

Prevalence of type 2 diabetes risk and the use of preventive strategies in primary healthcare

Elín Arnardóttir

DOCTORAL THESIS

University of Akureyri
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Prevalence of type 2 diabetes risk and the use of preventive strategies in primary healthcare

Utilizations of FINDRISC risk score, HbA1c, ICE-HEART Coronary Heart Disease risk calculator, and integration of Guided Self-Determination counselling in a randomized controlled trial

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Doctoral thesis

Nursing

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Notkun áhættureiknisins FINDRISK, HbA1c, ICE-HEART áhættureiknis á kransæðasjúkdóm og áhrif leiðbeinandi sjálfsákvörðunar í slembaðri samanburðarrannsókn

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Dedication

*To participants of the studies in this thesis,
my family, supervisors and friends who
encouraged me and supported me in my studies*

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Abstract

Aim: This thesis sought to determine the prevalence of prediabetes and undiagnosed Type 2 Diabetes (T2d) in North Iceland. Furthermore, a comparison of the Finnish Diabetes Risk Score (FINDRISC) with other instruments and measurements is conducted to identify individuals at risk of T2D in primary healthcare in Iceland, and to evaluate the differences in health literacy and well-being among participants. Additionally, this thesis examines how a nurse-led follow-up using the Guided Self-Determination (GSD) approach can help individuals at risk for T2d reduce their risk of coronary heart disease (CHD).

Methods: This thesis builds on a cross-sectional study and a randomized controlled trial (RCT). Data was analysed using descriptive statistics and, when appropriate, chi-square, means of *t*-tests or ANOVA, general linear models of repeated measures, correlation, regression, ROC curve analyses and non-parametric tests. Invited to participate in studies I and II were people aged 18-75, not diagnosed with diabetes, fluent in Icelandic or English, and living in the service area of the three largest primary healthcare centres of the Health Care Institution of North Iceland. Participants completed the Finnish Diabetes Risk Score, HbA1c levels, health literacy and well-being questionnaires, waist-to-height ratio measurements, and background information. The sensitivity and specificity of FINDRISC, waist-to-height ratio, and body mass index were compared by using the HbA1c measurements. The data were analyzed by gender and residency.

A randomized controlled trial was conducted in study III. This included a translation and back-translation of the GSD intervention instrument's reflection sheets and guidelines. A total of 81 participants from the database of studies I and II fulfilled the inclusion criteria of scoring ≥ 9 points on the Finnish Diabetes Risk Calculator and either or both a) HbA1c ≥ 40 mmol/mol and/or b) body mass index ≥ 30 kg/m². GSD counselling was provided over three months to the intervention group, while controls received a leaflet on healthy diet choices published by the Directorate of Health. The Icelandic Heart Association CHD risk calculator measurements were conducted at baseline (Time 1), 6 months (Time 2), and 9 months (Time 3) and used to assess changes in risk of CHD during and after the intervention.

Results: No undiagnosed T2d was found. Of 220 participants, 13.2% showed a prediabetes biomarker. The average age was 52.1 years ($SD \pm 14.1$), with 65.9% being female. High rates of overweight and obesity were observed, with 32% of men and 35.9% of women having a body mass index of ≥ 30 kg/m². The mean HbA1c readings in mmol/mol were 35.5 ($SD \pm 3.9$) for males and 34.4 ($SD \pm 3.4$) for women. Using cut-off points of ≥ 11 on FINDRISC yielded the highest

sensitivity and specificity for prediabetes detection, with an ROC curve of 0.814. A waist-to-height ratio $\geq .5$ was found in an additional 68 at increased overall health risk. Neither gender nor residency affected results. In the RCT, 56 of the 81 participants who met the inclusion criteria finished all measurements, 28 in each group. No significant difference was noticed between groups in CHD risk. Significant differences were observed in reduced body mass index ($p = 0.046$), HbA1c level ($p = 0.018$), and diastolic blood pressure ($p = 0.03$) were seen between times 1 and 3 in the intervention group. A decreased CHD risk, in the next ten years, was found for 54% of the 56 participants who completed all measurements at Time 3. The relative risk reduction showed that the CHD risk was reduced by 18% among participants in the RCT, and the number needed to treat for one to lower their risk was nine.

Conclusions: The non-invasive FINDRISC instrument, with a score of ≥ 11 points can be utilized as a reference point for T2d risk assessment in primary care. Although significant group differences were not found in the change in coronary heart disease risk following this 12-week intervention, regular measurements and the GSD counselling appear to be beneficial for within-group measures and the overall reduction of coronary heart disease risk factors.

Keywords: Finnish Diabetes Risk Score (FINDRISC), HbA1c, Type-2-Diabetes risk, Primary healthcare, Guided Self-Determination (GSD), Coronary Heart Disease (CHD) risk.

Ágrip

Markmið: Meginmarkmið rannsókna að baki ritgerðarinnar var að leitast við að ákvarða tíðni forstigseinkenna og ógreindrar sykursýki af tegund 2 (SST2) á Norðurlandi. Gerður var samanburður á næmni og sértæki finnska áhættumatslistans fyrir SST2 (FINDRISK) við aðrar mælingar í að finna einstaklinga í áhættu á að fá SST2 innan heilsugæslunnar hérlandis. Einnig var gerður samanburður á heilsulæsi og vellíðan þátttakenda. Jafnframt voru könnuð áhrif eftirfylgdar með aðferðinni Leiðbeinandi Sjálfsákvörðunar (GSD), sem hjúkrunarfræðingar á heilsugæslu veittu einstaklingum sem fundust í áhættuhópi fyrir SST2, við að minnka áhættu þeirra á kransæðasjúkdómi.

Aðferðir: Ritgerðin er byggð á þversniðsrannsóknum og slembaðri samanburðarrannsókn. Gögnin voru greind með lýsandi tölfræði, meðaltölum, kí-kvaðrat, t-prófum eða ANOVA, línulegum líkönum endurtekkinna mælinga, fylgni prófum, aðhvarfsgreiningu, ROC-kúrfugreiningu og prófum um óháða dreifingu, eftir því hvað við átti hverju sinni. Í rannsókn I og II var einstaklingum 18-75 ára boðin þátttaka ef þeir voru búsettir á þjónustusvæði einhverjar þriggja stærstu heilsugæslustöðva Heilbrigðisstofnunar Norðurlands, án þekkrar greiningar á sykursýki sem jafnframt töluðu og skildu íslensku eða ensku. Lagður var fyrir finnski áhættumatslistinn á sykursýki næstu 10 árin, auk spurningalista um heilsulæsi og vellíðan. Mæld voru HbA1c gildi ásamt mælingum á hlutföllum á þyngd og mittismáli við hæð auk skráningar bakgrunnsupplýsinga. Næmi og sértækni finnska áhættumatslistans, hlutfall mittis og hæðar og líkamsþyngdarstuðull voru borin saman við HbA1c gildi. Gögnin voru greind eftir kyni og búsetu. Í þriðja hluta var gerð slembuð samanburðarrannsókn, sem jafnframt fól í sér þýðingu og bakþýðingu á verkfærum íhlutunarrannsóknarinnar. Alls uppfylltu 81 þátttakendur úr rannsóknarhluta I og II inntökuskilyrði um að skora á ≥ 9 stig á FINDRISK og annað hvort eða bæði a) HbA1c ≥ 40 mmól/mól og b) líkamsþyngdarstuðull ≥ 30 kg/m². Leiðsögn með leiðbeinandi sjálfsákvörðun var veitt íhlutunarhópi í þrjá mánuði, en samanburðarhópurinn fékk bækling um hollt mataræði sem útgefin var af Embætti landlæknis. Mælingar voru gerðar fyrir upphaf íhlutunar (Tími 1), 6 (Tími 2) og 9 mánuðum (Tími 3) eftir lok íhlutunar til að meta breytingar á áhættu á kransæðasjúkdómum og færðar inn í áhættureiknivél Hjartaverndar.

Niðurstöður: Enginn reyndist með ógreinda SST2. Af 220 þátttakendum voru 13.2% með mæligildi sem bentu til forstigseinkenna sykursýki. Meðalaldur var 52.1 ár (staðalfrávik ± 14.1), þar af voru 65.9% konur. Há tíðni ofþyngdar og offitu sást, þar sem 32% karla og 35.9% kvenna höfðu líkamsþyngdarstuðul ≥ 30 kg/m². Meðalgildi HbA1c í mmól/mól voru 35.5 (staðalfrávik ± 3.9) fyrir karla og 34.4 (staðalfrávik ± 3.4) fyrir konur. Notkun viðmiðunarmarkanna ≥ 11 stig á

FINDRISK gaf hæsta næmi og sértækni fyrir greiningu forstigs sykursýki, með ROC-kúrfu upp á 0.814. Hlutfall mittis miðað við hæð $\geq .5$ leiddi í ljós að 68 voru einnig í aukinni heildar-heilsufarsáhættu. Hvorki kyn né búseta höfðu áhrif á niðurstöðurnar. Í íhlutunarrannsókninni luku 56 af 81, sem uppfylltu inntökuskilyrði, öllum mælingum 28 í hvorum hóp. Enginn marktækur munur sást á milli hópanna hvað varðar áhættu á kransæðasjúkdómi. Marktækur munur sást á lækkuðum líkamsþyngdarstuðli ($p = 0,046$), HbA1c gildum ($p = 0,018$) og þanbilsþrýstingi ($p = 0,03$) milli tíma 1 og 3 í íhlutunarhópnum. Lækkuð áhætta á kransæðasjúkdómi næstu tíu árin kom fram hjá 54% þátttakendanna 56 sem luku öllum mælingum. Hlutfallsleg áhættuminnkun benti til 18% minni áhættu með þátttöku í rannsóknarhluta III. Fjöldi einstaklinga sem þurfti að meðhöndla til að lækka áhættu hjá einum einstaklingi reyndist vera níu einstaklingar.

Ályktanir: Finnski áhættumatslistinn er ekki ífarandi. Viðmiðunargildið ≥ 11 stig, getur verið notað sem markgildi fyrir frekara áhættumat á sykursýki af tegund 2 í heilsugæslu. Þrátt fyrir að ekki greindist marktækur munur milli hópa eftir íhlutunartímamann, virðast reglulegar mælingar og GSD ráðgjöfin geta reynst gagnleg til almennar lækkunar áhættuþátta kransæðasjúkdóma.

Lykilorð: Finnski sykursýki áhættumatslistinn (FINDRISK), HbA1c, áhætta á Sykursýki-Tegund 2, Heilsugæsla, Leiðbeinandi Sjálfsákvörðun (GSD), áhætta á kransæðasjúkdómum.

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List of abbreviations

ADA:	American Diabetes Association
ANOVA:	Analysis of Variance
a ROC:	Area under the curve
ARR:	Absolute Risk Reduction
BMI:	Body Mass Index
BP:	Blood Pressure
CER:	Control Event risk
CHD:	Coronary Heart Disease
CHOL:	Cholesterol
CI:	Confidence Interval
CVD:	Cardiovascular Disease
EER:	Experimental Event Rate
EQ-5D-5L:	Europe Quality of Life Five Dimension Five Level Instrument
EQ-VAS:	Europe Quality Visual Analogue Scale
FBG:	Fasting Blood Glucose
FINDRISC:	Finnish Diabetes Risk Score
GLP-1:	Glucagon-Like Peptide-1
GSD:	Guided Self Determination
HbA1c:	Haemoglobin A1c protein, Glycated Haemoglobin
HDL:	High-density lipoprotein
HL:	Health Literacy
HLS-EUQ16-IS:	The European Health Literacy 16 questionnaire Icelandic version
HRQoL:	Health Related Quality of Life
HSN:	Health Institute of North Iceland
ICE-HEART:	Icelandic Heart Association's coronary heart disease risk calculator
IDF:	International Diabetes Federation
IFG:	Impaired Fasting Glucose
IGT:	Impaired Glucose Tolerance
LDL:	Low-density lipoprotein
NNT:	Number needed to treat
OGTT:	Oral Glucose Tolerance Test
OECD:	European Observatory on Health Systems and Policies
OR:	Odds ratio
PHC:	Primary Health Care
QUALY'S:	Quality of Adjusted Life Years
RCT:	Randomized Controlled Trial
RR:	Relative Risk

RRR:	Relative Risk Reduction
SD:	Standard Deviation
T2d:	Type 2 diabetes
TG:	Triglycerides
USA:	United States of America
VSN:	The Icelandic National Bioethics Committee
WHO:	World Health Organization
WHO-5:	World Health Organization Well-Being Index
WHR:	Waist-to-Hip Ratio
WHtR:	Waist-to-Height Ratio

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Overview of original articles

This doctoral thesis is based on the following original publications, which will be referred to in the text by their Roman numerals:

- I. Arnardóttir, E., Sigurðardóttir, Á. K., Graue, M., Kolltveit, B. C. H., & Skinner, T. (2023). Using HbA1c measurements and the Finnish Diabetes Risk Score to identify undiagnosed individuals and those at risk of diabetes in primary care. *BMC Public Health*, 23(1), 211. <https://doi.org/10.1186/s12889-023-15122-y>
- II. Arnardóttir, E., Sigurðardóttir, Á. K., Graue, M., Kolltveit, B. C. H., & Skinner, T. (2023). Can waist-to-height ratio and health literacy be used in primary care for prioritising further assessment of people at T2DM risk? *International Journal of Environmental Research and Public Health*, 20(16), 6606. <https://doi.org/10.3390/ijerph20166606>
- III. Arnardóttir, E., Sigurðardóttir, Á. K., Skinner, T., Graue, M., & Kolltveit, B. C. H. (2024). Prediabetes and cardiovascular risk factors: the effectiveness of a guided self-determination counselling approach in primary health care, a randomized controlled trial. *BMC Public Health*, 24(1), 3035. <https://doi.org/10.1186/s12889-024-20538-1>

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Declaration of Contribution to the Thesis

Elín Arnardóttir (EA), Árún K. Sigurðardóttir (ÁKS), Marit Graue (MG), Timothy Skinner (TS), and Beate-Christin Hope Kolltveit (BCHK) contributed to the planning, designing, and implementation of this doctoral thesis.

- Study I:** EA, ÁKS, MG, TS, and B-CHK participated in the study design. EA and ÁKS obtained ethical approval. Literature search, data collection and data analysis were performed by EA, supervised by ÁKS and TS. Funding was applied by ÁKS. The first draft of the manuscript was written by EA, and ÁKS, MG, TS, and B-CHK critically revised it. All authors read and approved the published version of the manuscript.
- Study II:** EA, ÁKS, MG, TS, and B-CHK, engaged in the study design. EA and ÁKS obtained ethical approval. Literature search, data collection, and data analysis were performed by EA, supervised by ÁKS. Funding was applied for by EA under the supervision of ÁKS. The first draft of the manuscript was written by EA and supervised by ÁKS and TS. ÁKS, MG, and B-CHK critically revised it. All authors read and approved the published version of the manuscript.
- Study III:** EA, ÁKS, MG, TS, and B-CHK, engaged in the study design. EA and ÁKS obtained ethical approval. Literature search, data collection and data analysis were performed by EA, supervised by ÁKS. Funding was applied by EA under the supervision of ÁKS. The first draft of the manuscript was written by EA and supervised by ÁKS and TS. ÁKS, MG, and B-CHK critically revised it. All authors read and approved the published version of the manuscript.
- Thesis:** EA authored the thesis under the supervision of AKS. MG, TS, and BCHK approved the final version of the thesis.

1 Introduction

1.1 The prerequisite for the research in the thesis

Diabetes is one of the fastest-growing challenges to good health worldwide (World Health Organization, 1999). Type 2 Diabetes (T2d) accounts for over 90% of all diabetes cases (Gregg et al., 2021; WHO.int, 2020). Worldwide around 529 million were living with diabetes in 2021 (Ong et al., 2023). Estimates indicate that if the prevalence of T2d continues to increase as in the last decade, by 2045 over 700 million individuals will be affected by T2d (Dall et al., 2014; Saeedi et al., 2019), and up to 1.31 billion in 2050 (Ong et al., 2023).

In Iceland the prevalence of T2d more than doubled from 2005 to 2018, with a prevalence of around 4.1% for men and 3.5% for women in 2018 (Thorsson et al., 2021). In 2021 the International Diabetes Federation estimated the prevalence of diabetes in Iceland to be 8.3% in adults and growing (*Idf.org/Europe, 2025*). In addition, research conducted in the capital area of Iceland indicates up to 29% underestimation in the T2d prevalence for the country according to prescribed diabetes drugs (Thorsson et al., 2021). In 2018, around the same time as the research in this thesis was being prepared, the Development Centre for Primary Healthcare in Iceland (DCPHI) was established to enhance coordination of procedures and collaboration within healthcare, and to promote quality development and improvement. One focus of the DCPHI was health promotion, including increased service for individuals with T2d within primary healthcare in Iceland (*Development Centre for Primary Healthcare in Iceland (DCPHI), 2025*). Following the establishment of the DCPHI, more primary health care facilities began offering specialised receptions for individuals with T2d, often including people with other health risks, to facilitate better follow-up and health promotion (*Development Centre for Primary Healthcare in Iceland (DCPHI), 2025*). The emphasis in primary healthcare remains predominantly on preventing disease progression rather than adopting a proactive strategy to mitigate the ongoing rise of T2d, which necessitates greater attention to an “*up-stream*” approach that incorporates those at risk of T2d or individuals at a prediabetic state (Fazli & Booth, 2023). Here, the emphasize is on prediabetes and ways that primary healthcare may be able to act at low cost to help people at the prediabetes stage and at risk of T2d toward health promotion and thereby lower the risk of the disease.

Prediabetes is defined as a stage of elevated glucose level and elevated haemoglobin A1c (HbA1c) level, not reaching the diagnostic level of T2d (Guo et al., 2014; World Health Organization, 2011a). The World Health Organization

(WHO), American Diabetes Association (ADA) and International Diabetes Federation (IDF) definitions of the prediabetes stage according to HbA1c level have slight variation in the lower limit of the prediabetes stage (Barry et al., 2017; Davidson et al., 2021). The decision was made to use the ADA levels of prediabetes, more specifically the diagnostic level of 39–47 mmol/mol, as T2d progression in Iceland appears to follow a similar path to that in the United States of America (USA) (Thorsson et al., 2021). Prediabetes biomarkers have been linked to an elevated risk of up to a 1:2 ratio that will progress to T2d (Beulens et al., 2019). Prediabetes prevalence in England was around 35.3% in 2011 (Mainous et al., 2014). In the USA, prediabetes biomarkers were found in approximately 1:4 of young adults in 2016 (Andes et al., 2020) and 34.5% in 2021 (Davidson et al., 2021). A meta-analysis found prediabetes prevalence in middle-aged individuals at around 27% when using both the WHO and ADA definitions of the biomarker stage of prediabetes (Barry et al., 2017). The ADA clinical guidelines recommend T2d risk screening for adults every 3 years and yearly after the age of 45 years (Care, 2023).

To prevent or halt progression from the prediabetes stage toward T2d, guidelines and growing recommendations from research results indicate that people should be screened for prediabetes biomarkers. It is also recommended that individuals identified at the prediabetes biomarker stage be referred to health-promoting counselling programmes within the primary healthcare system (2. Diagnosis and classification of diabetes: standards of care in diabetes—2024, 2024; 3. Prevention or delay of diabetes and associated comorbidities: standards of care in diabetes—2024, 2024; Dall et al., 2014; Davidson et al., 2021; Fang et al., 2022b; Herman, 2023; Huang et al., 2016; Jonas et al., 2021; World Health Organization, 2019). In addition, it may be equally important, and plausibly also cost beneficial, to find by screening those at elevated T2d risk and include them in offers of health promotion counselling, using the time from risk onset to diagnosis to work with risk factors and comorbidities, like obesity and cardiovascular diseases (CVD), to stop or slow progression to T2d (Cassidy et al., 2019; Connor et al., 2019; Gao et al., 2022). If it is plausible to further categorise in low- and high-risk prediabetes groups, more intensive approaches might be offered in primary healthcare for people found with higher risk factors of prediabetes biomarkers progressing to T2d or higher risk factors of coronary heart disease (CHD) (2. Diagnosis and classification of diabetes: standards of care in diabetes—2024, 2024; Ahlqvist et al., 2018; Ahlqvist et al., 2020; Care, 2023; Prystupa et al., 2023).

The prevalence of overweight and obesity is rising in Iceland (OECD & European Observatory on Health Systems and Policies, 2021; Thórsson et al., 2009). Reports suggest Iceland has one of the highest values of Body Mass Index (BMI) in Europe (OECD, 2023), with higher BMI for men than women and indications of differences in BMI found between countryside and town living

(Gudjonsdottir et al., 2015; OECD & European Observatory on Health Systems and Policies, 2021). This is important, as a strong link has been established between increased obesity and the prevalence of T2d (American Diabetes Association, 2021; American Diabetes Association, 2022; Schnurr et al., 2020).

The risk of CVD for individuals rises with age (Ke et al., 2023). CVD is the main morbidity and mortality cause for people with T2d (Boyko et al., 2019). Manifestation of T2d increases the individual CVD risk of the equivalent to 10 years in an older person without T2d (Jyotsna et al., 2023; Ke et al., 2023; Wong & Sattar, 2023). Furthermore, a new nationwide registry study in Denmark found over two times more CVD events occurred in people with T2d 25 to 30 years before diagnosis, and nearly three times more events of CVD in the five years before being diagnosed with T2d (Gyldenkerne et al., 2024). In addition, the Reykjavik study's 17-year follow-up found the relative risk of death from CHD higher for both men and women with T2d than other mortality causes in the cohort (Vilbergsson et al., 1998).

The onset of T2d is often silent, with a time lag from onset to diagnosis of up to several years (Kong et al., 2016). Research indicates that for the USA, the estimated interval from onset to diagnosis is seven years, with up to 30% of people with T2d undiagnosed (Zhang et al., 2015), with a lack of treatment increasing risk for diabetes complications (Brown et al., 2004). Furthermore, compared to individuals with normal glycaemic tolerance, individuals found at T2d risk or at prediabetes biomarker level (diabetes warning signs) have up to twelve times greater likelihood of diabetes diagnosis in the future (Albright & Gregg, 2013) and a higher risk of developing CVD and CHD compared to individuals with normal glucose metabolism (Dimova et al., 2015; Fayed et al., 2022). This highlights the necessity of identifying individuals at an early stage of T2d risk to prevent the onset of the disease and its plausible comorbidities (Albright & Gregg, 2013; Brown et al., 2004; Dimova et al., 2015; Fayed et al., 2022; Kong et al., 2016; Zhang et al., 2015).

1.2 The clinical relevance, novelty and importance of this thesis

The prevalence of prediabetes biomarker levels and T2d risk factor status in Iceland was unknown before starting the studies in this thesis (Andersen et al., 2017; Thorsson et al., 2021). In 2018 a working group from the Ministry of Welfare addressing the rising prevalence of diabetes in Iceland did not recommend screening for prediabetes (Benediktsson et al., 2018). However, recent research indicates an increase in T2d prevalence corresponding to the development of prevalence and incidence from 20 years earlier in the USA (Thorsson et al., 2021).

Therefore, research on the prevalence of prediabetes in Iceland and screening methods, is needed if the 2018 recommendation is to be reconsidered.

Gathering knowledge on of non-invasive, low-cost yet effective ways to screen for T2d risk within the primary healthcare (PHC) in Iceland is needed. Information on prediabetes prevalence in Iceland may enable the PHC to identify people with undiagnosed T2d, evaluate prediabetes biomarker prevalence, and empower individuals found at risk in making changes toward risk reduction. Previous Icelandic studies regarding the prevalence of diabetes have mostly used data from the capital area. Therefore, studies are needed on the prevalence of T2d and prediabetes among people living in the countryside and towns of North Iceland. Results may support changes toward health promotion for individuals with prediabetes biomarkers and high T2d risk, using low-cost approaches such as the easily adaptable Finnish Diabetes Risk Screening Instrument (FINDRISC), aiming to identify and approach individuals at high risk while minimizing the pitfalls of overtreatment.

1.3 Prevention through early intervention and T2d risk screening

Several RCT's suggest that lifestyle interventions, with or without pharmaceutical therapy, are cost-effective and secure methods that may delay or prevent the onset of T2d in patients with prediabetic biomarkers (Diabetes Prevention Program Research Group, 2002; Diabetes Prevention Program Research Group, 2015; Glechner et al., 2018; McMullen et al., 2024; Thórsson et al., 2009). Health promotion programmes targeting modifiable risk factors such as nutrition and physical inactivity therefore have the potential to prevent the progression to T2d (Schlesinger et al., 2022). When compared to a placebo, lifestyle intervention has been shown to reduce the incidence of T2d by 58% compared to 31% with metformin treatment (Diabetes Prevention Program Research Group, 2002). Research also demonstrates the lasting benefits of interventions that improve health in halting the progression of T2d (Albright & Gregg, 2013; Lindström et al., 2013).

Finding individuals with prediabetes biomarker levels earlier may therefore be a way to reduce the T2d disease burden, complications and cost for both individuals and society (Gregg et al., 2021; Wändell, 2005; World Health Organization, 2021b). However, the availability of suitable tools in the PHC for early identification may be one of the biggest challenges in promoting health and disease prevention (Lee et al., 2007; World Health Organization, 2021b). Prior research suggests that the implementation of nurse-led programs in the PHC can help patients decrease their risk of both T2d and CVD (Gilis-Januszewska et al., 2017). Implementing a nurse-led counselling programme focused on proactive

health promotion for those at risk of developing T2d within PHC settings could potentially help reduce the increasing prevalence of T2d (Liu et al., 2022).

1.4 Biological measures and instruments

1.4.1 Biological measurements

The World Health Organization (WHO) approves measurements of the test of glycated haemoglobin A1c protein (HbA1c) as a diagnostic method for T2d, in addition to prediabetes biomarkers, as elevated levels of HbA1c not reaching diagnostic levels of T2d (World Health Organization, 1999; World Health Organization, 2011a). The advantage of HbA1c measurements is that they can be taken without fasting prior to testing. This protein indicates the amount of glucose bound to haemoglobin during the lifetime of the red blood cells. Both IDF and WHO have defined the HbA1c diagnostic level of prediabetes signs as 42 mmol/mol to 47 mmol/mol (American Diabetes Association, 2021; Boyko et al., 2019; World Health Organization, 1999;). The ADA classifies individuals with HbA1c levels between 39 and 47 mmol/mol (5.7-6.4%) showing prediabetes signs and those with HbA1c levels of ≥ 48 mmol/mol ($\geq 6.5\%$) as having T2d (World Health Organization, 2011a).

The two-hour oral glucose tolerance test (2-h OGGT) and the one-hour oral glucose tolerance test (1-h OGGT) are also often used to evaluate the prediabetes stage and in diagnosis of T2d. In addition, testing for normal glucose tolerance (NGT), impaired glucose tolerance (IGT) and measurement of fasting glucose level. The tests are all approved by the WHO as diagnostic tests for prediabetes and T2d (World Health Organization, 1999; World Health Organization, 2011a). Recently, after data collection for studies in this thesis ended, IDF recommended the use of the one-hour oral glucose tolerance test in screening for people with prediabetes (>8.6 mmol/l) or T2d (>11.6 mmol/l), as it might be more easily applied and even more accurate in identifying people earlier than the longer version of the oral glucose tolerance test (Bergman et al., 2024).

Biological measurements to identify individuals at the prediabetes stage or early stages of T2d may be challenging to implement in sparsely populated areas and countries like Iceland (World Health Organization, 2011a). In addition to biological measurements, ratio measurements such as BMI for obesity, with as high as one-third of individuals at an obesity level of BMI ≥ 30 kg/m² have signs of prediabetes (Firestone et al., 2021). In addition, measurements like waist-to-hip ratio (WHR) and waist-to-height ratio (WHtR) have been used as testing for overall health risk assessments, diabetes and CVD risk (Ashwell et al., 2012; Browning et al., 2010), or integrated with other measurements as a part of risk evaluation instruments (Lindstrom & Tuomilehto, 2003).

1.4.2 The Finnish Diabetes Risk Score scale (FINDRISC)

FINDRISC is a validated, commonly used instrument that is inexpensive and non-invasive. Developed in Finland in the years of 1987-1992, it was designed to be a primary prevention by evaluating the risk of developing T2d in the next 10 years, finding individuals at high risk before they show signs of hyperglycaemia or T2d (Lindstrom & Tuomilehto, 2003). The risk scoring scale has been widely researched and is used worldwide for diabetes risk screening in different populations (Finnish Diabetes Association, 2006; Lindstrom et al., 2008; Lindstrom & Tuomilehto, 2003; Mavrogianni et al., 2019; Zatońska et al., 2021). FINDRISC has been found to be a useful tool in finding people who are undiagnosed or at risk for developing T2d in the next ten years (Guo, X. et al., 2023; Saeedi et al., 2019; Zatońska et al., 2021). The optimal cut-off values for identifying at-risk individuals may differ by country, ranging from 10 points in the high-altitude of Bolivia (Philco-Lima et al., 2021), 11 points in Bulgaria (Tankova et al., 2011), 14 points in the DE-PLAN study of a larger European cohort (Gabriel et al., 2021), 15 points in Norway (Jølle et al., 2019) and ≥ 17 points in Nigeria (Agbo et al., 2022). The cut-off point for Iceland is not known. Research indicates that lower income status may be one factor in altering the point level on FINDRISC (Mavrogianni et al., 2019).

Other screening instruments are available for diabetes risk, such as ADA seven-question diabetes risk questionnaire (Draznin et al., 2022). However, those tools have not knowingly been validated in Iceland and will hence not be assessed here.

1.4.3 Health literacy, health-related quality of life, wellbeing, and T2d risk

Health literacy (HL) is described as the ability to gather, understand, evaluate, apply, and follow health information and criteria that can promote health, prevent illness, and improve well-being (Ehmann et al., 2020; Sorensen et al., 2012). Thereby better HL may motivate the individual to improve his quality of life (Ehmann et al., 2020; Gustafsdottir et al., 2020; Sorensen et al., 2012). HL may be influenced by several factors addressing the clinical, functional or interactive level of HL, leading to variation of the status of HL between countries (Caruso et al., 2018). Evaluation of HL and health-related quality of life (HRQoL) may enable assessment of the effects of chronic disease or its management on the individual's life and enable comparison between populations (Sørensen et al., 2012; Sørensen et al., 2013; Sørensen et al., 2015).

A better health outcome has been shown to be positively influenced by better HL (Gustafsdottir et al., 2020). Conversely, a limited HL points to poorer health outcomes and may affect self-management and ability toward empowerment for people with T2d (Abdullah et al., 2019). Research has also shown an association

of inadequate HL with an elevated risk of diabetes (Tajdar et al., 2021). HL has also been indicated as the key in personalising self-management for patients with T2d (Caruso et al., 2018; Dahal & Hosseinzadeh, 2020). In Iceland, low self-rated health in the elderly population has been linked to decreased HL (Gustafsdottir et al., 2020). Research on HL among individuals in the USA with prediabetes biomarkers indicated that 19% had low HL, markedly reduced physical activity and an increased prevalence of inadequate sleep. The research indicated that the presence of prediabetes symptoms exerted both direct and indirect effects on health-related behaviours (Luo et al., 2020). In Norway research found almost one-third of people were at risk of developing diabetes, and one-quarter of people diagnosed with T2d showed inadequate HL scores. Results also showed a significant association of better HL and higher educational level for individuals at diabetes risk (Vågenes et al., 2024). The HL-EU-16Q list was decided for this thesis, as the instruments had been validated for Iceland (Gustafsdottir et al., 2020; Sørensen et al., 2012; Sørensen et al., 2013; Sørensen et al., 2015).

Well-being is the positive condition of daily life, as the individuals within a society experience their quality of life, and how the person within a society is enabled to contribute to daily life. Social, economic and environmental status may impact well-being and the ability to thrive (World Health Organization, 2021a). Well-being may affect resilience and the ability to act on challenges in life (World Health Organization, 2021a). Studies on well-being illustrate that low well-being scores have been found to negatively affect the control of diabetes (Topp et al., 2015). The association of poor mental health and well-being has been reported as an indicator of increased risk of prediabetes and progression to T2d (Deschênes et al., 2023). Both individuals at the prediabetes stage and with T2d with higher HL exhibit significantly better well-being and quality of life (Vågenes et al., 2024). In addition, the likelihood of depression may be double for people with T2d, compared to the general population (Darwish et al., 2018).

Using an HRQoL questionnaire may open a path to evaluate changes of self-reported health-related quality over a research period from the first measurement at the beginning of the intervention and map changes over time throughout the intervention period, thereby not only evaluating biological changes but also changes if found for HRQoL of participants (Hefford et al., 2011). Understanding the individual's perception of their health or health status is important, as that enables a better understanding of outcomes such as functional capacity (Dowd & Zajacova, 2007; World Health Organization, 2001). Prior research in several countries has aimed to explain HRQoL for people at the prediabetes stage with uncertain results, although using more than one type of HRQoL questionnaire (Anillo Arrieta et al., 2021). Research in Sweden found that prevention of prediabetes development improves HRQoL and lowers the risk of T2d disease (Neumann et al., 2014). In addition, research in North Iceland found depressed mood, higher BMI, inadequate income, and number of prescribed medications

each independently explaining lower self-rated health, emphasizing the importance of health promotion (Sigurdardottir et al., 2019). It is important to identify if these non-invasive, patient-reported measure screening tools of HL, well-being and/or HRQoL questionnaires may exhibit any traits within T2d risk and prediabetes stage categories. Thus, determine if a non-invasive screening, such as the selected questionnaires, can help within the primary healthcare to identify individuals at risk before conducting more intrusive testing and classifying them as low or high risk for T2d. Thus, allowing the PHC to prioritise high-risk people while employing less invasive approaches for low-risk ones (Graham et al., 2020; Wagner et al., 2021).

1.5 Theoretical background

Many factors may influence physical and psychological health and social wellbeing. Thereby have an influence on the quality of life of an individual (Bjørndal et al., 2025). Research on special characteristics of wellbeing and/or the view of one's health, as here prediabetes, is important for finding the most effective intervention toward health promotion and disease prevention.

The research in this thesis is grounded on health promotion theories and associated concepts, including person-centred care, integrated care, and empowerment, by early intervention using the approach of GSD (Zoffmann, 2004). The following provides a short overview of those theories, ideas and concepts.

1.5.1 Health promotion

The World Health Organization set the agenda for the primary healthcare role in health promotion and preventive health care with the Alma Ata declaration in 1978 (Wills, 2022; World Health Organization, 1978). Health promotion may be defined as: *“a range of activities and interventions that enable people to take greater control over their health”* (Wills, 2022, p. 55). The act of health promotion involves strategies presented with actions by the communities, health care professionals, families and individuals to encourage healthy lifestyles by promoting healthier products and education and thereby helping individuals to improve their health by taking control and responsibility over factors influencing their health (Nutbeam & Muscat, 2021; Wills, 2022). McKinlay and Marceau (2020) used the metaphor of river courses and estuaries to emphasize the importance of health promotion in public health, looking at the individuals' health condition within society and aiming toward diabetes prevention in the 21st century. The metaphor emphasizes that public policy of prevention strategies toward health promotion for the population needs to start at the beginning of the river, or 'upstream', seeking ways to influence lifestyle choices and surroundings in

populations, which may reduce health risk (here, the risk of prediabetes and T2d) for individuals in the population. At the 'midstream' stands the primary healthcare and 'downstream' the tertiary healthcare. Present reactions within the healthcare systems may still be more focused on individuals presenting the stage of T2d than those at risk (McKinlay & Marceau, 2000). It has been proposed that through the implementation of constructive changes in public policy and the encouragement of health-promoting transformations within communities, health promotion can, by educating, empowering, and supporting individuals and communities, diminish the burden of illness and cultivate healthy lifestyle behaviours (McKinlay & Marceau, 2000; Wills, 2022). Several known models and theories have been built to explain and understand the phenomenon of health promotion (Nutbeam, 2023; Wills, 2022). With the WHO conference in Ottawa in 1998, a new chapter of health promotion was written with the "*Ottawa Charter for Health Promotion*", identifying core requirements for health as food and shelter, education, social justice, peace, economic resources, sustainability and stable ecosystems (Nutbeam & Muscat, 2021). Theory of health promotion thus creates integration of processes toward promoting health, as it is not one action or thought but a theory of intertwined actions toward effective ways to promote health. Therefore, actions toward health promotion need to be examined from different perspectives and from levels of medicine, education, behavioural or social changes and empowerment (Nutbeam & Muscat, 2021; Wills, 2022). The theories have helped build interventions toward changes leading to health promotion. The process of health promotion for individuals, enabling them to improve their health by taking control of what influences their health (Nutbeam & Kickbusch, 1998; Wills, 2022), as well as promoting health within a society, cannot be simply implemented or elucidated from a singular perspective, since the comprehension of health promotion processes may be intricate (Wills, 2022). The process of raising awareness, providing information, motivating individuals toward changes that promote health and equipping them with new skills to enable them to take steps toward self-responsibility for one's own health may be a part of health promotion or seen as health education (p. 61) (Wills, 2022). The understanding of health promotion as a theory is still undergoing development. Thereby the intertwined simplicity and, at the same time, complexity of health promotion processes need to be better explained in the future. Enabling promotion of health of individuals and society to change behaviours toward choices that may improve health (Nutbeam, 2023; Wills, 2022). Within primary healthcare, health promotion provided with the concept of patient-centred care is preferred by patients (Little et al., 2001; Santana et al., 2018).

1.5.2 Patient-centred care and integrated care

The concept of Patient Centred Care (PCC) originated in psychiatry after the middle of last century with more focus on understanding that every individual is distinct and the need to involve the person in decision-making on one's health (Byrne et al., 2020). The PCC concept acknowledges the importance of education and information for the individual/patient, allowing them to make the decisions they consider most appropriate for themselves, based on their own views on health and illness. The PCC aims to address psychological, biological, and social needs to enhance treatment quality, reduce costs, and increase satisfaction for both patients and healthcare professionals (Byrne et al., 2020; Pelzang, 2010).

It has been observed that the PCC concept, in addition to revolving around individuals, may also be influenced by power and practice within health care (Byrne et al., 2020; Zoffmann et al., 2016). The presentation of the concept may shape or influence the allocation of resources by prioritising the healthcare professionals' recommendations rather than fostering individual autonomy in informed decision-making concerning their health improvement pathways (Byrne et al., 2020; Zoffmann et al., 2016). This may reveal or partly explain why the concept is unclear regarding its interpretation and application in healthcare (Byrne et al., 2020).

A more recent definition or pathway of care is the concept of integrated care. Similarities exist between the definition of integrated care and PCC. Integrated care can be defined as a comprehensive approach incorporating several different perspectives, including coordination, continuity, co-work, management, and care that emphasizes the patient first (Goodwin et al., 2017). The definition of the concept of integrated care may vary, depending on from which perspective it is defined. The patient's perspective may view integrated care as a form of care provided as coordinated person-centred care (Goodwin, 2016; Lewis et al., 2010). Whereas integrated care, from a healthcare perspective, may be defined as a holistic approach that spans the entire lifespan, in which healthcare systems coordinate and provide services across various levels, ensuring continuous and comprehensive care within the system, covering prevention, health promotion, treatment, and palliative care, and in addition, empowering people to be liable for their own health (Cash-Gibson et al., 2019; Goodwin, 2016). Integrated care examines the preparation and process from a "macro" level to "nano" level in promoting management of care as the best approach for both patients and organizations (Goodwin et al., 2017).

The integrated care pathway can therefore be used to achieve a holistic overview in designing new approaches in disease prevention inside the PHC, as patients' actions contribute and affect the work of the health care personnel, diverting the primary focus from curing diseases toward disease prevention and

working on minimising negative effects, or the “consequences of” that specific disease outcome, and toward empowerment (Goodwin et al., 2017; Lipset, 2017).

1.5.3 Empowerment

The philosophy of empowerment may be explained as a concept involving “the process of acquiring increased power or control over one’s life, through provision of information, development of skills and self-efficacy putting this new knowledge into practice toward a better life“ (p.61) (Wills, 2022). Thereby, empowerment may be seen as a learning process both for individuals and societies and a part of health education toward the process of promoting health for individuals and societies (Nutbeam, 2023; Wills, 2022; Zoffmann, 2004).

According to Anderson (2005), diverse strategies can be employed to facilitate empowerment, where individuals’ capacity to acknowledge their ability to manage their health is a significant factor. For healthcare professionals, enabling and encouraging individuals to reflect on challenges or negative influences in their lives is one of the most significant tools available (Anderson, 2005).

Empowerment demands that the individual is enabled to reflect on their own awareness, discipline, and knowledge and understanding of here their health problems, in addition to gaining increased power and capacity to confront and deal with his health problems (Sigurdardottir & Jonsdottir, 2008). The approach of the healthcare person teaching, and the patients listening, learning and conducting what the healthcare person lays out for them to implement is therefore different from the empowerment concept (Wills, 2022). Empowerment aims to find the best approach that may help the individual to find the most suitable way for himself to amend his current state of health (Wills, 2022). Empowerment enables more self-efficacy, taking care of health by better problem-solving, setting and reaching goals that are proactive and thereby improving health or a situation for the individual (Sigurdardottir & Jonsdottir, 2008). To become empowered, the person needs to gain knowledge, enabling them to make informed decisions to take care of their health. Without informed decisions, a person cannot become empowered with increased ability to improve self-care (Sigurdardottir & Jonsdottir, 2008; Zoffmann, 2004; Zoffmann et al., 2008; Zoffmann, Prip, & Christiansen, 2015; Zoffmann & Kirkevold, 2012).

Empowering an individual cannot be measured against the success of a healthcare professional (here, nurses) in improving the quality of life of an individual through intervention. Just as the process of feeling empowered is manifested in how the individual makes informed decisions towards improving his life situations (Sigurdardottir & Jonsdottir, 2008). The concept of empowerment, therefore, does not aim at counting the success or failure of the healthcare professional to “make” the individual “healthier” but rather to enable them to find the ways toward better health state management (Anderson, 2005).

Thereby, empowerment positions healthcare professionals alongside individuals to reflect on their life, provide direction, aid, and encouragement in achieving patients' self-management objectives and goals (Anderson, 2005). Healthcare professionals, such as nurses, can facilitate individual empowerment by creating an environment that fosters safety and acceptance of the patient's current state, enabling them to address their existing challenges (Anderson, 2005).

Several key elements need to be considered when elucidating the concept of individual empowerment. Empowerment is a process where the individual first identifies his problem. Second, he will reflect on his feelings about the problem. Third, he will plan and decide on which way to approach the problem. During this process, individuals need to set goals to overcome obstacles that will interfere with positive health outcomes. The depiction of these processes may differ between methodology approaches aiming for the goal of empowering the individual by enabling him to feel empowered; see Figure 1 (Anderson, 2005; Sigurdardottir & Jonsdottir, 2008).

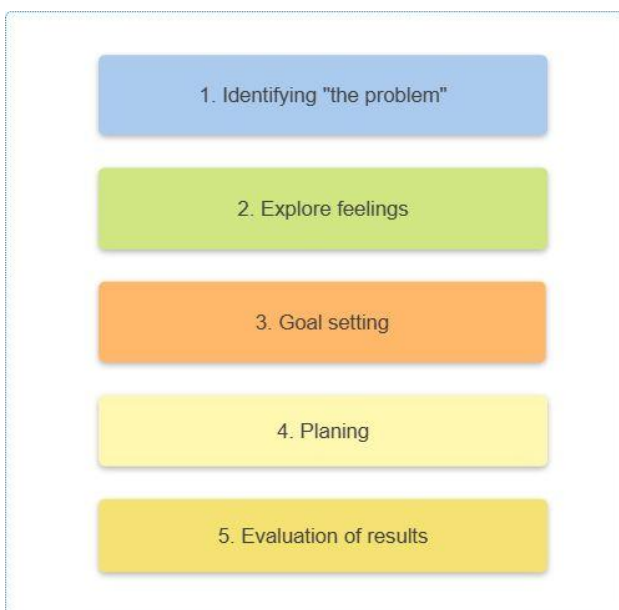


Figure 1: Five phases in approaching effective direction toward empowerment (Anderson, 2005).

Many different approaches based on empowerment have been structured, researched, and assessed as a method to help health professionals assist individuals to feel empowered. One approach is the Guided Self-Determination (GSD) counselling method (Zoffmann & Kirkevold, 2012).

1.6 The counselling method: Guided Self-Determination

The GSD counselling method is an evidence-based approach that has been utilized for over twenty years (Graue et al., 2024; Mathiesen et al., 2023; Zoffmann, 2004; Zoffmann & Lauritzen, 2006; Zoffmann et al., 2008; Zoffmann et al., 2016; Zoffmann et al., 2023). Built on grounded theories and the philosophy of empowerment-related concepts of humanistic principle, life skills and self-determination, which integrate research and concepts that involve empowerment, self-determination, life skills and humanistic values (Zoffmann, 2004; Zoffmann et al., 2008; Zoffmann, Prip & Christiansen, 2015; Zoffmann & Kirkevold, 2012).

The GSD counselling method was first designed and developed as a programme to promote life skills and health for people with Type 1 diabetes (T1D). Further, it was evaluated as an approach for equipping people with chronic illnesses with fundamental competencies to effectively manage the challenges associated with self-regulating their conditions (Zoffmann, 2004; Zoffmann et al., 2008; Zoffmann, Prip & Christiansen, 2015; Zoffmann & Kirkevold, 2012). In the 20 years of testing and developing the method, the GSD has been found to improve life skills (Zoffmann & Kirkevold, 2012; Zoffmann & Lauritzen, 2006), in addition to maintaining efficiency when faced with challenging and difficult obstacles both for the patient and healthcare provider, in T1D and T2d diabetes care (Graue et al., 2024; Husted et al., 2014; Kolltveit et al., 2014; Zoffmann et al., 2016; Zoffmann & Lauritzen, 2006), as well as other health conditions like cancer and schizophrenia (Jørgensen et al., 2014).

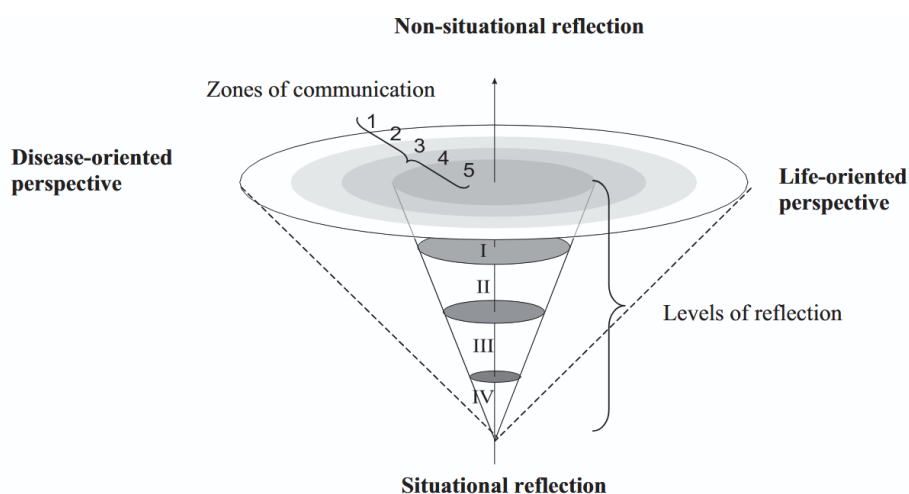
The aim of the GSD method is to start a process of reflection to motivate individuals to seek and work through obstacles in their daily life. Thereby, enable individuals with chronic diseases, and here T2d risk factors, to effectively manage the obstacles associated with their condition. Resulting in change and thus better management of their health condition. To reach this aim, the GSD method provides them with new skills to self-manage their condition (Mathiesen et al., 2023; Seidu et al., 2016; Zoffmann et al., 2016; Zoffmann et al., 2008; Zoffmann et al., 2023; Zoffmann & Kirkevold, 2012). By facilitating a reflective process, fostering collaboration, and inspiring individuals to examine and overcome the challenges they face in their everyday lives (Mathiesen et al., 2023; Zoffmann et al., 2016; Zoffmann et al., 2023).

GSD counselling, provided by healthcare professionals like nurses, consists of utilizing value-clarifying responses, active listening and mirroring in motivating and supporting the individual to attain their goals (Zoffmann et al., 2008; Zoffmann, Prip & Christiansen, 2015). Using a supportive instrument of reflection sheets alongside, fosters autonomy by aiding the individual in setting goals toward health promotion, enhancing their understanding of values, identifying opportunities, and deepening their comprehension of value toward readiness to change (Zoffmann et al., 2008).

The GSD method acknowledges the plausibility of conflicts due to various perspectives on life. In addition, recognise the importance of noting the potential for differing perspectives of individuals and health professionals regarding the impact risk factors or diseases may have on overall welfare. The GSD method confronts conflicts that may arise due to resistance to integrating into daily life, a battle against one's risk syndromes or disease, and the effects of risk or disease on the individual's general well-being (Zoffmann et al., 2008; Zoffmann et al., 2016; Zoffmann & Kirkevold, 2012).

The core of the GDS method is a fundamental shift from non-situational counselling, characterised by healthcare professionals discussing irrelevant topics or circumventing issues, to directly addressing the individual's current challenges. This approach emphasizes reflection and empowerment, enabling individuals to undertake self-directed actions to confront the obstacles in their lives (Zoffmann & Kirkevold, 2012); see figure 2.

Person-Centered Communication and Reflection Model



Key: Zones of Communication 1-5

1. Addressing unrelated issues
2. Addressing general health-related issues
3. Addressing issues of general significance for the patient group
4. Addressing issues related to the patient but currently not difficult
5. Focused communication addressing issues currently difficult for the patient

Levels of Reflection	Situational Reflection	
	Health Care Professional's (HCP) Activity	Patient's Activity
I	Reflecting independently on observable signs of person-specific difficulties	Being observed; not engaged in HCP's reflection
II	Reflecting independently or with colleagues on non-observable aspects of person-specific difficulties; gathers information from the patient but does not inform the patient of the issues reflecting on or invite the patient to assess the difficulties; conjectures remain unverified	Contributing information, but not engaged in HCP's reflection or informed about the issues reflected on; not asked to verify or assess assumed difficulties
III	Engaged in mutual reflection with the patient, exchanging thoughts and ideas of explicit difficulties related to the patient's responses to living with the illness; conjectures verified and knowledge of person-specific difficulties is co-created; importance, causes, meanings and possible solutions clarified	Engaged in mutual reflection with HCP, verifying and exchanging thoughts and ideas of explicit difficulties related to living with the illness; co-creating person-specific knowledge of the importance, causes, meanings and possible solutions
IV	Though not participating in reflection, HCP can motivate the patient to start reflection, e.g., by asking value-clarifying questions or by pointing out possible inconsistencies in patient responses to illness	Reflecting independently; autonomously clarifying and reassessing own responses to and stand on specific difficulties

Figure 2: Person-Centred Communication and Reflection Model*

*From "A person-centred communication and reflection model: Sharing decision-making in chronic care," by V. Zoffmann, I. Harder, and M. Kirkevold, 2008, *Qualitative Health Research*, 18(5), p. 674. Copyright 2008 by Sage Publications. Reprinted with permission number 5983740674070.

Research has found the GSD method to be cost-effective (Graue et al., 2023), inexpensive, novel and easily accessible in both training the provider and improving self-management for individuals with diabetes (Rasmussen et al., 2019). Research indicates that the counselling approach can have a positive effect on participants' measured outcomes. The method has been found beneficial toward health promotion for *individuals with Type I diabetes, T2d, mental illnesses, and cancer* (Graue et al., 2023; Jørgensen et al., 2014; Linnet Olesen & Jørgensen, 2023; Rasmussen et al., 2019; Zoffmann, Vistisen & Due-Christensen, 2015). Even when provided as online support in rural regions (Rasmussen et al., 2019).

1.7 Icelandic context of research in the thesis

Iceland is a sparsely populated country compared to the Nordic countries or Europe. The first healthcare centre was established in 1966 in Húsavík; prior to this, doctors predominantly operated in private practice (Sigurgeirsdóttir et al., 2014). As of 1 January 2021, 368,792 inhabitants were living in Iceland (Statistics Iceland, 2021). The country is now divided geographically into seven health districts. Each district has a healthcare institution coordinating the small area hospitals and healthcare centres located in town (urban) areas. The state finances primary healthcare (Skuladottir, 2019). Most of the centres are staffed by doctors, nurses, licensed practical nurses, midwives, and sometimes other professionals.

Larger centres also have biomedical engineers, radiologists, psychologists, exercise managers and other professionals. Doctors and nurses often work together in some form of teamwork at healthcare centres, for example, in health promotion clinics for people with diabetes. Other specialists like nutritionists and physiotherapists may assist regularly or be within reach (Sigurgeirsdóttir et al., 2014). Primary healthcare nurses work more independently in Iceland than is found in other countries like Norway, with doctors often only coming a few days a month to provide medical care (Sigurgeirsdóttir et al., 2014). The Healthcare Institution of North Iceland (HSN) services PHC in the North district of Iceland with 17 PCH clinics. Locations are based on settlement distributions, historical background, and challenges in travelling in winter; see Figure 3.



Figure 3: Service area of HSN shown with the broken line. The PHC clinics are represented by the dots. The size and colour of dots represent different services. Akureyri hospital is not part of the HSN (<https://island.is/s/hsn>).

On January 1, 2021, around 36,000 were living in the north Iceland health district. Thereof, around 17600 aged 18-75 years living in the service area of the PHCs of Akureyri, Húsavík and Sauðárkrúkur that participated in the studies (Statistics Iceland, 2021). The three locations enabled a comparison of results between the service areas, with Akureyri and the surrounding area defined as a town and Húsavík and Sauðárkrúkur each with one sub-rural town, defined as countryside areas. The provision of services in each region and the population distribution provide the terms ‘town’ and ‘countryside’ with more accurate descriptions of the areas than the urban/rural classification, according to Statistics Iceland’s population density definition (Stattice.is, 2023).

Although the GSD approach has been extensively researched and applied in patients with various chronic conditions, its implementation in Iceland has been limited. Notably, prior to this study, GSD had not been applied among individuals at risk of developing T2d or CHD in an Icelandic context. Wang et al. (2009) found individuals that exhibit varying perspectives and concerns regarding chronic diseases and associated risks, which may influence their comprehension of disease risk and their attitudes towards behaviors aimed at risk reduction. (Wang et al., 2009). It is therefore important to find people at risk, as their views on their health status may differ from people with a disease, depending on their perspective on the risk of e.g., T2d compared to heart disease or cancer (Wang et al., 2009). The need to feel empowered and willingness toward health promotion may therefore differ between people at risk and people with established disease (Wang et al., 2009). Finding suitable approaches in T2d prevention for people at risk, to research the efficiency of methods like the GSD is essential before adopting methods into daily PHC work. Cost-effectiveness and risk reduction of T2d in later life have been demonstrated by other lifestyle interventions, like the American National Prevention Program (Albright & Gregg, 2013) and the Finnish Diabetes Prevention Study (Lindström et al., 2013). However, those programmes were lasting for active intervention periods of up to six years, as in the case of the Finnish study (Lindström et al., 2013). Therefore, assessing the GSD method for use in primary healthcare in Iceland may give more possibilities and dimensions in approaching the rapidly growing prevalence of individuals at T2d and CHD risk toward health promotion within the primary healthcare.

2 Aims

The overall aim of this thesis was to determine the prevalence of prediabetes and undiagnosed T2d in North Iceland. Further, to compare the FINDRISC to other instruments and measurements in finding individuals at T2d risk in primary healthcare in Iceland. To evaluate the sensitivity and specificity of the FINDRISC and evaluate differences in health literacy and well-being of the participants. In addition, evaluating by an RCT how a nurse-led follow-up with the GSD approach can assist people at T2d risk to lower their CHD risk.

The objective of the studies in this thesis may be divided into three separate sections:

Study I: Assessing the prevalence of people exhibiting indications of prediabetes, indicating a plausible risk of acquiring T2d during the following decade, and evaluating the proportions of individuals with undiagnosed yet manifested T2d in the study region. In addition to evaluate the sensitivity and specificity of FINDRISC for Iceland utilizing HbA1 readings. Thus, assessing the utility of the FINDRISC score scale as a screening instrument in Icelandic primary healthcare for identifying patients at increased risk of developing T2d in the next 10 years, requiring additional examination for prediabetes or elevated T2d risk.

Study II: Determining which of the following: FINDRISC scale, Waist-to-hip ratio, body mass index, and waist-to-height ratio, is the most beneficial non-invasive tool to identify those at risk for T2d. By comparing the sensitivity and specificity of the FINDRISC scale using HbA1c values versus Waist-to-hip ratio, Body Mass Index, and waist-to-height ratio. Additionally, exploring if differences exist in HL and well-being scale scores between countryside and town residents in North Iceland. Furthermore, if such scores could be beneficial in identifying and concentrating on those who are vulnerable, requiring help because of the potential of developing T2d.

Study III: Evaluating the efficacy of a short 12-week intervention using the nurse-coordinated team-based counselling approach, the Guided Self-Determination (GSD), provided by primary healthcare nurses, in mitigating CHD risk factors for the intervention group relative to the control group in a RCT.

3 Material and methods

This thesis describes the Icelandic part of a larger research project conducted in Norway under the overall program title “*Effectiveness of a nurse-coordinated multidisciplinary follow-up program in general practice: a mixed-method complex intervention trial among people with chronic conditions and multimorbidity.*” The thesis comprises three quantitative studies: two employing cross-sectional methodologies, built on different parts of the same dataset, and one utilizing a RCT.

3.1 Study design

The selected design for the first two parts of the studies was a cross-sectional design with a single measurement. The initial segment served as the foundation for the subsequent intervention research, a RCT with repeated measures, one at baseline (Time 1) and two times after the intervention period finished (Time 2 and 3). To ensure the integrity of the study design and to identify methods for enhancing study quality while mitigating adverse influencing factors, the RCT and its components were submitted to and approved for publication by <https://www.clinicaltrials.gov/> number (NCT04688359). The 2010 CONSORT guidelines were employed to report the results (Schulz et al., 2010).

3.1.1 Study population, sample size, and allocation criteria for studies I, II & III

Eligible for participation in studies I and II were all 18-75 years old, living in the service area and attending one of the three participating PHCs, speaking and understanding Icelandic or English, and not with known diagnoses of T2d. The estimated sample size was according to calculations with calculator.net and the G*power 3.1 online calculator (GpowerNT.exe). For 85% Confidence Level (CL), 5% margin of error and a population proportion of 50% (men/women), approximately 205 participants were needed for the cross-sectional study I. For participation in the RCT, the inclusion criteria were based on results from studies I and II. The Finnish Diabetes Risk calculator of ≥ 9 points and either or both a) HbA1c ≥ 40 mmol/mol and b) BMI ≥ 30 kg/m². Calculations by the G*power calculator for the intervention indicated that as 81 fulfilled the inclusion criteria of the RCT, the probability of a type II error (β level), of no effect of the intervention when there is in fact an effect, was higher than the type I error (α level), of a genuine effect when in reality, no effect is to be found (Field, 2024).

Eligible participants for the RCT were given identity numbers by the PhD student. The numbers were first divided by gender, then in jars divided as under or over 50 years. A pair of numbers was taken within each jar, with the first number

belonging to the intervention and the second to the control group, until all numbers were selected. If one number was left in the end, it was decided that it would be in favour of the intervention group, with a ratio of 1.08:1.00, due to potential dropout over the study period.

3.2 Data collection

3.2.1 Data collection for studies I and II

Data collection took place, by one-to-one interviews with the PhD student, at three of the largest PHC clinics (Húsavík, Sauðárkrókur and Akureyri) in North Iceland. In Húsavík and Sauðárkrókur at the PCH centre and at the research centre at the University of Akureyri. Data for studies I and II were collected between February 2020 and May 2021.

Approaching participants with an information letter, offered by the PHC receptionist to potential participants when they visit one of the participating PHC clinics, was the original plan that needed to be changed. Restrictions due to the COVID-19 pandemic led to only the most essential visits to the PHC being allowed. Subsequently, half of the participants enrolled for studies I and II were recruited via advertisements in local papers and flyers. From February 2020 to May 2020, 101 participants were recruited at the PHC; the remaining 119 participants were recruited from January 2021 to May 2021 through advertisements.

Advertisements, flyers and information letters gave information about the study and how to contact the doctoral student; see Appendix II. Participants met the PhD student for data collection after their pre-booked appointment at the PHC clinic or at the research centre. But the participants recruited through advertisements contacted the PhD student via phone, SMS, or e-mail. They were then briefed about the study and sent a copy of the introduction letter via e-mail. If without an e-mail, the introduction letter was handed to participants before data collection when they came for measurements at a prearranged time. A new appointment was additionally offered twice; if a participant failed to appear at the scheduled time for data collection, they were thereafter regarded as refusing to participate.

3.2.2 Data collection for study III

For study III, quantitative data and biological measurements were collected from October to November 2021, prior to the intervention starting in December 2021. The intervention consisted of three consultations with nurses in PHC and lasted over a 12-week period. Measurements were repeated 3 and 6 months post-intervention, six and nine months after baseline, and ended in autumn 2022. The

same method of appointment for measurements was used for study III as in studies I and II, see; 3.2.1.

3.3 Demographic and biological measurements and instruments

Participants answered background questions and questionnaires on a laptop or, if preferred, on paper; see Appendix III. Participants with reading difficulties had the questions read aloud, but they answered on paper or a computer. Biological and demographic measurements were all taken by the PhD student and repeated throughout the studies, with additional measurements of CHD risk factors in study III. Information on the living status, age, year of birth, gender, educational level, occupational status, residency and smoking habits was gathered at all measurements. A list of data recorded in all studies that are demographic and biological measurements, in addition to all instruments, can be found in Table 1.

Table 1: List of data recorded in study I-III

Data Recorded	Study I	Study II	Study III
Age	x	x	x
Year of birth	x	x	x
Gender	x	x	x
Living status	x	x	x
Educational status	x	x	x
Occupational status	x	x	x
Smoking habits	x	x	x
HbA1c	x	x	x
2-hour FBG			x
Height	x		
Weight	x	x	x
Waist circumference	x	x	x
Hip circumference	x	x	x
Cholesterol			x
High-density lipoprotein			x
Low-density lipoprotein			x
Triglycerides			x
Blood pressure			x
BMI calculation kg/m ²	x	x	x
Waist-to-hip ratio	x	x	x
Waist-to-Height ratio	x	x	x
FINDRISC score	x	x	x
HLS-EU-Q16IS	x	x	x
WHO-5	x	x	x
EQ-5D-5L	x	x	x
ICE-HEART-calculator			x

Participants living around Akureyri were considered living in a town, but participants from the Húsavík and Sauðárkrókur areas were considered living in the countryside (Statice.is, 2023).

3.3.1 Prediabetes biomarker signs and the Haemoglobin A1c protein

A decision was made to use the ADA definition of the haemoglobin HbA1c level of 39-47 mmol/mol as a prediabetes marker, as the T2d prevalence in Iceland seems to be following the same pathway as the increase in T2d prevalence in the USA which was seen 20 years earlier (Thorsson et al., 2021).

To measure the HbA1c level, capillary blood samples were gathered at each measuring time and analysed using ‘DCA Vantage[®]’ (Siemens Medical Solutions Diagnostics Europe Limited, Dublin, Ireland).

3.3.2 Measurements of 2-hour fasting glucose.

To screen for alterations in levels of blood glucose in the RCT, a 2-hour fasting blood glucose (FBG) was added to measurements in study III. The OneTouch[®] Verio Flex blood glucose meter was used for capillary blood samples. This was according to the latest advice for diagnostic purposes for T2d, which is to utilize plasma or fasting plasma glucose (Sacks et al., 2023). A normal glucose level was defined as being less than 5.5 mmol/l (<100 mg/dl), a prediabetes glucose level between 5.5 and 6.9 mmol/l (100-125 mg/dl), and a T2d glucose level exceeding 7 mmol/l (≥ 126 mg/dl) (American Diabetes Association, 2021).

3.3.3 BMI calculation

Body mass index in kg/m^2 of body, is widely used in determining obesity. Underweight is considered below 18 kg/m^2 , normal weight 18-25 kg/m^2 , overweight >25-29.9 kg/m^2 and obesity ≥ 30 kg/m^2 (Romero-Corral et al., 2008). The BMI is included in the FINDRISC instrument (Lindstrom et al., 2008). For BMI calculations, height was recorded at the pre-allocation measurement in study I with a portable measuring tape, rounded to the nearest .1 centimetre. Weight was measured on a digital scale, in light clothing at each measurement appointment, and rounded to the nearest 100 grams (Romero-Corral et al., 2008). Microsoft Excel 7.0[®] was used in the execution of BMI calculations.

3.3.4 Waist-to-hip ratio and waist-to-height ratio calculation

The waist (2 cm over the navel) and hip (at the widest point) were measured using 1.5- or 3-metre capacity measuring tape (the measuring tapes were assessed for accuracy regularly). Those measurements were used for calculations of waist-to-hip ratio, which is waist/hip in cm (WHR), and waist-to-height ratio, which is waist/height in cm (WHtR). WHO has defined that WHR for European men at $\geq .94$ and $\geq .80$ for women may cause increased health risk (World Health Organization, 2011b).

In contrast to WHR, the WHtR is not influenced by ethnicity or gender. Prior research has suggested that WHtR may be a better and more accurate diabetes risk predictor than BMI (Ashwell & Gibson, 2016; Browning et al., 2010). No increased health risk is found if the waist-to-height ratio is $< .5$; an increased to higher health risk is detected if WHtR is between $.5$ and $.6$, and a WHtR $> .6$ indicates health risk (Ashwell & Gibson, 2016; Browning et al., 2010; Mirzaei & Khajeh, 2018). In addition, research indicates that the WHtR is stronger and more effective than the WHR in identifying individuals for both CVD and T2d risk (Ashwell et al., 2012; Ashwell & Gibson, 2016; Browning et al., 2010; Ke et al., 2022; Zhang et al., 2021).

3.3.5 Cholesterol and lipoprotein measurements

Cholesterol (CHOL), high-density lipoprotein (HDL), and triglyceride (TG) levels are a part of the Icelandic coronary heart risk (ICE-HEART) calculator (Aspelund et al., 2007), used for calculations in study III; see chapter 3.4.11. These three tests were repeated through study III. For these measurements the Mission® cholesterol meter was used; it is a point of care measurement from Swisspointofcare.com. In addition, the meter provides computed tests for low-density lipoprotein (LDL) and the ratio of total cholesterol to high-density lipoprotein (CHOL/HDL).

3.3.6 Blood pressure measurements

Systolic blood pressure is an item for calculating CHD risk in the ICE-HEART calculator. The participants' blood pressure (BP) was measured at the end of each section in study III, after they had been seated for a duration of 10 minutes. Utilizing the Medisana® upper arm meter for measuring (SPRINT Research Group, 2015). The treatment threshold for systolic pressure was set as ≤ 140 mm/Hg and for diastolic pressure as < 90 mmHg (Fuchs & Whelton, 2020). Research indicates that elevated BP raises the likelihood of developing CVD (Ashwell & Gibson, 2016).

3.3.7 The Finnish Diabetes Risk Score (FINDRISC) instrument

FINDRISC is an easy-to-use questionnaire, consisting of eight scoring items, with an increase in scores representing a higher risk of T2d (Lindstrom & Tuomilehto, 2003). The FINDRISC instrument includes modifiable risk factors such as diet, physical activity, and body weight. It consists of eight questions on age, gender, BMI, waist circumference, daily physical activity, consumption of fruit and vegetables, history of high blood pressure, previous history of diabetes and family history of diabetes (Finnish Diabetes Association, 2006; Lindstrom & Tuomilehto, 2003).

FINDRISC has been translated to several languages and validated in several populations (Gabriel et al., 2021; Silvestre et al., 2017), including Iceland (Ingvadóttir & Sigurdardóttir, 2017). Scores on FINDRISC vary from 0 to 26 points, with an elevated score indicating an increased probability of illness onset within the subsequent decade. A score below 7 points is classified as low risk of 1:100, 7–11 points denote a slightly higher risk of 1:25, 12–14 points signify moderate risk of 1:6, above 15 points indicates high risk of 1:3, and beyond 20 points represents very high risk of 1:2 (Finnish Diabetes Association, 2006).

Participants calculated their total scores when answering the questions and therefore became aware of their total risk score, as it is stated on the instrument. The total scores counted by participants were double-checked for miscalculations and corrected if needed before data analysis. The use of FINDRISC as a proactive and preventative strategy within the PHC in finding people at the prediabetes stage had not been done before in Iceland. The optimal sensitivity and specificity of a cut-off point for FINDRISC in finding people at an HbA1c level of prediabetes in Iceland was unknown.

3.3.8 Health Literacy (HL) questionnaire

The Health Literacy Survey Europe Questionnaire (HLS-EU-Q) is available in several versions (Sørensen et al., 2015) and is a widely used instrument in HL research (Anillo Arrieta et al., 2021). For Iceland, the sixteen-question version (HLS-EU-Q16-IS) had been translated and adapted (Gustafsdóttir et al., 2020). Valid responses include no more than two missing answers. Answers are on a four-scale ranging from ‘very difficult’ and ‘fairly difficult’ (giving 0 points) to ‘fairly easy’ and ‘very easy’ (giving 1 point). Summarised scores are from 0 to 16 points, with a higher score representing better HL. Scoring is categorised into inadequate HL (scoring 0–8), problematic HL (scoring 9–12), and sufficient HL (scoring 13–16) points (Gustafsdóttir et al., 2020). Higher scores indicate better well-being; lower scores may indicate depression.

The EU-HL-Q lists enable comparison of HL within and between European populations (Sorensen et al., 2012; Sørensen et al., 2013; Sørensen et al., 2015). As the outcome value of sufficient HL may vary between countries, questionnaires evaluating HL, like the HL-EU-Q16, may need a cross-cultural adaptation and evaluation for each country, as several influential factors may affect the interactive, clinical, and/or functional level of HL (Caruso et al., 2018; Gustafsdóttir et al., 2020). In the translation and adaptation of the Icelandic version, 72.5% represented a sufficient HL score, 22% a problematic HL and 5.5% an inadequate score. The research found, in addition, an independent predictor of lower score by lower self-rated health ($\beta = -.484, p = .08$) (Gustafsdóttir et al., 2020).

3.3.9 World Health Organization Well-Being Index (WHO-5)

The World Health Organization Well-Being Index (WHO-5) is a commonly used non-invasive questionnaire that evaluates subjective psychological well-being through five questions regarding the respondent's self-reported condition over the last two weeks (Topp et al., 2015). The WHO-5 has been used worldwide since 1998 and validated across several languages and nations (Topp et al., 2015), including Iceland (Guðmundsdóttir et al., 2014).

Responses to each of the five item enquiries on psychological well-being in the last two weeks are rated on a scale from 0 to 5, yielding a total possible score of 25 points. Multiplying the raw score of WHO-5 by four yields a well-being range from 0 (absence of well-being) to 100 (optimal well-being). A score below 50 signifies diminished psychological well-being, whereas a score of 28 or lower indicates depression (Topp et al., 2015). Research has indicated that the WHO-5 questionnaire can be used for depression screening and as an outcome measure in clinical trials (Topp et al., 2015). The questionnaire has been evaluated both for people with diseases, including diabetes, and in Iceland also for the general population (Guðmundsdóttir et al., 2014).

3.3.10 Europe Quality of Life 5-Dimension 5-Level Instrument

The Europe Quality of Life Five Dimension Five Level Instrument (EQ-5D-5L) is standardised instrument for assessing health status (EuroQol Research Foundation, 2019). The test comprises two components: a descriptive element with five dimensions (5D) of mobility, self-care, normal activities, pain/discomfort, and anxiety/depression. The dimensions are assessed on five levels (5L): (1) 'no', (2) 'slight', (3) 'moderate', (4) 'severe', and (5) 'unable/extreme' issues, yielding a total of 3125 possible outcomes (EuroQol Research Foundation, 2019).

The outcomes of each dimension are presented as a code. The number 11111 indicates a 'health condition' with no issues across all dimensions, whereas the value 11155 signifies a 'health state' with no problems in the first three dimensions but severe difficulties related to pain/discomfort and anxiety/depression. The EQ-5D-5L instrument was chosen for evaluation of health-related quality of life (HRQoL). Validation of standardisation of the coded outcomes in the evaluation of HRQoL for Iceland was not available when study II was conducted (EuroQol Research Foundation, 2019; Jensen et al., 2023).

The second component of the EQ-5D-5L has a Visual Analogue Scale (EQ-VAS) that assesses self-reported health status on a continuum from 0 (representing the worst conceivable health) to 100 (denoting the finest conceivable health) and was also used (EuroQol Research Foundation, 2019; Jensen et al., 2023).

The EQ-5D-5L is the only instrument, in the studies in this thesis, needing formal approval for use by Euroqol.org. The registration ID for the studies in this thesis is 52451.

3.3.11 The Icelandic Heart Association open access coronary heart disease risk calculator

The Icelandic Heart Association started comprehensive health studies in 1967 and has conducted many prospective studies on the prevalence of coronary heart disorders and death rates of CHD in Iceland (Andersen et al., 2017). One outcome of this scientific work is an online open-access heart disease risk calculator (ICE-HEART) in several languages, enabling calculations of an Icelandic individual's probability of CHD in the next ten years (http://risk.hjarta.is/risk_calculator/) (Aspelund et al., 2007).

The Systematic Coronary Risk Evaluation (SCORE) calculator that was developed by the European Society of Cardiology for estimating CVD risk and CHD risk has been compared to the ICE-HEART, with data from the Reykjavik study (Aspelund et al., 2007).

The ICE-HEART online CHD risk calculator gives an estimated risk for an individual in percentages compared to the same age and gender from the ICE-HEART cohort. Providing an estimate of the probability of developing CHD in the coming 10 years (Aspelund et al., 2007). The calculator includes measures of age (within the range of 35-75 years), height (ranging from 150 to 200 cm), weight (between 45 to 120 kg), systolic blood pressure (ranging from 100 to 200 mmHg), total cholesterol (CHOL) levels (ranging from 4 to 10 mmol/L), high-density lipoprotein (HDL) levels (ranging from .5 to 2.5 mmol/L), and triglycerides (TG) levels (ranging from .5 to 4.5 mmol/L). In addition, the ICE-HEART includes questions of physical activity, smoking patterns, presence of diabetes, and family history of CHD (Aspelund et al., 2007).

3.3.12 The intervention: Guided Self-Determination counselling approach

Several GSD reflection sheets that have been evaluated in research are available (Biener et al., 2025; Lie et al., 2018; Zoffmann et al., 2008). For study III, 16 GSD reflection sheets were used throughout the counselling sections (see appendix IV) and for preparing at home. The reflection sheets used in the counselling sections focus on “*Your life with prediabetes/diabetes*” (GSD-1st counselling time), “*Focus on change*” (GSD-2nd counselling time) and “*Work with change*” (GSD-3rd counselling time); see figure 4.

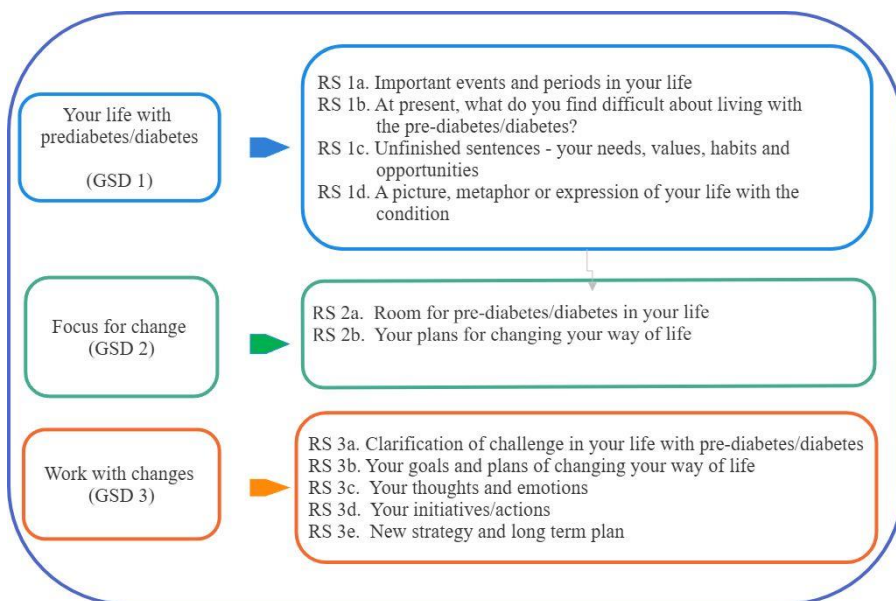


Figure 4: Overview of Guided Self-Determination (GSD) programme reflection sheets used here; GSD encounters 1 to 3, with patients and reflection sheets (RS) used in each encounter (Zoffmann, 2004, Jørgensen, et al., 2014).

The GSD counselling intervention had not been previously employed in Iceland however, the GSD reflection sheets distributed to the intervention participants were previously utilized in a study involving persons at risk of developing T2d and those with manifest T2d in Norway (Graue et al., 2023). The GSD reflection sheets were subsequently translated and back-translated from Norwegian to Icelandic for this research. To evaluate the translation, three patients not participating in the study answered the reflection sheets and gave comments that were considered and refined in the final version of the translation. In each consultation session, participants discussed their own notes in the reflection sheets with the nurse and set their own targets for their health promotion.

Nurses assigned to provide the GSD method attended a one-day workshop in March 2020 at the research centre on providing GSD counselling with PhD B-C.H. Kolltveit, a GSD teacher from Norway. All nurses were working within the three participating PHC clinics. The seminar included ongoing feedback and assessment. The nurses were handed the reflection sheets with questions and prompts, translated from English to Icelandic, for reflection, active listening, and mirroring to use as assistance tools when providing the GSD counselling. The nurses were also provided with a notebook for recording their thoughts and comments throughout the intervention period.

As the COVID-19 pandemic delayed studies I and II, an online meeting was conducted with the GSD teacher, the nurses and the doctoral student prior to starting the intervention to boost their skills in delivering GSD counselling. The GSD intervention began in late December 2021 and finished in April 2022. Throughout the intervention time, the nurses were able to communicate with the PhD student and the GSD teacher via an encrypted Microsoft Teams® channel or telephone. The nurses were also contacted over the research period by the PhD student and asked if they had any queries concerning the delivery of GSD or if they needed any support. Each of a total of three GSD counselling sessions (intervention) lasted roughly 60 minutes, occurring at intervals of 4 to 6 weeks. At the end of each counselling session, participants were advised to finish before the next GSD session the next part of the reflection sheets provided (Zoffmann et al., 2016).

3.4 Data analysis

For all three studies, descriptive statistics were used to describe the continuous variables in the calculation of means, standard deviations and ranges. Counts and proportions were used for categorical variables. Crosstabs were used for relative risk and odds ratio when appropriate. For calculations on characteristics of the sample, like normal HbA1c levels versus prediabetes HbA1c levels in comparing residency or groups, independent t-tests for continuous variables and chi-square tests for categorical variables were used. When comparing residency, results were controlled for age. All results were retested with ANOVA or nonparametric chi-square tests using IBM SPSS 27. For statistics in study III, in addition to SPSS 27, the R version 4.3.1 (2023-07-16 ucrt) was used for mixed ANOVA calculations using Lme4, mixed effect model, rstatix and lemerTest (Pallant, 2020). To calculate the BMI, WHR and, WHtR for each participant, a Microsoft Excel® 7.0 calculator was used. Significant statistical difference (two-tailed) was set as <.005.

For study I, in finding the best cut-off scores of the FINDRISC instrument to find people at prediabetes level and T2d risk, a chi-square test was conducted by dividing the sample into two groups of normal HbA1c level and prediabetes HbA1c level. The accuracy of different cut-off scores of the FINDRISC and the sensitivity and specificity in finding people at the prediabetes level were calculated. The results gave calculations of ROC curves and the area under the curve (AUC) calculations. The area under the ROC curve, or AUC, presents how well a test, *here the risk score of FINDRISC*, is utilizable to differentiate between cases, *here prediabetes or not*, by calculating the highest ROC curve cut-off points results by using different scores on FINDRISC and the results of HbA1c measurements. A perfect accuracy of aROC with neither false positives nor false negatives is reported as “1”, but “.5” indicates the results are no better than chance. The best cut-off points for identifying people with prediabetes biomarkers were

found with calculations of the shortest distance to the upper left corner of the ROC curve (Meijnikman et al., 2016). In study II, dividing participants into two groups according to results of HbA1c of prediabetes level or normal, the BMI, WHR and WHtR were compared using the chi-square test to find people at increased T2d risk. In addition to comparing with the ≥ 11 points of FINDRISC, we looked at how many were to be found at overall increased health risk.

In addition, in study II, to estimate if relationships existed among background factors and HLS-EU-Q16-IS and WHO-5 questionnaires, correlation and regression calculations were performed. As a value set for Quality of Adjusted Life Years (QUALY) calculations are not yet available for Iceland, the EQ-5D-5L is reported as the health state index of each of the five health dimensions from 1 to 5 (EuroQol Research Foundation, 2019).

The analysis of data collected in the RCT, study III, was conducted by using the ICE-HEART online calculator (http://risk.hjarta.is/risk_calculator/). The calculator has defined lower and upper limits of variables. Therefore, if a participant's score level of a variable was outside the ICE-HEART range, the score was automatically adjusted to the highest/lowest applicable score by the calculator (Aspelund et al., 2007). The ICE-HEART calculator presents the estimated outcome of CHD risk for each individual in percentages, compared to the same age and gender CHD risk. Therefore, when calculating the risk of participants of different ages and genders and comparing changes in the ICE-HEART risk of the intervention group to the control group in study III it was required that each individual's calculated risk was divided with the risk of the same age and gender risk from the ICE-HEART cohort, enabling comparison of combined outcomes between the intervention and control groups. Thereby reporting the outcome as the ratio of each participant's risk to same age and gender of the ICE-HEART cohort, with an outcome of <1 as lower CHD risk, 1 as the same CHD risk and >1 as higher CHD risk. This facilitated an analysis of changes in CHD risk across measurement periods both within and between groups.

Every participant's result required manual input into the ICE-HEART risk calculator. Therefore, the result of each participant's ICE-HEART risk was verified twice to avoid any potential input mistakes. The alterations in CHD risk among the research participants were evaluated from Time 1 to Time 3. This facilitated the computation of the "control event risk" (CER), "experimental event rate" (EER), and therefore the "absolute risk reduction" (ARR) via the formula $CER - EER = ARR$. The "Number Needed to Treat" (NNT) for a positive outcome is determined by the "Absolute Risk Reduction" (ARR). The "Relative Risk" (RR) was calculated by dividing the likelihood of an undesirable result in the intervention group by the probability of an unfavourable outcome in the control group. The "Relative risk reduction" (RRR) estimates the degree to which an intervention diminishes the likelihood of adverse outcomes in comparison to a control group (Ranganathan et al., 2016). The lack of any alteration in CHD risk

between Time 1 and Time 3 was deemed an unfavourable outcome. The objective was to mitigate risk, and stating no change as negative was regarded as a more prudent and conservative method of presenting the outcomes of this RCT. The groups were analysed by chi-squared calculations, and variations in risk between measurements were assessed using crosstabs for “odds ratio” (OR), relative risk (RR), and the “Number Needed to Treat” (NNT) calculations.

For study III, the general linear model of repeated measurements was used to calculate the interaction between and within groups of changes throughout time. Due to the potential sensitivity of small sample sizes to sphericity, a mixed ANOVA was added in analysing the data (Pallant, 2020).

The changes of RR for CHD were the primary outcome for the RCT. That enabled comparisons of changes in CHD risk of participants of different ages and genders, within and between intervention and control groups. Calculations of relative risk (RR) of each participant compared to the same age and gender were done for each measurement, using the ICE-HEART CHD risk online calculator (Aspelund et al., 2007).

All data was collected and analysed by the PhD student, and results were reviewed by the supervisors and statisticians when applicable. For the mixed ANOVA calculation, the statistics calculator R version 4.3.1 (2023-07-16 ucrt), using rstatix, lme4, mixed effect model and lemerTest, was performed by a second statistician, from the research centre of the University of Akureyri, to verify results. Missing data, if applicable, was excluded list-wise.

3.5 Ethical consideration

The overall studies were approved by the Icelandic National Bioethics Committee (VSN) (VSN-19-080-S1 approved 14/05/2019 and VSN-19-080-V1 approved 14/01/2020) and performed in accordance with the Helsinki Declaration (Shrestha & Dunn, 2019). The studies were also approved by the senior management of HSN.

In addition, the RCT was registered at www.ClinicalTrials.gov (NCT04688359) and approved on 29th December 2020. It is titled ‘Effectiveness of Nurse-coordinated Follow-Up Programme in Primary Care for People at Risk of T2d’. The CONSORT 2010 criteria were utilized for reporting the RCT, in study III (Schulz, 2010).

Participants received, before participating in the studies, a verbal and written information letter. All participants signed an informed consent form prior to participation. See further appendices I and II.

4 Results

4.1 Background information: Studies I and II

A total of 220 individuals participated in studies I and II. The inclusion criteria were being 18-75 years old and speaking either Icelandic or English. The exclusion criterion was being diagnosed with diabetes. For the people applying for participation, one did not fulfil the inclusion criteria of age, and one had a T2d diagnosis. enquiring to join the study I measurements, both were excluded and not counted as participants. However, both were offered and received measurements of HbA1c.

Studies I and II are built on the same database. Study I looked at the data from the perspective of the gender of participants, and study II analysed data from the perspective of residency.

Women ($n=145$) were 65.9%. The mean age was 52.1 ($SD\pm 14.1$) years. In study II, gender distribution between countryside and town was nearly equal, but mean age was significantly lower ($p < .001$) for the town, 48.9 ($SD\pm 14.3$) years versus 55.3 ($SD\pm 13.2$) years.

Nearly an equal number of participants in the dataset of studies I and II came from the town area of Akureyri ($n = 109$, 49.5%) and from the countryside areas (50.5%). From Húsavík came 18.2%, and 32.3% came from Sauðárkrókur. No significant difference was found in the living status nor occupational status according to gender nor residency.

The educational level was high, with almost half of participants with university degrees (45.9%), and 79.1% were working part- or full-time. In study II the town residents had a higher level of education ($p = .049$).

Background information according to residency is shown in Table 2.

Table 2: Background information according to residency

	Countryside		Town		<i>p</i>
	(N=111)		(N= 109)		
	<i>n</i>	(%)	<i>n</i>	(%)	
Gender					<i>p</i> = .602**
Male	36	(32.4)	39	(35.8)	
Female	75	(67.6)	70	(64.2)	
Age					
<45 years	19	(17.1)	35	(32.1)	
45-54 years	29	(26.1)	30	(27.5)	
55-64 years	31	(27.9)	25	(22.9)	
65 years and older	32	(28.8)	19	(17.4)	
Mean age in years (<i>M</i>)	55.3	(<i>SD</i> ±13.2)	48.9	(<i>SD</i> ±14.3)	<i>p</i> < .001*
Living status					<i>p</i> = .784**
Living alone	7	(6.3)	10	(9.2)	
Living with one other person	55	(49.5)	46	(42.2)	
Living with two or more persons	49	(44.1)	53	(48.6)	
Educational level					<i>p</i> = .049**
Elementary school/junior high school or equal	31	(27.9)	21	(19.3)	
Upper secondary school/vocational training/- - senior high school or equal	35	(31.5)	30	(27.5)	
University degree	44	(39.6)	57	(52.3)	
Educational level missing	1	(0.9)	1	(0.9)	
Occupational status					<i>p</i> = .632**
Working partly or full time	84	(75.7)	81	(74.3)	
Unemployed	2	(1.8)	4	(3.7)	
Pensioner (disabled/elderly pensioner)	20	(18.0)	13	(11.9)	
Other***/did not answer	5	(4.5)	11	(10.1)	

*Independent *t*-test. ** Chi-square test. *** Participants who marked multiple on the other three groups

4.2 HbA1c level studies I and II

Table 3 presents the HbA1c levels. Levels varied between 24 and 47 mmol/mol. No participants were identified with HbA1c levels indicative of diabetes of ≥ 48 mmol/mol. A total of 29 participants (13.2%) were identified as having prediabetes according to the ADA definition, with measurements ranging from 39 to 47 mmol/mol. Among these, 15 were women and 14 were men. The normal HbA1c group had a mean level of 33.8 mmol/mol (*SD*±2.7). Participants with prediabetes exhibited a mean HbA1c level of 41.5 mmol/mol (*SD*±2.2). No significant difference in HbA1c levels was found between genders; however, a trend indicating higher HbA1c levels in men was noted (*p* = .056).

Table 3: Participants' HbA1c level in study I according to gender, number and (percentage)

HbA1c Level mmol/mol	Total		Women		Men	
	<i>n</i>	(%)	<i>n</i>	(%)	<i>n</i>	(%)
24-38	191	(86.8)	130	(89.7)	61	(81.3)
39	5	(2.3)	3	(2.1)	2	(2.7)
40-41	12	(5.5)	3	(2.1)	9	(12.0)
42-47	12	(5.5)	9	(6.2)	3	(4.0)
Lowest level				25		24
Mean level (<i>M</i>)			34.44 (<i>SD</i> ±3.55)		35.48 (<i>SD</i> ±3.92)	

When looking at HbA1c according to residency, in study II, 100 (90.1%) of countryside and 91 (83.5%) of town participants presented with a normal HbA1c level of 24-38 mmol/mol. However, a significant difference was found in the higher mean score for town 35.3 mmol/mol (*SD*±4.0) versus countryside 34.2 mmol/mol (*SD*±3.4), $p = .048$. Of those living in town, 18 participants, or 16.5%, were found at the prediabetes level, but only 11 participants (9.9%) were living in the countryside.

4.3 The FINDRISC score studies I and II

Results of the FINDRISC scale are reported in Table 4 according to gender. No significant gender difference was found in mean score, as for men it was 9.0 (*SD*±5.3) and for women 9.7 (*SD*±4.9), $p = .332$. Of the participants, one in five (21.4%) had a first-degree relative with T2d. A significant difference between genders was found in daily consumption of fruit and vegetables in favour of women ($p = .004$).

Table 4: FINDRISC risk score according to gender

Questions on FINDRISC	Scoring Points (P)	Overall (N=220) <i>n</i> (%)	Gender		<i>p</i>
			Women (N=145) <i>n</i> (%)	Men (N=75) <i>n</i> (%)	
Q1. Age					<i>p</i> = .982
18–44 years	(0 P)	56 (25.5)	38 (26.2)	18 (24.1)	
45–54 years	(2 P)	56 (25.5)	37 (25.5)	19 (25.3)	
55–64 years	(3 P)	55 (25.0)	36 (24.8)	19 (25.3)	
65 years and older	(4 P)	53 (24.1)	34 (23.5)	19 (25.3)	
Q2. BMI					<i>p</i> = .838
< 25 kg/m ²	(0 P)	58 (26.4)	37 (25.5)	21 (28.0)	
25–30 kg/m ²	(1 P)	86 (39.1)	56 (38.6)	30 (40.0)	
≥ 30 kg/m ²	(3 P)	76 (34.5)	52 (35.9)	24 (32.0)	
Q3 Waist Circumference (2cm above navel)					NA
Men < 94 cm/Women < 80 cm	(0 P)	63 (28.6)	33 (22.8)	30 (40.0)	
Men 94–102 cm/Women 80–88 cm	(3 P)	49 (22.3)	35 (24.1)	14 (18.7)	
Men > 102 cm/Women > 88 cm	(4 P)	108 (49.1)	77 (53.1)	31 (41.3)	
Q4 Physically active ≥ 30 min/daily					<i>p</i> = .672
Yes	(0 P)	203 (92.3)	133 (91.7)	70 (93.3)	
No	(2 P)	17 (7.7)	12 (8.3)	5 (6.7)	
Q5 Fruit & vegetables daily					<i>p</i> = .004*
Every day	(0 P)	140 (63.6)	102 (70.3)	38 (50.7)	
Not every day	(1 P)	80 (36.4)	43 (29.7)	37 (49.3)	
Q6 Use of blood pressure medicine					<i>p</i> = .085
No	(0 P)	165 (75.0)	114 (78.6)	51 (68.0)	
Yes	(2 P)	55 (25.0)	31 (21.4)	24 (32.0)	
Q7 History of high blood glucose (including gestation diabetes)					<i>p</i> = .13
No	(0 P)	192 (87.3)	123 (84.8)	69 (92.0)	
Yes	(5 P)	28 (12.7)	22 (15.2)	6 (8.0)	
Q8 Family history of diabetes					<i>p</i> = .743
Non	(0 P)	138 (62.7)	90 (62.1)	48 (64.0)	
First degree relatives	(3 P)	47 (21.4)	30 (20.7)	17 (22.7)	
Second degree relatives	(5 P)	35 (15.9)	25 (17.3)	10 (13.3)	
FINDRISC Score total					<i>p</i> = .733
	≤ 8	104 (47.3)	67 (46.2)	37 (49.4)	
	9–11	43 (19.5)	27 (18.6)	16 (21.3)	
	12–14	39 (17.7)	26 (17.9)	13 (17.3)	
	15–20	27 (12.3)	21 (14.5)	6 (8.0)	
	21–26	7 (3.2)	4 (2.8)	3 (4.0)	

*Significant (two-tailed) at the < .05 level Independent *t*-test

On FINDRISC, 92.3% reported daily exercise. Those found with the HbA1c prediabetes biomarker were less likely to exercise ($t_{(218)} = 2.07$, $p = .04$ (two-tailed)). 62.7% had no family history of diabetes, 21.4% had a history of T2d by second relatives and 15.9% by first relatives. The independent *t*-test results on FINDRISC total scores by residence indicated a tendency towards a higher mean score in the countryside, with a mean of 10.1($SD\pm 4.5$) compared to 8.8($SD\pm 5.5$), $p = .056$. Notably, 16.5% of town inhabitants compared to 9.9% of the countryside had the HbA1c biomarker indicative of prediabetes, with town residents demonstrating a significantly higher mean HbA1c score ($p = .048$).

A significant difference was found between people at normal HbA1c level ($n=191$) and people at prediabetes HbA1c level ($n=29$), with FINDRISC scores of 8.6 ($SD\pm 4.5$, range 0-22) points versus 14.7 ($SD\pm 5.2$, range 3-24) points ($p < .001$). This made grounds for using the HbA1c level of prediabetes versus non-prediabetes as the criteria for evaluation of the sensitivity and specificity of the FINDRISC instrument and the best cut-off point for finding individuals at T2d risk in Iceland.

The FINDRISC points were utilized as the outcome, with the HbA1c level of prediabetes versus non-prediabetes serving as the criteria for evaluation of sensitivity and specificity of the FINDRISC. Of the total number of participants ($n=220$), 191 were defined as true negative with HbA1c below 39 mmol/mol. All others ($n=29$) who presented HbA1c ≥ 39 mmol/mol were defined as true positive at the prediabetes level according to the ADA standard. Figure 5 presents the results of FINDRISC sensitivity and specificity calculations using HbA1c of ≥ 39 mmol/mol as evaluation criteria.

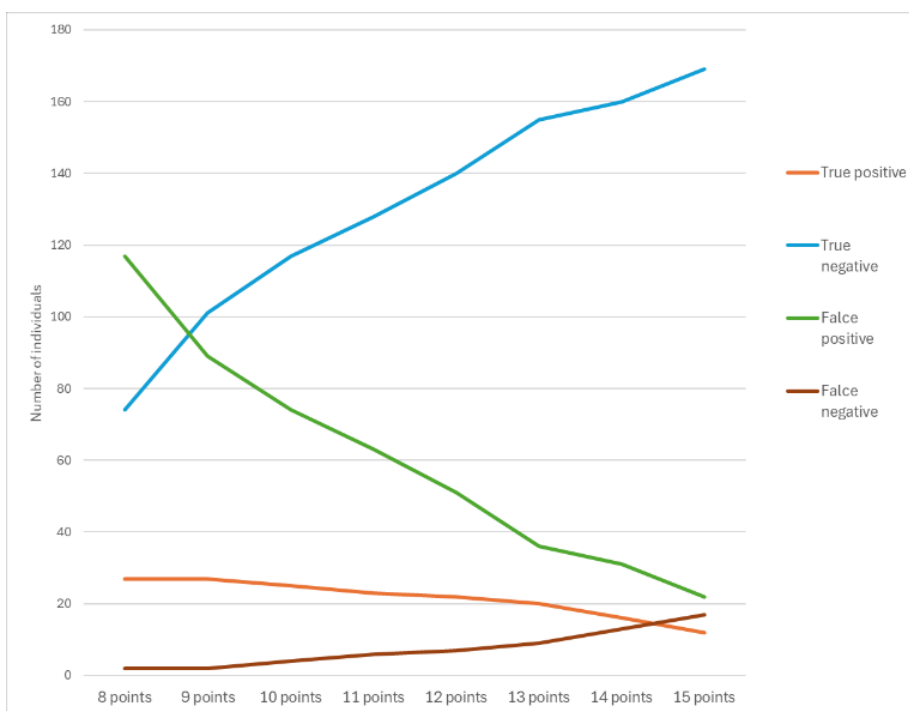


Figure 5: Using HbA1c as criteria for evaluation of FINDRISC sensitivity at different cut-off scores in finding people at the level of prediabetes biomarker on FINDRISC. Showing numbers of true positive and true negative individuals at cut-off points of 8 through 15 points.

The optimal sensitivity of FINDRISC was 93.1% at a threshold of ≥ 9 points, successfully identifying 27 out of 29 participants with HbA1c levels indicative of

prediabetes; however, the specificity was relatively low at 53.4%. The application of cut-off values of ≥ 11 or ≥ 12 points resulted in slightly reduced sensitivity (79.3% and 75.9%, respectively) while improving specificity (67% and 73.3%, respectively), leading to a decrease in false positives. The application of ≥ 15 points on FINDRISC yielded a sensitivity of 41.4%, thereby failing to identify over half of participants with a prediabetes HbA1c value, despite achieving a high specificity of 88.5%.

The use of ≥ 11 points as a cut-off value for FINDRISC resulted in an ROC curve analysis revealing an area under the curve (AUC) of .814; see figure 6. The 95% confidence interval (CI) ranged from a lower bound of .733 to an upper bound of .895, with a standard error (SE) of .041.

The findings demonstrated that the optimal accuracy for identifying individuals with prediabetes in North Iceland was a FINDRISC score of ≥ 11 points, which corresponded to the value nearest to the upper left corner of the ROC curve.

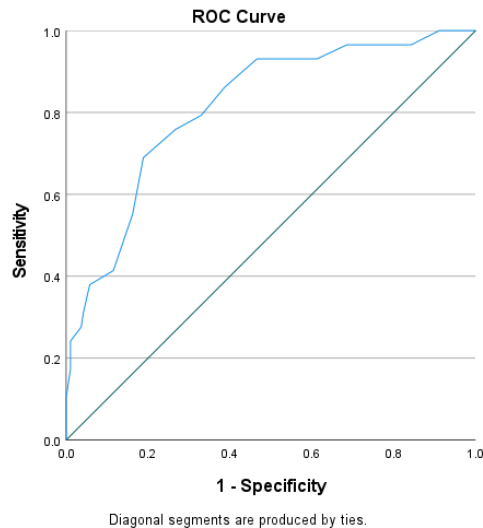


Figure 6: Area under the curve, ROC curve for sensitivity and specificity of FINDRISC from zero to 26 points, using HbA1c as criteria for evaluation

4.4 Body Mass Index studies I and II

No participant was found to be underweight. The BMI values ranged from 18.5 to 48.2 kg/m², with a mean of 28.8 ($SD\pm 5.4$) and a median of 27.7 kg/m². Results indicated that 39.1% of total participants were classified as overweight (25–30 kg/m²). While obesity (≥ 30 kg/m²) was observed in 34.5%. Additionally, 5%

of participants exhibited severe obesity with a BMI exceeding 40 kg/m²; see figure 7.

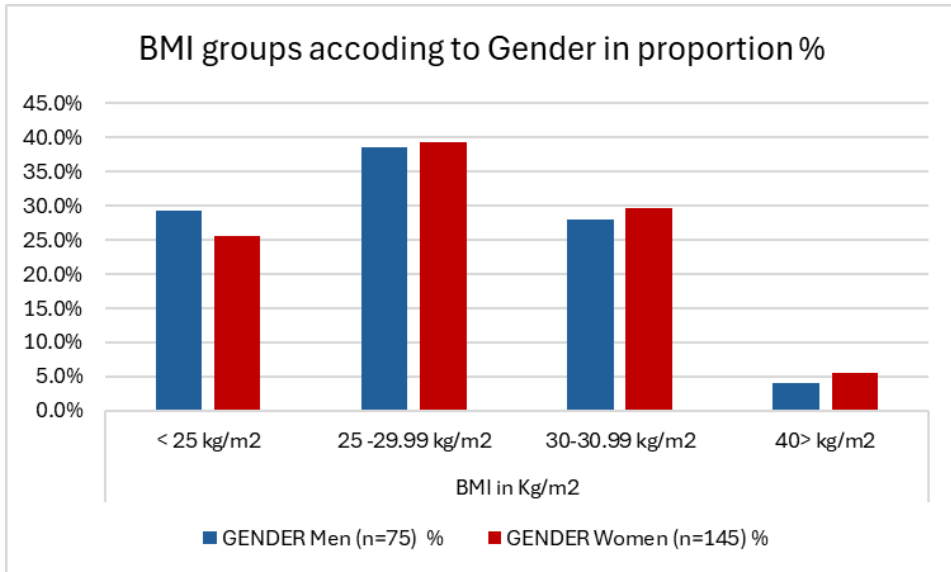


Figure 7: BMI groups according to gender, proportion %

No significant difference in BMI was observed with respect to gender ($p = .982$). However, when comparing the countryside to town residence, 78.4% of countryside versus 67.9% of town residence were overweight or obese, indicating a tendency to more obesity in the countryside, with an independent t -test, $M = 29.5$ ($SD \pm 5.5$) and $M = 28.1$ ($SD \pm 5.2$), $p = .053$.

Of the 29 participants with prediabetes, the BMI scores varied from a minimum of 24.4 kg/m² to a maximum of 48.2 kg/m², with a mean of 32.3 kg/m² ($SD \pm 5.7$). The BMI scores of the participants ($n=191$) without elevated HbA1c levels ranged from 18.5 kg/m² to 43.6 kg/m², with a mean of 28.3 kg/m² ($SD \pm 5.2$). The normal HbA1c group had a significantly lower BMI than the prediabetes biomarker HbA1c group, $M = 32.3$ ($SD \pm 5.7$); $t_{(218)} = -3.618$, $p < .001$.

A significant positive correlation existed between BMI and HbA1c levels among all participants. $R_{(218)} = .146$, $p = .044$. An aROC of the BMI calculation using HbA1c as a definition of prediabetes gave a result of an aROC of .713, $p < .001$ (CI .624-.803) sensitivity of 96.6% and specificity of 69.1% at a BMI of 25.0 kg/m².

4.5 Waist-to-Height and Waist-to-Hip: Results of Study II

Health risk evaluations revealed differences between countryside and town residents when utilizing either the Waist-to-Hip Ratio (WHR) or Waist-to-Height Ratio (WHtR); see Table 5. Among the prediabetes biomarker cohort, 89.7% were classified within the higher health risk WHR group, a classification that also applied to 62.3% of participants in the normal HbA1c group. Applying the WHtR calculations indicated that 93.1% of the HbA1c prediabetes biomarker group were classified at moderate to high health risk. The WHtR indicated 64.4% of participants with normal HbA1c at higher health risk, finding more people at risk than the WHR.

Table 5: HbA1c levels, FINDRISC score, BMI, WHtR, and WHR according to residency

Defined as	Countryside		Town		<i>p</i> -value Countryside/Town
	<i>n</i>	(%)	<i>n</i>	(%)	
HbA1c levels					
Mean (SD)	34.3 (SD±3.4)		35.3 (SD±4.0)		<i>p</i> = .048 *
24–38 mmol/mol	Normal	100 (90.1)	91 (83.5)		
39–47 mmol/mol	Prediabetes	11 (9.9)	18 (16.5)		
FINDRISC score					
Mean (SD)	10.1 (SD±4.5)		8.8 (SD±5.5)		<i>p</i> = .056 *
<11 points		62 (55.9)	72 (66.1)		<i>p</i> = .121 †
≥11 points		49 (44.1)	37 (33.9)		
BMI kg/m²					
Mean (SD)	29.5 (SD±5.5)		28.1 (SD±5.2)		<i>p</i> = .053 *
18–24.99	Normal	24 (21.6)	35 (32.1)		
25–29.99	Overweight	46 (41.4)	40 (36.7)		
30–39.99	Obese	33 (29.7)	31 (28.4)		
40>	Severely obese	8 (7.2)	3 (2.8)		
WHtR					
<0.5	No increased risk	22 (19.8)	48 (44.0)		<i>p</i> < .001 †
≥0.5 and <0.6	Increased to high risk	59 (53.2)	33 (30.3)		
≥0.6	Very high risk	30 (27.0)	28 (25.7)		
WHR					
♂ < 0.94 ♀ < 0.80	Low health risk	24 (21.6)	50 (45.9)		<i>p</i> < .001 †
♂ ≥ 0.94 ♀ ≥ 0.80	Higher health risk	87 (78.4)	59 (54.1)		

* Independent *t*-test, † Chi-square test, ♂ men, ♀ women.

Among participants identified as having an elevated overall health risk according to WHtR, 92.3% reported engaging in daily exercise on FINDRISC. Participants identified with HbA1c prediabetes biomarker exhibited a lower likelihood of engaging in exercise $t_{(218)} = 2.07, p = .04$, two-tailed. The calculation of the area under the receiver operating characteristic (aROC) curve, based on low or high health risk as determined by WHR, aimed to identify participants at prediabetes biomarker levels of HbA1c. The aROC was found to be .654 (CI .563–.745), with a sensitivity of 93.1% and a specificity of 62.3% ($p = .008$). The WHtR threshold

of .5 indicates an elevated health risk, supported by an area under the receiver operating characteristic curve (aROC) of .759 (95% CI .668–.851), $p < .001$, with a sensitivity of 93.3% and a specificity of 63.1%.

The odds ratio for the HbA1c biomarker indicative of prediabetes was determined to be 7.46 times higher in participants with a high-risk WHtR value compared to those with a low-risk value, with a 95% CI of 1.72 to 32.35 and a p -value of .002.

Among the 59 participants with normal HbA1c levels, a BMI >25 kg/m² and a score ≥ 11 points on FINDRISC, the WHR risk grouping classified 54 participants as having an overall higher health risk. WHtR indicated that all 59 participants exhibited an elevated overall health risk.

Analyses of WHtR and HbA1c results by gender revealed that 92.9% of men and 93.3% of women with the HbA1c prediabetes biomarker exhibited a WHtR score suggesting an elevated overall health risk.

Analyses of FINDRISC, with a cut-off point of ≥ 11 points, indicated that at the time of measurement 86 participants (39.1%) were at an increased risk for diabetes in the next ten years, thereof 23 at the prediabetes level and 63 at the normal HbA1c level. Where the WHtR identified 68.2% of participants as having an overall increased health risk at the time of measurement.

4.6 Health Literacy, Wellbeing and Health Related Quality of life instruments, study II

Health literacy among participants was high. With the mean score of 14.5 ($SD \pm 2.3$) for countryside and 14.8 ($SD \pm 1.7$) for town residents. Only one in each group (.9%) had an inadequate HL score. A sufficient score of 13-16 points was presented by 74.8% of country residents and 85.4% of town residents, but a problematic score was presented by 18% for the countryside and 11.9% for the town. Missing scores/insufficient answers were 6.3% and 1.8% for countryside and town, respectively. The difference of HL using the HL-Q16IS between countryside and town failed to show a significant difference ($p = .276$ (2-tailed)). Neither gender nor living status nor occupational status influenced the outcome of HL-Q16IS.

Several participants hesitated while responding to the HL instrument, indicating that certain items were not relevant to their experiences. Specifically, they noted that they had never encountered the situations described in Question 3: ‘*Understanding what your doctor says to you*’, Question 5: ‘*Judge when you may need to get a second opinion from another doctor*’, and/or Question 11: ‘*Judge if the information on health risk in the media is reliable*’. Some expressed verbally, “...*That is likely not an issue...*”

On the well-being index WHO-5, the countryside had a slightly higher mean score, but the standard deviation for both groups was high, and a significant difference was not found between the countryside and the town $M = 66.2$ ($SD \pm 24.7$) and $M = 60.9$ ($SD \pm 26.7$) respectively, $p = .140$. A total score of 50-100 points was 70.3% for countryside and 59.6% for town residence; 16.2% of countryside and 22.1% of residents of town scored 28-49 total points, indicating signs of depression. Of countryside residents, 9% scored under 28 points, and so did 11.9% of town residents; missing answers totalled of 12, 4.5% for countryside and 6.4% for town.

Results demonstrated a markedly elevated mean score for the prediabetes biomarker group ($M = 72.71$, $SD \pm 24.4$), in contrast to the normal HbA1c group ($M = 62.1$, $SD \pm 25.8$), $t_{(206)} = -2.035$; $p = .043$. Men demonstrated a significant difference in higher scores on the WHO-5, with $M = 68.8$ ($SD \pm 25.0$) compared to women with $M = 60.7$ ($SD \pm 25.9$), ($t_{(206)} = 2.161$, $p = .032$). A significant positive correlation was shown between WHO-5 scores and age, with $R_{(208)} = .273$ (CI .142–.39), $p < .001$.

Results of the reported health state of the EQ-5D-5L according to residency are reported in Table 6 and figures 8 to 12. As a “health state” represents answers to each of the 5 questions behind the five dimensions on the EQ questionnaire read from left to right. Where the number represents the answer to each dimension from no problem (1) to unable to do (5). Health state 11115 thereby indicates answers of the first level of no problem in the physical dimension but at the fifth level as substantial problems in the mental dimension.

Here the EQ-5D-5L data is presented for the predominant health state among participants in study II, categorised by residence, along with pie charts illustrating each dimension for the overall sample in Table 6 and figures 8-12.

Table 6: Health state results according to residency of the EQ-5D-5L

Health state	Town (N=109)		Countryside (N=111)	
	n	(%)	n	(%)
11111	36	(33.0)	22	(19.8)
11112	4	(3.7)	7	(6.3)
11121	20	(18.3)	26	(23.4)
11122	14	12.8)	19	(17.1)
11123	6	(5.5)	3	(2.7)
11131	4	(3.7)	5	(4.5)
21121	2	(1.8)	4	(3.6)
All other (49 groups)	23	(21.1)	25	(22.5)

Results from the EQ-5D-5L indicated that most participants reported no issues (Level 1) with mobility (84.1%), self-care (96.4%), and usual activities (87.7%). Only 31.8% reported no issue (Level I) with pain or discomfort, and 60% indicated no issue regarding anxiety or depression. For pain/discomfort, a level of 3 to 5 was reported by 41 participants (18.6%), and 22 (10%) reported a level of 3 to 5 for anxiety/depression. Answers to each dimension of the total sample are reported in figures 8-12.

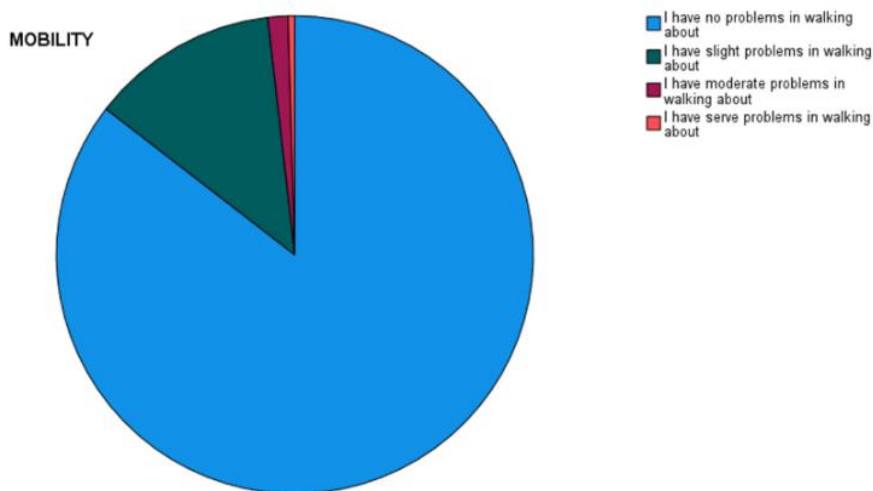


Figure 8: Total score on the Mobility dimension

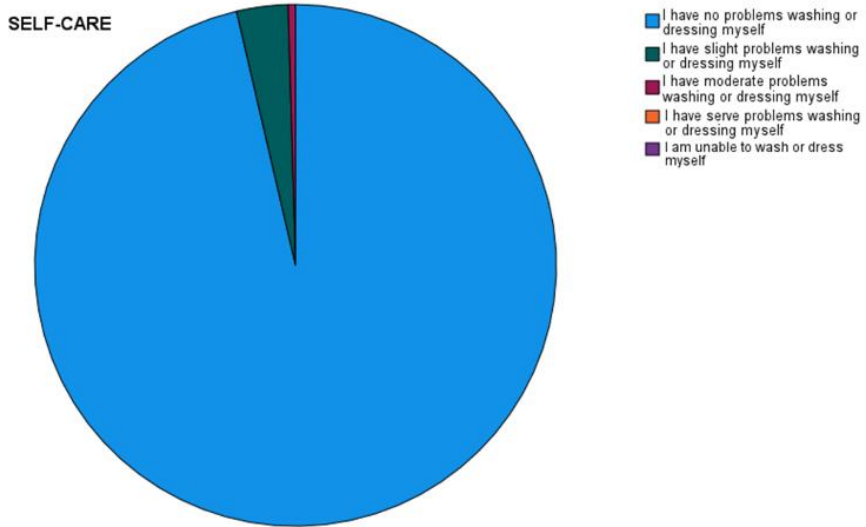


Figure 9: Total score on Self-care dimension

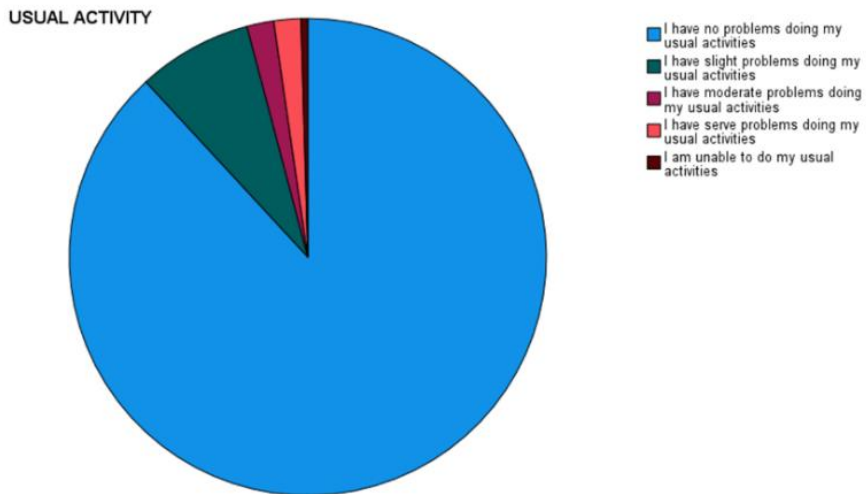


Figure 10: Total score on the Usual activity dimension

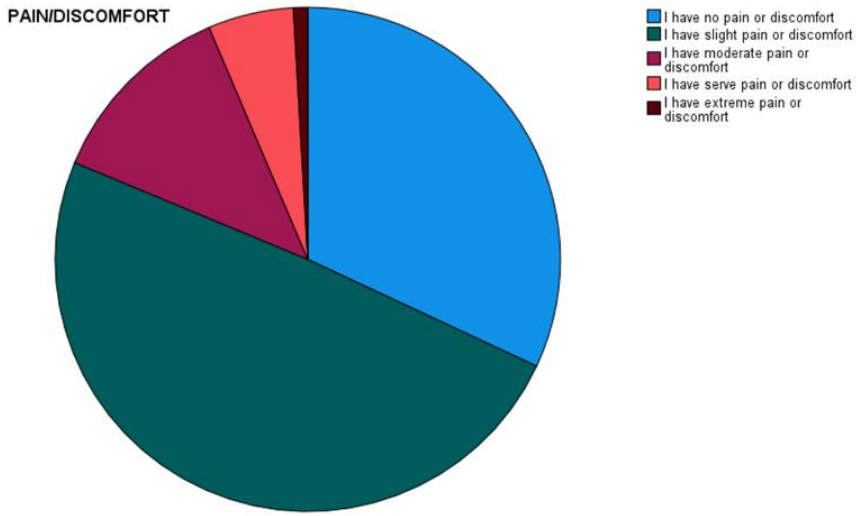


Figure 11: Total score on the Pain/Discomfort dimension

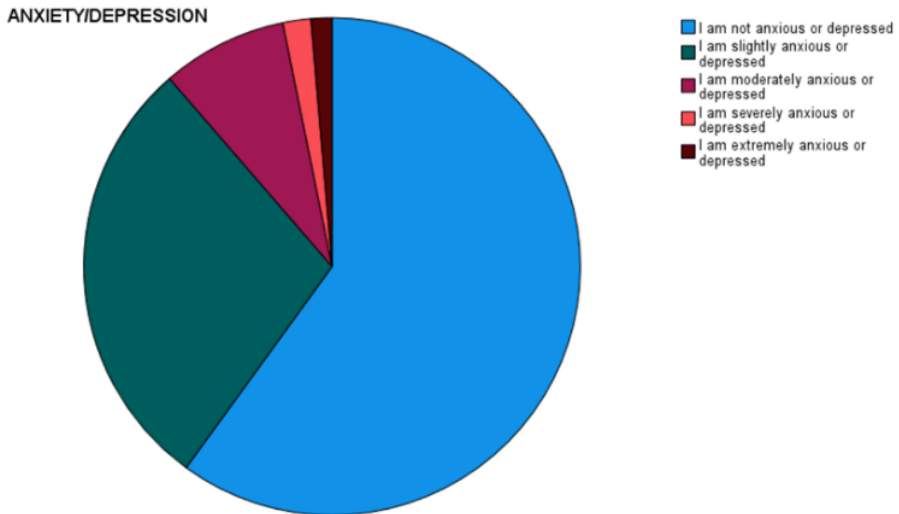


Figure 12: Total score on the Anxiety/Depression dimension

No significant correlation was found between the dimensions of mobility and anxiety/depression ($p = .125$), nor between the dimensions of self-care and anxiety/depression ($p = .991$). Other dimensions exhibited a correlation with one another at the $p < .001$ level.

A negative correlation was observed between anxiety/depression and the total score on the WHO-5 Well-Being Index; lower levels of anxiety/depression were associated with lower scores on the WHO-5 well-being ($p < .001$).

The EuroQol Visual Analogue Scale (EQ-VAS) scores demonstrated a significant correlation with all dimensions of the EQ-5D-5L ($p < .001$). The EQ-VAS scoring indicated that residency ($p = .320$), gender ($p = .726$), or HbA1c level of prediabetes ($p = .255$) did not impact the EQ-VAS score. The EQ-VAS scoring scale results are shown in Table 7.

Table 7: Scoring on the EQ-VAS scale according to residency

EQ-VAS scoring 0–100	Countryside ($N = 111$)		Town ($N = 109$)		p value [‡]
	n	(%)	n	(%)	
Mean (SD)	81.0	(SD±17.9)	83.2	(SD±14.8)	$p = .32$
<70	19	(17.1)	12	(11.0)	
70–89	45	(40.5)	40	(36.7)	
90–100	47	(42.3)	57	(52.3)	

[‡] Independent t -test.

Scoring on the best number describing one’s health on the day of participation indicated that most participants scored close to the best possible health, with a median of 85 for the total population and no significant difference according to residency.

4.7 Results of the RCT, Study III

4.7.1 Allocation criteria of study III

A total of 81 met the specific requirements for inclusion in the RCT out of a total of 220 participants in study I. Assigned to the intervention (I) group were 42 and 39 in the control I group. Participation at baseline (Time 1) measurements was 34 (81%) in the intervention group and 30 (76.9%) in the control group. The greatest number of dropouts transpired after the measurements for studies I and II and Time 1 (baseline), exhibiting a dropout rate of 8% in the intervention group and 9% in the control group. The dropout rate from Time 1 to Time 3 was 17.5% in the intervention group and 6.7% in the control group, as illustrated in the flow chart in Figure 13.



Figure 13: Flow Chart of Participation in the RCT Trial in North Iceland

Four participants withdrew from the study. They reported voluntarily, their reasons for withdrawal. One in the control group gave the reason of the ongoing COVID-19 epidemic. In addition, one from the intervention group and two from the control group gave the diagnosis of T2d as their reasons.

4.7.2 Participants of the RCT and background information

Of the 81, 64 showed up at the Time 1 (baseline) measurement. Dropout was higher amongst the male participants. A total of 56 participants completed the intervention and all measurements, an equal number in each group of 28 participants that are included in the results. Of the total participants, 71.4% were female, but both groups had equal numbers of males ($n=8$) and females ($n=20$). The difference found between the intervention and control groups prior to intervention was not significant (*chi-square test*), according to background information at Time 1; see further in Table 8.

Table 8: Background information of the RCT participants completing all measurements

		Intervention group ($n=28$)	Control group ($n=28$)	p value*
		n	n	
Age*	Mean** (SD)	55.7(\pm 11.8)	57.2(\pm 9.4)	$p = .601$
	< 50 years	8	6	
	50–59 years	7	11	
	60–69 years	9	8	
	70–75 years	4	3	
Weight (kg)	Mean** (SD)	99.03 (\pm 16.34)	98.15 (\pm 16.70)	$p = .842$
Coronary-CHD history by family member				$p = .105$
	Yes	9	15	
	No	19	13	
Educational level*				$p = .055$
	Elementary /junior high	8	7	
	Upper secondary school/vocational training	11	4	
	University degree	9	17	
Occupational status*				$p = .572$
	Working part or full time	18	22	
	Unemployed	1	1	
	Pensioner (disabled/elderly)	7	3	
	Other or did not answer	2	2	

* *Chi-square test* ***Independent t test*

Of the inclusion criteria, of FINDRISC score ≥ 9 , in addition to HbA1c >40 mmol/mol and/or BMI ≥ 30 , no significant difference was found between intervention and control groups according to the independent *t*-test. The mean score on FINDRISC for the intervention group was 13.7 (± 3.4) and 14.8 (± 4.0) for the control group, $p = .253$. BMI values of 25-30 kg/m² had two participants in the intervention group and four in the control, but all others had a BMI value of ≥ 30 kg/m² with the mean score of 33.9 kg/m² ($SD \pm 4.0$) and 34.2 kg/m² ($SD \pm 4.5$) for the intervention and control, respectively. The HbA1c mean score was normal in both groups: I: 36.2 mmol/mol ($SD \pm 4.5$) and C: 36.5 mmol/mol ($SD \pm 4.1$), $p = .78$.

Mean age in the intervention group was 55.7 ($SD \pm 11.8$) and 57.2 ($SD \pm 9.4$) for the control group. The majority of both groups had a high educational level and

were employed. Only one was a current smoker; five in each group had stopped smoking. Although CHDs were more common in the control group, the difference was non-significant.

For the WHR ratio, four participants in the intervention group and one in control showed low health risk ($p = .16$), but all participants except one in the intervention group were, according to WHtR, at increased health risk of $\geq .5$.

4.7.3 Primary outcomes of the ICE-HEART calculator

In this RCT no statistically significant change in CHD risk in the next 10 years was detected between groups over the research period from Time 1 to Time 3 using the ICE-HEART calculator.

A mixed ANOVA revealed that the assumption of homogeneity of variance (Levene's test) was met; however, the data exhibited non-normal distribution because of three extreme values. The only variable that significantly influenced the mixed-effect model was family history. Therefore, it cannot be concluded that the GSD intervention, provided over three brief consultations, reduced the risk of CHD in this small cohort that completed the RCT. At Time 1, the risk of CHD for each participant in this RCT ranged from .1% to 25.3%. The computed CHD risk for individuals in the ICE-HEART cohort, matched for age and gender, ranged from .1% to 7.3%. Presented in Table 9 and Figure 14 are the results of comparing the calculated mean 10-years CHD risk by the same age and gender as of the ICE-HEART cohort and the intervention and control groups calculated mean CHD risk in the next ten years at Times 1, 2 and 3.

Table 9: Results of calculated mean CHD risk in the next 10 years from Times 1, 2 and 3 compared to the calculated mean risk found for the same age and gender in the ICE-HEART cohort

Mean CHD risk* (\pm SD)	Intervention group ($n=28$)	Control group ($n=28$)	p -value**
ICE-HEART Risk: for same age and gender	2.40 ($SD \pm 2.45$)	2.42 ($SD \pm 2.10$)	$p = .98$
Participants ($N=56$) Time 1: Baseline	3.29 ($SD \pm 2.38$)	3.39 ($SD \pm 1.81$)	$p = .86$
Participants ($N=56$) Time 2: 6 months	2.96 ($SD \pm 2.39$)	3.71 ($SD \pm 2.80$)	$p = .28$
Participants ($N=56$) Time 3: 9 months	3.05 ($SD \pm 2.44$)	2.90 ($SD \pm 1.77$)	$p = .79$

*Mean CHD risk adjusted for same age and gender, using GLM of repeated measures calculations, (Standard Deviation) and the Huynh-Feldt correlated test of within-subjects effects.

** p -values between groups using independent t -test of measure of significant difference between intervention and control groups at each measurement.

At Time 1, participants exhibited a CHD risk that was as high as 11.8 times greater than that of individuals of comparable age and gender, as indicated by the ICE-HEART cohort. The ICE-HEART calculator indicates that the mean CHD risk for individuals of the same age and gender in both groups was $M = 2.41$, $SE (.30)$, with a 95% CI [1.81, 2.02]. Both the intervention and control groups exhibited significantly elevated mean CHD risk at Time 1 compared to the ICE-HEART

cohort risk calculations for the corresponding age and gender. A significant difference in CHD risk was observed between the cohort of this RCT and the ICE-HEART cohort, $p < .001$, 95% CI [2.46, 4.53].

The intervention group exhibited a lower CHD risk at Time 2 compared to Time 1; however, this difference did not achieve statistical significance, as illustrated in Figure 14. A significant decrease in CHD risk was observed between Time 2 and 3 for the control group. The paired sample t -test results for the control group indicated $t_{(27)} = 2.39$, $p = .024$, with a mean difference of .81 (± 1.80) and a 95% CI [.12, 1.51]. The control group exhibited a significantly reduced risk of CHD from Time 1 to Time 3, $t_{(27)} = 2.26$, $p = .032$, with a mean change of .49 (± 1.14), 95% CI [.05, .93]. Figure 14 illustrates the variations in the groups' mean CHD risk as determined by the ICE-HEART calculator, which results in the absence of zero on the y-axis.

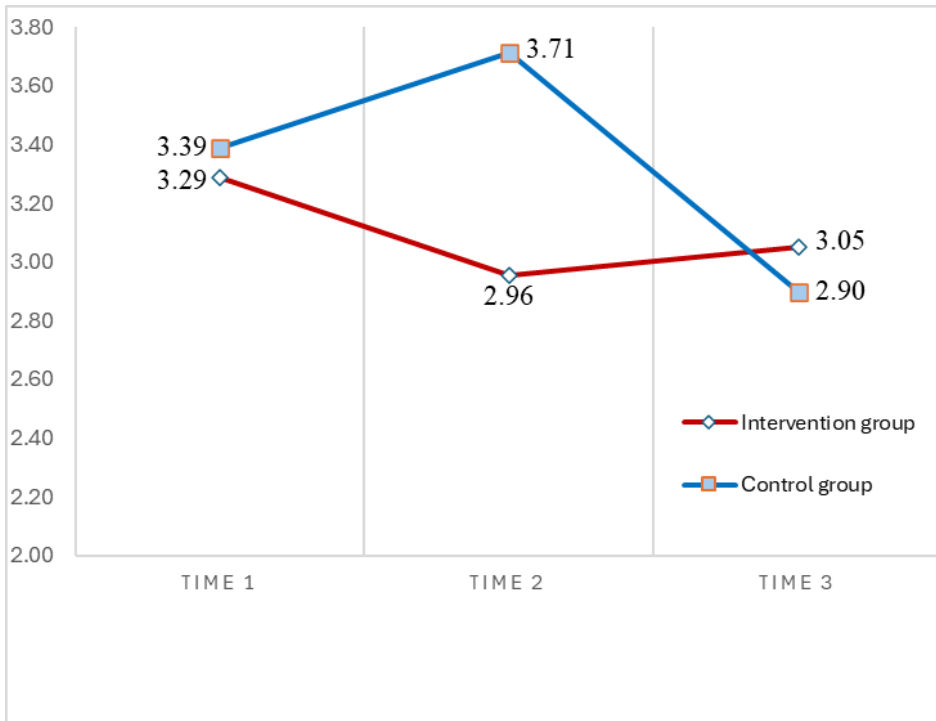


Figure 14: Changes in mean individual CHD risk in each group from Time 1 to Time 3

For the total sample ($n=56$), a statistically significant reduction in CHD risk was found from Time 1 to Time 3, $M = .354$ (± 1.08), $t_{(55)} = 2.53$, $p = .014$, with a 95% CI [.08, .65]. In the intervention group, 50% experienced a reduction in CHD risk from Time 1 to Time 3, while 60.7% of the control group showed a decrease in risk, the highest being 3.29 times lower risk, during the same period. The highest

increase in risk was 2.0 times higher risk at Time 3. Six participants had no change of risk over the research period of the RCT. The odds ratio for a one-point reduction in CHD-risk outcome at Time 3 compared to Time 1, associated with participation in the RCT, was .65, with a 95% CI [.22, 1.87].

Mauchly's test of sphericity revealed a Huynh-Feldt epsilon of .962, indicating a violation of sphericity, as the variance of the differences between scores for any two levels of a repeated measures factor did not remain constant; that is, the variances of the differences among all combinations of related groups were unequal in this small sample.

The relative risk reduction (RRR) for CHD risk in the next 10 years was 17.6%, while the absolute risk reduction (ARR) was 10.7% from Time 1 to Time 3. The number needed to treat (NNT) for one individual to benefit from participation in the GSD was nine. At Time 3, a lower risk of CHD was observed in 31 participants across both groups (Intervention: 14, Control: 17).

4.7.4 Secondary biological outcomes in study III

Despite general improvements in individual biological measures, the changes did not yield significant differences between groups. When looking at each group separately, the intervention group exhibited significant differences from Time 1 to Time 3 in lower BMI ($p = .046$), HbA1c level ($p = .018$), and diastolic blood pressure ($p = .03$). In the control group, only CHOL and TG exhibited a tendency towards a significant difference in lower outcome levels from Time 1 to Time 3, both with $p = .052$.

The general linear model of repeated measures showed that from the start of the research studies, with the pre-allocation measurements, until Time 3, the last measurement in the RCT, the average weight went down for participants of both the intervention and control groups. For the intervention group the mean weight of 99.03 kg ($SD \pm 16.34$) in study I, decreased to 95.54 kg ($SD \pm 16.62$) at Time 3 measurements in the RCT, and within the control group mean weight decreased from 98.15 kg ($SD \pm 16.70$) in study I, to 96.55 kg ($SD \pm 18.75$) at Time 3 in the RCT; see figure 15.

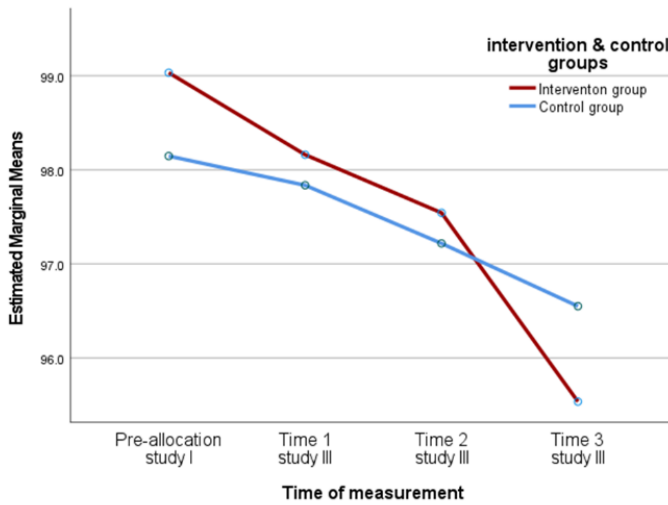


Figure 15: Changes of Marginal Means of weight in kg, from Pre-allocation to Time 3

In addition, a paired samples *t*-test indicated a significant difference of mean in the calculated BMI from pre-allocation to Time 3: $M = .90$ ($SD \pm 1.98$), $SE .26$, $95\%CI [.38 - 1.43]$ $t_{(55)} = 3.39$, $p = .001$ and from Time 1 to Time 3: $M = .69$ ($SD \pm 1.88$), $SE .25$, $95\%CI [.19 - 1.19]$ $t_{(55)} = 2.76$, $p = .008$.

Changes in waist circumference did not reach significant differences between groups, although both groups had slightly lower mean waist circumference at Time 3; see figure 16.

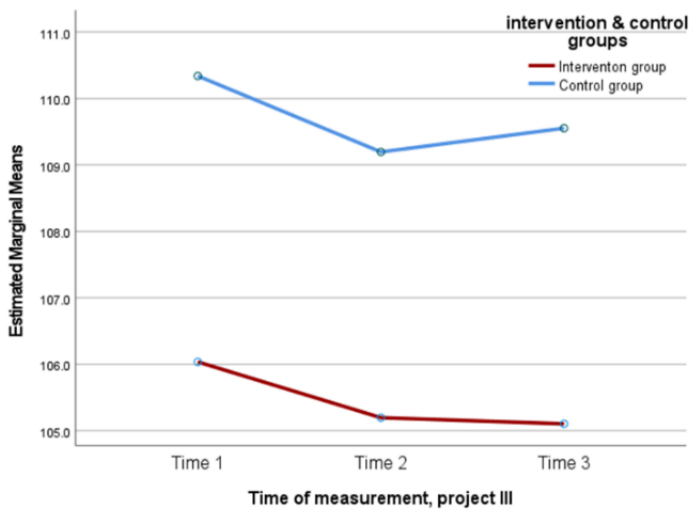


Figure 16: Changes of Marginal Means of Waist Circumference in Study III

The WHR changed with time, mostly though from Time 1 to Time 2, $M = 1.3$, $SE .016$, $95\%CI [1.23, 1.29]$; see figure 17.

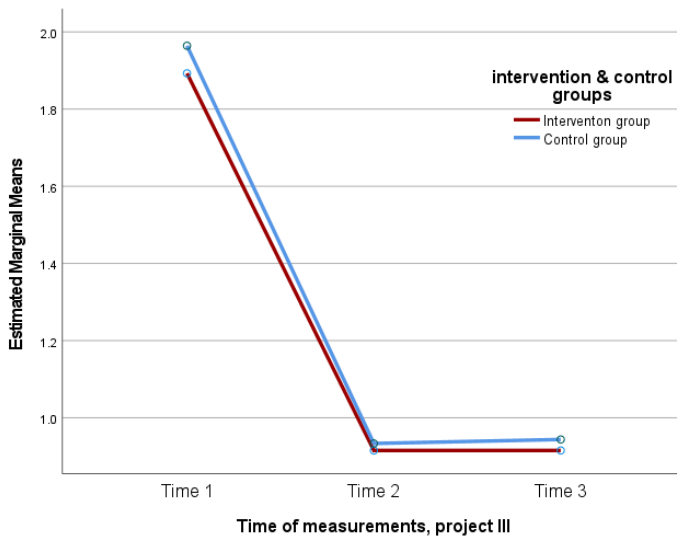


Figure 17: Estimated changes of Marginal Mean of WHR from Time 1 to Time 3

Interestingly, the mean HbA1c level of the total sample was higher at the endpoint (Time3) than at pre-allocation (Study I). Changes in the total sample estimated Marginal Means went from $M_{\text{Study I}} = 36.38$ SE .575, 95%CI [35.22, 37.53] in Study I, to $M_{\text{Time 3 Study III}} = 38.75$ SE .553, 95%CI [37.64, 39.86] at the last measurement of the RCT $p < .001$. When looking at each group individually, changes of HbA1c in the intervention group were from; $M_{\text{Study I}} = 36.21$ (SE .813, 95%CI [34.58, 37.84]) to $M_{\text{Time 3 Study III}} = 38.11$ SE .781, 95%CI [37.64, 39.67]. Changes for the control group were found to be: $M_{\text{Study I}} = 36.54$ (SE .813, 95%CI [34.91, 38.17]) to $M_{\text{Time 3 Study III}} = 39.39$ SE .781, 95%CI [37.81, 40.96]; see figure 18.

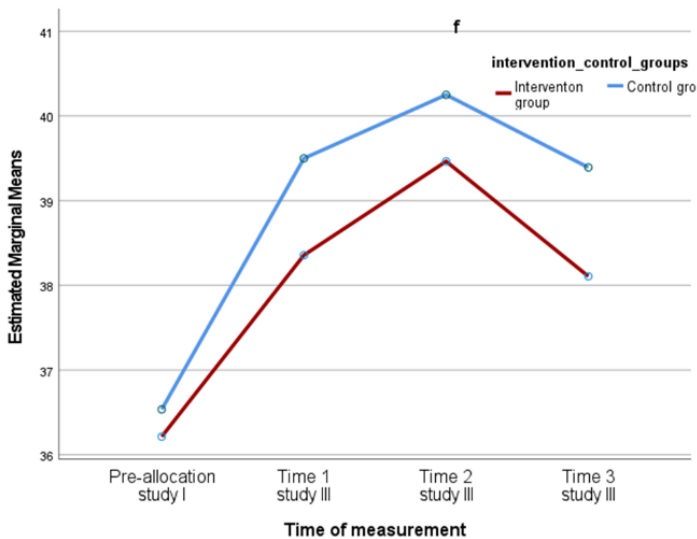


Figure 18: Estimated changes of Marginal Means of HbA1c from pre-allocation (study I) to Time 3 in study III

Although the 2-hour FBG did not show a significant difference between groups or the total sample from Time 1 to Time 3, it was interesting that the intervention group's 2-hour FBG decreased around .1 at each measurement (T1: 5.71 mmol/L ($SD \pm 1.2$), T2: 5.56 mmol/L ($SD \pm .79$), T3: 5.46 mmol/L ($SD \pm .83$)), but for the control group's the 2-hour FBG increased and was around .1 higher at each measurement (T1: 5.49 mmol/L ($SD \pm .72$), T2: 5.61 mmol/L ($SD \pm .64$), T3: 5.70 mmol/L ($SD \pm 1.19$)); see figure 19.

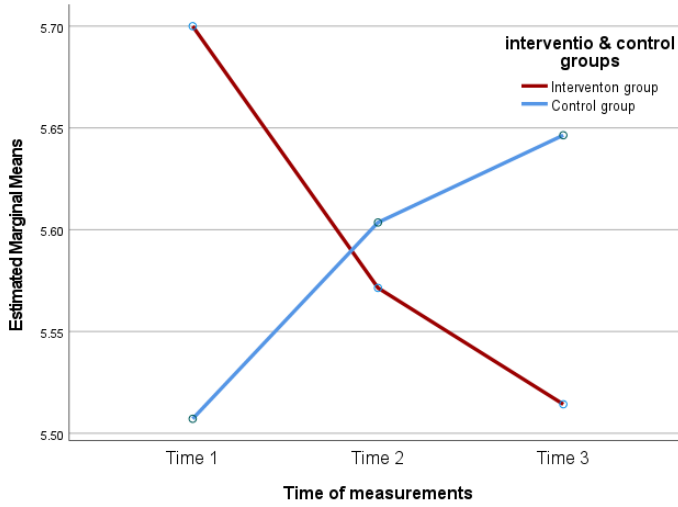


Figure 19: Changes of Marginal Means of 2-hour FBG in mmol/L from Time 1 to Time 3

Both systolic and diastolic blood pressure were lower at Time 3 than Time 1, with significantly lower levels of diastolic blood pressure for the intervention group, $M_{\text{Time 1}} = 89.2$ mmHg, SE = 1.97, 95%CI [85.26,93.17] and $M_{\text{Time 3}} = 82.96$ mmHg, SE = 1.82, 95%CI [79.32,86.61], $p = .003$; see figures 20 and 21.

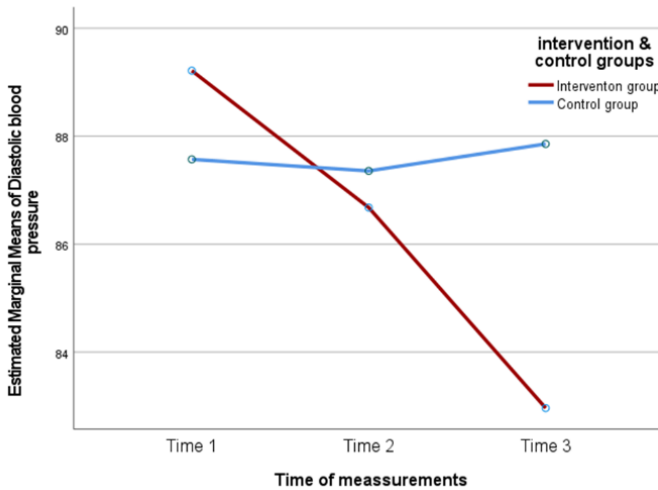


Figure 20: Changes of Marginal Means of diastolic blood pressure in mmHg from Time 1 to Time 3

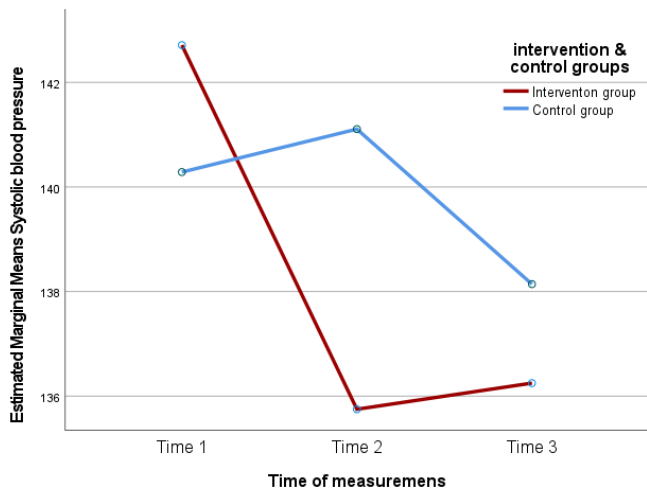


Figure 21: Changes of Marginal Means of systolic blood pressure in mmHg from Time 1 to Time 3

5 Discussions

This doctoral thesis builds on the results of a cross-sectional studies of prediabetes prevalence, using screening measurements and instruments to examine the prevalence of prediabetes and undiagnosed T2d in North Iceland. Following an RCT, the effects of nurse-led GSD counselling method for people found at risk for prediabetes within PHC were measured. This is the first examination of prediabetes prevalence and undetected T2d in Iceland, utilizing both HbA1c level assessments and the FINDRISC risk score.

While no subjects in our research exhibited undetected diabetes, the finding of 13.2% of participants with the HbA1c biomarker indicative of prediabetes was higher than expected. Calculations of sensitivity and specificity for FINDRISC gave the best cut-off point for finding people with prediabetes biomarkers when scoring ≥ 11 points. The proportion of overweight (39.1%) and obese (34.1%) individuals was found to be higher than in the latest findings from the OECD in 2023 for Iceland (OECD, 2023).

The sample reflected the general population in the three research locations regarding age and educational attainment; however, it did not align with the gender ratio, as 65.9% of the participants were female, while the gender ratio of the general population in the research locations is approximately equal (Skuladottir, 2019). Given that a higher number of men are diagnosed with T2d than women, the lower participation rate of men compared to women may help to clarify the absence of participants with undiagnosed T2d (Andersen et al., 2017).

A significant difference between the intervention and control groups in coronary heart disease risk was not found at 6 nor 9 months. Within the intervention group a significant difference was found between Time 1 and 3 in lower BMI, HbA1c, and diastolic blood pressure. It resulted in a lower level of nearly all risk factors of CHD, with 14 of 28 participants in intervention showing a lower CHD risk level at Time 3. Provision of GSD in only three consultations may not have been sufficient to reveal significant differences between groups (Graue et al., 2024). The total RCT time of 9 months may have served only as motivation for a change process, as lifestyle behaviour modifications typically necessitate a longer amount of time (Saaristo et al., 2010). Interestingly, by participating in the RCT, 55% of the total sample showed a lower CHD risk, with nearly 18% RRR and 10.7% absolute risk reduction (ARR) for the total sample in the intervention period, giving the NNT for a positive outcome of reduced risk for one person of CHD to be nine.

During the preparation of the RCT, one objective was to identify individuals with undiagnosed T2d; however, as no participants met these criteria, a comparison between individuals at risk for T2d and those who are undiagnosed could not be conducted in the RCT. Prior studies indicate that the implementation of simple lifestyle interventions in primary healthcare settings can reduce the

relative risk of both CHD and T2d (Lönnberg et.al., 2020; Rosenzweig et al., 2008; Saaristo et al., 2010).

5.1 The FINDRISC instrument and additional screening tools for finding people at prediabetes level and T2d risk.

The study I showed significant differences in higher scoring on FINDRISC for people at an HbA1c level of prediabetes compared to those at a normal level ($p < .001$). This established the basis for using the FINDRISC in finding people at the prediabetes level using ≥ 11 points for identifying individuals at risk for T2d in Iceland. With sensitivity and specificity calculations demonstrating the aROC of .814, which demonstrates a relevant resemblance to the findings of investigations from the statistical assessment of adapting risk scores for diabetes for the Icelandic public from May 2020. Data from the Ages-Reykjavík and REFINE studies found predictive capability for FINDRISC to be aROC = .84, but for the Framingham model aROC = .87, the latter necessitating the inclusion of FBG (Antonsson, 2020). The FINDRISC was originally designed in Finland for finding people at increased T2d risk in the next 10 years (Lindstrom & Tuomilehto, 2003; Lindstrom et al., 2003; Penno et al., 2009; Tuomilehto, 1995). The Study I demonstrated that using the FINDRISC instrument is acceptable for identifying people at the prediabetes level in Iceland.

Upon completing the FINDRISC questionnaire, participants estimated their FINDRISC findings, therefore receiving information on their T2d risk level, which ranged from low to very high, as part of the assessment documents in the RCT. Many women participants were surprised that their measures showed an elevated risk of T2d, particularly as elevated blood glucose levels during gestational diabetes give more risk on FINDRISC. This aligns with study findings from Norway indicating that women's knowledge about gestational diabetes may be limited (Borgen et al., 2022). This is of interest, as results from Portugal indicate that such knowledge is crucial for empowering people to address and integrate knowledge of risk factors as it is for the management of T2d (Sękowski et al., 2022).

5.2 Advantages of adding WHtR in screening for prediabetes

Results of study II indicated that the WHtR $\geq .5$ level was more effective in classifying participants at the prediabetes stage, with an aROC of .759, than BMI or WHR, with aROC of .713 and .654, respectively. Though the WHtR showed a lower aROC than FINDRISC, it indicated that being at an increased health risk on WHtR had a nearly 7.6 times greater odds ratio of having an HbA1c level indicating the prediabetes stage. The WHtR should be easily adaptable within

primary healthcare, as the ratio representing increased health risk is not age (including children's age), ethnic nor gender related. By comparison, while both WHR and BMI serve as predictors for T2d and CVD risk, they exhibit distinct criteria based on gender and ethnic groups, necessitating more calculations compared to the WHtR (Browning et al., 2010;).

Previous research supports the assertion that WHtR serves as a superior metric compared to WHR and BMI for assessing overall health risk, particularly in women (Zhang, F. et al., 2021), and for CVD risk of individuals (Ashwell et al., 2012; Ashwell & Gibson, 2016; Ke, J. et al., 2022).

5.3 Obesity

The fact that 39.1% of participants were overweight and an additional 34.5% were obese in studies I and II is concerning. OECD results indicate that obesity prevalence in Iceland was 20% in 2007 and went up to 27% in 2017, and in 2021, Iceland had one of the highest rates of obesity in Europe, with only Malta with a higher level (OECD & European Observatory on Health Systems and Policies, 2021). Earlier research has indicated higher rates of obesity among women living in more rural areas (Gudjonsdottir et al., 2015). Obesity may increase diabetes risk (Schnurr et al., 2020; Jakupovic et al., 2019), in addition to increasing the risk of CVD even before the diagnosis of T2d (Wong & Sattar, 2023).

Of the participants identified as overweight or obese, 47.4% scored ≥ 11 points on FINDRISC. This may be considered alarming, as in 2021 disability-adjusted life years (DALYs), the age-standardised rate for T2d was found to be 915.0 (782.6-1067.59) per 100,000, with high BMI contributing to up to 60% of DALYs due to T2d (Ong et al., 2023).

Throughout the RCT, there was an increase of participants with a BMI of ≤ 30 kg/m². During the pre-allocation assessments, 10.7% ($n = 6$, among them two in the intervention group and four in the control group) of the subjects had a BMI ≤ 30 kg/m². At Time 3, the proportion of participants with a BMI ≤ 30 kg/m² was 26.8% ($n=15$, including I=9/C=6). In addition, changes of BMI for all participants finishing all measurements ($n=56$) from pre-allocation to Time 3 indicated a significant difference in lower BMI at Time 3 ($p = .008$).

The efforts made by the Icelandic healthcare system to raise awareness of health risks and negative consequences associated with overweight and obesity have not yet succeeded in reversing the trend of the last decade's increasing obesity rates. Newly published results of dietary habits in Iceland 2019-21, indicate that people 60-80 years old show healthier diet choices than 18-39-year-olds. Higher education, a stable financial background, being female and regular exercise also all contribute to healthier food choices (Johannsdottir et al., 2024).

5.4 Additional benefits of using HL, WHO-5 and EQ-5D-5L instruments in prediabetes screening

The patient-reported outcomes of health literacy and well-being questionnaires offered supplementary insights that the FINDRISC instrument did not capture (Gustafsdottir et al., 2020). FINDRISC does not address symptoms of depression or anxiety; however, recent findings indicate that individuals exhibiting these symptoms are at an increased risk and more likely to develop T2d (Deschênes et al., 2016; Graham et al., 2020; Mersha et al., 2022).

High scores and therefore sufficient HL in study II for the majority (83.4%) of participants unrelated to age, living status, occupational status, residency, education or gender was somewhat surprising. Higher levels of HL have been found to correlate with higher education, whereas lower levels of HL are linked to inferior health and quality of life (Ehmann et al., 2020). Prior research has found an association between lower HL and increased T2d risk (O'Meara et al., 2019; Tajdar et al., 2021; Vågenes et al., 2024), the prediabetes stage and lower HL (Luo et al., 2020), and lower educational level and lower HL outcome (Sørensen et al., 2015). Self-selected participation in COVID-19 restriction time might explain partly the high educational level and therefore high HL scores. Findings from Denmark suggest that COVID-19 adversely impacted WHO-5 scores more significantly for women compared to men (Sønderskov et al., 2020). In addition, some participants may have chosen answers toward more positive response options, leading to higher scores, as they expressed out loud when answering that they had never been in those circumstances, but that would probably not be a problem for them. This may need further research.

While scores on WHO-5 showed that the level of depression was found for 9% of countryside and 11.9% of town residents, 60% indicated no signs of anxiety or depression on the EQ-5L-5D instruments. There was a notable increase in well-being scores as age increased, with men achieving significantly higher scores compared to women. This is of interest, as results from Statice.is (2022) found the prevalence of depression is higher among women at 9% compared to 6.3% for men in Iceland. This may also require additional research.

The group of prediabetes biomarker levels of HbA1c had higher mean scores on WHO-5, than the normal HbA1c group ($p = .043$). This was of interest, as a systematic review indicates that diabetes risk increases with depression regardless of the instrument used (Graham et al., 2020). The fact that people with prediabetes biomarkers had elevated overall scores on the WHO-5, indicating diminished symptoms of depression, is ambiguous. This underscores a comprehensive study demonstrating a higher frequency of reduced well-being and depression in patients with T2d (Ali et al., 2006).

The EQ-5D-5L found over 80% of the participants reported experiencing no issues in the initial three domains: 'Mobility' (84.1%), 'Self-care' (96.4%), and

'*Usual activities*' (87.7%). Only one-third indicated no issues related to '*Pain/Discomfort*', while 60% reported the same for '*Anxiety/Depression*', showing no variation based on gender or prediabetes biomarker.

The EQ-5L-5D instruments' levels of mobility, self-care, usual activities and pain/discomfort all showed correlation with one another, but not mobility and anxiety/depression nor self-care and anxiety/depression. The score on pain and depression was also higher than expected, especially as most of the participants were female. A systematic assessment of the EQ-5D-5L indicated that males with T2d exhibited greater utility value scores than females (Afshari et al., 2022).

HRQoL, well-being and HL instruments may add to the use of the FINDRISC instrument by helping to evaluate the best pathway of support for people at diabetes risk. The WHO-5 questionnaire could, from this viewpoint, aid the primary healthcare system in identifying individuals at risk for T2d who should be prioritised for additional interventions.

5.5 Results of the RCT

Results of the RCT performed in study III failed to show a significant difference between groups in CHD risk over the nine-month period. This timeframe of intervention, providing the GSD in only three consultations, may only have enabled motivation toward empowerment, and a longer time may be required for changes in lifestyle behaviour for people at potential risk of T2d to show a significant effect (Graue et al., 2024; Saaristo et al., 2010). Most prior research on the GSD method has looked at individuals with diagnosed diseases (Burke et al., 2020; Jørgensen et al., 2014; Linnet Olesen & Jørgensen, 2023; Zoffmann et al., 2008). A longer follow-up of participants and more intensive teaching and encouragement for the nurses providing GSD needs further evaluation (Kolltveit et al., 2024).

The GDS was found to be a promising approach for people at risk toward health promotion, though it was unable to present a significant difference between groups (Zoffmann & Lauritzen, 2006). As the GSD approach was found to empower individuals and promote lifestyle changes, GSD may be able to serve as a promising approach for individuals at risk of T2d, in addition to individuals with T2d, as found by Mathiesen et al. (2023). This is beneficial, as T2d has been found to be largely preventable and potentially reversible if found early (Ong et al., 2023).

Participation in the RCT resulted in that at Time 3, 55% of the total sample had a lower 10-year risk of CHD than at Time 1. This is a valuable result, as progression to T2d and CHD may take several years, and CVDs are the leading cause of mortality (Andersen et al., 2017). In addition, increased relative risk of CVD, CHD and stroke has been found for people at prediabetes level compared to people with normal glycemia (Cai et al., 2020; Huang et al., 2016). The PHC

may benefit from implementing the GSD, as it is found to be a low-cost, nurse-led intervention designed to empower people at risk of T2d and prior research indicates that such low-invasive interventions toward lifestyle changes are cost-effective and may reduce RR of T2d and CHD (Lönnberg et al., 2020; Rosenzweig et al., 2008).

As the RCT was conducted in real-life situations in primary healthcare settings, it is claimed that GSD may be recommended as a short intervention within PHC provided by nurses to empower individuals toward health promotion. The GSD method has been found to increase individuals' health awareness and help people with type 1 diabetes, T2d and other health challenges (Graue et al., 2023; Graue et al., 2024, Zoffmann & Lauritzen, 2006).

With GSD as a promising approach toward health promotion and empowerment, further tailoring of GSD provision may be needed, as the length of each consultation needs consideration. In personal communication with the PhD student at each measurement throughout the RCT, the intervention group became more interested in changes in biological results post intervention, that is, between measurements at Time 2 and 3. Meanwhile, the control group said when coming to the Time 3 measurement that participation had resulted in changes in their shopping habits and lifestyle. As for the participants who received GSD, they exhibited predominantly positive attitudes when coming to the last measurement, 3 months after GSD intervention ended.

It is noteworthy that the RCT was conducted in the shadow of COVID-19 restrictions, which might have influenced the results (Nomali et al., 2023), and before use of the glucagon-like peptide-1 (GLP-1) weight management began to rise (de Oliveira Almeida et al., 2024). Further study is necessary to examine the utilization of GSD as a counselling approach for those at increased health risk within the framework of health promotion in the PHC system.

5.6 Preventive pathways screening or not for prediabetes risk and undiagnosed T2d within the PHC settings

Studies I and II revealed 13.2% of 18-75-year-olds in North Iceland had a prediabetes biomarker, and that the participants were generally obese and had elevated CHD risk, which needs to be acted upon. The offer of answering non-invasive screening instruments like FINDRISC may be the first step for an individual to understand that they may be at increased risk for developing T2d, although not all found at prediabetes level will progress to T2d (Ahlqvist et al., 2018; Ahlqvist et al., 2020; Wagner et al., 2021). Measurements of WHtR are easily performed within the PHC, and HL questionnaires may help in identifying those at an insufficient level of HL, who might need more assistance toward health promotion. The results of studies aiming to subtype or to cluster individuals found

at prediabetes biomarker level, by using blood tests, metabolism testing and DNA genotyping have defined six clusters of people at prediabetes and T2d risk. The clusters 1 (“*healthy overweight*”), 2 (“*healthy, slim, low complication risk*”) and 4 (“*obesity, low glycaemic deterioration, metabolism moderately healthy*”) show lower T2d risk. Whereas the other three clusters indicate higher T2d risk: clusters 3 (“*elevated genetic risk, low insulin secretion, high T2d risk*”), 5 (“*fatty liver, very high T2d risk, CVD risk, nephropathy risk, higher mortality rate*”), and 6 (“*elevated renal sinus fat, high visceral fat, high risk of nephropathy even prior to T2d appearing, higher mortality*”) (Ahlqvist et al., 2018; Ahlqvist et al., 2020; Wagner et al., 2021). Individuals falling into higher risk of T2d have shown indications of higher CHD risk and higher mortality rate (Prystupa et al., 2023). Research suggests classification of T2d patients is also possible at the point of diagnosis assisting in identifying those more likely to develop diabetes complications, which again may help in choosing the most suitable form of treatment for the individual (Ahlqvist et al., 2018). A better classification of individuals found at the prediabetes level into groups of lower or higher risk of T2d may be cost-effective to use before invasive methods like blood tests, OGTT and other diagnostic approaches are used to distinguish between those at risk and people who are falsely found positively at risk (Wagner et al., 2021).

Diabetes and the prediabetes stage are associated with less HRQoL (Anillo Arrieta et al., 2021; Lu et al., 2017). The management of diabetes and associated comorbidities incurs significant costs for individuals’ HRQoL as well as for society. Due to the heightened financial burden on the healthcare system, it is important to reduce the prevalence of T2d and mitigate disease symptoms. Prescribed T2d medicine data have estimated that by 2040 as many as 24000 Icelanders might have T2d diagnoses (OECD & European Observatory on Health Systems and Policies, 2021). The results of Study I indicate that up to 35000 of approximately 266,000 inhabitants aged 18-75 (Statistics Iceland, 2021), may have had prediabetes signs in 2021. Research in the USA has reported that with enhanced screening, up to 90% of T2d may be detected and found a substantial decline in undiagnosed T2d from 1988 to 2020 (Fang et al., 2022b). An estimated up to 2% of all adults in the USA may have undiagnosed T2d (Fang et al., 2022a). A working group addressing the rising prevalence of diabetes in Iceland from 2018 did not recommend screening for prediabetes within the Icelandic population (Benediktsson et al., 2018). However, if Iceland is 20 years behind the T2d progression found in the USA (Thorsson et al., 2021), there may still be an opportunity to delay or reverse the progression in Iceland, due to the known time lag from risk onset until the progression of the T2d disease (Cassidy et al., 2019; Connor et al., 2019; Gao et al., 2022; Kong et al., 2016).

Preventative measures for T2d and CHD have demonstrated cost-effectiveness (Siegel et al., 2020). It is essential to enhance awareness of T2d risk and enable individuals to engage in proactive health behaviours to lower their risk of

developing these conditions in the increasing global prevalence of T2d and CHD risk (Chaudhary et al., 2024). It is therefore essential to address that a rationale must be presented for community screening of those who are at increased risk for a certain disease. The formulation of strategies regarding the screening for prediabetes biomarkers, T2d risk, CHD risk, and associated comorbidities, requires ongoing consideration by the government and local public health authorities. The result of the studies in this doctoral thesis can be the first step in considering screening of those at higher risk for T2d by using the FINDRISC instrument. In addition, the ICE-HEART CHD risk calculator is useful for the PHC in consultations to provide individuals with their results of CHD risk to increase the individual's awareness of their own health status.

Fearmongering around potential diseases is unlikely to effectively motivate individuals to adopt health-promoting behaviours. But when individuals answer the FINDRISC, the results are immediately apparent and may encourage individuals to consider their health status without imposing significant intervention or inducing fear. Those found at risk may then be clustered by low or increased risk, and those found at increased risk are offered more assistance toward empowerment and disease prevention with the GSD method when appropriate.

5.7 Strengths

The studies in this thesis are the first studies in North Iceland to measure the prevalence of prediabetes biomarkers and undiagnosed T2d. With all participants measured by the same person, the measurement differences were minimised, increasing the internal validity of the RCT. Using low invasive measurements and capillary blood samples, easily performed in all PHCs in the study area. For the sensitivity and specificity of FINDRISC calculations, it is a strength that the HbA1c level was used for the calculation.

The sample size was found to be relatively large compared to the population in the area (Statistics Iceland, 2021). The RCT evaluated a new way of using the GSD counselling approach in the PHCs. In the RCT, dropout was low in both intervention and control groups after first-time measurements, even in the shadow of COVID-19 restrictions. All the biological measurements, as BMI, blood pressure measurements, HbA1c, FBG, and use of the ICE-HEART calculator in the RCT, can be considered as a strength.

By participation, participants may have been enabled to become more aware of their health status and health risk factors in addition to empowering individuals at higher health risk. In addition, the nurses participating in the GSD gained new tools in their daily care of people at increased diabetes risk. Meeting the same person for all measurements may be regarded as person-centred care on its own

during COVID-19 time, as restrictions had an impact on the ability to access the PHC facilities.

5.8 Limitation

The sample chosen was only from the North of Iceland, with a large age range, and not a randomized cohort in the database of studies I and II. That limits the external validity of the RCT. Recruitment of the self-selected participants took longer due to the COVID-19 pandemic restrictions. This may have affected who volunteered participation, as women were in a majority over men and the majority of participants had a high educational level. Whereas being a man and having a lower educational level have been linked to increased T2d risk. A criticism has been made on FINDRISC, indicating the instrument does not capture gender and age impact (Jølle et al., 2016); although not observed in studies I and II, the uneven gender proportion may explain why no difference between genders was found within the FINDRISC scores.

The ongoing COVID-19 pandemic may have impacted mental well-being results, and thereby the results might not reflect overall anxiety in the population, as people generally showing lower anxiety might have been more willing to participate. As participants were living in small communities, information on the intervention could have spread between participants and groups in the relatively small sample of the RCT and therefore biased the results.

In the RCT, one person (a PHC nurse and PhD student), took all measurements but also informed the intervention group of the intervention. All participants were given results of each time biological measurement, ongoing. This can therefore not be considered a blinded study, and that may have affected the results. The estimated sample size needed for study I and II was 206 participants. With 81 of the 220 fulfilling inclusion criteria for the RCT, the assigned participants to intervention were 42 and 39 in the control group. Thereof, 34 of the intervention and 30 of the control groups came to the first-time measurement; the drop-out from Time 1 to Time 3 was 17.6% in the intervention but 6.7% in the control group. It may be seen as a limitation that although the same number of participants in both groups finished the RCT, the size of the RCT was small. Participation on its own may have resulted in increased health status awareness in both intervention and control groups. In addition, the information booklet on healthy food choices may have benefited the control group.

The six nurses providing the GSD had no prior experience with this counselling approach. Regardless of the same education on GSD before starting intervention, it cannot be fully affirmed that the implementation and integration of the GSD counselling was equally identical between all nurses.

5.9 Further studies of prediabetes, T2d prevention, and the GSD approach within primary healthcare

Further studies are needed to implement the best preventive ways in primary healthcare toward health promotion, prediabetes and disease prevention. Both the service recipients' and providers' views on ways to address upstream healthcare needs need to be researched. If the prevalence of prediabetes is as high as the results here indicate, it is essential to assess the most cost-effective way for health promotion and disease prevention for Iceland. As the results of Thorson et al. (2018) indicate T2d prevalence in Iceland is following the pathway of the USA from 20 years earlier; there may be time to act upon and hopefully reverse T2d risk prevalence. In addition, the results from study III, which found that the mean CHD risk was higher than in the cohort behind the ICE-HEART (Anderson et al., 2017), should encourage the use of preventive strategies in primary health care and additional research to develop the ICE-HEART calculator. Nurses play a crucial role in primary healthcare and should be encouraged to take an active part in strategy planning regarding the use of disease prevention in primary healthcare settings.

6 Conclusions

The overall findings of this thesis suggest that offering readily implementable and non-invasive assessments might improve primary healthcare strategies for the prevention of T2d. The studies in this thesis have examined several risk evaluation methodologies to identify individuals at heightened risk factors for T2d, categorised by residency and gender, a method not before attempted in Iceland. The significant prevalence of overweight and obesity also suggests that immediate action is necessary for Iceland to reverse the trends of prediabetes and T2d prevalence. The absence of individuals with undiagnosed T2d necessitates more investigation into its prevalence in Iceland.

The FINDRISC instrument is simply administered and validated for screening individuals for T2d risk and is effective for screening for prediabetes within PHC settings. FINDRISC may serve as an alternative to intrusive and more expensive testing procedures. This concise and non-invasive tool is recommended to be used as part of risk assessment within the PHC.

Implementing WHtR calculations in basic health care may enhance the early identification of people at increased risk for health complications. Incorporating other measures such as HbA1c tests, HL assessments, and well-being questionnaires may aid in identifying those at heightened risk for T2d and CHD and in so differentiating them from those with a lower overall health risk. In addition, to identifying those more likely to require help with lifestyle modifications.

The GSD approach is a non-invasive and inexpensive counselling strategy that may be used in PHC as an empowering method for people in implementing changes toward health promotion in their daily life. Participation in the GSD intervention resulted in a decrease in BMI, HbA1c, and diastolic blood pressure for the intervention group in the RCT, demonstrating the benefit of GSD. The GSD method may promote behavioural change and assist individuals toward making alterations to their everyday routines that may lower their risk of T2d. The three-session consultations of the GSD method employed by nurses are recommended for patients at increased health risk, functioning as a person-centred health promotion strategy.

Although this RCT did not demonstrate a significant difference in the risk of CHD in the next ten years, from Time 1 to 3 between groups, for 50% of the intervention group and 60.7% of the control group, the CHD risk had reduced from Time 1 to 3 with an RRR of 17.6% for the total sample. Utilizing biological measures to identify persons at risk for T2d and CHD, followed by providing lifestyle counselling to those identified, may function as an effective health promotion tool. In addition, educating individuals and implementing GSD with reflection sheets for those requiring support in health promotion.

In the light of the high prevalence of obesity and overweight in the Icelandic populations, there is a need to develop strategies in Iceland for formal screening within the PHC for individuals at risk of non-communicable diseases and especially T2d risk and T2d.

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RESEARCH

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Using HbA1c measurements and the Finnish Diabetes Risk Score to identify undiagnosed individuals and those at risk of diabetes in primary care

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Abstract

Background Prevalence of prediabetes and type 2 diabetes mellitus (T2DM) is increasing worldwide. The objective of this study was to determine the proportion of people in Northern Iceland with prediabetes, at risk of developing T2DM or with manifest undiagnosed T2DM, as this information is lacking in Iceland.

Methods A cross-sectional study. Clients of the three largest primary health care centres in the Health Care Institution of North Iceland (HSN) were invited to participate if fulfilling the following inclusion criteria: a) aged between 18 and 75 years, b) not diagnosed with diabetes, c) speaking and understanding Icelandic or English fluently and d) living in the included service area.

Data collection took place via face-to-face interviews between 1 March 2020 and 15 May 2021. Participation included answering the Finnish Diabetes Risk Score (FINDRISC), measuring the HbA1c levels and background information.

Results Of the 220 participants, 65.9% were women. The mean age was 52.1 years (SD \pm 14.1) and FINDRISC scores were as follows: 47.3% scored \leq 8 points, 37.2% scored between 9 and 14 points, and 15.5% scored between 15 and 26 points. The mean HbA1c levels in mmol/mol, were 35.5 (SD \pm 3.9) for men and 34.4 (SD \pm 3.4) for women, ranging from 24 to 47. Body mass index \geq 30 kg/m² was found in 32% of men and 35.9% of women. Prevalence of prediabetes in this cohort was 13.2%. None of the participants had undiagnosed T2DM. Best sensitivity and specificity for finding prediabetes was by using cut-off points of \geq 11 on FINDRISC, which gave a ROC curve of 0.814.

Conclusions The FINDRISC is a non-invasive and easily applied screening instrument for prediabetes. Used in advance of other more expensive and invasive testing, it can enable earlier intervention by assisting decision making, health promotion actions and prevention of the disease burden within primary health care.

Trial registration This study is a pre-phase of the registered study "Effectiveness of Nurse-coordinated Follow up Program in Primary Care for People at risk of T2DM" at www.ClinicalTrials.gov (NCT01688359). Registered 30 December 2020.

Keywords Prediabetes, Screening, HbA1c levels, FINDRISC, Type 2 diabetes

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Introduction

Type 2 diabetes mellitus (T2DM) is among the fastest growing challenges to good health [1, 2]. Prevalence has tripled worldwide the last twenty years [3]. Today, over 463 million people are estimated to be living with diabetes [4], by 2030, 478 million over 18 years will have the disease [3], and 700 million by 2045 [5].

T2DM is the most common type of diabetes, often characterized by a silent onset of increased insulin resistance or lack of insulin production [4]. T2DM accounts for over 90% of diabetes cases [4, 6]. There is often a time lag between onset and formal diagnosis [7]. In the United States (U.S.), average interval between the onset of T2DM and diagnosis was found to be 7 years [8], and it is claimed that up to 30% of people with T2DM are undiagnosed [8]. The International Diabetes Federation (IDF) estimates that up to half of cases (49.7%) may not know that they have the disease [3].

A study on prevalence of diabetes by the Icelandic Heart Association from 1967 to 2007 found one out of three people with T2DM were unaware of their condition, when measuring fasting blood glucose [9, 10]. This included data from several population studies: 17,757 people aged 45–64 years for T2DM and three additional studies of 20,519 people for BMI [9, 10]. Unawareness of T2DM may increase the risk of chronic diabetes complications [11–13]. Those complications, for example, coronary arterial disease, renal failure, and blindness, may reduce the health-related quality of life for the individual [14], while society pays a high price due to impaired working capacity and high medical costs [3, 15]. If untreated, early onset T2DM may confer a higher lifetime cardiovascular and premature death risk compared to later onset of the disease [16]. The development of T2DM is the result of interaction between multiple environmental, socioeconomic, and genetically driven causes, changes toward a more sedentary lifestyle and less healthy diet choices [3, 17–19].

A strong connection has been found between T2DM and obesity [20, 21]. Research indicates that obesity affects insulin resistance, and certain metabolites may show connection to both T2DM and obesity [22]. Until 1981, the mean BMI in Iceland was under 25 in all age groups (25–75 years) [9]. Between 1968 and 2012, the BMI of those aged between 50 and 69 years increased by 11% for men and 8% for women [9]. Data from the Icelandic Heart Association survey of 17,757 Icelandic people between 1967 and 2007 showed that four out of five people with T2DM were obese [9]. The prevalence of T2DM in Iceland more than doubled in both men and women between 2005 and 2018 [23].

Prediabetes is a state of elevated glucose levels in the blood, without reaching the diagnostic blood glucose

levels of T2DM [2]. The prevalence of prediabetes has risen in England, for example, from 11.6% in 2003 to 35.3% in 2011 [24]. In the U.S., biomarkers of prediabetes are found in about 25% of young adults [25]. A recent meta-analysis by Barry et al., showed that when combining data from five studies in middle-aged participants, that used both the WHO and ADA definition, the overall overlap prevalence of prediabetes was 27% [26]. The number of people with prediabetes in Iceland is unknown. Earlier Icelandic studies on the prevalence of T2DM have mostly used data from the capital area [23].

Emerging evidence from well-designed randomised controlled trials (RCTs) has shown that lifestyle intervention with or without pharmacological treatment can prevent or delay the onset of T2DM among people at the prediabetes stage [9, 18, 27]. Finding those at risk earlier may be a way to reduce the disease burden, complications and cost for both individuals and society [4, 11, 28]. The American Diabetes Association (ADA) recommends screening people at risk of developing T2DM at least every third year and yearly after reaching 45 years [20]. The availability of suitable tools in the primary health care (PHC) for early identification is one of the biggest challenges in promoting health and disease prevention [11, 29]. A non-invasive screening test for risk assessment, such as The Finnish Diabetes Risk Score (FINDRISC), may be a useful tool to find undiagnosed and those at risk for developing T2DM [5, 30].

Accordingly, the objective of this study was to identify people with prediabetes or undiagnosed T2DM in Northern Iceland and to determine the usability of FINDRISC as a screening tool in Icelandic PHC, by comparing the results of HbA1c measurement to the FINDRISC score by calculating sensitivity and specificity of FINDRISC.

Methods

Study design and settings

This was a cross-sectional study conducted within the Health Institution of North Iceland (HSN). The HSN runs 18 PHC centres and 4 small hospitals in the Northern Iceland, serving around 36,000 inhabitants or around 10.4% of the total population of 368,792 inhabitants in Iceland (as of 1 January 2021) [31]. The study's settings were the three largest PHC centres in the HSN. Located in Saudarkrokur, Akureyri and Husavik, they serve over half of the total population in the Northern part of Iceland. Primary health care in Iceland is funded by the state, although non-pensioners pay a small fee to visit the doctor or nurse (this was approximately 3.90 US\$/3.60 € in 2021). A routine health check-up with a doctor or a nurse is not standard in the PHC system, except for maternity care and infant protection programmes.

During the Covid-19 pandemic, only those with acute medical needs were allowed into PHC centres.

Study population

All inhabitants living in the three study areas were eligible for the study if they were aged between 18 and 75 years, had not been diagnosed with diabetes, and spoke and understood Icelandic or English fluently. Around 17,600 inhabitants living in the service areas of the three PHCs fulfilled the age criteria. Exclusion criteria was diagnosed with T1DM or with active treatment of T2DM.

Data collection

All data were collected in one-to-one interviews by the first author (EA). Data collection took place between February 2020 and May 2021. The original plan of approaching participants at the three participating PHC centres had to be changed as a result of strict restrictions on all unnecessary visits to the PCH centres due to the Covid-19 pandemic. Therefore, the first 101 participants were recruited via introduction letters handed out by a receptionist when they came for a visit to the PHC centre between February and May 2020. The remaining 119 participants were recruited via flyers and advertisements in local papers from January to May 2021.

The letters, advertisements and flyers gave information about the study and contact information for the first author. Participants who were approached at the PCH centres met the first author for data collection after their pre-booked appointment with their nurse or doctor at the PHC centre. However, participants recruited through advertisements or flyers, contacted the first author via phone, SMS, or e-mail. The first author then briefed them about the study and sent them in advance a copy of the introduction letter via e-mail. If that was not possible, the introduction letter was handed to participants before data collection at the prearranged time. Those who did not show up at the prearranged time for data collection were offered new appointments twice more but were then seen as unwilling to participate. Data from the participants were collected at the local PHC centres in Húsavík and Sauðárkrúkur. In Akureyri, data were collected at the research centre.

Biological and demographical measurements

Biological measurements were conducted by the first author and information on the results was given to each participant at the end of the data collection interview. BMI was calculated by weighing participants on a digital scale, in light clothing without shoes, to the nearest 100 g, and measuring their height to the nearest 0.1 cm with a portable measuring tape. Waist circumference was measured 2 cm above navel, with measuring tape of 1,5 m or

3 m capacity, constancy of both tapes was measured regularly. The HbA1c levels were analysed by a DCA Vantage[®] analyser, that is clinically proven correlating with lab methods [32], using capillary blood samples, and the device was calibrated according to instructions.

Participants answered the FINDRISC [33, 34] and gave additional background information on age, gender, educational level, occupation and living status using a laptop computer. They were offered paper as an alternative way to answer the questions and five participants requested this option. Another five participants informed the researcher that they had reading difficulties. For these participants, the questions were read out aloud, but the participants marked down their answers.

Definition of diabetes, prediabetes and the HbA1c measurements

Prediabetes is manifested and diagnosed by impaired fasting glucose (IFG) of 5.6 to 6.9 mmol/L, an impaired two-hour plasma glucose with 75 g oral glucose tolerance test (OGTT) results of 7.8 to 11.0 mmol/L or, as used here, elevated levels of glycated haemoglobin (HbA1c) [35]. HbA1c is a test of glycated haemoglobin that is approved by the World Health Organization (WHO) as a diagnostic test of diabetes [1, 2]. The ADA definition of prediabetes was used in this study [20]. As participants with HbA1c levels between 39 and 47 mmol/mol (5.7–6.4%) were classified as having prediabetes but, those with HbA1c levels of ≥ 48 mmol/mol ($\geq 6.5\%$) as having T2DM [17, 35].

Instrument

FINDRISC is a commonly used instrument, designed to screen for unidentified diabetes and to identify people with an elevated risk of developing T2DM within the next 10 years [19, 33]. It was developed in Finland between 1987 and 1992 and is claimed to be the most frequently used diabetes risk screening instrument worldwide [36].

The FINDRISC instrument includes eight questions on age, gender, BMI, waist circumference, daily physical activity, consumption of fruit and vegetables, history of high blood pressure, previous history of diabetes and family history of diabetes [33, 34]. Scores range from 0 to 26 points. A higher score represents a higher risk of developing the disease within the next 10 years. A score of under 7 points is regarded as low risk (1:100), 7–11 points represent a slightly elevated risk (1:25), 12–14 points indicate a moderate risk (1:6), over 15 points a high risk (1:3) and over 20 points (1:2) a very high risk [34].

FINDRISC is easy to use, non-invasive, inexpensive, includes modifiable risk factors such as diet, physical

activity, and body weight [19]. It has been validated in several populations [37, 38], as well as in Iceland [39].

Statistical analysis

Descriptive statistics were used for calculating means, standard deviations, and ranges to describe continuous variables. For categorical variables, counts and proportions were used. Comparison of the sample characteristics was performed using t-tests for continuous variables and chi-square tests for categorical variables. BMI calculations were done for each participant using the Microsoft Excel calculator and correlation for BMI and HbA1c results.

Chi-square tests were used to calculate the sensitivity and specificity of different FINDRISC points using the HbA1c results of all participants. Participants were divided into two groups: one with normal HbA1c levels and one with prediabetes levels of HbA1c.

When analysing the utility of FINDRISC to predict the future risk of developing T2DM or prediabetes in this cohort the receiver-operating characteristic (ROC) curves were constructed, by using different cut-off points of FINDRISC. Area under the ROC curve or AUC presents how well test, here FINDRISC, is capable to differentiate between cases, here prediabetes or not. An AUC of 1.0 indicates perfect test accuracy with

neither false positives nor false negatives. However, an AUC curve of 0.5 indicates that the results are no better than chance. With FINDRISC, the best cut-off points to identify prediabetes were those with the shortest distance to the upper left corner of the ROC curve [36].

The dataset was analysed with IBM SPSS statistics 27. Missing data, if applicable were excluded listwise. Significant statistical difference two tailed was set at $p \leq 0.05$.

Ethical considerations

The Icelandic National Bioethics Committee (VSN) (VSN-19-080-S1 approved 14/05/2019 and VSN-19-080-V1 approved 14/01/2020), also the Senior management of HSN, approved the research. All participants signed an informed consent form before participating in the study.

Results

Participants and background information

The background information of participants is described in Table 1. Mean age was 52.1 (SD ± 14.1, range from 18 to 75) years, and women were 65.9%. Almost half of the participants had completed a university degree.

Table 1 Background information by gender, age, living status, educational level, occupational status, and residency

	Total (n = 220)	Men (n = 75)	Women (n = 145)
Mean age in years (18–75 years)	52.1 (SD ± 14.1)	52.7 (SD ± 13.7)	51.8 (SD ± 14.3)
Living status	n (%)	n (%)	n (%)
Living alone	17 (7.7)	6 (8.0)	11 (7.6)
Living with one other person	99 (45.0)	36 (48.0)	63 (43.4)
Living with two or more persons	102 (46.4)	32 (42.7)	70 (48.3)
Living status missing	2 (0.9)	1 (1.3)	1 (0.7)
Educational level	n (%)	n (%)	n (%)
Elementary school/junior high school or equal	52 (23.6)	15 (20.0)	37 (25.5)
Upper secondary school/vocational training/senior high school or equal	65 (29.5)	30 (40.0)	35 (24.1)
University degree	101 (45.9)	29 (38.7)	72 (49.7)
Educational level missing	2 (0.9)	1 (1.3)	1 (0.7)
Occupational status	n (%)	n (%)	n (%)
Working partly or full time	174 (79.1)	61 (81.3)	113 (77.9)
Unemployed	6 (2.7)	2 (2.7)	4 (2.8)
Pensioner (disabled/elderly pensioner)	34 (15.5)	12 (16.0)	22 (15.2)
Other	6 (2.7)	0 (0.0)	6 (4.1)
PHC centre	n (%)	n (%)	n (%)
Akureyri	109 (49.5)	39 (35.8)	70 (64.2)
Husavik	40 (18.2)	13 (32.5)	27 (67.5)
Sauðarkrokur	71 (32.3)	23 (32.4)	48 (67.6)

HbA1c levels

The HbA1c levels are shown in Table 2. Levels ranged from 24 to 47 mmol/mol. None was found with HbA1c at diabetes level. A total of 29 participants (13.2%) were measured with the ADA definition of prediabetes at 39–47 mmol/mol, of these, 14 were men and 15 women. The normal HbA1c group had mean levels of 33.8 mmol/mol (SD ± 2.7). Contrast showed for the people with prediabetes HbA1c level had mean levels of 41.5 mmol/mol (SD ± 2.2). No significant difference in HbA1c was identified between genders, although a tendency toward higher HbA1c levels in men was observed ($p = 0.056$).

Body Mass Index

BMI ranged from 18.5 to 48.2 kg/m², with a mean 28.8 (SD ± 5.4) and median 27.7 kg/m². Results showed that 39.1% were overweight (25–30 kg/m²) and obesity (≥ 30 kg/m²) was found in 34.5% of participants, 5% had severe obesity of BMI over 40 kg/m². No significant difference in BMI was found regarding to gender ($p = 0.982$). The BMI scores among the 29 participants with prediabetes ranged between a minimum of 24.4 kg/m² and a maximum of 48.2 kg/m² with a mean of 32.3 kg/m² (SD ± 5.7). BMI scores among the 191 participants who did not have elevated HbA1c levels ranged between 18.5 kg/m² and 43.6 with a mean of 28.3 kg/m² (SD ± 5.2). There was a significant positive correlation between BMI and HbA1c levels for all participants: $r_{(218)} = 0.146, p = 0.044$.

FINDRISC scores

The characteristics of FINDRISC according to gender are reported in Table 3. One in five (21.4%) had first degree relatives with T2DM. A significant difference between gender was only found in the daily consumption of fruit and vegetables, in favour of women ($p = 0.004$). There was no significant gender difference in FINDRISC score, with a mean score for men of 9.0 (SD ± 5.3) and for women of 9.7 (SD ± 4.9), $p = 0.332$. However, there was a significant difference between the normal HbA1c group ($n = 191$) and the prediabetes group ($n = 29$) with FINDRISC

scores of 8.6 (SD ± 4.5, range 0–22) points and 14.7 (SD ± 5.2, range 3–24) points, respectively ($p < 0.001$).

Sensitivity and specificity

Table 4 shows the results of sensitivity and specificity calculations for different cut-off points of FINDRISC from 9 to 15 points, with FINDRISC set as an outcome in the sensitivity and specificity calculation using the HbA1c level of prediabetes/not prediabetes as criteria. Best sensitivity (93.1%) of FINDRISC was found at ≥ 9 points, finding 27 of 29 participants with HbA1c levels at prediabetes value, but specificity was low only 53.4%. Using cut-off value of ≥ 11 or ≥ 12 points gave a little lower sensitivity (79.3 and 75.9% respectively) but better specificity (67 and 73.3% respectively) with fewer false positive. Using ≥ 15 points on FINDRISC resulted in a sensitivity of only 41.4%, missing more than half of those with a prediabetes HbA1c value, though the specificity was high (88.5%).

By using ≥ 11 points as cut-off value of FINDRISC, calculations of the ROC curve showed area under the curve (AUC) to be 0.814, with 95% confidence interval (CI), lower bound of 0.733, an upper bound of 0.895 and standard error of 0.041. The result indicated that the best accuracy of finding people with prediabetes in this study was a FINDRISC score of ≥ 11 points, which gave the value closest to the upper left corner of the ROC curve.

Discussion

This is the first study of prediabetes and undiagnosed T2DM prevalence in Iceland using both measurements of HbA1c level and FINDRISC score. Although none of the participants in our study was found with undiagnosed diabetes, 13.2% had biomarkers of prediabetes. Our sample was similar to the general population in the three study areas according to age and educational level, but this was not the case with the gender ratio. In our study, 65.9% of the participants were women, whereas the ratio in the general population is even [40]. The fact that fewer men than women participated in the study may partly explain why no participants were found with undiagnosed T2DM as more men than women are diagnosed with T2DM [23].

If the results are representative for the prevalence of prediabetes in the Northern Iceland areas of the study, this gives us a cautious indication that approximately 2300 of 17,600 inhabitants, within the age limits of the study and more men than women, may unknowingly have biomarkers of prediabetes. This is a cautious indication as the calculation of the confidence level of the sample size gave an 85% confidence level with a 5% margin of error, which indicates that up to 35,000 of approximately 266,000 inhabitants in Iceland, aged

Table 2 HbA1c level of the participants according to gender, number and (percentage)

HbA1c Level mmol/mol	Total n (%)	Men n (%)	Women n (%)
24–38	191 (86.8)	61 (81.3)	130 (89.7)
39	5 (2.3)	2 (2.7)	3 (2.1)
40–41	12 (5.5)	9 (12.0)	3 (2.1)
42–47	12 (5.5)	3 (4.0)	9 (6.2)
Lowest level		24	25
Mean		35.48 (SD ± 3.92)	34.44 (SD ± 3.55)

Table 3 Overall FINDRISC scoring and according to gender

	Scoring Points (P)	Overall (n = 220)	Gender		P
			Men (n = 75)	Women (n = 145)	
Age		n (%)	n (%)	n (%)	.982
18–44 years	(0 P)	56 (25.5)	18 (24.1)	38 (26.2)	
45–54 years	(2 P)	56 (25.5)	19 (25.3)	37 (25.5)	
55–64 years	(3 P)	55 (25.0)	19 (25.3)	36 (24.8)	
65 years and older	(4 P)	53 (24.1)	19 (25.3)	34 (23.5)	
BMI					.838
< 25 kg/m ²	(0 P)	58 (26.4)	21 (28.0)	37 (25.5)	
25–30 kg/m ²	(1 P)	86 (39.1)	30 (40.0)	56 (38.6)	
≥ 30 kg/m ²	(3 P)	76 (34.5)	24 (32.0)	52 (35.9)	
Waist circumference (2 cm above navel)					
Men < 94 cm/Women < 80 cm	(0 P)	63 (28.6)	30 (40.0)	33 (22.8)	
Men 94–102 cm/Women 80–88 cm	(3 P)	49 (22.3)	14 (18.7)	35 (24.1)	
Men > 102 cm/Women > 88 cm	(4 P)	108 (49.1)	31 (41.3)	77 (53.1)	
Physically active ≥ 30 min/daily					.672
Yes	(0 P)	203 (92.3)	70 (93.3)	133 (91.7)	
No	(2 P)	17 (7.7)	5 (6.7)	12 (8.3)	
Fruit & vegetables daily					.004 ^a
Every day	(0 P)	140 (63.6)	38 (50.7)	102 (70.3)	
Not every day	(1 P)	80 (36.4)	37 (49.3)	43 (29.7)	
Use of blood pressure medicine					.085
No	(0 P)	165 (75.0)	51 (68.0)	114 (78.6)	
Yes	(2 P)	55 (25.0)	24 (32.0)	31 (21.4)	
History of high blood glucose (including gestation diabetes)					.130
No	(0 P)	192 (87.3)	69 (92.0)	123 (84.8)	
Yes	(5 P)	28 (12.7)	6 (8.0)	22 (15.2)	
Family history of diabetes					.743
Non	(0 P)	138 (62.7)	48 (64.0)	90 (62.1)	
First degree relatives	(3 P)	47 (21.4)	17 (22.7)	30 (20.7)	
Second degree relatives	(5 P)	35 (15.9)	10 (13.3)	25 (17.3)	
FINDRISC SCORE					.733
≤ 8		104 (47.3)	37 (49.4)	67 (46.2)	
9–11		43 (19.5)	16 (21.3)	27 (18.6)	
12–14		39 (17.7)	13 (17.3)	26 (17.9)	
15–20		27 (12.3)	6 (8.0)	21 (14.5)	
21–26		7 (3.2)	3 (4.0)	4 (2.8)	

^a Significant at the <0.05 level

between 18 and 75 years as of 1 January 2021 [31], may show biomarkers of prediabetes. That is nearly equal to the total population of North Iceland. As this is the first study to assess prediabetes in Iceland, we are unable to compare our results with other results or other areas in Iceland. Here, the prevalence of prediabetes was lower than reported in a cross-sectional study in the Faroe Islands conducted in the years 2011–12, using HbA1c measurements followed by the non-fasting and fasting

glucose and oral glucose tolerance test (OGTT). That study found that the prevalence of prediabetes was 22.3% in the age group of 44–77 years, with prevalence increasing with age [41]. The NANES cross-sectional survey estimated that the prevalence of prediabetes in the U.S. might be up to 38.6% in 2017 [42]. The fact that our sample included fewer men than in the general population in the area may partly explain why the prevalence of prediabetes was low. Also, that the participants

Table 4 Sensitivity and specificity of FINDRISC in predicting prediabetes risk, using cut-off-points at: ≥ 9 , ≥ 10 , ≥ 11 , ≥ 12 , ≥ 13 , ≥ 14 or ≥ 15 points and HbA1c level 39–47 mmol/mol as value for prediabetes

FINDRISC SCORE	Sensitivity true positive	Specificity true negative
≥ 9 points	93.1%	53.4%
≥ 10 points	79.3%	67.0%
≥ 11 points	79.3%	67.0%
≥ 12 points	75.9%	73.3%
≥ 13 points	69.0%	81.2%
≥ 14 points	55.2%	83.8%
≥ 15 points	41.4%	88.5%

were self-selected and had high educational level may have influenced the results. It should be kept in mind that the incidence of T2DM in Iceland is increasing. Research results using data on prescribed medicine for T2DM estimate that 10,600 individuals had T2DM in the year 2018 and that by 2040 up to 24,000 individuals may have the disease [43].

Obesity has been linked to an increased diabetes risk [21], and was found in 34.5% of the participants. That is much higher than earlier Icelandic results. The restriction on unnecessary visits to PHC centres during the Covid-19 pandemic may partly explain the high obesity figures. In 2007, obesity was found in 20% of Icelanders, whereas it was 27% in 2017, giving Iceland a ranking of number two in the prevalence of obesity within the OECD countries [43]. Earlier research indicates that women living outside the capital area in Iceland are more likely to be obese [44]. Public health care needs to find ways to reverse this trend by increasing awareness of the adverse consequences of obesity for the health of the population.

The results of our ROC curve calculations showed that the optimal cut-off point on FINDRISC was at ≥ 11 points, with AUC at 0.814, indicating the best sensitivity and specificity for predicting the risk of prediabetes in the sample. Our results are comparable to results from the HUNT study in Norway which suggests using ≥ 11 points on FINDRISC as the cut-off point for predicting risk of T2DM [45]. Other research suggests different cut-off points. Meijnikman et al. claim that a score of ≥ 13 points have the best sensitivity and specificity in overweight or obese people [36]. Using FINDRISC in a Lebanese University, Abdallah et al. found that the best cut-off score was ≥ 9.5 points for prediabetes and ≥ 10.5 points for undiagnosed T2DM [46]. The HUNT study and our study used a population-based sample to analyse the best cut-off score. In addition, the

health care systems in the Nordic countries are similar [43]. However, validation of the best cut-off score for each population should be confirmed [36].

FINDRISC is non-invasive and easily applied instrument within PHC to identify those that may benefit from intervention for health promotion [38, 46]. The results showed higher mean scores on FINDRISC for the group with HbA1c levels of prediabetes compared to the group with normal HbA1c levels. But within the normal HbA1c group, FINDRISC scores of up to 22 points were found, indicating an up to 50% likelihood of developing T2DM in the next 10 years. It can therefore be recommended that health care providers in PHC use FINDRISC to screen for elevated risk of T2DM among their clients aged between 18 and 75 years. Clients who score ≥ 11 points should also be examined by measuring their HbA1c levels or blood glucose.

Those found with HbA1c levels of prediabetes should be offered person-centred intervention towards lifestyle change, led by PHC nurses, with the aim to lower diabetes risk for the individual. Results of randomised trials on the effects of nurse-led interventions to help people at risk of or with T2DM, to move towards better self-management and better control of HbA1c, show signs of continuing benefits after the intervention is over [18, 47].

WHO calls for preventive pathways to find people at early stages of non-communicable diseases like prediabetes is in T2DM [48]. Research shows that only part of people with prolonged stage of elevated glycemia or prediabetes progress to diabetic stage while others return to normal glycemia [49–51]. It has been reported that lifestyle changes may reduce the relative risk of progressing from prediabetes to diabetes by 40 to 70% [52]. Prior research indicates that physician’s attitude toward diabetes prevention may make an impact on screening for and treatment of prediabetes in PHC [53, 54]. It may not be customary practice to treat people actively where prediabetes is found [55]. However, screening to find those at risk offers grounds for intervention and health promotion as there may be time for patients to bring glycaemia levels back to normal [49–51]. Lifestyle changes that minimise the risk of further development of prediabetes are found to be cost-effective [20].

Strength of the study

All participants were measured by the same person, minimising differences between measurements. The sample size is acceptable and representative according to the total population. This is the first study in Northern Iceland to measure the prevalence of prediabetes and undiagnosed diabetes.

Limitations

Due to the Covid-19 epidemic, the recruitment of participants took longer than anticipated and the recruitment plan had to be changed. The participants were self-selected, not randomly assigned to the study. This may have affected the study sample as the educational level was high and more women than men participated, although the gender ratio is almost equal in the study population [40]. In addition, as the prevalence of prediabetes was found to be lower compared to research in other countries, there is a possibility that low prevalence here might have affected results of level of the FINDRISC score of ≥ 11 points as screening for prediabetes, therefore further research is needed.

FINDRISC has been criticised for not fully capturing the impact of gender and age. It may identify more women than men as high-risk individuals and therefore the cut-off points on FINDRISC may need to be adjusted for gender [56]. This criticism was not sustained in this study, but the uneven gender proportion may explain why no gender difference was found in the FINDRISC scores.

Conclusion

Prevalence of overweight and obesity was high in this study. Despite the known increasing incidence of T2DM and association of overweight and higher risk of T2DM, this survey did not identify people with previously unknown T2DM. People found with biomarkers of prediabetes were fewer than expected in comparison to other countries. These favorable results may reflect the solid health care in Iceland. Also, plausible raising awareness of the importance of health promotion interventions within the Icelandic PHC.

FINDRISC is a short, non-invasive, easily applied instrument that this study found useful in screening within PHC for people at risk of prediabetes. The instrument can be used in advance of other more expensive and invasive testing for prediabetes or undiagnosed T2DM to enable earlier intervention by assisting decision making, health promotion actions toward prevention of T2DM.

Key results

13.2% was found with prediabetes level of HbA1c, unaware of their condition.

FINDRISC is a non-invasive and an effective screening tool within the PHC to find people at prediabetes level, using score of ≥ 11 to set as consideration of further testing of HbA1c level or other more invasive screening of T2DM.

Abbreviations

ADA	American Diabetes Association
FINDRISC	Finnish Diabetes Risk Score
HbA1c	Glycated Haemoglobin
HSN	Health Institute of North Iceland
IDF	International Diabetes Federation
IFG	Impaired Fasting Glucose
OGTT	Oral Glucose Tolerance Test
PHC	Primary Health care
T2DM	Type two Diabetes mellitus
VSN	The Icelandic National Bioethics Committee

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Conflict of interest

The author's state they have no conflict of interest.

Authors' contributions

The first author (EA) collected and analysed and interpreted the data and co-wrote the manuscript. AKS, a grant holder, developed the protocol and co-wrote sections of the manuscript. MG and BCHK developed the protocol and co-wrote the manuscript. TS analysed and interpreted the data and co-wrote the manuscript. The author(s) read and approved the final manuscript.

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Availability of data and materials

The datasets used and/or analyzed during the current study available from the corresponding author on reasonable request.

Declarations

Ethics approval and consent to participate

This study was performed in line with the principles of the Declaration of Helsinki. Approval was granted by Regional Ethical Committee of The Icelandic National Bioethics Committee (VSN-19-080-51 approved 14/05/2019 and VSN-19-080-V1 approved 14/01/2022). All participants signed an informed consent form before participating in the study. The approval from the Icelandic National Bioethics Committee is in Icelandic, if requested it can be provided.

Consent for publication

Not applicable.

Competing interests

All authors declare no competing interest. EA is RN at primary health care facility within the Health Institute of North Iceland. However, the study location did not include working area of EA and no participant are or have been EA patients. In this study EA is as doctoral student at the University of Akureyri.

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Article

Can Waist-to-Height Ratio and Health Literacy Be Used in Primary Care for Prioritizing Further Assessment of People at T2DM Risk?

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Abstract: Background: To identify people at risk of type 2 diabetes. Primary health care needs efficient and noninvasive screening tools to detect individuals in need of follow-up to promote health and well-being. Previous research has shown people with lower levels of health literacy and/or well-being scores are vulnerable but may benefit from intervention and follow-up care. Aims: This cross-sectional study, aimed to identify people at risk for type 2 diabetes by comparing the Finnish Diabetes Risk instrument with the waist-to-height ratio. Further, the difference was examined in health literacy and well-being scale scores in the countryside versus town areas, respectively. Results: In total, 220, aged 18–75 years, participated. Thereof, 13.2% displayed biomarkers at prediabetes level of HbA1c (39–47 mmol/mol); none had undiagnosed diabetes. Of the participants, 73% were overweight or obese. Waist-to-height ratio demonstrated 93.1% of the prediabetes group at moderate to high health risk and 64.4% of the normal group, with an area under the curve of 0.759, sensitivity of 93.3%, and specificity of 63.1%. Residency did not influence prediabetes prevalence, health literacy, or well-being. Conclusion: Waist-to-height ratio and the Finnish Diabetes Risk instrument may be suitable for identifying who need further tests and follow-up care for health promotion in primary care.

Keywords: prediabetes; countryside/town; screening; well-being; type 2 diabetes

1. Introduction

Type 2 Diabetes Mellitus (T2DM) risk or prediabetes biomarkers indicate elevated risk for the individual, contributing to the development of insulin resistance in the outlining of T2DM disease [1]. Prediabetes is defined by elevated levels of HbA1c, impaired fasting glucose (IFG), or impaired glucose tolerance (IGT), which is based on a 2 h oral glucose tolerant test (OGTT), above the normal range but not reaching the diagnostic level of T2DM [2].

Prediabetes biomarkers are linked to an increased risk of up to a ratio of 1:2 progression to T2DM and an increased risk for several serious comorbid conditions such as cardiovascular disease (CVD), which may be in progression before T2DM diagnosis [3]. Additionally, up to one-third of people with a body mass index (BMI) indicating obesity have prediabetes signs [1]. It is estimated that the interval between the onset and diagnosis of T2DM is reported to be up to 7 years in the US [4], with nearly half of cases unaware of their T2DM condition [5]. Current projections are that, by 2030, 478 million people worldwide will have T2DM [6]. A crude estimation of US adult prediabetes prevalence in 2017–2020 was 38% [7].

In Iceland, the prevalence of T2DM has been increasing, in 2018 prevalence in Iceland was 3.5% in women and 4.1% in men showing similarity in prevalence and incidence as of US 20 years earlier. According to the Icelandic Heart Association population study, a total of 10,600 individuals were diagnosed with T2DM in 2018 [8]. By comparing the medical prescription database and T2DM prevalence data, an underestimation of 29% in T2DM prevalence was established [8].

Population studies in Iceland show a high obesity prevalence [9], estimated to be 20% in 2007 and 27% in 2017 [8]. The prevalence of undiagnosed T2DM is uncertain in Iceland, but research indicates that, in northern Iceland, prediabetes prevalence, here as based on the HbA1c diagnostic level of American Diabetes Associations (ADA), may be 13.2% [10]. If the increasing levels of diabetes are to be stemmed, it is important to develop simple and effective screening strategies to identify those who are the most at risk, for instance, those with obesity or prediabetes.

Although biomedical tests such as HbA1c, 2 h OGTT and fasting glucose can be used for diagnostic purposes, these are not always readily implementable across sparsely populated countries, such as Iceland [2]. However, questionnaires like the Finnish Diabetes Risk Score (FINDRISC) have been designed to estimate the risk of developing T2DM over the next 10 years [11]. In addition, measurements ratios, including BMI for obesity, waist-to-height Ratio (WHtR), and waist-to-hip Ratio (WHR) have been used for overall, diabetes, or cardiovascular health risk assessments [12,13].

In addition to these traditional biometric measures, poorer mental health and well-being has been associated with an increased risk of prediabetes and progression to T2DM [14]. Persons with T2DM may also have double the likelihood of depression than in the general society [15]. Thus, measuring well-being, health-related quality of life (HRQoL), and depression signs may have additional benefits in identifying those with prediabetes and undiagnosed T2DM [16].

Health literacy (HL) is the capability to gather, understand, judge, and follow complex information and demands of what may be good for one's health to prevent disease and promote health [17], that is, motivating one to improve quality of life [17–19]. Better HL positively influences health outcomes [19]. A systematic review of limited HL prevalence in T2DM points to the fact that limited HL may affect self-management and empowerment and that may lead to poorer health outcomes for people with T2DM [20]. The status of HL between countries may vary because several factors may influence HL in addressing the interactive, critical, or functional level of HL [21]. However, the variance in HL may assist the addressing and decision-making of integrated healthcare services and follow-up aiming to improve HL for individuals [20].

Furthermore, HL has been found to be a key in self-management and in personalizing services for T2DM patients [21,22], correlating to lower health literacy and poorer wellbeing and worse T2DM management [18,20,22].

Primary healthcare (PHC) needs to address if and which noninvasive screening may identify people at T2DM risk, before further and more invasive testing and categorizing within the risk group are conducted. Also, if HL or well-being show any characteristics within risk groups. Giving the PHC the opportunity to concentrate first on high-risk individuals while providing less intrusive methods for low-risk individuals [23].

This cross-sectional study aimed to find the best suitable and noninvasive methods for identifying people at risk of T2DM, by using HbA1c measurement in comparing the sensitivity and specificity of FINDRISC scale scoring with WHtR, BMI, and WHR. Furthermore, the present study has examined if differences were found at the HL level and well-being scale scores among people living in northern Iceland, that is, in the countryside versus town. In addition, the present study has explored if HL and/or well-being scale scores may contribute to identifying vulnerable groups regarding T2DM risk, and who are in need of targeted support.

2. Materials and Methods

This was a cross-sectional study inviting participants at risk of diabetes but not diagnosed with diabetes to three of the largest Primary Health Clinics in North Iceland. The study was conducted as a pre-phase of an intervention study that followed. The research was launched at the early beginning of the COVID-19 pandemic in Iceland. Data collection was completed via one-on-one interviews with the first author between 1 March 2020 and 15 May 2021.

2.1. Participants and Data Collection

All inhabitants were eligible for participation if they were (a) aged 18–75 years and living in the service area of the three PHCs of the Health Institution of North Iceland included in the research, (b) not diagnosed with diabetes, and (c) spoke and understood Icelandic or English fluently.

The original plan was to recruit participants via introduction letters handed out by a receptionist to all patients fulfilling age criteria who visited the participating PHC clinics. But the authorities placed strict restrictions on all visits to PHC clinics both for the public and all ‘outsiders’ (researchers) when the COVID pandemic hit, resulting in changes from the original plan of approaching participants visiting the PHC clinics.

Almost half of the participants ($n = 101$) were recruited, as originally planned, from the end of February until the beginning of May 2020. The remaining ($n = 119$) participants were recruited via flyers and advertisements in local papers from January 2021 to May 2021.

The data were collected by the first author (EA) at the PHC clinics or at the research center when the PHC clinics were locked down because of COVID restrictions. We collected data on height, weight, waist, and haemoglobin A1c protein (HbA1c) (see Sections 2.3 and 2.3.1). In addition, the participants answered questionnaires to collect data on age, gender, educational level, working and living status, family history of T2DM, and whether they had been diagnosed with diabetes. In addition, question 7 in the FINDRISC instrument asks if an individual has ever been diagnosed with high glucose levels, including when pregnant. The participants also filled in diabetes risk, health literacy, and well-being questionnaires (see Sections 2.3.2–2.3.5).

2.2. Geographical Area and Layout of Primary Health Care in Iceland

Iceland is divided into seven health districts; in each, there is a health institution coordinating small area hospitals and PHC clinics, that are financed by the state. PHC locations have historical backgrounds, based on distribution of settlements, and challenging traveling in winter [24,25]. The northern district has scattered agricultural areas beside industry, service, and fishing settlements, with an increasing focus on tourism over the past decade [25]. Around 36,000 of the total 368,792 inhabitants of the country (as of 1 January 2021) [26] were living in northern Iceland, with around 17,600 in the service area of the three PHCs participating in the study. Location was Akureyri the town area and Husavik and Saudarkrokur the countryside areas, each with one sub-rural town. According to Statistic Iceland definition of population density in Iceland, that are based on international definitions. The terms town and countryside describe the areas better than the terms urban and rural according to density of inhabitants and service provided in the areas included in the study [26].

In Iceland, especially in northern Iceland, the winters are both cold and dark, and even though there are paved main roads, they are often filled with ice and snow. However, improved transportation in recent decades and the internet have significantly reduced isolation in more dispersed localities [26]. Though public transportation is limited, private cars are common [26]. Cultural activities and infrastructure are historically strong in smaller, more rural towns and in the surrounding areas in Iceland, with access to education such as high school, industrial, and vocational training [26].

2.3. Biological Measurements, Demographic Definitions, and Instruments

Measurements of height to the nearest 0.1 cm with a portable measuring tape and weight in light clothing on a digital scale to the nearest 100 g calculating BMI as kg/m^2 —in which overweight was determined as $>25 \text{ kg}/\text{m}^2$ and obesity was determined as $\geq 30 \text{ kg}/\text{m}^2$ —were taken [27]. Also, waist (2 cm over navel) and hip (at widest point) measurements, here with 1.5 or 3 m capacity measuring tape and evaluating consistency of the measuring tape regularly, enabled calculation of both WHR and WHtR. Using a definition from the World Health Organization (WHO) for Europe, WHR caused increased a health risk for men at ≥ 0.94 and ≥ 0.80 for women [28]. Former research indicates better predictive power for the waist-to-height ratio than BMI for diabetes risk, defining a WHtR of <0.5 as no increased health risk, 0.5–0.6 as increased to high health risk, and ≥ 0.6 as very high health risk [29].

2.3.1. Haemoglobin A1c Protein (HbA1c) Measurements, Diabetes and Prediabetes Definition Levels

The HbA1c level, which is an approved measurement as a diagnostic test of T2DM by WHO [2], was analysed with capillary blood samples by a ‘DCA Vantage⁶⁶⁰⁹’ (Siemens Medical Solutions Diagnostics Europe Limited, Dublin, Ireland). Here, the ADA classification was used, which define prediabetes stage as HbA1c levels between 39 and 47 mmol/mol (5.7–6.4%) and levels of $\geq 48 \text{ mmol}/\text{mol}$ ($\geq 6.5\%$) as having T2DM [30].

2.3.2. Finnish Diabetes Risk Score (FINDRISC) Instrument

FINDRISC was developed in Finland as a risk scale of T2DM in the next 10 years and is an approved diagnostic test of diabetes risk [31]. It is easy to use, inexpensive, non-invasive, and validated in several populations [32], including in Iceland [11]. It is scored on a scale from 0 to 26 points, with a higher score representing higher T2DM risk [31].

To identify those at risk, the reported best cut-off points may vary between countries, from 11 points in Bulgaria [33] to 15 points in Norway [34], where lower income status in the country may have an influence towards the lower cut-off point [35]. Here, using ≥ 11 points gave the best sensitivity and specificity for finding those at HbA1c level of prediabetes, with area under the curve (aROC) at 0.814 (CI 0.733–0.896) [10].

2.3.3. Health Literacy (HL) Questionnaire

The Icelandic version of the European Health Literacy questionnaire (HLS-EU-Q16) was used [19]. The HLS-EU-Q16 has been explicitly described before [36]. The Icelandic HLS-EU-Q16-IS consists of 16 questions on a four-answer scale ranging from ‘very difficult’ and ‘fairly difficult’ (either giving 0 points) to ‘fairly easy’ and ‘very easy’ (either giving 1 point). Scores are summarized, with the final score from 0 to 16 points; a higher score represents better HL, which is categorized into inadequate HL (scoring 0–8), problematic HL (scoring 9–12), and sufficient HL (scoring 13–16). Valid HLS-EU-Q16IS responses include no more than two missing questions [19].

2.3.4. World Health Organization Well-Being Index (WHO-5)

The WHO-5 questionnaire measures subjective psychological well-being with five questions, that ask the respondent about their well-being in the previous two weeks. Each question is answered on a scale from 0 to 5, giving a maximum of 25 points. Multiplying the raw scoring of WHO-5 by four gives a range of well-being on a scale from 0 (absent well-being) to 100 (maximal well-being). A score of <50 is an indicator of reduced psychological well-being and a score of ≤ 28 is an indicator of depression [37]. It has been validated in many languages and countries [37], including Iceland [38].

2.3.5. Europe Quality of Life Five Dimension Five Level Instrument (EQ-5D-5L)

The EQ-5D-5L is a standardized tool for health status measurement [39], that enables the measurement of HRQoL [40]. The instrument contains two parts: a descriptive com-

ponent with five dimensions (5D) of mobility, self-Care, usual activities, pain/discomfort, and anxiety/depression. The dimensions are responded to on five levels (5L): (1) 'no', (2) 'slight', (3) 'moderate' (4) 'serve', and (5) 'unable/extreme' problems, with a total of 3125 plausible results [39]. Results of each dimension are reported as a code. The code 11111 gives information of 'health state' of answering no problems of all dimensions, but the code 11155 a 'health state' of no problem with the first three dimensions but unable/extreme problems regarding pain/discomfort and anxiety/depression. The second part of the EQ-5D-5L includes a Visual Analogue Scale (EQ-VAS) that measures self-reported health status on a scale from 0 (the worst possible health you can image) to 100 (the best health you can image) [39,40].

2.4. Statistical Analysis

Descriptive statistics were used describing continuous variables to calculate means, standard deviations, and ranges. Relative risk and odd ratio were calculated using crosstabs. For categorical variables, counts and proportions were used. The sample characteristics, according to residency or groups of normal HbA1c levels versus prediabetes levels of HbA1c, were calculated by independent t-tests for continuous variables, chi-square tests for categorical variables, and retested with ANOVA or nonparametric chi-square tests when appropriate.

Microsoft Excel was used to calculate the BMI, WHR, and WHtR of each participant. Chi-square tests were used in calculations for comparison of WHtR and WHR in finding people at risk of T2DM; this was carried out by dividing the sample into two groups of the normal HbA1c group and prediabetes level group. Normal HbA1c or prediabetes level were used to compare the accuracy of sensitivity and specificity calculation to find people at prediabetes biomarkers with the cut off score of ≥ 11 points on FINDRISC [10] and the same aROC calculation of WHtR, BMI, and WHR. A perfect accuracy of aROC with neither false positives nor false negatives is 1, but 0.5 indicates the results are no better than chance. The best cut-off points for identifying people with prediabetes biomarkers were the shortest distance to the upper left corner of the ROC curve [41].

When comparing variables according to residency, results were controlled for age. Correlation and regression calculations were used for estimation of the background variable relationships to HLS-EU-Q16-IS and WHO-5 questionnaires. EQ-5D-5L is reported as the health state index of each of the five health dimensions from 1 to 5. A value set for calculations of Quality of Adjusted life Years (QUALY) is not yet available for Iceland [39].

The dataset was analysed using IBM SPSS statistics 27. If applicable, missing data were excluded listwise. Significant statistical difference (two tailed) was $p \leq 0.05$.

2.5. Ethical Considerations

The present study was performed in accordance with the Helsinki Declaration and with the approval of the Icelandic National Bioethics Committee (VSN), (VSN-19-080-V1 approved 14 January 2020. All participants received and read an informational letter and signed an informed consent form before participating.

Trial registration: This study is a pre-phase of the registered study 'Effectiveness of Nurse-coordinated Follow-Up Programme in Primary Care for People at Risk of T2DM' at www.ClinicalTrials.gov (NCT01688359) (accessed on 30 December 2020).

3. Results

3.1. Main Findings

The majority of participants reported daily exercise and had no family history of T2DM. But 13.2% were found with HbA1c biomarkers of prediabetes, none with undiagnosed diabetes. When controlled for age, neither residency nor gender influenced prevalence of prediabetes biomarkers. BMI levels of overweight and obesity were high. People with increased overall health risk according to WHtR had 7.463 greater odds of having HbA1c biomarkers of prediabetes. WHtR found 68.2% participants at overall increased health risk

when FINDRISC, using a cut-off point of ≥ 11 points, found 39.1% to be at increased diabetes risk. Residency had no influence on well-being, but being a man, age, and prediabetes biomarkers showed correlation to higher score on WHO-5. Health literacy and well-being questionnaires gave added information not included in the FINDRISC instrument. Findings will now be described in more details.

3.2. Characteristics of the Study Participants According to Residency

A total of 220 individuals participated, of which 66% were female. The background information is presented in Table 1. There was an equal gender distribution between residencies. Countryside residents were significantly older than town residents $p < 0.001$. The educational level was high, but town residents had a higher educational level $p < 0.05$.

Table 1. Background characteristics of countryside vs. town participants.

	Countryside (n = 111)	Town (n = 109)	<i>p</i> Countryside/Town
Mean age (in years, 18–75 years)	55.3 (SD \pm 13.2)	48.9 (SD \pm 14.3)	$p < 0.001$ *
Age	n (%)	n (%)	
<45 years	19 (17.1)	35 (32.1)	
45–54 years	29 (26.1)	30 (27.5)	
55–64 years	31 (27.9)	25 (22.9)	
65 and over	32 (28.8)	19 (17.4)	
Gender	n (%)	n (%)	$p = 0.602$ **
Male	36 (32.4)	39 (35.8)	
Female	75 (67.6)	70 (64.2)	
Living status	n (%)	n (%)	$p = 0.784$ **
Alone	7 (6.3)	10 (9.2)	
With one other person	55 (49.5)	46 (42.2)	
With two or more persons	49 (44.1)	53 (48.6)	
Educational level	n (%)	n (%)	$p = 0.049$ **
Elementary/junior high or equal	31 (27.9)	21 (19.3)	
Upper secondary/vocational training/	35 (31.5)	30 (27.5)	
Senior high school or equal			
University degree	44 (39.7)	57 (52.3)	
Educational level missing	1 (0.9)	1 (0.9)	
Occupational status	n (%)	n (%)	$p = 0.632$ **
Working partly or full time	84 (75.7)	81 (74.3)	
Unemployed	2 (1.8)	4 (3.7)	
Pensioner (disabled/elderly)	20 (18.0)	13 (11.9)	
Other ***/did not answer	5 (4.5)	11 (10.1)	

* Independent *t*-test. ** Chi-square test. *** Participant who marked multiple of the other three groups; one did not answer occupational status.

3.3. Biological Measurements and Results from FINDRISC

The results of biological measurements and score on FINDRISC are shown in Table 2. No individuals were found to have undiagnosed T2DM and 13.2% of the participants had an HbA1c level indicative of prediabetes.

On FINDRISC, 92.3% reported daily exercise. Those found with HbA1c prediabetes biomarkers, were less likely to exercise ($t_{(218)} = 2.07$, $p = 0.04$ (two tailed)). No family history of diabetes was reported by 62.7%, 21.4% had T2DM history by second relatives and 15.9% by first relatives. Supported by participants with HbA1c biomarker levels of prediabetes and family history, the majority had no family history of diabetes (62.1%), but 34.5% had first relatives with diabetes.

Table 2. HbA1c levels, FINDRISC score, BMI, WHtR, and WHR according to residency.

Defined as		Countryside (n = 111)	Town (n = 109)	p-Value Countryside/Town
HbA1c levels		n (%)	n (%)	
Mean (SD)		34.3 (SD ± 3.4)	35.3 (SD ± 4.0)	<i>p</i> = 0.048 *
24–38 mmol/mol	Normal	100 (90.1)	91 (83.5)	
39–47 mmol/mol	Prediabetes	11 (9.9)	18 (16.5)	
FINDRISC score		n (%)	n (%)	
Mean (SD)		10.1 (SD ± 4.5)	8.8 (SD ± 5.5)	<i>p</i> = 0.056 *
<11 points		62 (55.9)	72 (66.1)	<i>p</i> = 0.121 †
≥11 points		49 (44.1)	37 (33.9)	
BMI kg/m ²		n (%)	n (%)	
Mean (SD)		29.5 (SD ± 5.5)	28.1 (SD ± 5.2)	<i>p</i> = 0.053 *
18–24.99	Normal	24 (21.6)	35 (32.1)	
25–29.99	Overweight	46 (41.4)	40 (36.7)	
30–39.99	Obese	33 (29.7)	31 (28.4)	
40>	Severely obese	8 (7.2)	3 (2.8)	
WHtR		n (%)	n (%)	<i>p</i> < 0.001 †
<0.5	No increased risk	22 (19.8)	48 (44.0)	
≥0.5 and <0.6	Increased to high risk	59 (53.2)	33 (30.3)	
≥0.6	Very high risk	30 (27.0)	28 (25.7)	
WHR		n (%)	n (%)	<i>p</i> < 0.001 †
σ < 0.94 & ρ < 0.80	Low health risk	24 (21.6)	50 (45.9)	
σ ≥ 0.94 & ρ ≥ 0.80	Higher health risk	87 (78.4)	59 (54.1)	

* Independent *t*-test, † Chi-square test, σ men, ρ women.

FINDRISC scores were significantly lower for the normal HbA1c group than the prediabetes group, at 8.6 (SD ± 4.5) and 14.7 (SD ± 5.2), respectively (*p* < 0.001). Using a cut-off point of ≥11 points on FINDRISC gave a sensitivity of 79.3% and a specificity of 67%, showing 86 participants at increased T2DM risk, thereof 63 with normal HbA1c levels and 23 at prediabetes HbA1c levels.

BMI ranged from 18.5 to 48.2 kg/m². The results showed that no participants were underweight, but 78.4% of the countryside and 67.9% town residents were overweight or obese (see Table 2).

The normal HbA1c group had a lower BMI, at *M* = 28.3 (SD ± 5.2), than the prediabetes biomarker HbA1c group *M* = 32.3 (SD ± 5.7); *t*₍₂₁₈₎ = −3.618, *p* < 0.001. An aROC of the BMI calculation using HbA1c as a definition of prediabetes gave a result of an aROC of 0.713, *p* < 0.001 (CI 0.624–0.803) sensitivity of 96.6% and specificity of 69.1% at a BMI of 25.0 kg/m².

Differences in health risk evaluation were found between countryside and town residents when using either the WHR or WHtR (see Table 2). Of the prediabetes biomarkers group, 89.7% were in the higher health risk WHR group, but this was also true for 62.3% of the normal HbA1c group. WHtR measurements found 93.1% of the HbA1c prediabetes biomarkers group at a moderate to high health risk and 64.4% of the normal HbA1c group.

An aROC curve calculation using low or high health risk according to the results of WHR to find people at prediabetes biomarker levels of HbA1c showed the aROC to be 0.654 (CI 0.563–0.745) with a sensitivity of 93.1% and a specificity of 62.3% (*p* = 0.008). For WHtR, 0.5 was used as a point of increased health risk, with an aROC of 0.759 (CI 0.668–0.851), *p* < 0.001, a sensitivity of 93.3% and a specificity of 63.1%.

The odds ratio of having HbA1c biomarkers of prediabetes was found to be 7.46 times greater for those with high risk WHtR value than those of low risk, (95% confidence interval 1.72 to 32.35), *p* = 0.002.

Looking at the 59 participants with normal HbA1c levels, who scored ≥ 11 points on FINDRISC and had a BMI > 25 kg/m², the WHR risk grouping identified 54 as having higher health risk. However, WHtR identified all 59 as having an overall higher health risk. Analyses of WHtR and HbA1c results according to gender showed that 92.9% of men and 93.3% of women with HbA1c prediabetes biomarkers had a WHtR indicating a higher overall health risk.

3.4. Health Literacy and Wellbeing Instruments

Table 3 reports the results of HLS-EU-16IS, EQ-5D-5L, EQ-VAS, and WHO-5 instruments, finding no significant difference according to residency. Of the 220 participants, 211 fulfilled the requirements of the HLS-EU-16IS and were included in the HL results. The majority (83.4%) scored sufficient HL. Some participants paused when answering the HL instrument reporting that some items in the HL instrument did not apply to them because they had never been in the situation presented in Q3: 'Understanding what your doctor says to you', Q5: 'Judge when you may need to get a second opinion from another doctor' and/or Q11: 'Judge if the information on health risk in the media is reliable'. Some then said out loud 'well that would probably not be a problem'.

Table 3. Scoring of the HLS-EU-Q16IS, the EQ-5D-5L, the EQ-VAS scale, and the WHO-5 instruments according to residency.

The HL-Q16IS Instrument	Countryside (n = 111) n (%)	Town (n = 109) n (%)	p Value [‡]
Mean (SD)	14.5 (SD \pm 2.3)	14.8 (SD \pm 1.7)	0.276
Sufficient HL (13–16 points)	83 (74.8)	93 (85.4)	
Problematic HL (9–12 points)	20 (18.0)	13 (11.9)	
Inadequate HL (0–8 points)	1 (0.9)	1 (0.9)	
Missing/Insufficient answers	7 (6.3)	2 (1.8)	
WHO-5	n (%)	n (%)	
Mean (SD)	66.2 (SD \pm 24.7)	60.9 (SD \pm 26.7)	0.140
<08 total points	10 (9.0)	13 (11.9)	
28–49 total points	18 (16.2)	24 (22.1)	
50–100 total points	78 (70.3)	65 (59.6)	
Missing	5 (4.5)	7 (6.4)	
The EQ-5D-5L instrument	n (%)	n (%)	
	Health state		
11111	22 (19.8)	36 (33.0)	
11112	7 (6.3)	4 (3.7)	
11121	26 (23.4)	20 (18.3)	
11122	19 (17.1)	14 (12.8)	
11123	3 (2.7)	6 (5.5)	
11131	5 (4.5)	4 (3.7)	
21121	4 (3.6)	2 (1.8)	
All other (49 groups)	25 (22.5)	23 (21.1)	
EQ-VAS scoring 0–100	n (%)	n (%)	
Mean (SD)	81.0 (SD \pm 17.9)	83.2 (SD \pm 14.8)	0.320
<70	19 (17.1)	12 (11.0)	
70–89	45 (40.5)	40 (36.7)	
90–100	47 (42.3)	57 (52.3)	

[‡] Independent t-test.

The WHO-5 result found a significantly higher mean score $M = 72.71$ (SD \pm 24.4) for the prediabetes biomarker group than the normal HbA1c group $M = 62.1$ (SD \pm 25.8), $t_{(206)} = -2.035$; $p = 0.043$. Men scored significantly higher than women on WHO-5 $M = 68.8$ (SD \pm 25.0) and $M = 60.7$ (SD \pm 25.9), respectively, ($t_{(206)} = 2.161$, $p = 0.032$). Positive

correlation was found between the scoring of WHO-5 to age $r_{(208)} = 0.273$ (CI 0.142–0.39) $p < 0.001$.

Scoring on the EQ-5D-5L showed that most defined themselves as having no problems (Level 1) with mobility (84.1%), self-care (96.4%), and usual activities (87.7%). Only 31.8% did so for pain/discomfort and 60% for anxiety/depression; 41 reported levels 3 to 5 in pain/discomfort and 25 did so for anxiety/depression. Interestingly, there was no significant correlation between the dimensions of mobility and anxiety/depression ($p = 0.125$ two-tailed) which was also true for the dimensions of self-care and anxiety/depression, ($p = 0.991$ two-tailed). Other dimensions showed correlation between each other at the $p < 0.001$ level (two-tailed). There was a negative correlation between anxiety/depression and the total score on the WHO-5 Well-Being index; a lower reported level of anxiety/depression correlated to a lower score on WHO-5 well-being ($p < 0.001$).

In 14.1% of the answers, the score on EQ-VAS was < 70 . There was correlation of the EQ-VAS scoring to all dimensions of EQ-5D-5L ($p < 0.001$). On EQ-VAS scoring, neither residency ($p = 0.320$), gender ($p = 0.726$), nor HbA1c at ADA level of prediabetes ($p = 0.255$) influenced the EQ-VAS score.

4. Discussion

This study used different screening methods to identify people at risk of T2DM in PHC clinics in need of follow-up to promote health and well-being. Residency did not influence the results. Interestingly, with aROC = 0.814 for FINDRISC, 82 of the 86 with ≥ 11 points on FINDRISC were at increased overall health risk based on WHtR, in addition 68 participants were at increased risk according to WHtR but scored < 11 points on FINDRISC. Therefore, WHtR ratio found more people at an overall higher health risk, and for this cohort, it might suggest a plausible underestimation of future T2DM risk in the next 10 years when using only the FINDRISC.

WHtR of ≥ 0.5 , gave lower aROC = 0.759 than FINDRISC, but nearly 7.6 greater odds ratio of having HbA1c biomarkers of prediabetes. Distinguishing better those at prediabetes biomarker risk than BMI or WHR (aROC = 0.713 and 0.654, respectively). Supported by earlier research, indicating WHtR to be a better overall health risk measurement, especially for women [42]. In addition, the results indicate that WHtR may be more suitable than WHR or BMI for identifying individuals at risk of prediabetes level, T2DM disease, and/or CVD [43,44]. In a systematic review, WHtR has been found to show increased health risk at 0.5 for adults, children, and different ethnic groups and there is high specificity and sensitivity for WHtR outcome measurements of T2DM and CVD risk [13]. Though both WHR and BMI have been found to be predictors of T2DM and CVD risk, they have different criteria for both gender and ethnic groups and need more calculations than WHtR [13].

The prevalence of overweight (39.1%) and obesity (34.1%) was higher than the OECD country health profile of 2021 reporting obesity to be 27% in 2017 in Iceland [45]. Nearly half (47.4%) of the overweight or obese scored ≥ 11 points on FINDRISC. The PHC must respond to this as research show satisfactory results of interventions within the PHC without medications helping people to reduce weight [46,47].

Prediabetes prevalence in the cohort was 13.2% according to HbA1c biomarkers alone [10]. Because the HbA1c indicates the glycation of red blood cells for the last two to three months using only one measurement of HbA1c, as was carried out here, we may have missed out individuals at T2DM risk [48]. It has been argued that this is why HbA1c cannot alone predict further development towards T2DM; rather, it gives indications for the need of further follow-up [48]. Although using the cut-off point of ≤ 38 mmol/mol has allegedly been said to exclude prediabetes [49], when individuals present risk through WHtR and FINDRISC results of > 11 points, normal HbA1c will not exclude T2DM risk as found here. Research has also indicated that caution is needed when using HbA1c alone as a diagnostic tool to find people with T2DM because it may miss people at the IGT stage [48].

The PHC challenge is to select the most appropriate, simplest and accurate, non-invasive measurements and instruments finding individuals at T2DM risk, prioritizing

assistance to high-risk individuals towards health promotion [12]. Therefore, before considering further and more invasive and costly tests and interventions, our suggestions are to use WHtR in PHC for the first measurement as an indicator of overall health risk and in screening for prediabetes and T2DM risk. Then, for the second measurement the FINDRISC (with ≥ 11 points marker for Iceland), should be added, followed by HbA1c, fasting blood glucose, and then OGTT measurement of those screened at higher T2DM risk.

4.1. Adding Health Literacy and Well-Being Questionnaires into the Screening Equation

High mean score of HLS-EU-Q16IS, with 83.4% having sufficient HL was not surprising considering the participants' high educational level. Better HL has been associated with higher education, but lower HL with poorer health and quality of life [17].

Some participants reported that some items in the HL instrument did not apply to them because they had never been in the situation presented in Q3, Q5, and/or Q11. It remains unclear if this affected their responses in grading themselves with a higher HL, because, some said, 'Well that would probably not be a problem'. However, scoring low on Q3 ('Understanding what your doctor says to you') had a correlation with increased health risk of WHtR, supported by research where 19% of adults with prediabetes presented low HL, scoring worse on questions on; 'understanding health care professionals', 'difficulty in obtaining information', and 'understanding written information' [50]. Adding the HLS-EU-Q16IS questionnaire to a non-invasive screening may assist in prioritizing an educational intervention for people at T2DM risk or higher health risk within the PHC.

Well-being scores increased with age and men scored significantly higher than women. Uneven gender proportion, self-selected participation and COVID-19 might have affected the results. Results from Denmark indicate that COVID-19 had a greater negative effect on WHO-5 scores for women than men [51]. In Iceland, depression is more prevalent among women (9%) than men (6.3%) [26]. We are unable to explain why participants with prediabetes biomarkers presented higher total scores on WHO-5, indicating fewer signs of depression. This contrasts a systematic review showing higher prevalence of lower well-being and depression in people with T2DM [52]. Neither depression nor anxiety symptoms are addressed in FINDRISC, but newly published results demonstrate that people with depressive or anxiety symptoms had a higher likelihood of T2DM [53]. The WHO-5 questionnaire might, from this perspective, assist the PHC in categorizing who at T2DM risk needs to be prioritized for further interventions.

The results of EQ-5D-5L of self-reported HRQoL showed over 8 out of 10 participants scored themselves with no problems on the first three levels: 'Mobility' (84.1%), 'Self-care' (96.4%), and 'Usual activities' (87.7%). Only one third reported no problems for 'Pain/Discomfort' and 60% for 'Anxiety/Depression', with no difference according to gender or prediabetes biomarkers. A systematic review on the EQ-5D-5L found higher utility value scores for men than women with T2DM [54]. This is in line with our WHO-5 results, of anxiety/depression with 10.5% scoring < 28 points. Which is higher anxiety/depression rate than the 7.7% found in the Icelandic population in 2019 [26].

4.2. Plausible Effects of the Characteristics of the Participant's Backgrounds

High Gross Domestic Product (GDP) of Iceland, accessible low cost PHC and high informational accessibility through common internet access [55], might explain no differences in HL and well-being according to residency.

The uneven gender distribution, favouring women, needs to be addressed if it influenced the results, as generally, more men are diagnosed with diabetes [8] and in the general population of the areas, the gender distribution is near equal [25]. If T2DM risk prevalence in the next 10 years are equal to the results, the prevalence of T2DM may greatly increase in the coming decades. It is therefore important that the PHC finds those at risk to reverse the progression to T2DM in the future.

5. Conclusions

Results revealed that WHtR and FINDRISC seem to be effective and useful non-invasive measurements identifying people at T2DM risk. Starting with WHtR calculations in the PHC may categorize in advance those at higher health and T2DM risk from those at lower overall health risk. Also, three questions in the HLS-EU-Q16IS and the WHO-5 instrument were found helpful in categorizing further who might be in need of intervention. In PHC, the approach of using the simple WHtR measurement before more invasive and expensive testing methods can therefore be recommended.

5.1. Limitation

It is a limitation to this study that the study was conducted during the COVID-19 pandemic. Thus, the recruitment of patients from partly locked down clinics was more difficult. In addition, we gained an uneven gender distribution. Moreover, the anxiety measurements might not reflect the overall anxiety in the population because of the ongoing COVID pandemic and its impacts on mental well-being. It would have strengthened the data to have more than one measurement of HbA1c.

5.2. Strength of the Study

All measurements by one researcher.
Sample relatively large compared to the population.

5.3. What This Paper Adds

Prediabetes prevalence in North Iceland is 13.2% according to HbA1c biomarkers, which is lower than expected.

Surprisingly, residency did not influence well-being and the HbA1c prediabetes biomarker group reported higher well-being.

High BMI may call for turning to alternative measurements like WHtR that better identifies those at higher health risk than BMI.

Using the third question on HLS-EUQ16IS and WHtR, in addition to a FINDRISC score of ≥ 11 , and HbA1c measurements may distinguish those needing further follow-up due to increased risk of developing T2DM.

5.4. What Is Already Known on This Subject

Prediabetes prevalence is uncertain as prevalence of T2DM is rapidly increasing worldwide. Iceland is now around 20 years behind the US in T2DM prevalence.

HbA1c has been criticized as sole biomarker for prediabetes identification as it may miss out individuals at high T2DM risk.

WHtR is an easily applicable measurement, showing increased early health risk for all, if results are over 0.5.

Primary health care needs simple, non-invasive, and non-expensive methods for identifying people at increased T2DM risk in order to turn the evolution of T2DM backward.

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Data Availability Statement: The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

Conflicts of Interest: The authors declare no conflict of interest. E.A. is working within primary health care of the Health Institution of North Iceland located far from the research area. The funders had no role in the design of the study; in the collection, analyses, or interpretation of data; in the writing of the manuscript; or in the decision to publish the results.

Abbreviations

ADA	American Diabetes Association
aROC	Area under the curve
BMI	Body Mass Index
CVD	Cardiovascular Disease
EQ-5D-5L	Europe Quality of Life five Dimension five level instrument
EQ-VAS	Europe Quality Visual Analogue Scale
FINDRISC	Finnish Diabetes Risk score
HBA1C	Haemoglobin A1c protein
HL	Health Literacy
HLS-EUQ16-IS	the European Health Literacy 16 questionnaire Icelandic version
HRQoL	Health Related Quality of Life
IFG	Impaired Fasting Glucose
IGT	Impaired Glucose Tolerance
OGTT	Oral Glucose Tolerance Test
PHC	Primary Health Care
QUALY's	Quality of Adjusted life Years
T2DM	Type two Diabetes Mellitus
WHO	World Health Organization
WHO-5	World Health Organization Well-Being Index
WHR	Waist to Hip Ratio
WHR	Waist to Hight Ratio

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RESEARCH

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Prediabetes and cardiovascular risk factors: the effectiveness of a guided self-determination counselling approach in primary health care, a randomized controlled trial



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Abstract

Background Identify individuals who are at risk of Type 2 diabetes, who also are at a greater risk of developing cardiovascular disease is important. The rapid worldwide increase in diabetes prevalence call for Primary Health Care to find feasible prevention strategies, to reduce patient risk factors and promote lifestyle changes. Aim of this randomized controlled trial was to investigate how a nurse-lead Guided Self-Determination counselling approach can assist people at risk of type 2 diabetes to lower their coronary heart disease risk.

Methods In this randomized controlled study, 81 people at risk of developing type 2 diabetes were assigned into an intervention group ($n = 39$) receiving Guided Self-Determination counselling from Primary Health Care nurses over three months and a control group ($n = 42$) that received a diet leaflet only. Measurements included the Finnish Diabetes Risk Score questionnaire and biological measurements of Hemoglobin A1c protein, Body Mass Index, fasting blood glucose, Blood pressure, Cholesterol, High-density lipoprotein, and triglycerides, at baseline (time1), 6 (time2) and 9 months (time 3).

Results A total of 56 participants, equal number in intervention and control groups, completed all measurements. A significant difference between the intervention and control groups, in coronary heart disease risk was not found at 6 nor 9-months. However, within-group data demonstrated that 55.4% of the participants had lower coronary heart disease risk in the next ten years at the 9-month measurement. Indicating an overall 18% relative risk reduction of coronary heart disease risk by participating in the trial, with the number needed to treat for one to lower their risk to be nine. Within the intervention group a significant difference was found between time 1 and 3 in lower body mass index ($p = 0.046$), hemoglobin A1c level ($p = 0.018$) and diastolic blood pressure ($p = 0.03$).

Conclusions Although unable to show significant group differences in change of coronary heart disease risk by this 12-weeks intervention, the process of regular measurements and the guided self-determination counselling seem to be beneficial for within-group measures and the overall reduction of coronary heart disease risk factors.

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Trial registration This study is a part of the registered study 'Effectiveness of Nurse-coordinated Follow-Up Programme in Primary Care for People at Risk of T2DM' at www.ClinicalTrials.gov (NCT04688359) (accessed on 30 December 2020).

Keywords Prediabetes, Type 2 diabetes, Cardiovascular heart diseases, Guided self-determination, Health promotion

Introduction

The risk of developing cardiovascular disease (CVD) rises with age [1]. Furthermore, diagnosis of type 2 diabetes (T2D) increases the CVD risk in individuals to a level that is equivalent to someone who is 10 years older and does not have T2D. For T2D patients, CVD are the main cause of morbidity and mortality [1–3]. Individuals identified as being at T2D risk have a significantly increased likelihood, up to twelve times greater, of developing diabetes in the future compared to those with normal glycaemic tolerance [4]. Additionally, persons who are identified as being at risk for T2D or at the prediabetes stage may also have a higher risk of developing CVD compared to individuals with normal glucose metabolism [5, 6].

By 2045, it is projected that prediabetes symptoms would impact almost one in every ten individuals worldwide. Characterized by one or more of the following: impaired fasting glucose (IFG), impaired glucose tolerance without meeting the diagnostic criteria for T2D, and/or increased levels of HbA1c [7].

Prediabetes warning signs are accompanied by health risk indications that also may raise the risk of cardiovascular problems, such as high body mass index (BMI), high blood pressure and dyslipidaemia [8]. In addition, diabetes-related comorbidities including retinopathy and food ulcers [1] are not only a burden for individuals, but also a concern for the society [1]. By implementing health-promoting strategies aiming at reducing risks for individuals in the prediabetes stage, it is possible to effectively decrease the elevated health risks [7]. Identifying individuals in the prediabetes stage and offering them a comprehensive health promotion program that focuses on modifiable risk factors such as nutrition and physical inactivity has the potential to avoid the progression to diabetes [9]. Research on diabetes preventive programs, such as the National Diabetes Preventive Program in the US and the Finnish Diabetes Prevention Study, have demonstrated the lasting benefits of interventions that improve health in halting the progression of T2D [4, 10]. Prior research also suggests that the implementation of nurse-led programs in Primary Health Care (PHC) can help patients decrease their risk of both T2D and CVD [11]. Furthermore, lifestyle counselling has been proven to be both cost-effective and a secure method for reducing the likelihood of individuals with prediabetes progressing

to T2D [12]. Implementing a nurse-led counselling program focused on proactive health promotion for those at risk of developing T2D within PHC settings could potentially help reduce the increasing prevalence of T2D [13].

Guided Self-Determination (GSD) is a counselling approach that draws upon research and concepts related to empowerment, self-determination, life skills, and humanistic principles [14, 15]. The objective of this method is to empower persons with chronic illnesses, equipping them with the essential abilities to proficiently navigate the challenges involved with self-managing their condition [14–16]. Reflection sheets are used as a supporting instrument to foster autonomy by assisting individuals in establishing goals for health promotion, deepening comprehension of values, recognizing opportunities, and fostering a readiness to change [14]. Healthcare professionals employ mirroring, active listening, and value-clarifying responses to support and motivate individuals in attaining their goals [14, 17]. The goal in GSD is to promote a reflection process, cooperation and motivate individuals to investigate and conquer the existing obstacles they encounter in their daily life [18–20].

The GSD counselling method acknowledges that conflicts may emerge due to an individual's perspective on life, their resistance to integrate their "disease/risk symptoms" into their daily life, and the impact of these symptoms on their overall welfare [14, 15, 19]. The rising prevalence of T2D and prediabetes and therefore CHD calls for further development and implementation of cost-effective and non-invasive counselling approaches, like the GSD, which may be easily included into PHC systems in a sustainable way. Prior lifestyles interventions using other methods in their interventions [4, 10], have demonstrated to be cost effective and reduce risk of T2D later in life. However, they were time-consuming and lasting for extended intervention periods, like for the Finnish diabetes prevention study [10], with active intervention of one to six years with medium of 4-years [10]. The objective of this randomised controlled trial (RCT) was to investigate whether a short intervention of three times GSD counselling over 12 weeks, provided by PHC nurses to patients identified as being at risk of developing T2D, would lead to a reduction in CHD risk factors in the intervention group compared to the control group.

Materials and methods

Recruitment of participants

Participants were selected from a pool of 220 participants who had previously taken part in a prediabetes screening study. The recruitment took place at the three largest PHC clinics in North Iceland [21, 22]. The power estimates for sample size were derived using a population size of 21,000 individuals aged 18–75 years living in the research area in the year 2019, as reported by Statistics Iceland [23]. In the calculation of sample size to establish eligibility for allocation in the RCT the confidence interval (CI) level was set at 85% with a margin of error of 5%. A minimum sample size of 206 participants in the screening study was needed to conduct this RCT, and at least 30 in each group at time 1 measurement. Although a larger sample, at 378 would be good and provided CI level of 95% with a 5% margin of error, this was not a viable sample size to recruit, given the population size and dispersion in the sparsely populated research area at the time of the Covid-19 pandemic.

Individuals between the ages of 18 and 75 who resided in the service area of the participating PHC clinics, were eligible for participation. Participants were required to not have a diagnosis of T2D and had fluent proficiency in either Icelandic or English. The enrolment criteria were based on achieving a score of ≥ 9 points on the Finnish diabetes risk score scale (FINDRISC), in addition either or both, BMI ≥ 30 kg/m² and/or HbA1c of ≥ 40 mmol/mol. The FINDRISC scoring scale estimates the risk of developing T2D within the next 10 years, using eight questions and assigns a score ranging from 0 to 26 points, with increasing risk with higher scores [21, 24].

Allocation into intervention and control groups

The 81 eligible participants, who satisfied the enrolment criteria, were allocated a numerical identity by the first author (EA). These identifiers were then placed in separate jars based on age (below or over 50 years) and gender. The second author (AKS) picked a pair of numbers from each of the two jars. The first number in each pair belonged to the intervention group, while the second number belonged to the control group. This procedure persisted until all the numbers were selected. Subsequently, the author EA reached out to the participants to arrange a single measurement session, either at the nearest PHC station or at the research centre. The allocation ratio was in favour of the intervention, with a ratio of 1.08:1.00. This preference was taken for any potential dropouts throughout the intervention. Of the 81 eligible 64 participated in time 1 measurement or 79%.

The intervention group

The GSD counselling approach intervention had not been previously employed in Iceland. Hence, the six nurses, two assigned to each PHC clinic who were implementing the intervention, attended a one-day workshop on GSD in March 2020 at the research centre, facilitated by the last-author BCHK. The seminar included ongoing assessment and feedback. Prior to starting the intervention, an online meeting was conducted with the six nurses and BCHK to enhance their proficiency in providing GSD counselling. The participants were given a notebook to record their thoughts and comments in, as well as a sheet with prompts and questions for reflection, mirroring, and active listening during the GSD intervention. During the intervention period, the nurses were contacted by EA over an encrypted Microsoft Teams® channel and phone. They were asked if they had any questions regarding the delivery of GSD or if they needed any assistance. In addition, the nurses had the option to communicate with EA or BCHK by phone or through the Teams channel for any inquiries.

The GSD intervention started in late December 2021 and finished in April 2022. The duration of each GSD counselling section (intervention) was approximately 60 min, with 4–6 weeks intervals in total of 12–16 weeks. Between counselling sections, the participants were instructed to complete the GSD reflection sheets that were given to them during their first GSD counselling with the nurse [19]. The sixteen GSD reflection sheets handed to participants had previously been used in a study with individuals at risk of developing T2D and with manifest T2D in Norway. The sheets were then translated from Norwegian to Icelandic for the purpose of this research. During each consultation session, the participants engaged in discussions with the nurse on their notes on the reflection sheets, while also establishing objectives for their health promotion. Following the measurements at time 1 (baseline), the intervention group was notified by EA that a nurse from the nearest PHC would contact them for three GSD consultations, spanning a duration of three to four months.

The control group

The control group were at time 1, following the measurements, given a booklet from the Icelandic Directorate of Health [25] on healthy diet choices, and informed that the next part of the research would be repeated measurements that would take place in 6 and 9 months from time 1 measurement.

Instruments, and biological measurement

Primary outcome, the Icelandic Heart Association coronary heart disease risk calculator

For more than 50 years, the Icelandic Heart Association has gathered data from a comprehensive health survey, which includes statistics on the prevalence and death rates of coronary heart disorders (CHD) [26]. An outcome of this scientific research is the development of an open access heart disease risk calculator (ICE-HEART), which evaluates an individual's probability of CHD over the course of the following decade [27]. The ICE-HEART is comparable to the SCORE risk calculator developed by the European Society of Cardiology [27]. The ICE-HEART CHD risk calculator (http://risk.hjarta.is/risk_calculator/) provides an estimate of an individual's probability, expressed as a percentage, of developing CHD during the following 10 years. This estimate is compared to the average probability of CHD for individuals of the same gender (male/female) and age [27].

The primary outcome of this RCT was set as a change in the relative risk (RR) of CHD, when compared to individuals of the same age and gender, both within and between the intervention and control groups. This was assessed using the open access online ICE-HEART CHD risk calculator [27]. The calculator incorporates measures of age (within the range of 35–75 years), height (ranging from 150–200 cm), weight (between 45–120 kg), systolic blood pressure (ranging from 100–200 mmHg), total cholesterol (CHOL) levels (ranging from 4–10 mmol/L), high density lipoprotein (HDL) levels (ranging from 0.5–2.5 mmol/L), and triglycerides (TRG) levels (ranging from 0.5–4.5 mmol/L). Furthermore, the variables required for the assessment of CHD risk include the levels of physical activity, smoking patterns, presence of diabetes, and family history of CHD [27].

The height was recorded using a portable measuring tape, rounded to the nearest 0.1 cm, while the weight was measured on a digital scale, rounded to the nearest 100 g. The measurements were taken when the person was wearing light clothes [28].

The cholesterol (CHOL), high-density lipoprotein (HDL), and triglycerides (TRG) levels were measured using a Mission[®] cholesterol meter. In addition, ICE-HEART provides computed tests for low-density lipoprotein (LDL) and the ratio of total cholesterol to high-density lipoprotein (CHOL/HDL).

Participants' blood pressure (BP) was measured at the end of each section after they had been seated for a duration of 10 min. Utilizing the Medisana[®] upper arm meter for measuring [29]. The treatment threshold for systolic pressure is commonly set as ≤ 140 mm/Hg and for diastolic pressure as < 90 mmHg [30]. Research indicates that

elevated BP raises the likelihood of developing CVD [31, 32].

Secondary outcomes and definition of T2D and prediabetes level

The Body Mass Index (BMI) ≥ 30 kg/m² [2] was one of the inclusion criteria, calculated using height and weight, reported in kg/m². A BMI ≥ 25 kg/m² indicates overweight and a BMI ≥ 30 kg/m² indicates obesity [32]. The measurements of waist circumference, taken 2 cm above the navel, and hip circumference at the widest point, as well as height in centimetres, were recorded using a measuring tape with a capacity of either 1.5 or 3 m. The accuracy of the measuring tapes was frequently assessed. The waist-to-height ratio WHtR was computed by dividing the waist measurement in cm by the height measurement in cm. The WHtR is not influenced by gender or ethnicity. Previous study suggests that it may be a more accurate predictor of diabetes risk compared to BMI. A WHtR ratio of less than 0.5 indicates no increased overall health risk, while a ratio between 0.5 and 0.6 indicates an elevated risk. A WHtR ratio of 0.6 or above indicates a very high overall health risk [31, 33, 34]. Previous studies have suggested that the WHtR is a more effective screening tool than the Waist-to-Hip ratio (WHR) for identifying individuals at risk of cardiovascular disease (CVD) and T2D. This is because an elevated WHtR is a stronger indicator of both conditions compared to an elevated WHR [22, 31, 34–36].

WHO has approved the HbA1c level as a diagnostic test of T2D [37]. We employed the DCA Vantage[®] system (manufactured by Siemens Medical Solutions Diagnostics Europe Limited, based in Dublin, Ireland) to analyse capillary blood samples. The American Diabetes Association classifies HbA1c levels between 39 and 47 mmol/mol (5.7 – 6.4%) as prediabetes, whereas levels of 48 mmol/mol (6.5%) or more are considered indicative of T2D [38].

Fasting glucose (FBG) was measured using a capillary blood sample and the OneTouch[®] Verio Flex blood glucose meter. The latest advice for diagnostic purposes for T2D is to utilize plasma or fasting plasma glucose [39]. The objective was to conduct a screening for alterations in blood glucose levels during the duration of the RCT. Normal glucose level is defined as being less than 5.5 mmol/l (< 100 mg/dl). Prediabetes is classified as having a glucose level between 5.5–6.9 mmol/l (100–125 mg/dl), whereas diabetes is diagnosed when the glucose level exceeds 7 mmol/l (≥ 126 mg/dl) [40].

Participants in addition answered questions regarding background characteristics, and the FINDRISC tool to record changes over the RCT time [41]. FINDRISC is a questionnaire consisting of eight questions. Each

question is scored on a scale of 0 to 26 points. A higher score implies a higher chance of developing T2D in the following 10 years. The FINDRISC has been authorized as a diagnostic test for assessing the risk of developing T2D [42].

Data collection

Baseline measurements were collected from the end of October 2021 to the middle of December 2021, and the next measurement in late spring 2022, and the last in late autumn 2022. Figure 1 displays a visual representation of the measurement timeline. Each participant was given a document with the current biological measures as well

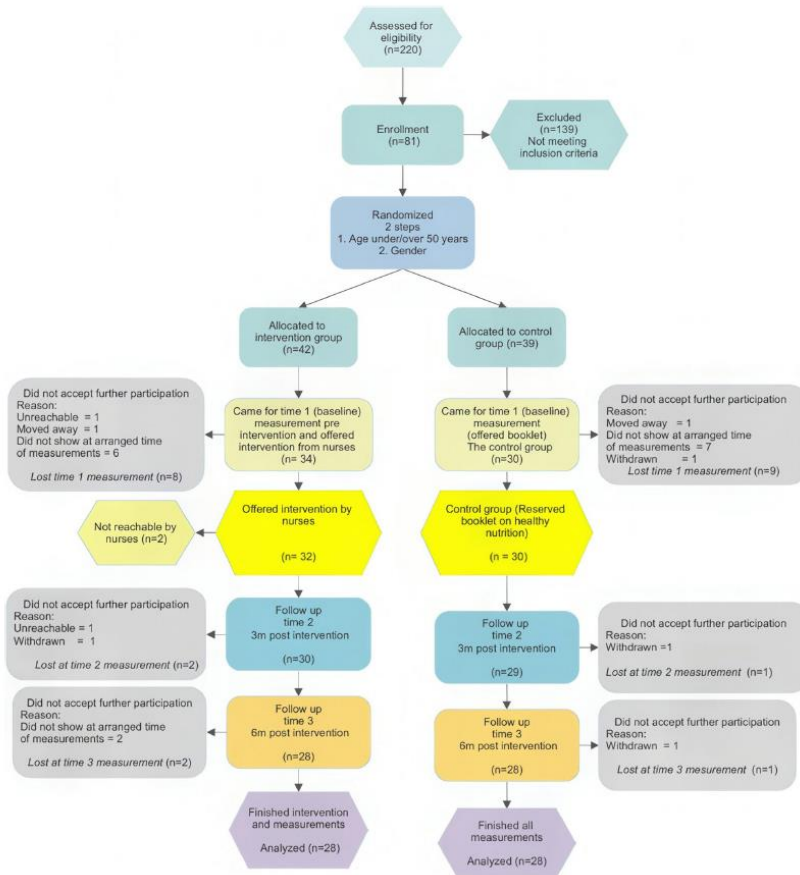


Fig. 1 Flow Chart of eligible participants in the intervention

as one-time prior measurement at each session. Consequently, they were able to see and compare the differences between the present measurement and a previous measurement.

To reduce the number of dropouts, those who did not appear at the scheduled time for measurements were given the opportunity to reschedule their appointment at least two more times before being classified as dropouts. Researcher EA personally interacted with and performed all the measurements on every participant.

Statistical analysis

The ICE-HEART calculator available online at http://risk.hjarta.is/risk_calculator/, was used to calculate predicted CHD risk for each participant. The ICE-HEART risk calculator includes defined lower and upper limits of values for the variables. The calculator automatically adjusted variables to the highest/lowest applicable score if a participant's value went outside the range of the ICE-HEART variables. The ICE-HEART calculator provides an individual's estimated CHD risk, in the next 10 years, in percentages as well as the average risk for the same age and gender. To be able to compare the risk of participants of different ages and genders, the individual risk of each person was divided by the risk of the ICE-HEART same age and gender risk. This enabled calculation of mean CHD risk of each group of participants in comparison with the mean CHD risk of the ICE-HEART cohort. The outcomes were reported as the ratio of the risk for each participant divided by risk of an individual of same age and gender, according to the ICE-HEART risk calculator. Calculations for each participant were verified twice to avoid any potential input mistakes.

The study participants' changes in CHD risk were assessed from time 1 to time 3. This allowed for the calculation of the "control event risk" (CER), "experimental event rate" (EER), and subsequently the "absolute risk reduction" (ARR) using the formula $CER - EER = ARR$. The Number Needed to Treat (NNT) for a favourable result is defined as the outcome of the ARR. The relative risk (RR) was determined by dividing the chance of an adverse outcome in the intervention group by the probability of an unfavourable outcome in the control group. Relative risk reduction (RRR) is a measure that quantifies the extent to which the risk of negative outcomes is lowered by an intervention compared to a control group [43]. The absence of any change in CHD risk between time 1 and time 3 was considered a poor outcome. This was because the goal was to decrease the risk, and reporting no change was seen as a more careful and cautious approach to presenting the results of this RCT. Descriptive statistics were employed to analyse continuous data and calculate means, standard deviations, and ranges.

The groups were compared using chi-squared calculations, and changes in risk between measurements were calculated using crosstabs for odds ratio (OR), RR, and NNT calculations. The independent t-test was employed to compare the means of continuous variables between groups.

The General Linear Model of repeated measurements was used to calculate the interaction between and within groups throughout time. Due to the potential sensitivity of small sample sizes to sphericity, a mixed ANOVA, was added in analysing the data [44].

Data was analysed using IBM SPSS Statistics 27 and for mixed ANOVA the R version 4.3.1 (2023-07-16 ucrt), using `rstatix`, `lme4`, mixed effect model and `lmerTest`. Missing data, was if applicable, excluded listwise. Statistically significant difference was set at $p \leq 0.05$ (two tailed).

Ethical considerations

The present study was performed in accordance with the Helsinki Declaration and with the approval of the Icelandic National Bioethics Committee (VSN), (VSN-19-080-V1 approved 14/01/2020). All participants received verbal and written information and signed an informed consent form before participating. This study is registered at www.ClinicalTrials.gov (NCT01688359) on 30th December 2020. It is titled 'Effectiveness of Nurse-coordinated Follow-Up Programme in Primary Care for People at Risk of T2DM'. The CONSORT 2010 criteria are utilized for reporting the randomized trial [45].

Results

Participant characteristics at enrolment

Out of the 81 participants who met the enrolment criteria, 42 were assigned to the intervention group and 39 were assigned to the control group. At baseline (time 1) 34 (81%) in the intervention- and 30 (76.9%) in the control group participated. Furthermore, the dropout rate from time 1 to time 3, was 17.5% in the intervention and 6.7% in the control group, see Flow Chart in Fig. 1. Most dropouts occurred during the period between enrolment and time 1, with a dropout rate of 8% for the intervention and 9% for the control group. Four participants voluntarily withdrew from the study, citing the ongoing Covid-19 epidemic (I:0/C:1) and a diagnosis of T2D (I:1/C:2) as reasons. A total of 56 participants, with 28 in each group, completed the intervention and all measurements.

Background information of participants

There was no significant difference between the intervention and control groups at enrolment. In both groups participants had a high educational level, and the majority were employed either half- or full-time. Females were in majority, and all participants except one were at

increased health risk according to WHtR. However, it is worth noting that only one reported being a smoker, enrolment characteristics are presented in Table 1.

Primary outcome (The ICE-HEART risk calculator) Table 2 shows the mean CHD risk of the ICE-HEART cohort and the intervention- and control groups (not

Table 1 Background information on enrolment and score of FINDRISC

		Intervention group (n = 28)	Control group (n = 28)	p value*
Gender	Male	8	8	1.0
	Female	20	20	
Age*	<50 years	8	6	
	50–59 years	7	11	
	60–69 years	9	8	
	70–75 years	4	3	
	Mean**	55.7(± 11.8)	57.2(± 9.4)	.601
WHR*	Low health risk Men: < 0.94 / Women: < 0.80	4	1	.160
	Higher health risk Men: ≥ 0.94 / Women: ≥ 0.80	24	27	
WHtR*	< .5 low increased health risk	1	0	.124
	≥ .5 Increased health risk	27	28	
Weight (kg)	Mean**	99.03 (± 16.34)	98.15 (± 16.70)	.842
BMI*	25–30 kg/m ²	2	4	.388
	> 30 kg/m ²	26	24	
	Mean**	33.89 (± 4.03)	34.24 (± 4.46)	.757
Smoking*	Yes	1	0	.600
	No	22	23	
	Stopped smoking	5	5	
Coronary-CHD family member*	Yes	9	15	.105
	No	19	13	
Educational level*	Elementary /junior high	8	7	.055
	Upper secondary school/vocational training	11	4	
	University degree	9	17	
Occupational status*	Working part or full time	18	22	.572
	Unemployed	1	1	
	Pensioner (disabled/elderly)	7	3	
	Other or did not answer	2	2	
HbA1c	Mean**	36.21 (± 4.47)	36.54 (± 4.13)	.781
FINDRISC	Mean score**	13.7 (± 3.4)	14.8 (± 4.0)	.253

* Chi-square test

** Independent t test

Table 2 Comparison of mean calculated CHD risk of same age and gender of ICE-HEART cohort and CHD risk for the intervention and control groups at time 1, 2 and 3

	ICE-HEART Risk: Same age and gender mean risk (± SD)	Time 1: Baseline Mean CHD risk* (± SD)	Time 2: 6 months Mean CHD risk* (± SD)	Time 3: 9 months Mean CHD risk* (± SD)
Intervention group (n = 28)	2.40 (± 2.45)	3.29 (± 2.38)	2.96 (± 2.39)	3.05 (± 2.44)
Control group (n = 28)	2.42 (± 2.10)	3.39 (± 1.81)	3.71 (± 2.80)	2.90 (± 1.77)
p-value**	.981	.860	.282	.789

* Mean CHD risk adjusted for same age and gender, using GLM of repeated measures calculations, (Standard Deviation) and **Huynh-Feldt within-subjects effects, p-values between groups using Independent t-test of measure of significant difference between intervention and control groups at each measurement

individuals) changes from time 1 to time 3. For these small groups of participants of the intervention and control, the measurements between groups did not detect a statistically significant difference in the risk of CHD in the next ten years, from time 1 to 3. General linear model of repeated measurements indicated plausible sphericity. A Mixed ANOVA indicated that the assumption of homogenous variance (Levene) was satisfied, but the data was not normally distributed due to the presence of a few extreme values (3 in total). The sole variable that had a noteworthy impact in the mixed effect model was family history. Hence, it is not possible to infer that GSD intervention, administered in three consultations spanning short duration, had a beneficial impact on lowering the risk of CHD in this limited group that completed the RCT. At time 1, the risk of CHD for each participant in this RCT varied from 0.1% to 25.3%. Compared to the computed CHD risk for individuals in the ICE-HEART cohort, matched for age and gender, that varied from 0.1% to 7.3%. At time 1, participants had a CHD risk that was up to 11.8 times higher than that of individuals of the same age and gender according to the ICE-HEART cohort.

Figure 2 shows changes in the groups mean CHD risk according to the ICE-HEART calculator and therefore does not have zero on the y-axis. For the intervention group CHD risk was lower at time 2 than before the intervention (time 1) but did not reach significant difference, see Fig. 2. But surprisingly a decrease in CHD risk was found significant between time 2 and 3 for the control group, paired sample *t*-test for the control group showed $t_{(27)}=2.39$ $p=0.024$, with mean difference of $0.81(\pm 1.80)$ and 95%CI [0.12, 1.51]. The control group

also showed a significantly lower CHD risk from time 1 to time 3, $t_{(27)}=2.26$ $p=0.032$ with a mean change of $0.49(\pm 1.14)$ 95%CI [0.05, 0.93].

According to the ICE-HEART calculator the mean CHD risk for same age and gender for both groups was $M=2.41$ SE (0.30) and 95%CI [1.81, 2.02]. Both the intervention and control groups had significantly higher mean CHD risk at time 1, than the ICE-HEART cohort calculations risk for the same age and gender behind the ICE-HEART. Significant difference of CHD risk was found between this RCT's cohort compared to ICE-HEART cohort, $p < 0.001$ 95%CI [2.46, 4.53].

Calculations of changes in CHD risk between time 1 and time 3, found significant lower CHD risk for the total sample ($n=56$) in this RCT; $M=0.354$ (± 1.08), $t_{(55)}=2.53$ $p=0.014$ with 95%CI [0.08, 0.65]. But failed to find significant lower CHD risk within-groups. However, for 50% of the intervention group and 60.7% of the control group the CHD-risk had reduced from time 1 to time 3. Odds Ratio for one-point lower CHD-risk outcome at time 3, than at time 1, by participating in the RCT was 0.65, 95% CI [0.22, 1.87]. The CHD relative risk reduction (RRR) was 17.6% and absolute risk reduction (ARR) 10.7% from time 1 to time 3. NNT for one to benefit from the participation in the GSD was nine. For participants in both groups at time 3, lower CHD risk was found for 31 participants (1:14/C:17).

Secondary outcomes

Outcomes of biomarkers at each time point are reported in Table 3. Even though the general measurements became better, the changes did not reach significant difference between groups.

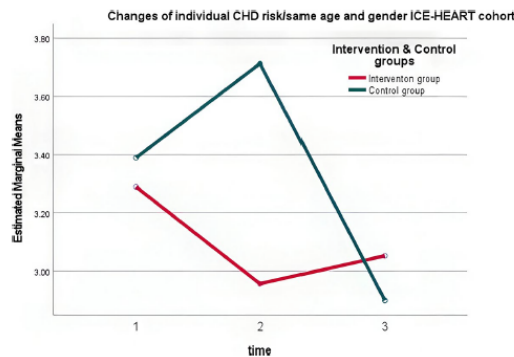


Fig. 2 Changes from time 1 to time 3 of mean individual CHD risk in each group

Table 3 Secondary biological outcomes

Outcomes	Intervention group (n = 28)	Control group (n = 28)	Mean difference 95% Confidence Interval [95%CI]	Repeated measured, between groups p-value*
HbA1c mmol/mol				
Time 1 (baseline)	38.36 (± 4.45)	39.50 (± 3.95)	-1.14 [-3.40, 1.11]	.998
Time 2	39.46 (± 4.96)	40.25 (± 4.65)	-.79 [-3.36, 1.79]	
Time 3	38.11 (± 4.24)	39.39 (± 4.03)	-1.29 [-3.50, .93]	
Fasting blood glucose				
Time 1 (baseline)	5.70 (± 1.17)	5.51(±0.72)	.19 [-.33, .71]	.940
Time 2	5.57 (± 0.78)	5.60(±0.65)	-.03 [-.42, .35]	
Time 3	5.51 (± 0.89)	5.65(± 1.15)	-.13 [-.68, .42]	
Weight in Kg				
Time 1 (baseline)	98.16 (± 17.32)	97.84 (± 17.01)	.33 [-8.87, 9.52]	.979
Time 2	97.54 (± 17.28)	97.22 (± 17.95)	.33 [-9.11, 9.77]	
Time 3	95.54 (± 16.62)	96.55 (± 18.75)	-1.01 [-10.51, 8.48]	
BMI kg/m ²				
Time 1 (baseline)	33.58 (± 4.52)	34.15 (± 4.68)	-.57 [-3.04, 1.89]	.786
Time 2	33.40 (± 4.69)	33.88 (± 4.79)	-.48 [-3.02, 2.05]	
Time 3	32.70 (± 4.49)	33.70 (± 4.49)	-.93 [-3.50, 1.64]	
Systolic BP (mmHg)				
Time 1 (baseline)	142.7 (± 15.9)	140.3(± 12.7)	2.43 [-5.28, 10.14]	.965
Time 2	135.8 (± 15.7)	141.1(± 16.2)	-5.36 [-13.92, 3.20]	
Time 3	135.8 (± 15.7)	141.1(± 16.2)	-1.89 [-11.17, 7.38]	
Diastolic BP (mmHg)				
Time 1 (baseline)	89.2 (± 9.8)	87.6 (± 11.0)	1.64 [-3.95, 7.24]	.997
Time 2	86.7 (± 10.7)	87.4 (± 11.1)	-.68 [-6.52, 5.16]	
Time 3	82.9 (± 8.2)	87.9 (± 10.8)	-4.89 [-10.05, 0.26]	
Cholesterol				
Time 1 (baseline)	5.76 (± 1.76)	5.81 (± 1.10)	-.04 [-.83, .74]	.930
Time 2	5.82 (± 1.85)	5.85 (± 1.71)	-.02 [-.98, .93]	
Time 3	5.56 (± 1.52)	5.33 (± 1.33)	.24 [-.53, .99]	
HDL				
Time 1 (baseline)	1.30 (± 0.46)	1.27 (± 0.46)	.02 [-.22, .27]	.994
Time 2	1.36 (± 0.44)	1.29 (± 0.47)	.07 [-.18, .31]	
Time 3	1.22 (± 0.42)	1.23 (± 0.42)	-.01 [-.23, .22]	
LDL				
Time 1 (baseline)	3.47 (± 1.57)	3.56 (± 1.30)	-.97 [-.87, .68]	.982
Time 2	3.51 (± 1.78)	3.51 (± 1.85)	.00 [-.97, .98]	
Time 3	3.52 (± 1.33)	3.31 (± 1.38)	.22 [-.51, .95]	
Triglycerides				
Time 1 (baseline)	2.09 (± 0.92)	2.16 (± 1.00)	-.07 [-.59, .44]	.953
Time 2	1.87 (± 0.95)	2.01 (± 0.76)	-.14 [-.61, .32]	
Time 3	1.80 (± 0.74)	1.77 (± 0.66)	.03 [-.34, .40]	

The values for intervention- and control groups are means and standard deviation (SD)

* p-value are differences between groups from time 1 to time 3. Mean difference and 95% CI are independent t-test for total sample

Within the intervention group, there was a significant difference from time 1 to time 3: for the BMI ($p=0.046$), the HbA1c level ($p=0.018$) and the diastolic blood

pressure ($p=0.03$). Where for the control group only CHOL and TGL showed a tendency to significant difference from time 1 to time 3, both ($p=0.052$).

Discussion

This RCT intervention found no statistically significant differences between the GSD intervention and control groups. The timeframe of 12–16 weeks of the GSD intervention and the total time of 9-months of this RCT, could only have been a motivation for a change process, as changes in lifestyle behaviour may require longer time [46]. By providing GSD in only three consultations, it may have been too short to demonstrate significant differences between groups [47]. However, the GSD approach have been found to promote lifestyle changes and may be a promising counselling method for people at T2D risk as here the NNT for a positive outcome in CHD risk was nine [20]. Also, in this RCT, the GSD was used for a group of people found at health risk aiming toward health promotion, where most prior research on GSD have focused on people with diseases [15, 48–50]. In addition, this RCT might have been influenced by unforeseen factors like the Covid-19 pandemic [51].

However, looking at the primary outcome of the ICE-HEART online calculator, results demonstrated that by participating in this RCT, 55% of the participants had lower CHD risk in the next ten years at time 3 measurement. Additionally, the absolute risk of CHD decreased by 10.7%. This is of interest as CVDs are the most common course of mortality [26]. The CVD risk increases with prediabetes as a meta-analyse comparing the absolute risk difference between those with prediabetes signs and those with normal blood sugar levels revealed a difference of 189.77 (95%CI: 117.97 – 271.85) in CVD risk. The difference for CHD and all-cause mortality risk was 4.62 (95%CI 5.42–78.549) [52].

The secondary outcomes showed not significant difference between groups. But, for the intervention group, diastolic blood pressure, BMI and HbA1c were significantly lower at time 3 than time 1. Lowering those outcomes may lower the risk of further development toward T2D and prevention of CVD [52]. Prior research indicates that the silent progression toward T2D may take several years and T2D risk may be reduced with preventive interventions [7].

The increase in BMI and T2D in Iceland is alarming [53]. For the BMI, being one of inclusion criteria for allocation, was found to be high in the prediabetes prevalence study (39.5% with BMI \geq 30 kg/m²), this reflected the high BMI of the participants [21]. In addition, as BMI is a part of the ICE-HEART calculator, further studies are needed to find if the higher CHD mean risk in this trial reflects a higher mean CHD score in North Iceland, than found for same age and gender cohort behind the ICE-HEART calculator, which is based on data from the past 50 years [26, 27, 53]. This may indicate the need to further develop the ICE-HEART calculator. However, for

the PHC the need for setting a public health agenda and strategy toward health promotion that might reduce risk factors is essential [27]. Therefore, the ICE-HEART CHD risk calculator, accessible online and easy-to-use, the calculator is useful for the PHC in consultations to provide individuals with their results of CHD risk, to increase the individual's awareness of one's own health status [27].

When preparing this trial, one of the objectives was to find individuals with undiagnosed T2D, but no one fulfilled these criteria, thus we could not compare individuals at T2D risk and undiagnosed individuals in this trail [21, 22]. However, with increasing prevalence of T2D it is important to establish that changes in lowering CHD risk factors and CVD risk can be made in PHC with low-cost interventions as GSD. Previous research has also shown that implementing uncomplicated lifestyle interventions in PHC settings can lower the relative risk of both CHD and T2D [46, 54, 55]. Additionally, it is important to mention that this RCT was conducted before the rise in use of Glucagon-like peptide-1 (GLP-1) analogues, became as strong as has been observed [56].

To effectively combat the escalating global incidence of T2D and reduce the risk of CHD, it is crucial to raise awareness and empower individuals to take proactive actions to minimize their risk of developing these conditions [57]. To emphasize the need for setting a public health agenda and strategy toward health promotion that might reduce risk factors is essential [27]. In addition, research indicates that people showing indicators of prediabetes stage may be clustered to six groups of lower to higher risk of further progression to T2D. As the low-risk clusters may never proceed to T2D it may enable the PHC to focus on high-risk individuals and reduce risk of over-treatment [58]. The strong indicators of prediabetes risk of high BMI, high HbA1c and high score on FINDRISC may be used to find people at T2D risk. But, in using the FINDRISC score, considering that the cut-of-score of risk may vary between countries is important [21]. In prioritizing intervention for people at risk, methods like WHtR measurements, are a non-invasive way to give indication to higher health risk for the individual [22, 31, 34–36]. Lifestyle interventions have shown to lower the relative risk of T2D and found to be cost effective in the long run [12].

For the PHC the GSD may be a promising approach toward health promotion for people not yet with a manifest disease, though unable here to show significant difference between groups [59]. GSD may be tailored to increased health awareness for the public in preventing progress from prediabetes to a diabetes state. Preventions for T2D and CVD have been found cost effective [60]. Preventing or delaying progress to T2D actions as the GSD method, led by nurses, may therefore lower

disease burden for individuals as well as having positive effects on the workload for doctors within the PHC, and lower cost for the society [19, 24, 48, 61, 62]. As the GSD intervention was a completely new approach for the nurses who provided the counselling method, deeper educational and preparational processes might have been needed for the nurses. This needs further investigation. For the participants, in personal communication to the first author the participants expressed great satisfaction with being able to participate. Some said that participation had resulted in saving their lives, given them better health conditions, a better insight into one's health, and awareness of healthy food choices. This is in line with results from prior research indicating that at improvements may be seen when person-centred approaches are used [15, 47, 48, 63].

We claim that the GSD can be recommended for the PHC as an alternative short intervention provided by nurses, even though unable to find significant difference between groups in this trial, the GSD method have been found to be effective for people with T1D, T2D and psychiatric challenges [59, 64]. As well as increasing individuals at risk's awareness of one's own health status [47]. The GSD approach facilitates health promotion by assisting individuals in implementing changes in their everyday lives that may promote their health. Here the focus was on those identified as being at risk of illness, namely at the prediabetes stage. We claim that at the GSD may be a feasible option within the PHC, but the GSD needs to be integrated into general health promotion programs within the PHC. Additional research involving larger cohorts may be required to validate the efficacy of GSD in health promotion initiatives for individuals identified at risk for diseases such as elevated BMI, High cholesterol, hypertension, $WtHR \geq 0.5$, all acknowledged as health-risk factors, to facilitate their capacity for change in health behaviours [20, 59, 65].

Strengths and limitations

Low dropout after first measurements and low number needed to treat to show success are found to be strength of this RCT.

Several challenges occurred during this RCT period and may have impeded the effectiveness of the study. Firstly, researching health promotion within the PHC context at the time of the Covid-19 pandemic restrictions may have influenced the results. For example, the pandemic may have impacted the willingness to participate, resulting in the highest dropout between enrolment and time 1. The daily life of participants may have been altered due to the pandemic, though dropout was low from time 1 to time 3 [51]. From time 1 to time 3 three rejected further participation (1:I/C:2) due to Covid

pandemic. Some participants had to ask for a new pre-arranged time due to being sick of Covid-19. One in the control group had to withdraw further participation from the trial as a T2D diagnosis was revealed. But, for ethical reasons, participants were not obliged to give reason for dropout and those not attending the pre-arranged time did not have to give any reason.

Secondly, the small, self-selected sample with large age ranges, from 18 to 75 years, and short time frame of intervention, may have influenced that significant differences were not found between groups.

Thirdly, the intensity of the intervention, needing to take a break from work and fasting before coming for repeated measurements may have had an impact [64]. A limitation to this RCT is that in a small community participants could probably find out which group they belonged to. As the same study nurse met all the participants, informed the intervention group of the intervention, and took all measurements, this RCT was not blinded, that may have affected the results. This RCT might therefore be considered as a pragmatic RCT [66].

In addition, it might be regarded as "person centered care" and an intervention on its own for both groups that all participants met the same person repeatedly for all measurements [64]. Also, that all participants were provided results of one previous and present measurements might have caused bias in the research process, leading to awareness of changes between measurements. For the control group it could have affected measurements at time 3. In addition, research [17, 47, 59], has demonstrated positive results by participating in lifestyle research, as participation may have led to an increased awareness of own health status in both groups. Moreover, the information booklet and participation in outcome measurements may have been beneficial for the control group [64].

The participating nurses who provided the intervention had no prior experience of providing the GSD approach. Further studies are required on the teaching and preparation phase, to estimate if additional time was needed in integrating the new GSD counselling into practice. In addition, that the participants were not diagnosed with a disease, may have had an impact on their willingness to implement lifestyle changes into their daily life.

Conclusion

The GSD approach is a non-invasive and low-expensive counselling method for the PHC that resulted in reduction of BMI, HbA1c and diastolic blood pressure for the intervention group. The GSD approach facilitate behaviour change by assisting individuals in implementing changes in their everyday lives that may promote their health. This short GSD approach conducted by nurses

can be recommended for people at increased health risk as a person-centred health promotion strategy. Although, this RCT failed to demonstrate significant differences between groups participation, it seems to be beneficial to lower CHD risk within the groups. Further studies are needed to explore deeper the use of GSD as a counselling approach for people at increased health risk toward health promotion in PHC. Using simple measurements to find people at CHD and T2D risk providing those found at risk with GSD counselling, may be a useful health promoting strategy.

Abbreviations

ANOVA	Analysis of Variance
ARR	Absolute Risk Reduction
BMI	Body Mass Index
BP	Blood Pressure
CER	Control Event risk
CHD	Coronary Heart diseases
CHOL	Cholesterol
CI	Confidence Interval
CVD	Cardiovascular diseases
EER	Experimental Event Rate
FBG	Fasting Blood Glucose
FINDRISC	Finnish Diabetes Risk score
GLP-1	Glucagon-Like Peptide-1
GSD	Guided Self Determination
HbA1c	Hemoglobin A1c protein, Glycated Hemoglobin
HDL	High density lipoprotein
ICE-HEART	Icelandic heart Association's risk calculator (estimator of the probability to get coronary heart disease in the next 10 years)
IFG	Impaired Fasting Glucose
LDL	Low density lipoprotein
NNT	Number needed to treat
OR	Odds ratio
PHC	Primary Health Care
RCT	Random Control Trial
RR	Relative Risk
RRR	Relative Risk Reduction
SD	Standard Deviation
T2D	Type 2 Diabetes
TRG	Triglycerides
WHR	Waist-to-Hip Ratio
WHtR	Waist-to-Height Ratio

Supplementary Information

The online version contains supplementary material available at <https://doi.org/10.1186/s12889-024-20538-1>.

Supplementary Material 1.

Acknowledgements

To all participants in the study. The statistical assistance of K. Olafsson and B.E. Dagsdóttir.

Limitation

Few participants had a negative impact on the research power. The covid-19 pandemic might also have had a negative impact on implementation of GSD and perhaps also willingness of participation.

Strength of the study

Low dropout after first measurement. To find people at risk simple measurements, using portable equipment, tests performed by nurses, may have positive effects on health promotion for people at T2D risk.

What this paper adds

This self-selected group at allegation was undiagnosed group but found at high CHD and T2D risk. GSD may be feasible and beneficial for prevention and health promotion within the PHC. It is possible to reduce CHD and T2D risk with simple low invasive and low-cost measurements.

What is already known on this subject

GSD has been tested with positive outcome for people with T2D, T1D and other conditions. Prediabetes stage includes increased CVD risk. The time lag from prediabetes stage to diagnoses of T2D may be approximately 7 years or more, indicating that there is time to have positive effects with health promoting interventions. Health promotion has shown positive effects on smoking habits, cholesterol, and other CHD risk factors.

Authors' contributions

Conceptualization, E.A., Á.K.S., T.S., M.G. and B.-C.H.K.; methodology, E.A., Á.K.S., T.S. and M.G.; software, E.A.; validation, E.A., Á.K.S., T.S., M.G. and B.-C.H.K.; formal analysis, E.A., Á.K.S. and T.S.; investigation, E.A.; resources, E.A. and Á.K.S.; data curation, E.A.; writing—original draft preparation, E.A., Á.K.S., T.S., M.G., and B.-C.H.K.; writing—review and editing, E.A., Á.K.S., T.S., M.G. and B.-C.H.K.; visualization, E.A.; supervision, Á.K.S., T.S., M.G. and B.-C.H.K.; project administration, E.A., Á.K.S. and M.G.; funding acquisition, E.A. and Á.K.S. All authors have read and agreed to the published version of the manuscript.

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Data availability

The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request. Institutional Review Board Statement: The present study was conducted in accordance with the Helsinki Declaration and with the approval of the Icelandic National Bioethics Committee (VSN), (VSN-19-080-V1 approved 14/01/2020). All participants received an informational letter and signed an informed consent form before participating. Trial registration: This study is a phase of the registered study 'Effectiveness of Nurse-coordinated Follow-Up Programme in Primary Care for People at Risk of T2DM' at www.ClinicalTrials.gov (NCT01688359) (accessed on 30 December 2020).

Ethics approval and consent to participate

Institutional review board statement: The present study was conducted in accordance with the Helsinki Declaration and with the approval of the Icelandic National Bioethics Committee (VSN), (VSN-19-080-V1 approved 14/01/2020). All participants received an informational letter and signed an informed consent form before participating.

Informed consent statement: Informed consent was obtained from all subjects involved in the study.

Trial registration: This study is a part of the registered study 'Effectiveness of Nurse-coordinated Follow-Up Programme in Primary Care for People at Risk of T2DM' at www.ClinicalTrials.gov (NCT01688359) (accessed on 30 December 2020)

Competing Interests

The authors declare no competing interests.

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Appendices

Appendix 1

Approval letters from the Icelandic National Bioethics Committee (VSN) and ClinicalTrials.gov



VÍSINDASÍÐANEFND

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Háskólinn á Akureyri
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arun@unak.is

Reykjavík 14. maí 2019

Tilv.: VSNb2019030004/03.01

Efni: 19-080-S1 - Mat á áhættu að fá sykursýki tegund 2: Áhrif af hjúkrunarstýðri fræðslu innan heilsugæslu, slembuð rannsókn með íhlutun

Umsókn þinni til Vísindasíðanefndar hefur verið gefið númerið **VSN-19-080**. Við förm vinsamlegast fram á að það númer verði notað í samskiptum vegna þessarar umsóknar.

Meðrannsakendur þínir eru:

Jóhanna Margrét Ingvarsdóttir, M.Sc hjúkrunarfræðingur og doktorsnemi. Heilbrigðisstofnun Norðurlands,

Dr. Árún Kristín Sigurðardóttir, prófessor, Háskólinn á Akureyri,

Dr. Marit Grue, prófessor við Western Norway University of Applied Sciences (HVL),

Beate-Christin Hope Kolltveit, nýdoktor og mun leiða fræðslumeðferð á Íslandi og samskonar fræðslu í Noregi og

Dr Timothy Skinner, heilsusálfræðingur, prófessor við Háskólann í Kaupmannahöfn,

Á fundi sínum 14.05.2019 fjallaði Vísindasíðanefnd um umsókn þína og svarbréf vegna ofangreindrar rannsóknaráætlunar. Í svarbréfi þínu er einnig eftirfarandi viðbót: „Óskað er eftir að bæta við WHO-5 vellíðunarspurningalista við rannsókn 2. Hann yrði þá lagður fyrir þáttakendur 3 sinnum eins og heilsulæsislistinn (HLS-EU-Q16-IS) og lífsgæðalistinn (EQ-5D-5L). WHO-5 spurningalistinn (íslensk þýðing), er aðgengilegur á heimasíðu WHO og öllum frjálst að nota ham."

Úrtak rannsóknarinnar eru skjólstæðingar HSN, á Akureyri, Húsavík og Sauðárkróki. Ef þeir falla innan skilgreiningamarka rannsóknarinnar og samþykkja þátttöku í rannsókninni. Ekki á að afla heilbrigðisupplýsinga úr gagnasöfnum. Þátttakendur verða beðnir um að veita leyfi til blóðprufu til að mæla HbA_{1c} gildi. Þeir sem greinast innan áhættu verða beðnir um sömu blóðprufu 2x í viðbót á rannsóknartímabilinu. Búið er að fá tæki (DCA Advantage) frá Medor að láni til að greina HbA_{1c} gildi. Doktorsnemi mun taka prufuna og greina á staðnum, svo fólk fær strax niðurstöður úr blóðprufu. Niðurstöður verða einungis vistaðar hjá rannsakanda (doktorsnema) ekki í lífsýnasöfnum.

Þáttökunúmer eða dulkóðunarlykill verða geymd í læstu skjali í læstri tölvu doktorsnema.

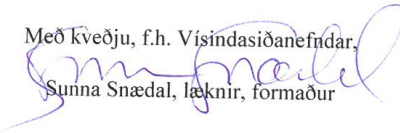
Persónugreinanlegum gögnum þ.m.t. dulkóðunarlykli verður eytt innan fimm ára eftir að rannsókn líkur. Rannsóknarlok eru 28.06.2024

Með vísan til l.mgr. 12. gr.laga nr. 44/2014, um vísindarannsóknir á heilbrigðissviði, er rannsóknaráætlunin endanlega samþykkt með þeim almenna fyrirvara að lögbundið samþykki skráarhaldara skv. 2. mgr. 27. gr. laga nr. 44/2014 verður að liggja fyrir áður en vinna með

heilbrigðisgögn viðkomandi stofnunar/skráarhaldara hefst.

Vísindasiðanefnd áréttar að ábyrgðarmaður rannsóknarinnar ber ábyrgð á að sótt sé um viðeigandi leyfi fyrir rannsókninni hjá þeim stofnunum sem við á. Óheimilt er að hefja framkvæmd rannsóknarinnar fyrr en þau liggja fyrir. Afrit leyfa/samstarfsyfirlýsinga þurfa að berast nefndinni. Áréttað er að allar fyrirhugaðar breytingar á þegar samþykktu rannsóknaráætlun þurfa að koma inn til nefndarinnar til umfjöllunar. Jafnframt ber ábyrgðarmanni að sækja um breytingar til þeirra stofnanna, sem veitt hafa leyfi vegna framkvæmdar rannsóknarinnar eða öflunar gagna, um framangreint, ef við á. Vísindasiðanefnd bendir rannsakendum vinsamlegast á að birta VSN tilvísunarnúmer rannsóknarinnar þar sem vitnað er í leyfi nefndarinnar í birtum greinum um rannsóknina. Minnt er á að tilkynna rannsóknarlok til nefndarinnar.

Með kveðju, f.h. Vísindasiðanefndar,


Sunna Snædal, lækni, formaður



VÍSINDASIÐANEFND

Borgartúni 21 - 4. hæð
105 Reykjavík,

Sími: 551 7100

netfang: vsn@vsn.is www.vsn.is

Árún Kristín Sigurðardóttir
Prófessor
Háskólinn á Akureyri
arun@unak.is

Reykjavík 14. janúar 2020

Tilv.: VSNb2019030004/03.01

Efni: VSN-19-080-V1- Mat á áhættu að fá sykursýki tegund 2: Áhrif af hjúkrunarstýðri fræðslu innan heilsugæslu, slembuð rannsókn með íhlutun.

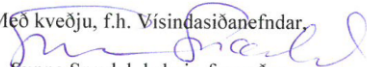
Á fundi sínum 14. janúar sl. fjallaði Vísindasiðanefnd um umsókn þína dags. 17. desember, vegna viðbótar nr. 1 við ofangreinda rannsóknaráætlun. Í erindi þínu segir:

„Ég tilkynni hér með að Jóhanna Margrét Ingvadóttir hefur dregið sig úr rannsókninni: Mat á áhættu að fá sykursýki gerð 2: Áhrif af hjúkrunarstýðri fræðslu innan heilsugæslu, slembuð rannsókn með íhlutun“ VSN-19-080. Í hennar stað er komin doktorsnemi sem heitir: Elín Arnardóttir KT 031167 3109 Eyraflöt 12 580, Siglufirði“

Vísindasiðanefnd hefur farið yfir bréf þitt og gerir ekki athugasemdir við tilgreindar breytingar. Viðbót nr. 1 við ofangreinda rannsókn, er endanlega samþykkt af Vísindasiðanefnd.

Vísindasiðanefnd bendir á að ábyrgðarmaður rannsóknarinnar ber ábyrgð á að sótt sé um viðeigandi leyfi vegna viðbóta/breytinga hjá þeim stofnunum sem við á. Óheimilt er að hefja framkvæmd rannsóknarinnar fyrr en slík leyfi liggja fyrir. Afrit leyfa/samstarfsyfirlýsinga þurfa að berast nefndinni. Jafnframt ber ábyrgðarmanni að tilkynna þeim stofnunum, sem veitt hafa leyfi vegna framkvæmdar rannsóknarinnar eða öflunar gagna, um framangreint, ef við á. Óheimilt er að breyta framkvæmd rannsóknarinnar fyrr en slík leyfi liggja fyrir.

Með kveðju, f.h. Vísindasiðanefndar,


Sunna Snædal, lækni, formaður



ClinicalTrials.gov Registration <register@clinicaltrials.gov>

To:  Elín Arnardóttir

Cc: register@clinicaltrials.gov



Tue 12/29/2020 12:02 PM

Message generated by ClinicalTrials.gov Protocol Registration and Results System

ClinicalTrials.gov Identifier: NCT04688359

University of Akureyri Protocol Record UAkureyri,
Effectiveness of Nurse-coordinated Follow-up Program in Primary Care for People at Risk for T2DM,
is registered and will be posted on the ClinicalTrials.gov public website.

Appendix 2

Introduction letters and confirmation paper (English version).



**Risk Assessment of Type 2 Diabetes:
Effects of Nursing Education in Health Care,
Randomized Intervention Study**

Presentation letter to participants

Dear recipient

The purpose of this letter is to invite you to participate in the above research. This study is being conducted at the Nordic Institute of Health. It involves checking to see if you have any type of risk factors for type 2 diabetes. Essentially, your involvement is in answering a questionnaire and measuring long-term blood glucose levels. It is estimated to take about 15 minutes.

If there is interest in participating in the study then the next step is that you talk to a receptionist who will refer you to Elín Arnardóttir nurse, as you will discuss with you what participation in the study entails.

The purpose of the study is to investigate whether and how large a proportion of persons aged 18 to 75 are considered at risk of developing type 2 diabetes over the next 10 years or have pre-existing type 2 diabetes. As well as to examine health literacy, current quality of life. And whether support from healthcare will benefit those at risk of developing type 2 diabetes over the next 10 years.

The aim of the study is to increase knowledge of the number of people at risk of developing type 2 diabetes in the North of Iceland. Also, see if the needs of people at risk for type 2 diabetes can be met with low support within healthcare. Those at risk of developing type 2 diabetes will therefore be invited to participate in a follow-up study following this study.

Participants and conditions for participation

Participants are those who have a booked time with a doctor or nurse at the Nordic National Institute of Health in Húsavík, Akureyri or Sauðárkrók during the research period.

The condition for participation is to be between the ages of 18 and 75, not to have known diabetes and have good authority in either Icelandic or English language.

What is involved?

Your participation means that Elin Arnardóttir, a nurse and a doctoral student, will meet you after you have completed your appointment with your doctor or nurse. Then Elin will measure weight, height, waist circumference, measure long-term blood sugar and take you through short questionnaires. It is estimated to take about 15 minutes.

Participants will be divided into Group A and Group B. The study period is expected to take 12 months. During that period, both groups need to meet a nurse at least 2-4 times, that is, at the beginning, after 5-6 months and then after about 11-12 months.

Publication of results

The results of the study will be presented at foreign and national conferences and scientific articles will be written in foreign and national professional journals.

Processing and deletion of data

Each participant in the study receives a participation number which will be recorded on the research papers. A separate sheet containing the name and number of the participants will be stored in a location that only the researcher and doctoral student will have access to and are bound by a silent procedure. The data from the study will be processed in special statistical programs where all information becomes impersonal. Answers to individual participants cannot be traced when the results of the study are published. The data of the study will be deleted five years after the completion of the study.

Benefits and risks

Your personal benefit from participating in the study is that you get information about your health from questionnaires, measurements and blood tests. Those at risk of developing type 2 diabetes are being offered support within their clinics. An indirect benefit is to build scales to improve knowledge of the health and well-being of people in the North. The risk of participating in the study is insignificant.

Right to refuse and cancel participation

You are under no obligation to participate in this study and you may cancel at any stage, without explanation. If you choose not to participate or cancel your participation, it will not have any consequences for you and it will not affect the health care you receive. If you wish to avoid answering individual questions, you are free to do so. However, it should be pointed out that due to data processing and the reliability of the results, it is desirable that as many questions as

possible are answered.

The study states:

Signed, dr. Árún K. Sigurðardóttir, professor at the University of Akureyri, is responsible for this research. Other researchers include: Elin Arnardóttir, nurse and doctoral student, Dr. Marit Graue Professor at the University of Western Norway, (Bergen), Beate-Christine Hope Kolltveit, New Doctorate at the University of Western Norway, (Bergen) and Dr. Timothy Skinner Health Psychologist at the University of Copenhagen in Denmark.

The researcher will ask you to sign an informed consent for the study prior to the interview.

The study has been reported to the Data Protection Authority and has been approved by the Science Ethics Committee.

If you have any questions or would like to make any comments or complaints regarding the investigation, you are welcome to contact the undersigned.

With advance gratitude,



Árún K. Sigurðardóttir

Phone: 867-0723

e-mail: arun@unak.is

If you have questions about your rights as a participant in the study, you can contact the Science Ethics Committee, Borgartún|21, 105, Reykjavik. Phone 5517100, email: visindasidanefnd@vsn.stjr.is.

Statement of consent from the participant in the study:

**Risk Assessment of Type 2 Diabetes: Effects of Nursing Education in
Health Care, Randomized Intervention Study**

I have signed / signed the presentation of the above study and consent to participate in the study as described. I acknowledge that I have the right to cancel participation at any time without notice, and trust complete anonymity about my participation.

Date _____

Signature of informed consent of the participant

Name or Label instead of name

Researcher

Mat á upplifun hjúkrunarfræðinga á að veita einstaklingum í áhættu á að þróa með sér sykursýki af tegund tvö ráðgjöf með aðferðinni Guided Self Determination (GSD)

Kynningarbréf til hjúkrunarfræðinga sem þátt taka

Ágæti viðtakandi

Tilgangur þessa bréfs er að bjóða þér að taka þátt í ofangreindri rannsókn. Rannsókn þessi fer fram á Heilbrigðisstofnun Norðurlands. Í meginráttum felst þátttaka þín í að veita GSD og að því loknu að taka þátt í eigindlegri rannsókn á upplifun á að nota þessa aðferð í ráðgjöf til einstaklinga sem greindir hafa verið í áhættu á að þróa með sér tegund 2 sykursýki. Hjúkrunarráðgjöfin fer fram að lokinni leiðsögn um aðferðina. Eigindlega rannsóknin í kjölfarið felst í að tekið verður viðtal eitt eða tvö þar sem farið er í gegn um upplifun af því að veita þessa þjónustu. Atvinnurekandi hefur gefið vilyrði fyrir að hjúkrunarráðgjöfin falli undir vinnutíma þinn. Viðtölin verða tekin á vinnutíma og er áætlað er að það taki um 15-45 mínútur.

Tilgangur rannsóknarinnar er að kanna áhrif aðferðar við ráðgjöf sem ekki hefur verið reynd áður á Íslandi fyrir einstaklinga á aldrinum 18 til 75 ára sem teljast í áhættu að fá sykursýki af tegund 2 á næstu 10 árum eða eru komnir með forstíg sykursýki af tegund 2. Einnig upplifun hjúkrunarfræðinganna sem veita þjónustuna af því hvernig þessi ráðgjafaraðferð er frá þeirra sjónarhóli.

Markmið rannsóknarinnar er að athuga hvort koma megi til móts við þarfir fólks í áhættu að fá sykursýki tegund 2 með litlum stuðningi innan heilsugæslu og hvernig hjúkrunarfræðingar meta þessa aðferð til ráðgjafar fyrir þessa einstaklinga.

Þátttakendur og skilyrði fyrir þátttöku

Þátttakendur eru þeir hjúkrunarfræðingar sem eftir viðtal við sinn yfirmann hafa samþykkt hafa að taka þátt í rannsókninni.

Hvað felst í þátttöku?

Þátttaka þín felur það í sér að Elin Arnardóttir hjúkrunarfræðingur og doktorsnemi og Beat Christine Hope Kolltveit nýdoktor við rannsóknarháskólann í Bergen í Noregi (HVL) munu leiðbeina um GSD ráðgjafaraðferðina. Elin og Cristine mun veita stuðning á meðan á rannsóknartímanum stendur. Í lok rannsóknartímans verða tekin eitt eða tvö viðtöl við hvern hjúkrunarfræðing.

Birting niðurstaðna

Niðurstöður rannsóknarinnar verða kynntar á erlendum og innlendum ráðstefnum og skrifaðar verða vísindagreinar í erlend og innlend fagtimarit.

Úrvinnsla og eyðing gagna

Viðtöl við hjúkrunarfræðinga verða tekin upp á segulband, um rituð á ensku þar sem öllum persónugreinanlegum auðkennum verður eitt. Að loknum umritunum verður upptökum eytt. Ábyrgðarmaður rannsóknarinnar, doktorsnemi og Nýdoktor munu hafa aðgang að gögnunum og eru þeir bundnir þagnareid. Unnið verður úr gögnum rannsóknarinnar með eigindlegum rannsóknaraðferðum. Ekki verður hægt að rekja svör til einstakra þátttakenda þegar niðurstöður

rannsóknarinnar verða birtar. Gögnum rannsóknarinnar á pappír verður eytt fimm árum eftir að rannsókn lýkur.

Ávinningur og áhætta

Persónulegur ávinningur þinn af þátttöku í rannsókninni er að þú færð kennslu í nýrri nálgun hjúkrunarráðgjafar sem hefur verið gagnreynd víða erlendis með ólíkum sjúklingahópum og þú hefur leyfi til að nota. Óbeinn ávinningur er að leggja lóð á vogaskálar til að bæta þekkingu á ráðgjafaraðferðinni og bæta mögulega liðan fólks á Norðurlandi sem er í áhættu á að fá sykursýki af tegund tvö eða er með forstigseinkenni af sykursýki. Áhætta vegna þátttöku í rannsókninni er óveruleg.

Réttur til að hafna og hættu þátttöku

Þér ber engin skylda til að taka þátt í þessari rannsókn og þú getur hætt á hvaða stigi sem er, án útskýringa. Kjósir þú að taka ekki þátt eða hættu þátttöku mun það ekki hafa neinar afleiðingar fyrir þig og það hefur ekki áhrif á þá heilbrigðisþjónustu sem þú færð. Óskir þú þess að sleppa því að svara einstökum spurningum er þér frjálst að gera það. Rétt er þó að benda á, að vegna úrvinnslu gagna og áreiðanleika niðurstaðna, er æskilegt að sem flestum spurningum sé svarað.

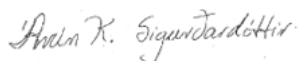
Að rannsókninni standa:

Undirrituð, dr. Árún K. Sigurðardóttir prófessor við Háskólann á Akureyri, er ábyrgðarmaður þessarar rannsóknar. Aðrir rannsakendur eru: Elin Arnardóttir, hjúkrunarfræðingur og doktorsnemandi, Dr. Marit Graue prófes sor við háskólann í Vestur Noregi, (Bergen), Beate-Christine Hope Kolltveit, nýdoktor við háskólann í Vestur Noregi, (Bergen) og Dr. Timothy Skinner heilsusálfræðingur við Kaupmannahafnarháskóla.

Rannsakandi mun biðja þig um að skrifa undir upplýst samþykki fyrir þátttöku í rannsókninni áður en viðtalið hefst .

Rannsóknin hefur verið tilkynnt til Persónuverndar og hlotið samþykki Visindasiðanefndar. Hafir þú spurningar eða viljir koma á framfæri athugasemdum eða kvörtunum í tengslum við rannsóknina, er þér velkomið að hafa samband við undirritaða.

Með fyrir fram þakklæti,



Árún K. Sigurðardóttir Sími: 867-0723 tölvupóstur: arun@unak.is

Ef þú hefur spurningar varðandi rétt þinn sem þátttakandi í rannsókninni getur þú snúið þér til Visindasiðanefndar, Borgartúni 21, 105, Reykjavík. Sími 5517100, tölvupóstur: visindasidaneftd@vsn.stjr.is.

Appendix 3

Questionnaire of FINDRISC, Eq-5D-5L, WHO-5 and HL-EU-Q16IS – English version, instruments and background information.

Research at Heilbrigðisstofnun Norðurlands

„Risk Assessment of Type 2 Diabetes: Effects of Nursing Education in Health Care, Randomized Intervention Study“

Mat á áhættu að fá sykursýki tegund 2: Áhrif af hjúkrunarstýðri fræðslu innan heilsugæslu, slembuð rannsókn með íhlutun

Researcher: Elín Arnardóttir doktorsnemandi við Háskólann á Akureyri

Researchgroup:

Árún K. Sigurðardóttir prófessor HA

Dr. Marit Graue prófessor við Háskólann í Vestur Noregi

Dr. Beate Kollveit lektor við Háskólann í Vestur Noregi

Dr. Timothy Skinner prófessor við Kaupmannahafnar Háskóla

Thank you in advance for participating in the study

TYPE 2 DIABETES RISK ASSESSMENT FORM

Circle the right alternative and add up your points.

1. Age

- 0 p. Under 45 years
- 2 p. 45–54 years
- 3 p. 55–64 years
- 4 p. Over 64 years

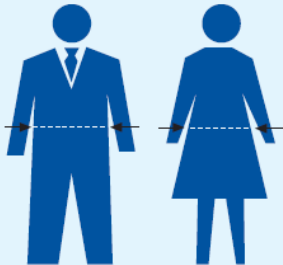
2. Body-mass index

(See reverse of form)

- 0 p. Lower than 25 kg/m²
- 1 p. 25–30 kg/m²
- 3 p. Higher than 30 kg/m²

3. Waist circumference measured below the ribs (usually at the level of the navel)

	MEN	WOMEN
0 p.	Less than 94 cm	Less than 80 cm
3 p.	94–102 cm	80–88 cm
4 p.	More than 102 cm	More than 88 cm



4. Do you usually have daily at least 30 minutes of physical activity at work and/or during leisure time (including normal daily activity)?

- 0 p. Yes
- 2 p. No

5. How often do you eat vegetables, fruit or berries?

- 0 p. Every day
- 1 p. Not every day

6. Have you ever taken medication for high blood pressure on regular basis?

- 0 p. No
- 2 p. Yes

7. Have you ever been found to have high blood glucose (eg in a health examination, during an illness, during pregnancy)?

- 0 p. No
- 5 p. Yes

8. Have any of the members of your immediate family or other relatives been diagnosed with diabetes (type 1 or type 2)?

- 0 p. No
- 3 p. Yes: grandparent, aunt, uncle or first cousin (but no own parent, brother, sister or child)
- 5 p. Yes: parent, brother, sister or own child

Total Risk Score

The risk of developing type 2 diabetes within 10 years is

Lower than 7	Low: estimated 1 in 100 will develop disease
7–11	Slightly elevated: estimated 1 in 25 will develop disease
12–14	Moderate: estimated 1 in 6 will develop disease
15–20	High: estimated 1 in 3 will develop disease
Higher than 20	Very high: estimated 1 in 2 will develop disease

Please turn over

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WHAT CAN YOU DO TO LOWER YOUR RISK OF DEVELOPING TYPE 2 DIABETES?

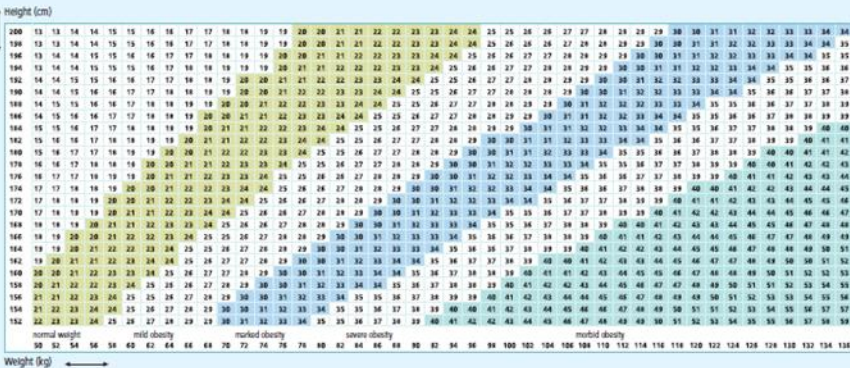
You can't do anything about your age or your genetic predisposition. On the other hand, the rest of the factors predisposing to diabetes, such as overweightness, abdominal obesity, sedentary lifestyle, eating habits and smoking, are up to you. Your lifestyle choices can completely prevent type 2 diabetes or at least delay its onset until a much greater age.

If there is diabetes in your family, you should be careful not to put on weight over the years. Growth of the waistline, in particular, increases the risk of diabetes, whereas regular moderate physical activity will lower the risk. You should also pay attention to your diet: take care to eat plenty of fibre-rich cereal products and vegetables every day. Omit excess hard fats from your diet and favour soft vegetable fats.

BODY-MASS INDEX

The body-mass index is used to assess whether a person is normal weight or not. The index is calculated by dividing body weight (kg) by the square of body height (m). For example, if your height is 165 cm and your weight 70 kg, your body-mass index will be $70/(1.65 \times 1.65)$, or 25.7.

BODY-MASS INDEX CHART





Health Questionnaire

English version for the UK

UK (English) © 2009 EuroQol Group EQ-5D™ is a trade mark of the EuroQol Group

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

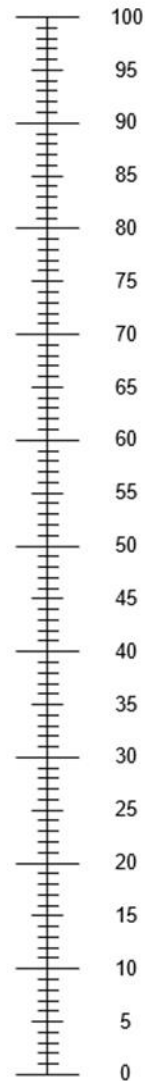
ANXIETY / DEPRESSION

- 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.
- The scale is numbered from 0 to 100.
- 100 means the best health you can imagine.
0 means the worst health you can imagine.
- Mark 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 =

The best health
you can imagine



The worst health
you can imagine



WHO (Five) Well-Being Index (1998 version)

Please indicate for each of the five statements which is closest to how you have been feeling over the last two weeks. Notice that higher numbers mean better well-being.

Example: If you have felt cheerful and in good spirits more than half of the time during the last two weeks, put a tick in the box with the number 3 in the upper right corner.

	<i>Over the last two weeks</i>	All of the time	Most of the time	More than half of the time	Less than half of the time	Some of the time	At no time
1	I have felt cheerful and in good spirits	<input type="checkbox"/> 5	<input type="checkbox"/> 4	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1	<input type="checkbox"/> 0
2	I have felt calm and relaxed	<input type="checkbox"/> 5	<input type="checkbox"/> 4	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1	<input type="checkbox"/> 0
3	I have felt active and vigorous	<input type="checkbox"/> 5	<input type="checkbox"/> 4	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1	<input type="checkbox"/> 0
4	I woke up feeling fresh and rested	<input type="checkbox"/> 5	<input type="checkbox"/> 4	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1	<input type="checkbox"/> 0
5	My daily life has been filled with things that interest me	<input type="checkbox"/> 5	<input type="checkbox"/> 4	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1	<input type="checkbox"/> 0

Scoring:

The raw score is calculated by totalling the figures of the five answers. The raw score ranges from 0 to 25, 0 representing worst possible and 25 representing best possible quality of life.

To obtain a percentage score ranging from 0 to 100, the raw score is multiplied by 4. A percentage score of 0 represents worst possible, whereas a score of 100 represents best possible quality of life.

(this page 2 was not handed out)

Interpretation:

It is recommended to administer the Major Depression (ICD-10) Inventory if the raw score is below 13 or if the patient has answered 0 to 1 to any of the five items. A score below 13 indicates poor wellbeing and is an indication for testing for depression under ICD-10.

Monitoring change:

In order to monitor possible changes in wellbeing, the percentage score is used. A 10% difference indicates a significant change (ref. John Ware, 1995).

HLS-EU-Q16-IS Health Literacy Survey (in English)

Please mark X at the column that is best suits you

	On the scale from very easy to very difficult, how easy would you say it is to...	Very easy	Fairly easy	Fairly difficult	Very difficult
1	...find information on the treatments of illness that concern you?				
2	...find out where to get professional help when you are ill?				
3	...understand what your doctor says to you?				
4	...understand your doctor's or pharmacist's instructions on how to take a prescribed medicine?				
5	...judge when you may need to get a second opinion from another doctor?				
6	...use information the doctor gives you to make decisions about your illness (treatment)?				
7	...follow instructions from your doctor or pharmacist?				
8	...find information on how to manage mental health problems like stress or depression?				
9	...understand health warnings about behavior such as smoking, low physical activity and drinking too much?				
10	...understand why you need health screenings?				
11	...judge if the information on health risk in the media is reliable?				
12	...decide how you can protect yourself from illness based on information in the media?				
13	...find out about activities that are good for your mental wellbeing?				
14	...understand advice on health from family members or friends?				
15	...understand information in the media on how to get healthier?				
16	...understand health warnings about behavior such as smoking, low physical activity and drinking too much?				

Útlenska útgáfan af HLS-EU-Q16 er höfð og útdrátt af Dr. Arum K. Sigurðssonur (arum@umak.is) professor, Guðrunn Heiða Kristjánsdóttir meistari Sonju Stelly Gustafsdóttur (sonjag@umak.is) lektor, við heilbrigðisvísindasvið Háskólans á Akureyri, með leyfi frá Kristine Sorensen (healthliteracyeurope@gmail.com). Heiðild: HLS-EU Consortium (2012): HLS-EU-Q. Measurement of health literacy in Europe. Söfn af: <http://www.forumitess.com/wp-content/uploads/2015/02/HLS-EU-Q-tools-and-introduction-2.pdf>

Background-questions ¶

1. Sex: ¶

- → Male: _____ ¶
- → Female: _____ ¶
- → Don't define my gender as male or female: _____ ¶

2. What year are you born: _____ ¶

3. How many residents live now at your home beside you? _____ ¶

4. If other than you are residents at your home, then who? Mark all that apply: ¶

- → Spouse _____ ¶
- → Parents: _____ ¶
- → Siblings: _____ ¶
- → Children-/grandchildren: _____ ¶
- → Others: _____ ¶

5. What is your education level? ¶

- Elementary school, Compulsory education or equivalent: _____ ¶
- Graduation Highschool/Industrial or Vocational Studies/Comprehensive school: _____ ¶
- Completed university degree: _____ ¶

6. How many years have you finished in school? _____ ¶

7. I live in the community of: ¶

- Húsavík or other community nearby Húsavík: _____ ¶
- Sauðárkrókur or other community in Skagafjörður: _____ ¶
- Akureyri or community nearby: _____ ¶
- I live in another community in Northern part of Iceland: _____ ¶
- I do not live in the Northern part of Iceland: _____ ¶

8. How is your employment participation at this point? Mark what is appropriate. ¶

- I am working full-time job: _____ ¶
- I am working part-time job: _____ ¶
- I am unemployed: _____ ¶
- I am on disability benefit: _____ ¶
- I am retiree: _____ ¶
- Other: _____ ¶

9. Are you diagnosed with diabetes by a doctor? → No: _____ Yes: _____ No not know: _____ ¶

10. HBA1c value: _____ mmol/mol (result of the measurement today) ¶

Appendix 4

Reflection sheets (Icelandic).



Yfirlits og endurspeglunarblöð (LEIÐSÖGN UM SJÁLFSÁKVÖRDUN)

FYRIR EFTIRFYLGNI SKJÓLSTÆÐINGA Í HEILSUGÆSLU

Speglunarblöð	Blað afhent	Blað sent	Blað rætt	Skipulagt samtal (dagsetning)
SAMTAL 1.				
Samvinnuferli um þitt líf núna				
1.a Tilboð um samvinnu				
1.b Hvað finnst þér sem stendur krefjandi, erfitt eða veldur þér áhyggjum af heilsu þinni/aðstæðum núna?				
1.c Ókláraðar setningar, um gildi, reynslu og þarfir				
1.d Myndir/samlíking				
SAMTAL 2.				
Að breyta áherslum				
2.a Svo mikil hefur heilsufar þitt fyllt líf þitt				
2.b Áform um að breytingar á lífsháttum/venjum				
SAMTAL 3.				
Vinna við breytingar /Lífsstílsbreytingar				
3.a Birtingamynd vanda/áskorana				
3.b Þín markmið og fyrirætlanir/áform				
3.c Þínar hugsanir og tilfinningar				
3.d Þínar aðgerðir				
3.e Ný stefna og langtíma áætlun				

Vinnublað speglunar fyrir samtal 1.

- 1a. Tilboð um samvinnu
- 1b. Hvað finnst þér sem stendur krefjandi, erfitt eða veldur þér áhyggjum af heilsu þinni/ástandi núna?
- 1c. Ókláraðar setningar um gildi, reynslu og þarfir
- 1d. Mynd, myndlíking

1a. Tilboð um samvinnu

Hvað viljum við vinna saman með?

- Við veljum eitthvað sem þú upplifir krefjandi og erfitt í þínu daglega lífi

Hvaða hlutverk hefur hvert okkar?

- Bæði þín og mín þekking og reynsla er mikilvæg og nauðsynleg
- Við þurfum bæði að taka þátt og verja tímanum vel í það sem okkur þykir mikilvægt
- Hluta af tímanum vinnum við í sitthvoru lagi og hluta af tímanum saman.

Hvernig á samvinnan að vera?

- Það er allt í lagi og getur verið jákvætt, að við sjáum ólíka hluti
- Það er nauðsynlegt að við þekkjum skoðanir hvors annars
- Það er í lagi að tilfinningar geti reynst erfiðar
- Það er í lagi að sýna tilfinningar

Hver er kosturinn við speglunarblöðin og til hvers á að nota þau?

- Þú getur lesið vinnublöðin í ró og næði til að hugsa um og skilja aðstæður þínar betur
- Við betum notað þau til að fá yfirsýn yfir það sem er mikilvægt í þínum aðstæðum
- Blöðin geta gert það léttara að tala um það sem annars getur verið erfitt að tala um
- Blöðin geta hjálpað þér við að taka ákvarðanir sem eru réttar fyrir þig
- Eftir að þú hefur notað speglunarvinnublöðin, geta þau áfram hjálpað þér að halda fast í það sem er mikilvægt fyrir þig

1c. Ókláraðar setningar – um gildi, reynslu og þarfir

Þeir sem þekkja minn lífnaðarhátt, finnst ég...

Það sem ég er bestur í þegar kemur að minni heilsu/ástandi er ...

Það sem er verst við að hafa það svona er

Það sem ég er verstur í, er

Heilsufar/aðstæður mínar hefur hindrað mig í ég

Það fær ekki að hindra mig í að...

Eftir eitt ár vil ég

Ég ætti ekki að kenna heilsufari/ aðstæðum mínum um...

Þegar ég á að fara til læknis/heilsugæsluna, þá hugsa ég....

Ég vil gjarnan læra meira um

Eitthvað sem getur valdið vandamálum heima, er ...

Mér finnst mínir samstarfsfélagar og vinir ...

Eitthvað sem ég reyni að beyta hjá sjálfum mér, er ...

Vani sem ég á erfitt með að hætta með, er

Ég á erfitt með að standast brýsting frá....

Ég fæ góðan stuðning frá

Ég fæ of lítinn stuðning frá

Hamingjusamasti dagur lífs míns var þegar

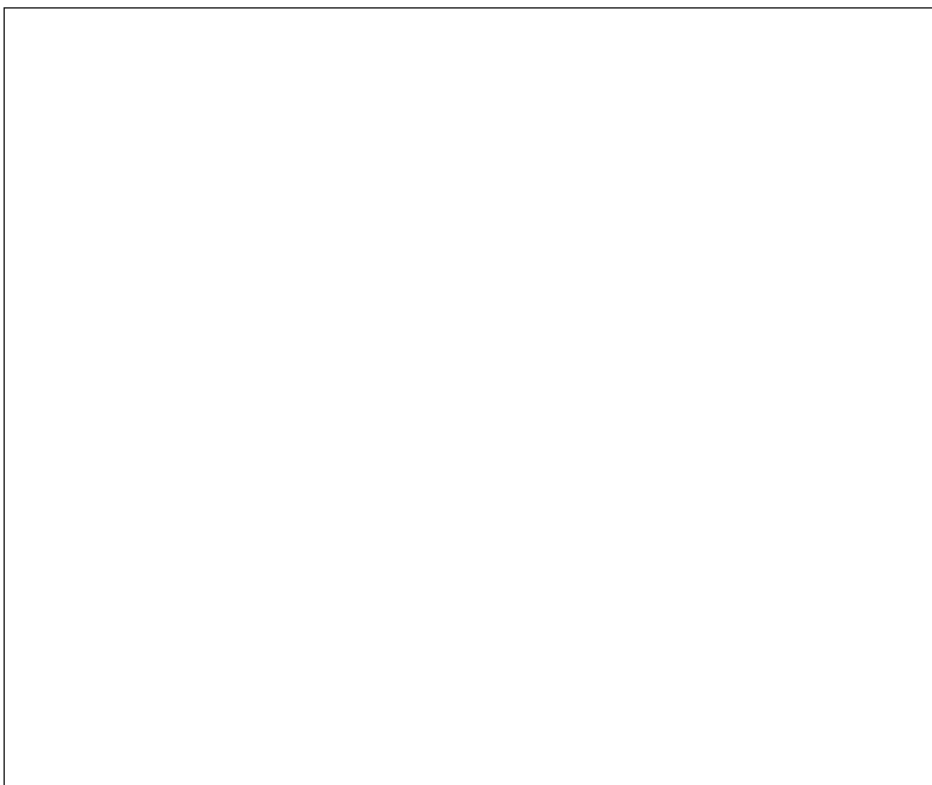
Sorglegasti dagur lífs míns var þegar

Það sem ég óska mér allra mest, er

Þegar ég verð gamall, vil ég gjarnan geta litið til baka og séð að ég hef

1d. Mynd, samlíking eða dæmigerð leið að tjá það sem þér finnst um heilsufar þitt

(Skrifaðu og/eða teiknaðu)



Speglunarblöð fyrir samtal 2.

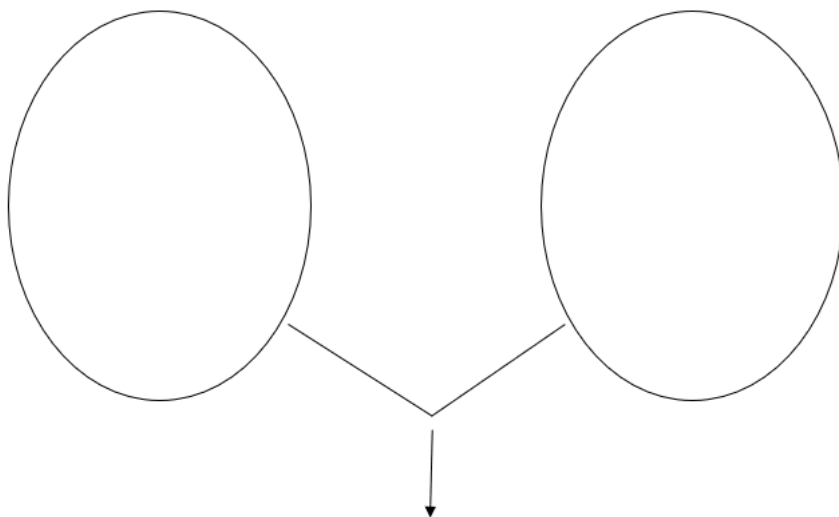
Samvinnuverkefni um framfarir í lífinu með heilsufar þitt

- 2a. Svo mikið hefur heilsufar þitt fyllt líf þitt
- 2b. Áætlanir um breytingar á lífsháttum/venjum

2a. Rými sem heilsufar þitt hefur í lífi þínu

Svona mikið hefur heilsufarið fyllt lífið fram að þessu
(fylltu upp í reitinn það sem á við í dag)

Svo mikið á það að fylla lífið
(fylltu upp í reitinn sem þú
óskaðir þess að eigi við í dag)



Í hverju liggur munurinn?

A large, empty rectangular box intended for the student to write their answer to the question above.

2b. Áætlanir um breytingar á lífsháttum/venjum

Mikið af því sem ráðlagt er um líf með heilsufar mitt getur verið erfitt að aðlaga daglegu lífi.

Settu kross í vinstri dálk við þær setningar sem þér finnst eiga við þitt daglega líf.

Merktu við með kross í dálka til hægri ef það er eitthvað sem þú vilt breyta eða halda áfram með.

Eftirfarandi einkennir daglegt líf mitt (settu kross)	Ég vil breyta þessu: (settu kross)			Ég áætla ekki að breyta þessu (settu kross)
	Á fyrsta mánuðinum	Á fyrsta hálfu árinu	Eftir fyrsta hálfu árið	
Ég borða of mikið				
Ég borða of lífið				
Mig vantar þekkingu á því hvað mat er hentugt fyrir mig að borða				
Ég hreyfi mig ekki reglulega				
Ég hreyfi mig ekki nægilega til að púlsinn minn verði hraðari				
Ég hreyfi mig of lítið dagsdaglega				
Ég veit ekki hvernig ég á að taka inn/nota lyfin mín				
Ég sleppi af og til að taka lyf sem ávísað er fyrir mig				
Ég veit ekki nóg um heilsufar mitt og mögulega fylgikvilla				
Ég er of þung/ur				
Ég er of létt/ur				
Ég reyki				
Ég á í vandræðum með neyslu áfengis / vímuefna				
Annað:				

Speglunarblað fyrir Samtal 3.

Samvinnuverkefni um framfarir í lífinu með heilsufar þitt

Vinna við breytingar

- 3a. Birtingarmynd á vanda/áskorunum
- 3b. Þín markmið og fyrirætlanir/áform
- 3c. Þínar hugsanir og tilfinningar
- 3d. Þínar aðgerðir
- 3e. Ný stefna og langtíma áætlun

3a. Vandamál eða áskoranir sem þú sérð í lífi þínu með heilsufar þitt

Listi yfir það sem er krefjandi/erfitt. Húkrunarfræðingur fyllir inn á eftir sjúklingi. Má gjarnan vera mismunandi.

Listinn minn: Þú hefur fyllt hann út heima

Listi hjúkrunarfræðings: Fyllist út í samtali 3

Óskir um beytingar: Þetta fyllum við út saman í samtali 3.

Sameiginleg skýring
okkar á einhverju sem
getur gagnast eða breytt
getu þinni til að stjórna
lífsháttum þínum

Mótuð á þann hátt sem
þú ert sammála og sem
við teljum bæði
fullnægjandi



3.b Þín markmið og fyrirætlanir/áform

Hvað er mikilvægt fyrir þig? Hverju óskar þú að ná fram?

.....

.....

.....

Hvað græðir þú á að áskorunin leysist?

Hverju getur þú tapað?

Til skamms tíma

Til skamms tíma

Til langstíma

Til langstíma

Hefur þú tekið ákvörðun um að takast á við áskorunina eða leysa vandamálið í heild sinni eða að hluta til?

Ef að hluta til – hvaða hluta?

3c. Þínar hugsanir og tilfinningar

Hverju telur þú að áskorunin eða vandamálið tengist?

.....

.....

.....

Hvað gerir þetta verra?

Hvað gerir þetta betra?

Hvað hindrar þig í ?

hverju nærð þú fram með því?

Hvað hefur það mikil áhrif á þig?

3.d Þínar aðgerðir

Hverju hefur þú hingað til náð í sambandi við að ráða við áskoranirnar eða að leysa vandamálið?

.....

.....

.....

Þegar?

Hversu oft?

Hvað hefur þú gert án árangurs?

Hver hefur hjálpað þér?

Frá hverjum hefur þú saknað að fá hjálp frá?

Hvern hefur þú beðið um hjálp?

Frá hverjum hefðir þú gjarnan átt að biðja um hjálp frá?

3.e Ný stefna og langtíma áætlun

Hverju hefur þú náð hingað til?

Ertu með markmið varðandi heilsufar þitt sem hægt er að ná og ef svo er, finnst þér það mikilvægt og þýðingarmikið fyrir þig?

Athugasemdir við eigin markmið

Hvað þarf til að halda ferlinu í gangi?

Hver getur hjálpað til í áframhaldandi ferli?

3.e Ný stefna og langtíma áætlun

Hverju hefur þú náð hingað til?

Ertu með markmið varðandi heilsufar þitt sem hægt er að ná og ef svo er, finnst þér það mikilvægt og þýðingarmikið fyrir þig?

Athugasemdir við eigin markmið

Hvað þarf til að halda ferlinu í gangi?

Hver getur hjálpað til í áframhaldandi ferli?
