriers that affect a patient's self-management of their illness. Some of these barriers are medication noncompliance due to lack of education, social support, living situation, and socioeconomic status (Kandukuri, Khan, & Soltys, 2010).

A review by Watt, Groenvold, Rasmussen, Bonnema, Hegedüs, Bjorner and Feldt-Rasmussen, (2006) showed that about half of the patients with hypothyroidism had reduced overall quality of life and general health limitations in usual activities as well as social and



emotional problems. Two-thirds were fatigued and about one-third were anxious and had cognitive as well as sexual problems.

#### **Problem Statement**

Studies show that only about 50 percent of patients follow treatment recommendations for hypothyroidism. When compared with other chronic illnesses (eg., hypertension, diabetes mellitus, hypercholesterolemia, or osteoporosis) that require more multifaceted treatment plans and monitoring, noncompliance rates are the same for hypothyroidism (Briesacher, Andrade, Fouayzi, & Chan, 2008).

I work in a private endocrine practice and I have observed non-adherence to the treatment plan and complaints of poor quality of life in patients with hypothyroidism due to a lack of education. Some patients do not understand their condition or why they need to take thyroid hormones. Others believe that they can skip thyroid medication for some time if they are feeling fine. Some patients do not know how to properly take thyroid medication and are unaware of possible interactions with other medications. This lack of knowledge demonstrates a need for proper education of patients with hypothyroidism

Furthermore, some patients do not seem to have adequate knowledge regarding diet and exercise in the treatment of hypothyroidism. Due to a lack of time during office visits, I perhaps spend about ten minutes educating my patients on proper medication administration and the role of diet and exercise in the management of hypothyroidism. Many studies have been conducted to assess the perceived health status of patients with hypothyroidism, but few have examined the effects of a formal educational program on quality of life.



#### Purpose

The purpose of this study was to determine if there is a change in score in the quality of life in patients diagnosed with hypothyroidism before and after a formal educational program. The program included a formal lecture provided to participants, which was 45 minutes in length with 25 slides that covered the pathophysiology of hypothyroidism, proper medication administration, the importance of diet and exercise in the management of hypothyroidism and available community resources for patients. Depending on the findings of the study, I would like to set up more educational programs and support groups for patients diagnosed with hypothyroidism to help them better manage their condition.

# Aims

1. Created a formal hypothyroidism educational class that consisted of a 45-minute lecture provided by myself, the nurse practitioner in a private endocrinology practice. The lecture covered the pathophysiology of hypothyroidism, symptoms, proper medication administration, the importance of diet and exercise in the management of hypothyroidism and resources available to patients in the community.

2. Implemented a formal educational class for hypothyroid patients in my private endocrine practice.

3. Measured quality of life before and four weeks after implementation of a formal hypothyroidism educational class and determined change in the composite score of the seven subscales of the ThyPRO-39us survey and the scores of four additional subscales.

The long-term aim of my study was to create more formal educational programs for patients with hypothyroidism to improve health outcomes.



# Hypotheses

To achieve the aims of the study, the following hypotheses were tested:

- 1. There is a difference in the ThyPRO-39us goiter subscale scores before vs. after a formal hypothyroidism educational class.
- 2. There is a difference in the ThyPRO-39us hyper subscale scores before vs. after a formal hypothyroidism educational class.
- There is a difference in the ThyPRO-39us hypo subscale scores before vs. after a formal hypothyroidism educational class.
- There is a difference in the ThyPRO-39us eyes subscale scores before vs. after a formal hypothyroidism educational class
- 5. There is a difference in the ThyPRO-39us appearance/cosmetic scores before vs. after a formal hypothyroidism educational class
- 6. There is a difference in the composite scores of the ThyPRO-39us quality of life survey before vs. after a formal hypothyroidism educational class. The ThyPRO-39us includes the seven physical, mental, and social well-being and function subscale scores (memory, tension, psychological wellbeing, mood, relationships with others, daily activities, effect of thyroid disease on appearance) and the single quality of life question.

#### Significance

This study is important to nursing as it will help nurse practitioners better understand the most common factors affecting the quality of life in patients with hypothyroidism in a suburban private practice setting and if a formal educational class improves the quality of life in this patient population. Once we have the knowledge about the factors affecting the quality of life in



patients with hypothyroidism, we can educate our patients accordingly and help them better manage their condition.

Many studies have looked at the perceived quality of life in patients with hypothyroidism, but few have assessed the effect of an intervention such as an educational program. My study not only provided a formal educational program but also assessed the quality of life in patients with hypothyroidism before and after the intervention, which may possibly improve patient management of their condition. Findings from this study may help guide future educational programs that are more appropriate and convenient, benefitting both patients and providers.

Busy practices need to find effective ways to ensure that their patients receive the information they need to manage their condition effectively. One method of accomplishing this is through group visits/educational programs. Currently in my practice, I perhaps only spend about ten minutes educating my patients. Most of my patients do not even understand the pathophysiology of hypothyroidism or the symptoms associated with it, so they always have plenty of questions for a short office visit.

One of the most common barriers in the management of patients with hypothyroidism is incorrect knowledge, beliefs and practices regarding hypothyroidism due to a lack of education. There is a need for education on the pathophysiology of hypothyroidism, symptoms one may experience, proper administration of thyroid medication, importance of diet and exercise in the management of hypothyroidism and resources available to patients in the community.

If the aims of the study are attained and the study improves quality of life in patients with hypothyroidism, more providers may be able to use formal hypothyroidism educational classes to increase patient knowledge and to help them better manage their condition.



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#### **Summary of Literature Review**

Through literature review, I have found many studies that have evaluated patient education and thyroid disorders, effects of online education on increasing patient knowledge and quality of life of patients with hypothyroidism. No studies were found that examined the effect of a formal lecture style educational program on the quality of life in patients with hypothyroidism.

Twelve studies were reviewed. Six of those studies had an intervention related to the management of hypothyroidism. CINAHL and Medline databases were utilized for this literature search. The literature search is broken down into sections to include thyroid disease and patient education, patient education/learning, quality of life in hypothyroidism/chronic illnesses, and quality of life measurement tools.

#### Thyroid Disease and Patient Education

A study by Crilly & Esmail (2005) evaluated the effect of an educational booklet on thyroid medication adherence and quality of life of patients. The study does not state what information was included in the educational booklet. Patients diagnosed with hypothyroidism were recruited from three primary care practices in England. In an unblinded randomized clinical trial, 332 patients were randomized to either obtain an 'educational booklet' or 'usual care'. The intervention group showed a mean change in TSH of -0.11mIU/L and the control group showed a mean change in TSH of -0.12 mIU/L - an absolute difference of 0.01 mIU/L (95% confidence interval [CI] -0.93 to 0.94 mIU/L). The percentage of patients with an "undetectable TSH" at baseline was higher in the intervention group than the control group (20% vs 13%). When adjusted for the differences in baseline TSH (ANCOVA), the difference between groups was 0.12 mIU/L (95% CI=-1.97 to 1.95). The study also showed that the quality



of life of patients with hypothyroidism (measured by the SF-36 health survey) and thyroid medication adherence were not significantly improved with the use of an educational booklet.

#### Patient Education/Learning

Chan and Davey (2014) led a study to examine the effectiveness of producing and dispensing a patient educational booklet titled 'Starting radiation therapy: helpful tips for patients with head and neck cancer in an effort to guide cancer patients within the hospital system. Usefulness of the booklet was assessed by having the staff and patients answer a questionnaire. When it came to patient education, 67% of the staff utilized the booklet. About 98% of patients found the booklet useful in finding services within the hospital and in the community. Furthermore, the staff and patients found the chapter with a list of phone numbers and services to be the utmost valuable. Overall, the patients found the educational booklet useful for getting around the hospital system.

A study by Siddhanamatha, Heung, Lopez-Olivo, Abdel-Wahab, Ojeda-Prias, Willchockson & Suarez-Almazor (2017) assessed the quality of online education on rheumatoid arthritis (RA). The correctness, completeness, practical elements, design/esthetics, readability, and user-friendliness of the websites was evaluated by two autonomous experts. Forty-six websites were included in the study. Correct information was provided by almost all of the websites (98%). It was noted that none of the websites had all RA related subjects included. Important subjects often omitted included: "epidemiology, pathogenesis, treatment and disease monitoring, complications, self-management, risks and benefits of treatment, prognosis, treatment adherence, questions for patients to ask their doctors, and costs" (Siddhanamatha et. Al., 2017, p. 14). All of the websites revealed their proprietorship and about ten of the websites had the date of last updated content. The average reading level was noted as grade 12.1. The



majority of the websites (78%) were user-friendly, while only 33% were easy to navigate for those with visual and/or hearing impairments. Overall, the study identified that most websites were not updated often and did not provide comprehensive RA related educational information designed for patients.

Steele, Jones, Clark, Shiao, Wei, Shoemaker, & Parmar (2017) evaluated the effectiveness of online education on increasing patients' knowledge about radiation in diagnostic imaging. A total of 2,226 patients diagnosed with cancer participated and were randomized to receive information about ionizing radiation in the following ways: a web-based interactive education group, document education group, or no focused education (control group). Survey completion rates were as follows: Interactive group 40.5%, document group 49.1% and control group 74.4%. Participant satisfaction was highest in the interactive group (84%; n = 745), with 79% of this group indicating that they would recommend the program. In summary, an online educational program about radiation in diagnostic imaging proved to be satisfactory among patients.

A study by Koonce, Guise, Kusnoor, Hurley, and Fei (2015) evaluated the effectiveness of educational material tailored to participants' learning styles and health knowledge on patients' diabetes knowledge in a community clinic setting. Patients with a diagnosis of type 2 diabetes mellitus, age 18 years or older, and English or Spanish speakers were included in the study. A hundred and sixty patients participated, of which, 81 were randomized to the intervention group and 79 were in the control group. There were two tools used, the Diabetes Knowledge Test and Subjective Numeracy Scale. Patients completed the tools at baseline and again after two and six weeks. After two weeks, a significant increase was noted in the mean number of diabetes knowledge questions answered appropriately by the intervention group  $(\Delta=2.66, P=0.000)$ ,



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which continued at six weeks ( $\Delta$ =2.46, P=0.00). There was no change noted at two or six weeks in the control group. Overall, the patients' diabetes knowledge was significantly improved when information was tailored to their learning style and health literacy level.

#### Quality of Life in Hypothyroidism and/or Chronic Illness

A study was conducted in Iran by Rakhshan, Ghanbari, Rahimin, and Mostafayi (2017) on the quality of life and mental health of patients with hypothyroidism and euthyroid individuals referred to Motahari Clinic of Shiraz University of Medical Sciences. A total of 190 participants were divided into the intervention group (those diagnosed with hypothyroidism) and 95 patients in the control group (no diagnosis of hypothyroidism). The General Health Questionnaire (physical symptoms, anxiety, social function disorder, depression) and the Quality of Life Questionnaire (an adaptation of the WHOQOL-BREF questionnaire) were used to collect data. An independent t- test, Pearson correlation coefficient and variance analysis were used to analyze the data collected. The results did not show any significant difference in the quality of life of the two groups of participants. However, when comparing mental health levels, those with hypothyroidism showed statistically significant difference in reporting more depression and anxiety (P<0.001).

Another study conducted in the United Kingdom by Razvi, Ingoe, McMillan, and Weaver (2005), evaluated the perceived health status of patients with sub-clinical hypothyroidism (SCH) and those without it. Seventy-one adults with SCH, aged 18-64 were included in the study. The Short Form-36 (SF-36) version 2 questionnaire was used to measure the quality of life of patients. Results were relayed in z-scores with a negative score indicating poor health status. Participants with SCH scored significantly lower on all subscales of the SF-36. Vitality and role limitations due to decreased physical function were the most markedly diminished with z-scores



(95% confidence intervals) of -1.01 (-0.74 to -1.29) and -0.73 (-0.43 to -1.04) correspondingly. In short, those diagnosed with hypothyroidism had significantly lower perceived health status when compared to those without a diagnosis of hypothyroidism.

Vigário et al. (2009) used the SF-36 Health Survey to assess the health status of 232 women with overt hypothyroidism (n=14), and subclinical hypothyroidism (n=152) compared with a control group (n=66). Clinical signs and symptoms were measured using the Billewicz scale. With this scale, higher scores are associated with a higher number of symptoms of hypothyroidism. Furthermore, higher scores on the Billewicz scale of hypothyroid symptoms were correlated with lower scores on the SF-36 as noted (physical function r = -0.80, p < 0.01; bodily pain r = -0.74, p < 0.01). When compared to the other two groups, those with overt hypothyroidism scored lower on the SF-36 (p<0.05) The study results revealed a poorer health status perception among women with overt hypothyroidism.

An observational study by Van Heest, Mogush, and Mathiowetz (2017) used a onegroup, pretest–posttest, follow-up design. A total of 49 patients completed all phases of the study. Inclusion criteria were: a diagnosis of a chronic disease, moderate to severe fatigue, age 18 years or older, and the ability to read and understand English. All patients joined a one-onone fatigue management course in an outpatient or community-based setting. The intervention consisted of five modules entitled: "(1) Basics of Fatigue, (2) Communication and Fatigue, (3) Body Mechanics and Making the Most of Your Environment, (4) Analyzing and Modifying Activities, and (5) Living a Balanced Lifestyle" (Van Heest et al., 2017, p. 3). The Functional Assessment of Chronic Illness Therapy–Fatigue Scale (r = .90) was used to measure fatigue (Smith, Lai & Cella, 2010); the Functional Assessment of Cancer Therapy–General (r = .92 for the total scale and ranging from .82 to .88 for the subscales) measured quality of life (Cella et al.,



1993); and the Self-Efficacy for Performing Energy Conservation Strategies Assessment ( $\alpha$  = .93) (Liepold & Mathiowetz, 2005) was used to measure self-efficacy. Assessments were performed pretest, immediately post-intervention, and then six weeks later. Patients demonstrated statistically significant increases in self-efficacy and quality of life and a decrease in fatigue that persisted over the six-week post-intervention period. The results did not show significant changes on the Social Well-Being subscale. The results of the study showed that participants greatly benefited from a one-to-one fatigue management course.

#### Quality of Life (QoL) Measurement Tools

Some common tools used to measure health-related quality of life include the SF-36 Health Survey, and disease-specific questionnaires such as the ThyPRO-39us scale. The most common health-related quality of life (QoL) tool is the SF-36 Health Survey, measuring eight subdomains including "physical functioning, bodily pain, role limitations due to physical health problems, role limitations due to personal or emotional problems, emotional well-being, social functioning, energy/fatigue, and general health perceptions" (Rand Health, 2017). It also integrates a single item that shows perceived variation in health (Rand Health, 2017). Each question is scored on a 0 to 100 range with '0' being the lowest and '100' being the highest score possible. However, the scoring is complex and involves multiple steps (Rand Health, 2017). Another tool, the ThyPRO-39us, which is specific to thyroid disorders was found to be valid and reliable for patients with thyroid disease (Watt, Bjorner, Groenvold, Cramon, Winther, Hegedüs, Bonnema, Rasmussen,Ware, & Feldt-Rasmussen, 2015). I reviewed both tools and selected the ThyPro-39us because of its ease of use and specificity to the population of interest. The ThyPRO-39us is discussed in detail in the Methods section.



#### **Theoretical Foundations**

The Health Belief Model was utilized for this project (Jones, Jensen, Scherr, Brown, Christy, & Weaver, 2015). The Health Belief Model was developed in the 1950s and has six concepts: perceived susceptibility, severity, benefits, barriers, cue to action and self-efficacy. These concepts provide a useful framework for addressing problem behaviors that induce health concerns. This model theorizes that people's beliefs about their predisposition to disease and their view of benefits of trying to avoid it, impact their willingness to act (Jones et al., 2015).

This model helped guide me regarding information to include in my educational intervention and ways to present the information so that it motivated patients and fostered selfefficacy. Based on the model, if a patient is not able to perceive their susceptibility to a disease, then they are not going to take steps to combat it, which leads to poor management of their condition.

#### **Study Variables**

The independent variable in this study was the formal hypothyroidism educational class, which was categorical. The categories are as follows: no class (pre-survey) = 0 and after class (post-survey) =1. The dependent variables were quality of life scores before vs. after attending the class which were interval level data, as the numbers were based off a 0–4 Likert scale. Demographic variables such as age, race, marital status and educational attainment were all explanatory and categorical, except for the variable, gender, which was dichotomous as 1=female and 2= male. Refer to Table 1 for a detailed report of the variables.



#### Methods

## Design

A prospective pretest-posttest quasi-experimental study was used to examine short-term differences in ThyPRO-39us quality of life scores before and after administration of a formal hypothyroidism educational class to patients with hypothyroidism.

#### **Study population**

English speaking adults aged 18 through 85 years with a diagnosis of hypothyroidism were evaluated in this study. Convenience sampling was employed, and participants were recruited from a private endocrinology practice in Fairfax, Virginia. Inclusion criteria were as follows: (1) Patients with a diagnosis of hypothyroidism, (2) aged 18-85, (3) all ethnic groups (4) males and females (5) and had access to the internet and an email address. Exclusion criteria were the following: (1) pregnancy, (2) a diagnosis of thyroid malignancy and (3) diagnosis of dementia, or (4) history of psychiatric illness.

#### Sample size

Power analysis was used to determine the sample size. For the anticipated effect size, 0.5 was used. For the desired statistical power level, 0.8 was used. For the probability level, 0.05 was used. For a two-tailed hypothesis, I needed a minimum total sample size of 128. Due to the short duration of this study, I aimed to recruit 40 patients following Institutional Review Board (IRB) approval. Recruitment took place between November 29 and December 15th, 2017.



#### **Recruitment of subjects**

I recruited participants via a flyer that I created and distributed to patients during their office visits (Appendix A). I am a nurse practitioner in a private endocrinology practice in Fairfax, VA. I work with a physician but only I did the recruiting and I had her permission to recruit patients from the practice (Appendix B). During the recruitment days, I identified patients with hypothyroidism from the daily office schedule who were at least 18 years of age and not older than 85 and asked if they had access to the internet and an email address. If they did, I handed them a flyer, explained the project, and encouraged them to join the study. I then discussed the purpose of the study and the intervention. I also informed them that they needed to fill out the ThyPRO-39us quality of life survey before the class and four weeks after the class, along with demographic questions.

The recruitment flyer included information on inclusion and exclusion criteria, what the class offered, what participants needed to do if they agreed to participate and my contact information. The flyer was attached to a consent statement form (Appendix C) as well as an enrollment form (Appendix D) that asked for the participant's name, and e-mail address. Participants were asked to fill out the enrollment form before they left the office and to leave it at the front desk with the secretary if they chose to participate in the study.

# Setting

Participants were recruited in a two-weeks time period in December 2017 from a private endocrinology practice in located in Fairfax, VA. The office personnel consisted of a physician, a nurse practitioner, one receptionist and one office administrator. The only education provided to patients was during short office visits, which was not adequate. The setting in which the



intervention took place was the spacious endocrinology office waiting room area on a Sunday afternoon.

#### Intervention

The hypothyroidism educational program was a formal lecture that was 45 minutes in length presented by myself, the nurse practitioner in a private endocrinology practice. The objectives of the class included discussion of the (1) pathophysiology of hypothyroidism, (2) clinical manifestations, (3) proper thyroid medication administration, (4) the role of diet and exercise in the management of hypothyroidism and (5) support groups available to patients in the community. The PowerPoint presentation consisted of about 20 slides that discussed all the aforementioned topics (Appendix E). The lecture was presented in the private endocrinology office on a Sunday at 2pm as most patients came from afar and were only familiar with the office location.

Once the 45-minute presentation ended, participants had a chance to ask questions or engage in a discussion for up to two hours. In addition, participants that wanted to discuss individualized treatment plans, were informed to do so during office visits for safety and confidentiality reasons.

#### Instrumentation/Measurements

Initially, I created a short demographics survey through SurveyMonkey which included age, race, gender, marital status, and educational level with categories for responses (Appendix F). Then I measured the pre-and post- intervention quality of life using the ThyPRO-39us survey.

The ThyPRO-39us survey is an abbreviated version of the original ThyPRO survey. The original survey consists of 85 questions summarized in 13 subscales and was tested with



thousands of patients in Europe. The 39 questions version was also tested for validity and internal reliability. The abbreviated version (ThyPRO-39us) is comprised of seven three-item scales about physical, mental, and social well-being and function, one 14-item scale about symptoms, one two-item scale about tiredness, a single item scale about vitality and another oneitem about impact on overall quality of life (Watt et al., 2015). Thus, the survey consists of 39 questions summarized in 11 subscales (Appendix G). Each of the 11 short-form scales can be described separately, but the seven well-being and function scales can also be summarized in one single composite score which also includes the overall quality of life question (Watt et al., 2015) (Appendix H).

The hypothyroid symptoms scale in the ThyPRO-39 us is identical to the original ThyPRO hypothyroid symptoms scale. Each item is rated on a 0–4 Likert scale, from no symptoms/problems (not at all) = 0 to severe symptoms/problems (very much) = 4. As part of the scoring procedure, items 3b, 6g and 7h are reversed, i.e. 'Not at all' scored as 4, 'A little' as 3, 'Some' as 2, 'Quite a bit' as 1 and 'Very much'/'Completely scored as 0. When there is missing data, the mean of the completed items is substituted for the missing items. All scales are transformed linearly to range 0-100 and the scales are scored as follows: Transformed score= (raw sumscore/16)\*100 (Appendix I & J). For instance, if a patient answered, 'Not at all' to one item, 'A little' to two items, and 'Some' to the last item, they would have a raw score of 4 (0+1+1+2). The transformed 0-100 score would then be 4/16\*100=25 (Appendix J). The composite scale is based on the 22 items from the tiredness, cognitive complaints, anxiety, depressivity, emotional susceptibility, impaired social life, impaired daily life, and the negative influence of thyroid disease on overall quality of life scale questions (Watt, n.d.). The raw score for the composite scale is by summation (with imputation for missing), to range 0-88. The raw



score is transformed to 0-100 according to the formula: Transformed score = (raw sumscore/88)\*100 (Watt, n.d.) (Appendix J).

Validity of the ThyPRO-39us survey was demonstrated through confirmatory factor analysis (Watt et al., 2015). The study does not mention the validity value. The questions for ThyPRO-39us were selected from existing questions in the original survey and score levels on the long version are comparable to score levels of the short version, ThyPRO-39us. Watt et al., (2015) found very high intra-class correlations (0.89-0.98) in the short versus long version of the questionnaire. Test–retest reliability was similarly supported in the short-form scales. For goiter scale, the test-retest reliability was 0.83 [0.74-0.90], hyper scale was 0.89 [0.82-0.93], eye scale was 0.78 [0.63-0.89], cosmetic/appearance scale was 0.75 [0.61-0.85] and the composite scale was 0.90 [0.84-0.940] (Watt et al., 2015). Overall, good validity, test–retest reliability, responsiveness to clinical change, and sensitivity to relevant clinical differences were established by the ThyPRO-39us (Watt et al., 2015). One of the authors of the survey, Torquil Watt, was notified for permission to use the survey and I have his consent.

#### **Data collection procedures**

The project was explained to patients during office visits by myself, the nurse practitioner. A flyer attached to a consent statement form and an enrollment form were given to patients. The flyer conveyed the same information that I provided in person. Patients who chose to participate in the study, returned the enrollment form to the front desk. The enrollment form asked for the patient's name and email address. These forms were used to create a code book of participant contact information and study identification numbers that were kept separate from the survey responses. Up to three reminder emails about attending the educational class were sent to participants a week prior to the class date (Appendix K). The same consent statement form was



handed out to participants at the beginning of the class. I distributed paper and pencil versions of the demographics survey and the ThyPRO-39us quality of life survey to participants the day of the intervention and collected them at the end of the session.

Participants were asked to fill out the demographics survey and the ThyPRO-39-us quality of life survey before the lecture started and to put their study number on the demographics form, the ThyPRO-39us survey and an envelope. Participants were asked to address the envelopes to themselves. The envelopes were collected separately from the surveys to maintain the anonymity of survey responses. I later put the same code on the post-lecture survey that I sent them in the envelope they addressed. For instance, someone named Jane Smith would have labeled all her forms "1" and someone named Sam Williams would have labeled all his forms "2". Both surveys took no longer than ten minutes in total to complete. At the end of the class, participants were informed that I would send them another copy of the ThyPRO-39us survey in the mail in four weeks and to fill it out and return to me right away. Up to three reminder emails were sent to patients to fill out the post survey (Appendix L). The pre-and post ThyPRO-39us surveys along with the demographics survey were linked by the study identification number so that a tailored analysis could be performed.

#### Data analysis plan

SPSS 23 was used to store and analyze the data collected. I worked with Dr. Quiping Zhou, who is a statistician at the School of Nursing at the George Washington University. Data from the demographics sheet and the ThyPro-39 pre- and post-surveys was manually entered by the researcher, Tahimina Popal into an Excel sheet (Appendix M). To assure accurate data entry, a 100% check was performed on all data by myself and then again by the office secretary. For categorical variables such as age, race, gender, marital status, and educational level, frequency



and percentages were reported. For each participant, subscale calculations and a composite score were computed for the pre-and post-surveys. For the research hypotheses, differences in the ThyPRO-39us subscores before vs. after the formal hypothyroidism educational class were calculated. Wilcoxon Sign Rank tests were performed, and significance was set at 0.05.

#### **Ethical considerations**

Participation in the study was voluntary. To protect the privacy of subjects, participants were instructed not to include any personal identifiers on the demographic survey or the pre and post ThyPRO-39us quality of life surveys. They were to only put their study number on all surveys. To maintain the confidentiality of data, I collected data in paper and pencil forms and the forms and data entry sheet did not have personally identifiable information on them. All study related paper forms were kept in a locked file cabinet and the code book and Excel data files resided on a password protected computer that was secured when not in use. Only I had access to the computer that was used to store and analyze the data on SPSS 23. Once data collection was completed, e-mail addresses from the enrollment forms were erased from my e-mail history and the enrollment forms were shredded along with all the surveys. Again, there were no identifiers such as names on any of the surveys, only a study number. This proposal was submitted to The George Washington University IRB for approval.

#### Results

Fifty participants were recruited from a private endocrinology practice in Fairfax, VA. Of the 50 participants that filled out and returned the enrollment form, only 15 participants attended the formal educational class. Of the 15 participants, only 12 of them fully completed the pre and post ThyPRO-39us surveys along with the demographics data sheet. Demographic data are



summarized in Table 2. The majority of participants were between the ages of 18 and 34 (n=6, 50%). Ages 35 to 54 comprised 16.7% (n=2) of the participants and 33.3% (n=4) were aged between 55 and 85. Furthermore, 8.3 % (n=1) of the participants were Black or African American, 67.7% (n=8) were White, 16.7% (n=2) were Hispanic and 8.3%( n=1) identified as Other. Females made up the majority of the participants 83.3% (n=10), whereas, males comprised 16.7% (n=2) of the participants. Also, 50% (n=6) of the participants were married and 50% (n=6) were not. When it comes to educational status, 8.3% (n=1) had high school or less education and 91.7% (n=11) had college education.

The data was analyzed using SPSS 23 and significance was set at 0.05. Initially a paired t-test was to be used, but due to the smaller sample size (less than 30 participants), Wilcoxon Signed Rank Tests were performed. The first hypothesis stated that there would be a difference in the subscale score of goiter before vs. after the intervention and a statistically significant difference was found (p=0.042). The second hypothesis stated that there would be a difference in the hyperthyroid subscale scores before vs. after the intervention. The p-value for the Wilcoxon Signed Rank Test for this subscale analysis was .009 allowing for rejection of the null hypothesis. The third hypothesis stated that there would be a difference between the hypothyroid subscale scores before vs. after the intervention and there was a statistically significant difference (p=0.036). The fourth hypothesis stated that there would be a difference in the subscale score of eyes before vs. after the intervention. However, the Wilcoxon Signed Rank Test did not demonstrate a statistically significant change (p=0.073) for the eyes subscale. The fifth hypothesis stated that there would be a difference in the appearance/cosmetic subscale before vs. after the intervention. The Wilcoxon Signed Rank Test yielded a p-value of .045, showing statistically significant change. The sixth hypothesis stated that there would be a difference in the



composite score of the ThyPRO-39us before vs. after the intervention and analysis determined that the p-value was .010, showing statistically significant change.

To determine reliability of the ThyPRO-39us subscales used for assessing participants' quality of life scores before vs. after the educational class, a Cronbach's alpha score was obtained for the 11 subscales and the composite score of the pretest (0.896) as well as the 11 subscales and the composite score of the posttest (0.854). Both alpha scores showed acceptable reliability.

#### Discussion

There were statistically significant differences between the pre- and post-educational class scores for 10 of the 11 subscales of the ThyPRO-39us. This is consistent with previous studies that have found statistically significant improvement in the quality of life of patients diagnosed with chronic illnesses. Van Heest et al., 2017 evaluated the effectiveness of a one-on-one fatigue management course in patients diagnosed with chronic fatigue. Statistically significant change was found in all scales used: The Functional Assessment of Chronic Illness Therapy–Fatigue Scale (r =.90), the Functional Assessment of Cancer Therapy–General (r = .92 for the total scale and ranging from .82 to .88 for the subscales), and the Self-Efficacy for Performing Energy Conservation Strategies Assessment ( $\alpha$  = .93) (Van Heest et al., 2017).

However, the eyes subscale did not show statistically significance improvement after the educational class. This may be due to the fact that "underactive thyroid (hypothyroidism) isn't usually associated with eye disease" (Nippoldt, 2018). Doctor Nippoldt (2018) goes on to discuss that swelling of the eye muscles may occur in severe cases of hypothyroidism over time. Because



reevaluation of symptoms took place four weeks after the intervention, it did not allow enough time for significant changes, if any, to be noted in the eyes subscale.

Overall improvement in the quality of life scores was documented in the participants that attended the formal educational class. We can conclude that patients diagnosed with hypothyroidism significantly benefited from the formal educational class.

When determining the reliability of the scale used to measure the quality of life of participants, all the subscales of the ThyPRO-39us, including the pre-scores and the post-scores found good reliability. This is similar to the findings by Watt et al. (2015) in their inquiry of determining the reliability of the ThyPRO-39us subscales: goiter (0.83) hyper (0.89), eyes (0.78), cosmetic/appearance (0.75) and the composite scale (0.90).

The literature also defines other facets that can influence the quality of life of patients with hypothyroidism, such as social support, living situation, and socioeconomic status (Kandukuri, Khan, & Soltys, 2010). I did not assess these and the sample size was too small to explore differences in scores related to these factors.

## **Study Limitations**

One of the limitations of this study is that survey response rate did not meet the goal of at least 40 participants, so this may not be a representative sample of the patient population diagnosed with hypothyroidism. Only 12 participants out of the 15 that attended the educational class filled out the pre and post surveys completely, making the data satisfactory for analysis. The survey response rate was 80% which was decent for a mailed survey. Another limitation was time constraints on recruitment. Due to a delay in IRB approval, the time frame originally planned for recruitment was reduced, allowing only two weeks for recruiting.



Furthermore, since the educational class was held during the holiday season

(December/January), most participants who would have liked to attend, were not able to, due to prior commitments. I believe the time frame between testing, which was four weeks, was just right. Earlier than four weeks may not have shown great improvement and longer than four weeks may have resulted in patients forgetting to fill out the post-survey. The study by Koonce, Guise, Kusnoor, Hurley, and Fei (2015) evaluated the effectiveness of educational materials tailored to participants' learning styles and health knowledge on patients' diabetes knowledge in a community clinic setting. Patients were contacted after two weeks, and a significant increase was noted in the mean number of diabetes knowledge questions answered appropriately by the intervention group ( $\Delta$ =2.66, P=0.000), which continued at six weeks ( $\Delta$ =2.46, P=0.00). This is similar to my study as it showed that the change persisted at follow up. I, however, did not measure changes immediately after the intervention. This is because my survey focused more on symptoms, rather than knowledge which made it unsuitable to reassess immediately after the intervention.

#### **Implications/Recommendations**

Although this study showed that an educational can improve quality of life scores of patients diagnosed with hypothyroidism, I would recommend for future studies to include a larger sample size to improve generalizability. Furthermore, similar studies need to be conducted in which different modes of education are used to aid in improving quality of life of patients, such as formal education, booklets/handout, and an online platform for those with a geographical hindrance. Furthermore, future studies could examine factors affecting the quality of life of patients diagnosed with hypothyroidism such as age, ethnicity, educational status, comorbidities, and socioeconomic status. Lastly, since patient education improved the quality of life of the



participants, more education is warranted in the future. I would suggest using billing codes for patient education so that the practice can support the time and determination needed to educate patients.

#### Conclusions

This study's findings provide evidence that a formal educational class is effective in improving the quality of life in patients diagnosed with hypothyroidism. Improvements were noted in 10 of the 11 subscales of the ThyPRO-39us quality of life survey. The findings of this study were consistent with findings of previous studies researching thyroid management education on quality of life in patients with hypothyroidism. Therefore, future classes of thyroid management may help to improve quality of life in patients with hypothyroidism.



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Table 1. Defining and Identifying Variables	1. Defining and Identifying Variables	
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Variable Name		Theoretical/Descriptive Definition	Operational Definition/ Specification
Pre-post intervention quality of life scores	Dependent Interval	ThyPRO-39us survey consists of 39 questions summarized in 11 scales about the impact of thyroid disease on quality of life.	Each item is rated on a 0-4 Likert scale, from no symptoms/problems = 0 to severe symptoms/problems = 4. The composite score equation is: (raw sumscore/88)*100. The subscale scores equation is: (raw sumscore/16)*100.
hypothyroidism	Independent	In-person educational class	No class (pre-survey) = 0
educational program	categorical	consisting of a 45 minute lecture and 25 slides with information on pathophysiology, symptoms, proper medication administration, the role of diet and exercise and support groups in the community for patients with hypothyroidism	After class (post-survey) =1
Age	Demographic/ Explanatory/Categorical	Participant's age in a given range	Age range: 1=18 to 34 2=35 to 54 3=55 to 85
Race	Demographic/ Explanatory/ Categorical	Participant's racial or ethnic background as self-identified	Black or African American=1 White=2 Hispanic=3 Other=4
Gender	Demographic/Explanatory/ Dichotomous	Patient's biological sex	Male=1 Female =2
Marital Status	Demographic/Explanatory/ Categorical	Patient' relationship status as self-identified	Married=1 Not Married=2
Education Level	Demographic/Explanatory/ Categorical	Level of education completed	High School or less=1 College=2



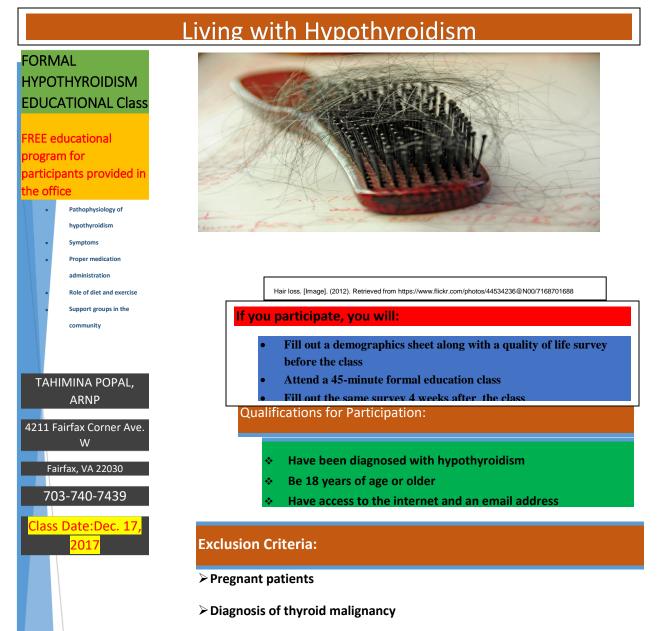
# **Table 2. Demographics Data Analysis**

Variable	Number (%)	
	N=12	
Age		
18 to 34	6 (50%)	
35 to 54	2 (16.7%)	
55 to 85	4 (33.3%)	
Race		
Black or African American	1 (8.3%)	
White	8 (67.7%)	
Hispanic	2 (16.7%)	
Other	1 (8.3%)	
Gender		
Male	2 (16.7%)	
Female	10 (83.3%)	
Marital status		
Married	6 (50%)	
Not married	6 (50%)	
Educational Attainment		
High school or less	1 (8.3%	
College	11 (91.7%)	



# Appendix A

# **Recruitment Flyer**



> History of dementia or psychiatric illness



## **Appendix B**

# Approval of Recruitment of Subjects by Physician

My name is I own my practice, . Tahimina Popal, NP, employed by me in my practice has explained her research study to do with hypothyroidism and I give her permission to conduct this study in my office and recruit patients from the practice. If you have any questions, you can contact me at Thank You,

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## Appendix C

## **GW IRB Consent Statement**

Title of Study: Educational Program to Improve Quality of Life of Patients Diagnosed with Hypothyroidism: A Quasi-Experimental Study IRB #: Principal Investigator Name: Linda Briggs, Tahimina Popal Version Date: Summer 2017

You are invited to participate in a research study under the direction of Tahimina Popal, a doctoral student of the George Washington University School of Nursing. Taking part in this research is entirely voluntary. Further information regarding this study may be obtained by contacting \_Linda Briggs\_\_ (Principal Investigator) at (202) 994-6259 or email at <u>briggs10@gwu.edu</u>. You may also contact Tahimina Popal at (703) 740-7439 or email at tpopal1@gmail.com

The purpose of this study is to assess the quality of life in patients with hypothyroidism before and four weeks after a formal hypothyroidism educational class.

If you choose to take part in this study, you will be asked to fill out a demographics data (age, race, gender, educational level, marital status) sheet along with a quality of life survey at the beginning of the class. You will then participate in a formal educational class and fill out the same survey four weeks after the class. The total amount of time you will spend in connection with this study is ten minutes to fill out the demographic survey and the quality of life survey before the class. It should take less than ten minutes to fill out the same survey after attending the class. The lecture style class is 45 minutes in length and will be held in the endocrinology office, Sunday (date). You may refuse to answer any of the questions and you may stop your participation in this study at any time.

Possible risks or discomforts you could experience during this study include: psychological stress related to answering survey questions related to quality of life.

During the discussion at the end of the class, while we cannot guarantee the confidentiality of the discussion, we request that all present respect the group by not repeating what is said, outside the group.

You will not benefit directly from your participation in the study. The benefits to science and humankind that might result from this study are: This study is important to nursing as it will help nurse practitioners to better understand the effect of an educational class on the quality of life of patients diagnosed with hypothyroidism. Once we have the knowledge about the quality of life of patients, we will be able to educate our patients better and help them manage their condition appropriately.

Every effort will be made to keep your information confidential, however, this cannot be guaranteed. All participants are asked to put their assigned study identification number on all surveys to link the pre and post surveys as well as the demographic survey for an individualized analysis. If results of this research study are reported in journals or at scientific meetings, the people who participated in this study will not be named or identified.

The Office of Human Research of George Washington University, at telephone number (202) 994-2715, can provide further information about your rights as a research participant.

To ensure anonymity your signature is not required, unless you prefer to sign it. Your willingness to participate in this research study is implied if you proceed.



### **Appendix D**

### **Enrollment Form**

### Enrollment Form for the Formal Hypothyroidism Educational Class Study

If you choose to participate in the study, please fill out this form and give to the front desk. I will contact you by email three times to provide the details for the date, time and location of the study.

Full name:\_\_\_\_\_

E-mail address: \_\_\_\_\_



### Appendix E

## Hypothyroidism PowerPoint



MUSCULAR AND NEUROLOGICAL SYMPTOMS

- · Cold totolerance
- Parestassis and serve entropenent syndromer
- Massfe pein

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- Joèst paix
- Weakaess in the extremities



## MENTAL AND EMOTIONAL SYMPTOMS

- Enotional lability, mental impeinted
- Foggtfalscor
  Impaired reserves
- Imparts manage
   Imparts manage
   Imparts manage



## Appendix F

## **Demographic Data Collection Tool**

Demographic Survey
1. What is your age?
18 to 34
35 to 54
55 to 85
2. What is your race?
C Black or African American
C White
C Hispanic
C Other
3. What is your gender?
C Male
C Female
4. What is your marital status?
C Married
C Not married
5. What is your educational level?
C High school or less
C College



## Appendix G

## Quality of Life Survey (ThyPRO-39us)

The first section of the questionnaire is about symptoms, tiredness, memory, mood, and health. Please base your **answers on how you have been feeling** in general

during the past 4 weeks.

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## 1. The first questions are about symptoms

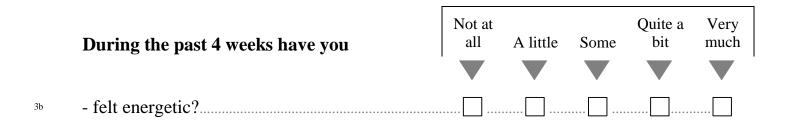
	During the past 4 weeks have you	Not at all	A little	Some	Quite a bit	Very much
1a	- had the sensation of fullness in the neck?					
1c	- felt pressure in your throat?					
1h	- felt discomfort swallowing?					
11	- had trembling hands?					
1m	- had a tendency to sweat a lot?					
ln	- experienced palpitations (rapid heart beat)?					
1q	- been sensitive to cold?					
1t	- had an upset stomach?					
1w	- had the sensation of dryness or "grittiness"					
ĨŴ	in the eyes?					
1x	- had impaired vision?					
1bb	- been very sensitive to light?					

1cc	- had swollen hands or feet?
1dd	- had dry skin?
lee	- had itchy skin?

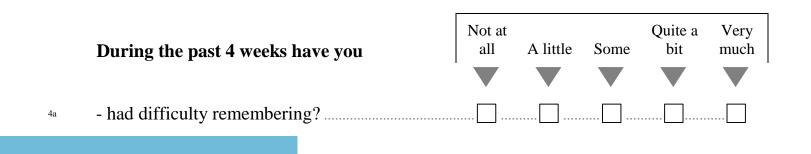
	During the past 4 weeks have you	Not at all	A little	Some	Quite a bit	Very much
2a	- been tired?					
2c	- had difficulty getting motivated to do anything at all?					

# 3. The following question is about your vitality

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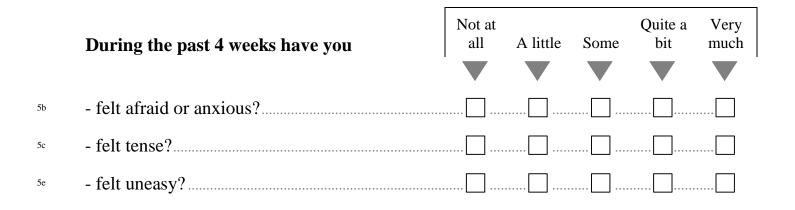
4. The following questions are about memory and concentration



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4b	- had slow or unclear thinking?
4f	- had difficulty concentrating?

5. The following questions are about nervousness and tension



# 6. The following questions are about psychological well-being

	During the past 4 weeks have you	Not at all	A little	Some	Quite a bit	Very much
ба	- felt sad?					
6e	- felt unhappy?					
	During the past 4 weeks have you	Not at all	A little	Some	Quite a bit	Very much
6g	- had self-confidence?					



## 7. The following questions are about having difficulty coping or having mood swings

	During the past 4 weeks have you	Not at all	A little	Some	Quite a bit	Very much
7c	- noticed you easily felt stressed?	•	▼	•	•	•
7d	- had mood swings?					
		Not at all	A little	Some	Quite a bit	Com- pletely
7h	- felt in control of your life?	· •	▼	▼	•	



The remainder of the questionnaire is about **how your thyroid disease may have** affected various aspects of your life

The following questions are about your relationships with other people 8.

	During the past 4 weeks, <u>has your thyroid</u> <u>disease caused</u> you to	Not at all	A little	Some	Quite a bit	Very much
8a	- have difficulty being together with other people (for example, spouse, children, boy/girlfriend, friends, or others)?					
8b	- feel you were a burden to other people?					
8c	- have conflicts with other people?					

#### 9. The following questions are about your daily activities

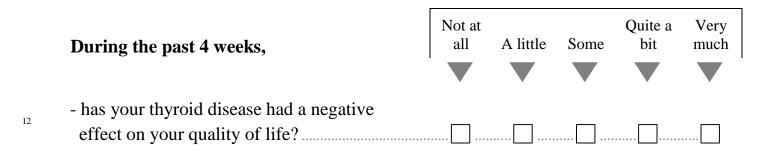
	During the past 4 weeks, <u>has your thyroid</u> <u>disease caused</u> you to	Not at all	A little	Some	Quite a bit	Very much
9a	- have difficulty managing your daily life?					
9c	- not be able to participate in life around you?					
9e	- feel as if everything takes longer to do?					



10. Thyroid diseases (or their treatment) may affect your <u>appearance</u>. (For example, by causing swelling of the neck, swollen face, hands, or feet, or changes in weight or to the eyes.)

	During the past 4 weeks,	Not at all	A little	Some	Quite a bit	Very much
11a	- has your thyroid disease <u>affected your</u> <u>appearance</u> (for example, swelling of the neck, eye changes, weight changes)?					
11d	- have you been bothered by other people looking at you?					
11e	- has your thyroid disease influenced which clothes you wear?					

12. The final question is about to what extent your thyroid disease has affected you overall during the past 4 weeks



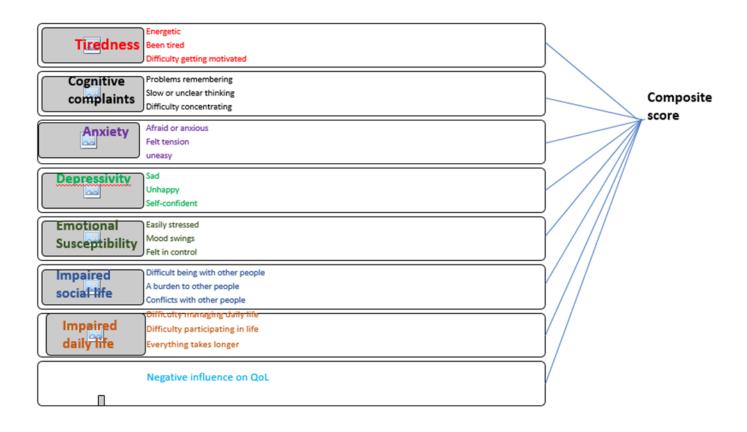
Please go back and check that you have answered all the questions.

Thank you very much for your help answering this questionnaire!



### Appendix H

## **Questions Comprising the Composite Score**





## Appendix I

## Conversion of Raw Scores of the ThyPRO-39us

					Final	rescaled	l short-form	score			
Raw sum score	Goiter	Hyper	Eye	Tired	Cognition	Anxiety	Depressivity	Susceptibility	Social Life	Daily Life	Appearance
0	2	2	1	0	1	1	0	1	0	0	1
1	10	8	8	8	7	10	7	7	8	7	12
2	15	13	14	17	14	18	14	13	17	15	21
3	20	18	20	25	21	26	22	21	25	22	28
4	26	23	25	33	29	34	29	28	33	30	36
5	31	28	32	42	37	41	37	36	42	38	43
6	37	33	38	50	44	49	45	44	50	46	51
7	43	38	45	58	52	56	54	52	58	54	59
8	49	44	52	67	60	63	63	60	67	62	66
9	57	49	60	75	68	71	71	68	75	71	73
10	64	55	68	83	76	79	80	77	83	80	80
11	73	60	78	92	85	87	89	86	92	89	87
12	84	66	89	100	95	96	97	95	100	98	96
13		71									
14		77									
15		84									
16		90									



## Appendix J

# Scoring of the ThyPRO-39us

1	ransformation of the Hypothyroid Symptoms scale:
	The ThyPRO-39 Hypothyroid Symptoms is identical to the original ThyPRO Hypothyroid symptoms scale and is thus transformed to 0-100 according to the formula
1	ransformed score=(raw sumscore/16)*100
l	For example, if a patient answered 'Not at all' to two items, 'A little' to one item and 'Some' to the ast item, she would have a raw score of $3 (0+0+1+2)$ . The transformed 0-100 score would then be $/16*100=19$ .
2	ransformation of the Overall QoL-impact scale/item:
	The Overall QoL item (TQ12) is rescaled to 0-100 simply by taking the mean raw score and nultiply by 25.
	icoring the Composite scale
1	
I	The Composite scale is based on the 22 items from the Tiredness, Cognition, Anxiety, Depressivity
1 E 1	The Composite scale is based on the 22 items from the Tiredness, Cognition, Anxiety, Depressivity Emotional Susceptibility, Impaired Social life Impaired Daily Life and Overall QoL scales: TQ2A TQ2C TQ3B TQ4A TQ4B TQ4F TQ3B TQ3C TQ3E TQ6A TQ6E TQ6G TQ7C TQ7D



### Appendix K

### **Reminder Email to Patients**

Dear Participant,

This is a reminder of your interest in attending the formal educational class on hypothyroidism provided in the endocrinology office on Sunday (December 15, 2017) at 2pm as part of a research study. The class is 45 minutes in length and snacks will be provided. There will be a discussion following the class for up to two hours. Please RSVP by email. I would be delighted to see you in class!

Thank you for your time,

Tahimina Popal, BSN, MSN, FNP-C

George Washington University DNP student



## Appendix L

### **Reminder Email to Patients**

Dear Participant,

This is a friendly reminder to complete your ThyPRO-39us survey this week if possible. Please disregard this e-mail if you have already submitted the survey. Thank you for your time and participation.

Tahimina Popal, BSN, MSN, FNP-C George Washington University DNP student



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# Appendix M Excel Data Collection Sheet



## Appendix N

## **DNP Project Timeline**

Contact primary advisor	15-Aug	31-Aug
IRB application	20-Aug	31-Aug
Recruitment of subjects (Pending IRB approval)	1-Oct	1-Nov
Intervention/ data collection	15-Nov	31-Dec
Data entry/data analysis	Jan-18	Jan-18
Revision of Final Draft	1-Jan-18	5-Feb-18
Submit Final Draft to Advisor	6-Feb-18	6-Feb-18
Revision of Final Paper	7-Feb-18	5-Mar-18
Submission of Final DNP Project Proposal for Review	6-Mar-18	6-Mar-18
Create Project Poster	7-Mar-18	19-Mar-18
Submit Final DNP Project Poster	20-Mar-18	20-Mar-18
Present Final DNP Project Poster	17-May-18	20-May-18

