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Preventing overweight, obesity and type 2 diabetes in the Norwegian Primary Health Care

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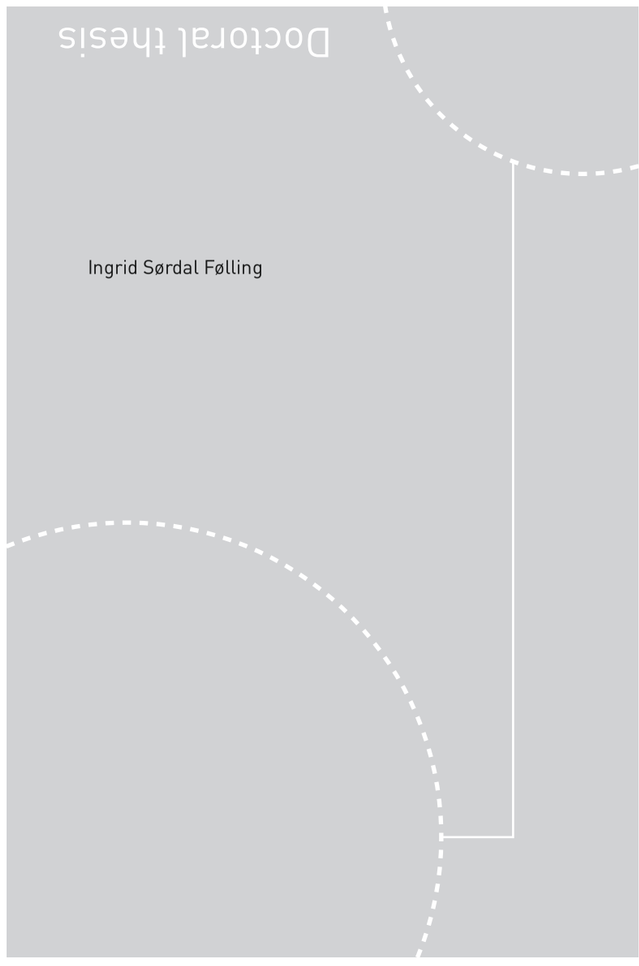

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“ Folkehelse handler ikke bare om kropp,

men om sjel og fellesskap”

Viktig er da disse fem om dagen:

1. *Verdighet*
2. *Handlingsrom i eget liv*
3. *Tilhørighet*
4. *Mening*
5. *Trygghet*

Per Fugelli

Norsk sammendrag

Deltakere i Frisklivssentraler sine forutsetninger for livsstilsendring
-forebygging av overvekt, fedme og diabetes type 2 i norsk primærhelsetjeneste

Forekomsten av overvekt, fedme og diabetes type 2 øker i store deler av verden, inkludert i Norge. Endring av levevaner via livsstilsendringstilbud har vist seg å være utfordrende for deltakere med overvekt og fedme. Studier har derimot vist at det er mulig å forebygge diabetes type 2 når deltakere endrer levevaner via livsstilsendringstilbud. Studiene er stort sett eksperimentelle, det vil si at livsstilstilbudene er designet og gjennomført i kontrollerte settinger. Livsstilstilbudenes effekt kan avhenge av innhold og ressurser, samt setting. I Norge har fokus økt de siste ti årene på at primærhelsetjenestens skal være setting for å forebygge livsstilssykdommer. I 2011 anbefalte helsemyndighetene at alle norske kommuner bør ha en Frisklivssentral med tilbud til de som har behov for å endre levevaner. For å tilpasse og utvikle tilbudene ved Frisklivssentraler på best mulig måte er kunnskap om deltakerne viktig. Deltakerne ved Frisklivssentraler sine forutsetninger for livsstilsendring, og om tilbudet er med på å redusere overvekt og fedme og å forebygge diabetes type 2 er lite utforsket.

I denne avhandlingen var hovedmålet å øke forståelsen omkring deltakere på Frisklivssentraler sine forutsetninger for livsstilsendring, og undersøke om deltakelse bidrar til å redusere overvekt, fedme og å forbygge utviklingen av diabetes type 2. I artikkel 1 var målet å studere deltakeres erfaringers betydning for livsstilsendring, i det de startet på et tilbud ved en Frisklivssentral. For artikkel 2 ble selekterte deltakere med avdekket høy risiko for diabetes type 2 i Helseundersøkelsen i Nord Trøndelag (HUNT3) studert mens de deltok på et ettårig tilbud ved en Frisklivssentral i Værnesregionen (VEND-RISK studien). Målet i artikkel 2 var å utforske deltakernes opplevelse av egen livsstil og betydningen av det å ha økt risiko for diabetes type 2. I artikkel 3 var målet todelt. Første del var å undersøke deltakere med avdekket høy risiko for diabetes type 2 i HUNT3 sin effekt av å delta på VEND-RISK studien, ett år etter avsluttet tilbud. Andre del var å se om det var forskjeller i karakteristikkene i mellom de som hadde takket ja og nei til deltakelse til VEND-RISK studien.

Både kvalitativ (artikkel 1 og 2) og kvantitativ metode (artikkel 3) ble benyttet for å besvare avhandlingens mål. Semi-strukturerte dybdeintervjuer ble utført for artikkel 1 og 2. I artikkel 1 ble deltakere (n=23) intervjuet i begynnelsen av deres oppstart på tilbud ved en Frisklivssentral. I artikkel 2 ble deltakere (n=26) intervjuet i løpet av perioden de deltok på det ettårige tilbud i VEND-RISK studien. I første del av artikkel 3 ble et longitudinelt, ikke-randomisert, en-armet, observasjons, pre-post design brukt for å studere endringer i helseeffekt av deltakere (n=45) etter ett års deltakelse i VEND-RISK studien. Helsevariabler ble målt baseline, etter endt tilbud og ett år etter endt tilbud. I andre del av artikkel 3 ble et tverrsnittdesign brukt for å sammenligne karakteristikkene fra HUNT3 for de som takket ja (n=45) eller nei (n=287) til å delta i VEND-RISK studien.

I artikkel 1 fant vi at deltakerne opplevde å sitte fast i gamle mønster av levevaner og de hadde en tung emosjonell bagasje med negative livserfaringer fra barndom frem til

i dag. Dette gjorde det vanskelig for dem å starte med en livsstilsendring. I artikkel 2 fant vi at deltakerne beskrev tilgjengelige ressurser med familie i nærheten, i tillegg til et sosialt nettverk, som betydningsfullt for å ha en aktiv livsstil. Ulike reaksjoner på å ha fått beskjed om høy risiko for diabetes type 2 ble uttalt. En familiehistorikk med diabetes og relaterte komplikasjoner ble vektlagt som viktigere for endring enn det å få vite at de hadde høy risiko, og å delta på tilbudet. I artikkel 3 var deltakernes gjennomsnittlige HbA_{1c} signifikant lavere ett år etter endt deltakelse i VEND-RISK studien sammenlignet med da de startet. Videre hadde kvinner i studien redusert den gjennomsnittlige livvidden med 4 cm ved ettårsoppfølgingen. De som takket nei til å delta på VEND-RISK studien hadde relativt like helsekarakteristikker ved HUNT3 som de som takket ja til deltakelse. Kvinner som takket nei hadde færre år med utdanning, de scoret lavere på arbeidsdeltakelse og rapporterte oftere at deres helse påvirket deres sosiale relasjoner, sammenlignet med kvinner som deltok på tilbudet.

Med bakgrunn i funnene fra de tre artiklene i denne avhandlingen blir det stilt spørsmål om hvem som kan nyttiggjøre seg å delta i tilbudet på Frisklivssentraler. Det vil videre være nyttig å se på hvilke ressurser og tilnærmingsmetoder som bør vektlegges i tilbudet for at deltakere skal lykkes med en varig livsstilsendring. Primærforebyggende tenkning og helsefremmende strategier på populasjonsnivå som treffer hele befolkningen bør være fremtidig fokus for å forebygge den økende forekomsten av overvekt, fedme og diabetes type 2.

Navn kandidat: *Ingrid Sørdal Følling*
Institutt: *Samfunnsmedisin og sykepleie*
Veileder(e): *Anne-Sofie Helvik (Dr. philos.), Bård Kulseng (Dr. med.), Kristian Midthjell (Dr. med.), Vegar Rangul(Ph.d))*
Finansieringskilde: *Nord Universitet*

Ovennevnte avhandling er funnet verdig til å forsvares offentlig
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I want to express my gratitude to all the 49 participants who have shared their stories with me. I am grateful for their time, their trust and personal investment. In addition, thanks to participants in the HUNT3 Survey and the VEND-RISK Study for their contribution making this PhD thesis possible.

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Ingrid S. Følling
Levanger, 12. Febrary 2017

Abstract

The prevalence of overweight, obesity and type 2 diabetes is increasing worldwide, including in Norway. Reducing overweight and obesity through lifestyle programmes is found challenging. Studies have shown, however, that it is possible to prevent type 2 diabetes when participants change health habits through lifestyle programmes. Most of these studies have been experimental; the programmes had been designed and conducted within randomized controlled trials. The effects of lifestyle programmes depend on their contents, the resources available, and the setting in which they are offered. Interest in Norway in improving public health within the context of primary health care has been increasing during the last 10 years. In 2011, the health authorities recommended that all Norwegian municipalities establish Healthy Life Centres (HLC) with programmes for people who need to change their lifestyle. Little is known about the effectiveness of such programmes, i.e. whether they have helped participants with overweight and obesity and have kept them from developing type 2 diabetes. Knowledge about participants attending HLC is important to help adapt and develop the programmes to best meet their needs.

The main aim for this thesis was to increase the knowledge and understanding of participants' presumptions for lifestyle change when attending HLC lifestyle programmes. Furthermore, the aim was to study whether participation in a lifestyle programme might contribute to reduce overweight, obesity and prevent type 2 diabetes. Paper I sought to explore the importance of participants' experiences as they entered a lifestyle programme in an HLC. For paper II, participants with identified high risk of type 2 diabetes in the third Nord-Trøndelag Health Study (HUNT3 Survey) studied while they attended a one-year HLC lifestyle programme (the VEND-RISK Study). The aim was to elucidate how they experienced their own lifestyle, as well what impact it had had on them to be at high risk of type 2 diabetes. Paper III aimed first at ascertaining whether a health effect could be seen among participants at high risk for type 2 diabetes a year after they concluded the VEND-RISK Study. The second aim for paper III was to study if characteristics of individuals at high risk for

type 2 diabetes who had been invited to and participated in the VEND-RISK Study differed from those who had been invited but declined to participate.

Both qualitative (papers I and II) and quantitative methods (paper III) were used. Semi-structured, in-depth interviews were performed for both paper I and II. In paper I, the participants (n=23) were interviewed upon entering a lifestyle programme. In paper II, participants (n=26) were interviewed while they were attending the VEND-RISK Study. Two quantitative method designs were applied in paper III. First, a longitudinal, non-randomized, single-arm, observational, pre-post design was used to investigate the changes in health variables of participants (n=45) in the VEND-RISK Study. Second, a cross-sectional quantitative design was used to explore possible differences in characteristics (from the HUNT3 Survey) for those who accepted (n = 45) or declined (n = 287) invitation to participate in VEND-RISK study.

In paper I, we found that the participants experienced themselves being stuck in old patterns. They had emotional baggage, i.e. negative experiences from childhood to the present that made it more difficult to initiate lifestyle change. In paper II we found that participants experienced having resources available both for an active lifestyle and to make lifestyle changes when necessary. Their experiences of learning that their risk for type 2 diabetes was high differed. A family history of diabetes was described as a greater reason to change their lifestyle than was learning that they themselves were at high risk. In paper III, part one, we found that mean HbA1c had decreased significantly for all participants. In addition, women reduced the mean waist circumference significantly, by 4 cm one year after the end of the VEND-RISK Study. In paper III, part two, through the HUNT3 Survey measures we found that those who declined the invitation to participate in the VEND-RISK Study had relatively similar health measures as those who accepted invitation to participate. However, women who declined to participate had fewer years of education, were more frequently unemployed and reported that their health more often affected their social relationships, than women who participated.

On the background of our findings, questions were raised regarding who is most likely to benefit from the HLC lifestyle programmes, and what resources and approaches should be emphasized for participants to achieve a lasting lifestyle change.

Scientific Environment

This PhD project was conducted at Nord University, Levanger and Department of Public Health and Nursing, Faculty of Medicine and Health Sciences, NTNU in cooperation with Innherred Samkommune, HUNT Research Centre and Centre for Obesity Research and Innovation (ObeCe), St. Olav University Hospital. Nord University, Levanger, funded the PhD project.

The connected research group and academic environment has been the group for General Practitioners (GPs), Allmennmedisinsk Forsknings Enhet (AFE) at Department of Public Health and Nursing, Faculty of Medicine and Health Sciences, NTNU.

During the work with this PhD, I have been affiliated to the Norwegian Directorate of Health (2014-2016) working with the revision of the National Guidelines for Diabetes regarding “Lifestyle, overweight and obesity”, and “Communication, coping and motivation”.

Prologue

My interest in this PhD project's aims was awakened as I worked at the Center for Obesity Research and Innovation (ObeCe) at St. Olav's Hospital, Trondheim from 2006-2012. ObeCe is the unit responsible for research and development work relating to the themes of overweight and obesity in Mid-Norway. As the only established treatment for overweight and obesity has been bariatric surgery, the more conventional lifestyle treatment approaches were in need of being researched.

My main responsibility at ObeCe was to help municipalities in Mid-Norway to implement lifestyle programmes for overweight and obese people. In addition, I worked with various projects regarding conventional lifestyle change treatment approaches, following overweight and obese people at rehabilitation centers as well as pre- and post-obesity surgery groups. It became clear that rehabilitation center patiens needed more local support if they were to maintain lifestyle changes. Limitations to achieving the desired results from bariatric surgery alone seemed to be related to the unreliability of some patients' adherence to lifestyle changes afterwards. It was a challenge to identify which patients would be most likely to experience success when applying the various treatment approaches designed to help them integrate new habits into their daily lives. I had also become aware that better cooperation between the primary and specialist health care was needed to facilitate adequate treatment for people to change their lifestyles.

As the number of people being overweight or obese increased, both primary and secondary health care personnel recognised that their knowledge was insufficient. A pilot project was started at the ObeCe in 2008 for primary and specialist health care workers to share their knowledge and experiences in working with different aspects of lifestyle change, overweight and obesity, and also to establish of lifestyle programmes in the municipalities. The aim of the pilot project was to bridge the gap between primary and secondary health care in order to offer adequate treatment for persons with lifestyle issues. The cooperation began with six Mid-Norway municipalities in 2008 and had been extended to 34 municipalities by 2011. Furthermore, ObeCe initiated a prospective intervention study in four municipalities in the mid-Norway

Værnesregionen to prevent overweight, obesity and Type 2 Diabetes (T2D) among those at risk of developing T2D. A cooperation with the Nord-Trøndelag Health Study (HUNT) was also started in which those identified as being at high risk for T2D in the HUNT3 Survey were invited to participate in the lifestyle programme in the HLC in Værnesregionen in 2012.

Meanwhile, the Norwegian Health Authorities acknowledged the need for lifestyle programmes within primary health care and new policy laws, guidelines and political actions highlighted the demand. At the time, however, not much research had been done on intervention content nor on the effectiveness of each intervention for prevention of overweight and obesity within the primary health care. A presentation about lifestyle interventions at a Specialist Course in Obesity (SCOPE) in Cambridge which I attended in 2011, reported achieving successful results for people with obesity and T2D (The Look Ahead Trial). I grew interested in finding out more about how they had performed the interventions and what might have accounted for their success.

In 2011, the Centre for Health Promotion Research HIST/ NTNU and Nord University conducted a pilot project establishing Healthy Life Centres (HLCs) in the Levanger and Verdal municipalities (“Innherred Samkommune”) entitled: "Physical activity, Health and Interaction, Innherred Model Step 1". The intention of the pilot project was to evaluate the need for establishing a HLC in Innherred Samkommune. Following this pilot project, financing of a PhD project at Nord University was made available. Through a scholarship from Nord University, I was given the opportunity to design the project myself. However, the scholarship required the cooperation of Innherred Samkommune (Levanger and Verdal) and HUNT Research Centre.

During 2009-2012, HLCs became a primary health care service, serving people in several of the municipalities in need of making lifestyle changes. As I cooperated in this during my work at ObeCe, I could integrate more of the work of the mid-Norway municipalities and the HUNT Research Centre into the PhD project. On that basis, I was given the opportunity to pass my work on with the intention of preventing overweight, obesity and T2D. This included the opportunity to study how well suited to partipants’ needs for the prevention of overweight, obesity and T2D the lifestyle progammes in the Norwegian primary health care setting actually were.

The idea was that HLC, a low-threshold municipal lifestyle programme, might be valuable for people who sought to implement lifestyle changes into their daily lives, rather than expecting that to be accomplished during a stay at a rehabilitation centre. People seeking help and being admitted to primary health care programmes such as HLC might also become more aware of and focused on preventing diseases, rather than on treating diseases as those seeking treatment in the specialist health care.

I wanted to find out if HLC lifestyle programmes in primary health care settings for people with overweight, obesity and T2D could function effectively to help people in need of lifestyle change. I hope that this PhD project might serve as another step in building the knowledge foundation necessary to further develop lifestyle programmes and to help meet the growing public health challenge of overweight, obesity and T2D.

List of papers

This thesis is based on the following three papers:

Paper I: *Følling IS, Solbjør M, Helvik AS. Previous experiences and emotional baggage as barriers to lifestyle change - a qualitative study of Norwegian Healthy Life Centre participants. BMC Fam Pract. 2015 Jun 23;16:73. doi: 10.1186/s12875-015-0292-z.*

Paper II: *Følling IS, Solbjør M, Midthjell K, Kulseng B, Helvik AS. Exploring lifestyle and risk in preventing type 2 diabetes -a nested qualitative study of older participants in a lifestyle intervention program (VEND-RISK). BMC Public Health 2016 Aug 25: 16:876. DOI 10.1186/s12889-016-3559-y.*

Paper III: *Følling IS, Kulseng B, Midthjell K, Rangul V, Helvik AS. Individuals at high risk for type 2 diabetes -the VEND-RISK Study follow-up and the HUNT Study characteristics of participants and non-participants in a lifestyle programme. Submitted BMJ Open Diabetes Research and Care 25.11. 2016. Resubmitted after revision 20. Jan.2017.*

List of abbreviations

ACE Adverse Childhood Experiences

AL Allostatic load

BMI Body Mass Index

CI Confidence Interval

CLI Combined Lifestyle Intervention

CVD Cardio-vascular Diseases

DE-PLAN Diabetes in Europe-Prevention through Lifestyle, Physical Activity and Nutrition

DPP Diabetes Prevention Program (USA)

DPS Diabetes Prevention Study (Finland)

FIN-D2D Finnish Diabetes Prevention Study in primary health care setting

FINDRISC The Finnish Diabetes Risk score

GP General Practitioner

$HbA1_c$ Hemoglobin A1C

HLC Healthy Life Center

HUNT The Nord-Trøndelag Health Study (Helseundersøkelsen i Nord-Trøndelag)

IASO International Association for the Study of Obesity

IGT Impaired glucose tolerance

MI Motivational Interviewing

NAV Norwegian Labour and Welfare Administration

NCD Non-communicable diseases

OGGT Oral Glucose Toleranse test

ObeCe Centre for Obesity Research

REK Regional Ethical Committee

RCT Randomized Controlled Trial

SES Socioeconomic Status

SD Standard Deviation

SDT Self-Determination Theory

SCT Social Cognitive Theory

SOC Sense of Coherence

STC Systematic Text Condensation

T2D Type 2 Diabetes

TTM Transtheoretical Model for behavioral change

VEND-RISK Prevention of overweight, obesity and type 2 diabetes in Værnesregionen

WC Waist Circumference

WHO The World Health Organization

1. BACKGROUND

1.1. In the Public Health picture

From the beginning of the 19th century until now, there has been a shift in the disease panorama from infectious diseases to chronic diseases (**figure 1**) [1].

"Public Health" refers to all organised measures to prevent disease, promote health, and prolong life among the population as a whole [2]. The public health challenges facing the world today are tied in great part to unhealthy lifestyles [3, 4]. Lifestyle is directly connected to the health behaviour of an individual or groups of individuals, and varies systematically according to social background [5]. An unhealthy lifestyle may lead to conditions such as high blood glucose, lipids, blood pressure and cholesterol, as well as overweight, obesity and increase in the risk for non-communicable diseases (NCDs) and/or other lifestyle-related diseases [6]. Lifestyle-related diseases are found to be more common among people with low socioeconomic status (SES) [5].

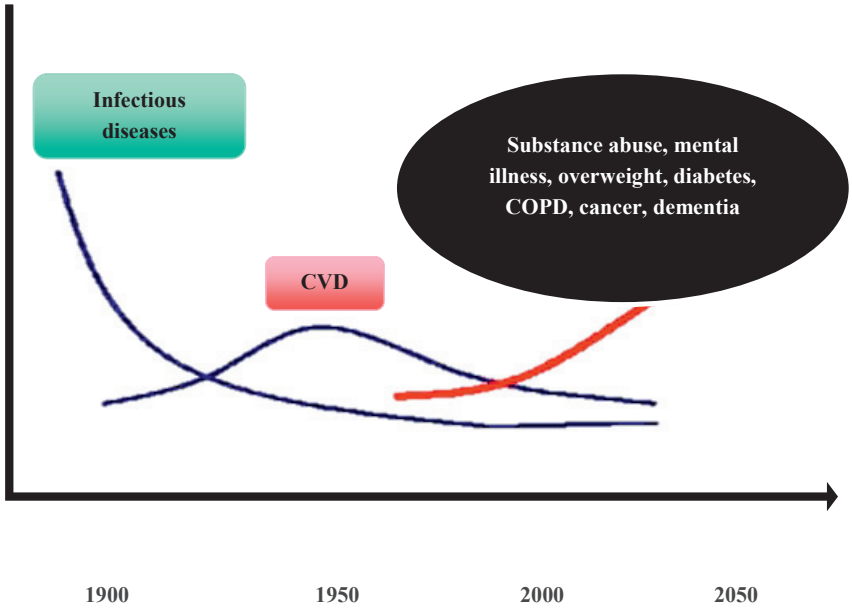

Figure 1: The change in the disease panorama during the last century. Reproduced with permission from *The Norwegian Ministry of Health [7]*.

WHO points out that the four most important reasons for lifestyle-related diseases are unhealthy diet, physical inactivity, use of tobacco and alcohol [8]. Of all global deaths, 63 % are due to diseases related to lifestyle [9]. WHO aims to reduce lifestyle-related diseases by 25 % by 2025; maintenance of healthy weight is key to the prevention of a burden of lifestyle-related diseases [9].

Lifestyle-related diseases seem to interact with each other and seldom occur alone. There are strong associations among comorbidities such as overweight, obesity, T2D, hypertension and dyslipidemia [10].

In Norway in 2012, lifestyle-related diseases such as cardiovascular disease (CVD), cancer, chronic airway disease and diabetes caused approximately 87% of all deaths [11].

1.2. Overweight and obesity

Overweight and obesity are characterized by an increase in Body Mass Index (BMI) [12], i.e. weight (kg) divided by height (m) squared (kg/m^2). Overweight is defined by WHO as a BMI $\geq$ 25 kg/m^2 and obesity as a BMI $\geq$ 30 kg/m^2 [13].

The number of individuals with overweight and obesity is rapidly increasing [14, 15]. The worldwide prevalence of overweight and obesity almost doubled from 1980 to 2008, and in 2008 more than 1.4 billion people >20 years were overweight and about 500 million people were obese [16]. The modelled trends from 1980 to 2008 indicated a steady increase in the prevalence of people with overweight and obesity in every region of the world, with the steepest increases in higher income countries [17].

In Norway, the prevalence of people with overweight and obesity has increased significantly over the last thirty years [18-20]. From the first survey in the Nord-Trøndelag Health Study (HUNT1) in 1984-1986 to the third survey in 2006-2008 (HUNT3) there was a steady increase (see **figure 2a**), leaving 75% of all men (**figure 2b**) and 61% of all women being overweight, an increase from 50% and 43% from HUNT1(**figure 2c**). HUNT3 also found that every fifth adult was obese, and the increase in the prevalence of people with obesity was more pronounced among young adults [21].

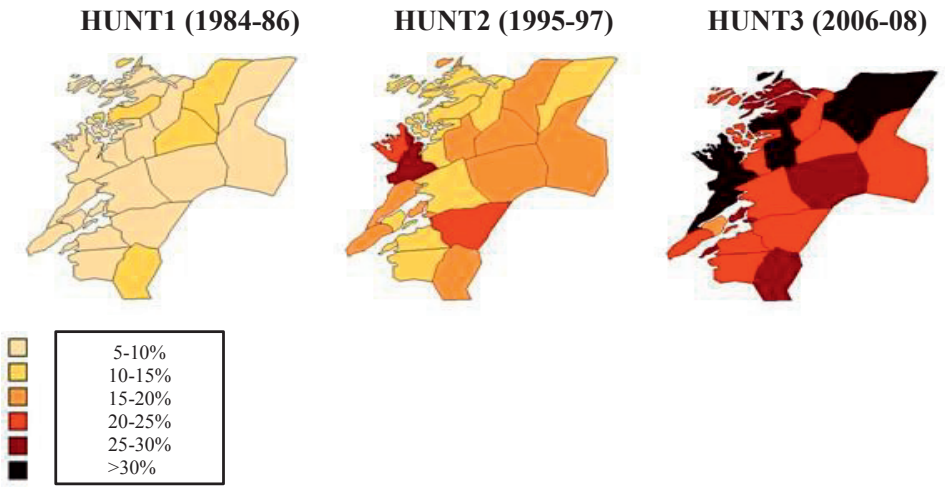

Figure 2a): Prevalence (%) of overall adult obesity (BMI ≥ 30 kg/m^2) in HUNT. Reproduced with permission from *The HUNT Study, Norway* [22].

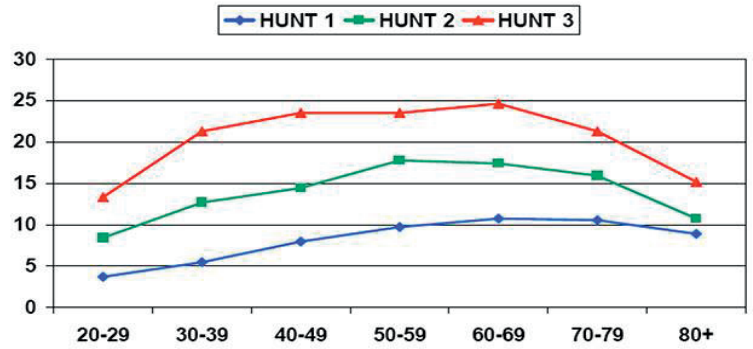

Figure 2b): Prevalence (%) of obesity (BMI ≥ 30 kg/m^2) among men of different age groups in HUNT. Reproduced with permission from *The HUNT Study, Norway* [22].

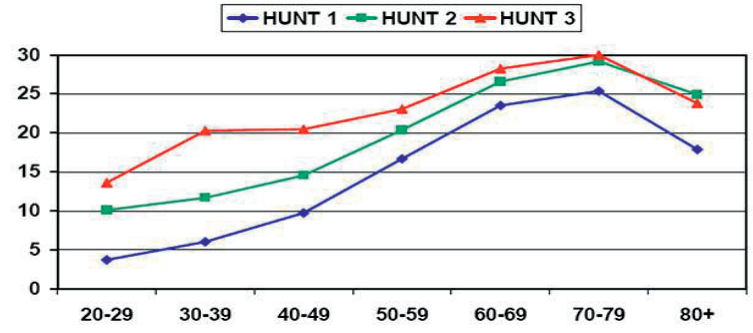

Figure 2c): Prevalence (%) of obesity (BMI ≥ 30 kg/m^2) among women of different age groups in HUNT. Reproduced with permission to from *The HUNT Study, Norway* [22].

The conditions of overweight and obesity can lead to a variety of additional comorbidities, which may result in reduced health and quality of life, premature death, excess mortality [23] and major societal health costs [9, 24]. Cardiovascular diseases (CVDs), mental illness, musculoskeletal disorders and some types of cancers (breast, abdominal, uterus, ovary, kidney and pancreas), stress disorders, and sleep apnoea are all associated with overweight and obesity [25]. Type 2 diabetes (T2D) is the disease most commonly associated with overweight and obesity [26], and people with obesity have an attributable risk of 50% of developing T2D [27, 28]. People with overweight and obesity are more prone to developing depression, anxiety, or other emotional disorders [29]. Overweight and obese people are often perceived as transgressing social norms and as being morally reprehensible, which, in turn, shapes their identities and experiences [30].

1.2.1. Aetiology and risk factors for overweight and obesity

The causes of overweight and obesity in the population today are embedded in a very complex group of genetic and epigenetic systems, interacting within an equally complex social framework that determines behaviour and environmental influences [31, 32]. About 70% of the variation we see in overweight and obesity in the population is found to be due to genetic variation [33]; heritability of obesity is found to be attributable to 20–60% [34]. However, the obesogenic environment also contributes to weight gain for those who are predisposed [35].

A disruption in energy balance can complicate how the body compensates for both increasing and decreasing weight with changes in metabolism. Metabolism (both at rest and during physical activity) can decrease at least 2-300 kcal more than can be calculated simply on the basis of percentage weight loss [36]. The body's defence mechanisms, in the form of reduced metabolism and increased appetite, may contribute to actual weight gain [31].

Decreased physical activity and increased sedentary behaviour [37] are extrinsic factors that may affect the increase in body weight [38]. In the past, physical activity

was necessary for survival [39], but due to more sedentary work situations there is now an increase in sedentary behaviour [31, 40]. There seems to be a clear difference between the activity levels of people with normal weight and those with overweight and obesity [41], i.e. those with higher levels of physical activity have lower weight gain [42]. According to activity level measurements in Norway, only 20% of the population met the recommendation of 30 minutes daily of moderate to vigorous physical activity [43].

Availability of cheap and high calorie foods is another extrinsic factor that may affect the increase in overweight and obesity [38]. The nutrition patterns of food consumption, the abundant access to energy-dense foods and snacks, larger portion sizes and food eaten out rather than prepared at home have increased significantly in the last thirty years [44, 45]. There was a shift between 1977 and 1996 regarding food eaten out as opposed to at home [44]. Frequent consumption of fast-food has been associated with increased weight gain, prospectively [45]. Consumption of fast-food has also been associated with eating more energy-dense food, with higher fat intake and increased consumption of drinks containing sugar [46, 47].

Eating processed food with high fat and sugar content and little nutritional value is found to be more common among people with lower socioeconomic status (SES) [48]. Low SES tends to have a higher prevalence among people with overweight and obesity [49, 50]. Unfavourable SES status in childhood is found to be associated with higher BMI in adulthood [51, 52]. Furthermore, adverse effects of a low psychosocial position in childhood affects the risk of overweight and obesity in later life [53]. Some people with overweight and obesity may have grown up in markedly dysfunctional households with low functional support systems at home [54]. For people with overweight and obesity, childhood abuse [55, 56] and traumatic life experiences during childhood and adolescence have also been found to be more common [54]. The Adverse Childhood Experience (ACE) study has reported that the more a child had been subjected to painful and difficult experiences (e.g. abuse, neglect, growing up with parents who take drugs / depressed), the more morbidity was seen in adulthood (such as CVD, T2D, obesity, eating disorders, alcoholism) [57].

1.2.2. Treatment for people with overweight and obesity

As early as the years between 460-377 B.C., the Greek physician, Hippocrates, claimed that people with overweight and obesity should eat less and exercise more [58]. Throughout the ages, various treatments to help people with overweight and obesity have been used, principally involving diets and physical activity. A recommended, sustained loss of a 5%–10% reduction of baseline body weight is defined as successful weight loss [59]; a weight reduction of 5% leads to a substantial decrease in the risk of comorbidities [60].

Lifestyle programmes have been attempted in various countries all over the world [14]. Combined lifestyle intervention (CLI) programmes including advice on both nutrition and physical activity have been advocated as an effective means to reduce overweight and obesity [61]. Combining CLIs with specific cognitive and behavioural strategies has resulted in a higher weight reduction than nutritional advice and physical activity alone [62]. A successful response to lifestyle programmes is related to an increased self-efficacy [63], a higher self-esteem and motivation, a good self-determination of realistic goals for weight loss and weight expectations, and the ability to lose weight early in the programme [64-66]. Higher motivation, self-efficacy, and self-regulation skills are found as factors associated with beneficial weight and physical activity outcomes, that is, for weight control and positive body image [67].

Surgery may be an option for people with overweight and obesity who do not succeed with conventional lifestyle treatment and when their health is severely affected by their body weight [68]. Requirements for bariatric surgery are a BMI $\geq$ 35 kg/m^2 with comorbidities, or a BMI $\geq$ 40 kg/m^2 [68]. While bariatric surgery may serve to initiate a process toward achieving permanent weight loss, it may not result in the individuals' reaching their ideal weight, and their weight loss goals may be unrealistic [69].

There are also anti-obesity medications (Orlistat and Sibutramine), which are distributed as a treatment option for those who have a BMI $\geq$ 30 kg/m^2. The long-term effectiveness of anti-obesity medications in promoting weight loss, however, is found to be modest [70].

It is well known that the long-term management of overweight and obesity remains very difficult with a high risk of failure and weight regain [71]. In contrast to achieving immediate, short-term changes [72, 73], it has been found difficult to sustain the lifestyle changes which are required to prevent weight regain among overweight and obese people [74, 75]. Between 10% and 80% of individuals entering weight loss programmes do not complete them [76]. Individuals who focused solely on nutrition and physical activity often revert to their old habits after an intervention period [77-79].

Some people with overweight and obesity hope a "quick –fix" will bring lasting change [78]. Thus, the failure to recognize, acknowledge and address causes, complications and barriers is likely to result in poor compliance and high rates of recidivism of overweight and obesity [12]. Failed attempts to make lifestyle changes may cause frustration [80], and after several failed attempts some participants seek bariatric surgery [81]. It is reported that low enrolment rates, high drop-out rates and incomplete implementation have limited the effectiveness of lifestyle programmes in primary health care settings [82].

1.3. Type 2 diabetes (T2D)

As early as 3500 years ago, the ancient Egyptians recognised diabetes [83]. In about the year 600 BC, ancient Indians detected diabetes when ants were attracted to the urine of people with overweight and obesity [84]. However, Harold Himsworth recognised T2D as an independent disease as recently as in 1936 [85].

T2D was previously referred to as non–insulin-dependent diabetes, or adult-onset diabetes, referring to individuals who have insulin resistance and usually some degree of insulin deficiency [86]. T2D is characterised by hyperglycaemia resulting from a combination of resistance to insulin's action and an inadequate compensatory insulin secretory response, when the degree of hyperglycaemia is great enough to cause pathological and functional changes in various target tissues [86, 87]. T2D is diagnosed by Haemoglobin A1c ($HbA1_c$) level ≥ 6.5 mmol/l, confirmed with a repeat HbA1c test [88] (**figure 3**).

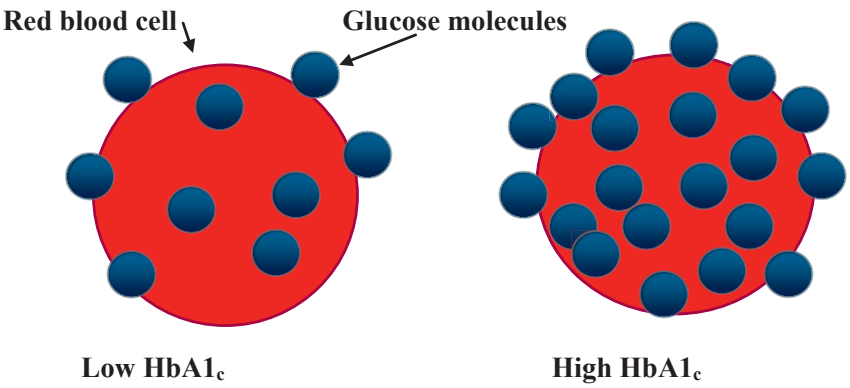

Figure 3: Model of red blood cell with low and high $HbA1_c$.When a blood cell has a low amount of glucose molecules attached the HbA1c is normal, whilst when several glucosemolecules are attached to the red blood cell the HbA1c is high. Reproduced with permission from *Cray Diabetes Education Centre* [89].

Some individuals are considered pre-diabetics when they do not meet the criteria for T2D but have glucose levels that are higher than what is defined as normal [90, 91]. The indication for pre-diabetes is impaired fasting glucose (IFG), fasting plasma glucose (FPG) levels 5.6 mmol/l to 6.9 mmol/l, or impaired glucose tolerance (IGT) (2-h 11.0 mmol/l) [90, 91]. The risk of T2D is also defined by different risk scores. Most often used in Norway is a score ≥ 15 on the Finnish Diabetes Risk Score (FINDRISC) questionnaire (range:0-26), which indicates at least a 30% higher risk of developing T2D during the next ten years [92].

The prevalence of T2D is increasing considerably [15] worldwide [87, 93] and the incidence of T2D has been rising since the 1970s [94]. It is estimated that the total number of people with T2D will have risen from 171 million in 2000 to 366 million by 2030 [95]. The number of individuals with pre-diabetes [96] and people at high risk for T2D in the world is also increasing [95]. Accordingly, the number of Norwegians with T2D during the last thirty years has increased by about 1.4% per calendar year, with variations among sub-groups [97]. In addition, it is presumed that approximately 50% of all cases of T2D in Norway remain undetected [28, 97].

Without clinical symptoms, T2D may go undiagnosed for years: hyperglycaemia develops gradually and often, at its early stages, is often not severe enough for the individual to notice any of the classic symptoms [86, 87].

Individuals with T2D have an increased incidence of atherosclerotic cardiovascular, peripheral arterial and cerebrovascular disease, also of hypertension and abnormalities of lipoprotein metabolism [86]. Long-term complications of T2D include retinopathy with potential loss of vision, amputations, peripheral neuropathy with risk of foot ulcers, nephropathy that may lead to renal failure, Charcot joints, autonomic neuropathy causing gastrointestinal, genitourinary, and cardiovascular symptoms and sexual dysfunction [86]. T2D can shorten life expectancy by as much as 15 years, with up to 75% of patients dying of macro-vascular complications [98].

1.3.1. Risk factors for type 2 diabetes (T2D)

T2D is often associated with a strong genetic predisposition, with a heritability ranging from 30–70% [99]. People with a first-degree family member with T2D have five to ten times greater lifetime risk for T2D as compared with those having no family history of T2D [100]. There is limited evidence relating to gene/lifestyle interactions for T2D [101], but genome-wide association studies have successfully identified genetic variants underlying T2D [102, 103].

Individuals with BMI $\geq$ 40 kg/m^2 have an approximately 64% higher risk of T2D compared with normal weight individuals [25]. People with T2D and people at high risk for T2D are found to have lower SES compared to people without T2D [104] and without risk for T2D [105]. Adverse effects of a low psychosocial position in childhood affects the risk for T2D [53] and traumatic life experiences during childhood and adolescence are also found to be more common among those with T2D [53]. T2D is found to occur more frequently in individuals with hypertension or dyslipidaemia, in certain ethnic subgroups, and in women with prior gestational diabetes [86]. The risk of T2D also increases with age and peaks at 60-74 years [106].

It has been found that the high increase of people with T2D may be attributed to the changes in lifestyle in the Western world [106], and maintaining a sedentary lifestyle over years is a strong risk factor for T2D [107]. The dietary pattern in the Western world, with a high intake of red and processed meats as well as refined carbohydrate foods, [108, 109] and a diet lower in fibre and with a high glycaemic index [110], has been found to be associated with increased risk of T2D. Also, specific

dietary fatty acids may differentially affect insulin resistance and the risk of T2D [111].

1.3.2. Treatment of type 2 diabetes (T2D)

The general aim of treatment and management of T2D is to keep blood sugar levels closer to normal. For many years, however, treatments for T2D were unsuccessful; oral medications were not developed until the 1950s. As the prevalence of overweight and obesity has increased, the importance of healthy eating and regular exercise for the treatment of T2D has gained acceptance. In addition to or instead of insulin therapy, medications have become part of the normal treatment as such medications which do not lead to weight gain have been developed, e.g. Metformin, Sulfonylureas, Thiazolidinedione's, DPP-4 inhibitors, GLP-1 receptor agonists, SGLT2 inhibitors.

Having bariatric surgery has proved efficient in curing T2D as this result has been reported in 64-93% of the T2D cases undergoing the surgery [112-114]. For some individuals, however, remission of T2D has also proved feasible through intensive lifestyle modification [115].

According to the Look-Ahead Trial, a year long, intensive lifestyle programme with a focus on calorie restriction, physical activity and lasting behavioural change, also led to clinically significant (≥ 5%) and long-lasting weight loss for individuals with T2D [116, 117] .

1.3.3. Prevention of type 2 diabetes (T2D)

The prevention of T2D has been emphasized and improved during the last thirty years [15, 118, 119]. The World Health Organization (WHO) has estimated that 90% of all cases of T2D could be prevented through changes in diet, physical activity and smoking habits [38].

The Finnish Diabetes Prevention Study (DPS) found that T2D could be prevented through interventions that affect the lifestyles of individuals at high risk, with a risk reduction of 58 % with a mean follow-up of 3.2 years [120]. In addition, the US Diabetes Prevention Programme (DPP) found that lifestyle intervention reduced the incidence of T2D by 58% with a mean follow-up of 2.8 years [121] (see

table 1). The mean weight loss was 3.5 kg in the DPS [120] and 5.6 kg in the DPP [121] lifestyle intervention groups, respectively. The reduction in risk of T2D among high-risk individuals in DPS [120] and the DPP [121] was achieved through frequent visits to the outpatient clinic and individual and group counselling sessions.

According to the DPP study, moderate weight loss combined with a moderate increase in physical activity was found to reduce the incidence of T2D by 50% for individuals at high risk [121]. While the effects of drug treatment on prevention of T2D seemed to vanish rapidly [122, 123], the effects of lifestyle intervention seemed to be longer lasting [124, 125]. Lasting changes were also found among individuals at high risk of T2D, or with other clinical risk factors such as obesity and high blood pressure; frequent contact was the intervention component most associated with increased changes in physical activity and diet [126], if, in addition to the established techniques for lifestyle change, they also received social support [127]. Later, several studies reported that lifestyle interventions could postpone the onset of T2D in individuals at high risk [120, 121, 128, 129] (see **table 1**).

Table 1: Lifestyle intervention studies performed with RCT design in clinical settings showing the efficacy of T2D prevention. The table is made by the author.

Study information	DPS **Finland** *Tuomilehto J et al.2001* *N Eng J Med*	DPP **US** *Knowler WC et al. 2006* *N Eng J Med*	Da Quing **China** *Li G et al. 2008* *Lancet*	IDPP-1 **India** *Ramachandran A et al.2006* *Diabetologia*	**----------Japan** *Kosaka K et al. 2005* *Diabetes Res Clin Pract*	**----------Australia** *Moore SM et al. 2011* *Psychol Health*
Sample	*n*= 522 middle aged people with overweight and at high risk for T2D.	*n* = 3234 middle aged people with overweight and prediabetes. 45 % from minority groups.	*n* =577 high risk individuals.	*n* =531 Asian Indians with IGT younger, leaner and more insulin resistant than DPS, DPP and Da Quing.	*n* =458 men with IGT.	*n* = 307 with pre-diabetes
Purpose	If T2D can be prevented by interventions that affect the lifestyles of subjects at high risk for T2D.	If sedentary lifestyle with a lifestyle-intervention program or the administration of metformin would prevent or delay the development of T2D.	Effects of insulin resistance and insulin secretion on the development of T2D in individuals with IGT who got lifestyle interventions.	Could progression to T2D be influenced by interventions in native Asian Indians.	Prevention of T2D by intensive lifestyle intervention designed to achieve and maintain ideal body weight.	Whether participation in the programme led to changes in modifiable risk factors forT2D among at-risk pre-diabetic controls.
Intervention	Each subject in the intervention group received counseling aimed at reducing weight, total fat, saturated fat and increasing intake of fiber and physical activity for 1 year, follow up for 3.2 years.	Intensive training in diet, physical activity, and behaviour modification. Eating less fat and fewer calories and exercising for a total of 150 minutes a week for 2.8.years.	Diet change and/or increased physical activity interventions. Followed for 6 years for development of T2D.	4 intervention groups: Group 2 was given advice on lifestyle modification, Group 3 was treated with metformin and Group 4 was given LSM plus metformin.	Detailed instructions on lifestyle were every 3-4 months during hospital visits. A 100g OGGT performed every 6 months to detect improvement of glucose tolerance. The subjects were seen in an ordinary outpatient clinic.	A 6-month, group-based diabetes prevention programme, The Healthy Living Course and a population educational/support-based lifestyle programme
Control	No special programme.	Two control groups: *850 mg of metformin twice a day.*Placebo. Both groups received information about diet and exercise.	No special programme.	Group 1: controls.	Standard intervention with advise to maintain BMI of <24.0 kg/m2 and of <22.0 kg/m2, by diet and exercise.	The control group was on a waiting list but received standard care from their GPs.
Outcome	T2D risk reduction of 58%. The intervention group 11% got T2D vs 23% in the control group. Weight lost the end of year 1 was 4.2 kg in the intervention group and 0.8 kg in the control group; by the end of year 2, 3.5 kg mean weight loss in intervention group and 0.9 kg in the control	T2D risk reduction of 58 % with lifestyle intervention and 31% with metformin compared to placebo. Incidence of diabetes at 3 years: 14%, 22% and 29% in the lifestyle-intervention metformin and placebo groups. Mean weight loss of 5.6 kg.	Lifestyle changes resulted in 50 % risk reduction. Both insulin resistance and insulin secretion significantly associated with development of diabetes. Lifestyle interventions were more effective in those with lower insulin resistance and higher insulin secretion at baseline.	3 year cumulative incidences of diabetes were 55.0 %, 39.3 %, 40.5 % and 39.5 % in Groups 1-4. The relative risk reduction was 28.5 % with lifestyle modification, 26.4 % with metformin and 28.2% with lifestyle modification + metformin compared to control group.	The 4-year incidence of T2D was 9.3 % in the control group, vs 3.0 % in the intervention group. Risk reduction in of T2D was 67.4 %. Body weight decreased by 0.4 kg in the control group and by 2.2 kg in the intervention group. The incidence of T2D was positively correlated with the changes in body weight.	Intervention group significantly improved their diabetes knowledge, motivation, healthy eating and activity levels and significantly reduced weight, BMI, WC, diastolic blood pressure and IGGT compared to controls. Intervention group also changed from pre-diabetes to non-diabetes at a greater rate than controls.

Thus, despite having knowledge regarding how to prevent T2D, is it difficult to manage and maintain the required lifestyle changes over time [130]. Individual and environmental barriers are associated with failure to attend and/or to maintain physical activity for persons with T2D [131]. According to most of the studies that have been conducted with Randomized Controlled Trials (RCTs) in comprehensive experimental settings, T2D can be prevented when individuals at high risk make lifestyle changes [120, 121, 125, 128, 129, 132] (in **table 1**). RCTs have also shown a higher degree of change towards a healthier lifestyle if individuals at high risk for T2D were offered more individual counselling rather than only activity and nutrition interventions [132-134], also when performed by Norwegian GPs [135]. Lifestyle interventions for participants at high risk of T2D when translated into routine practice in clinical settings were found to be feasible but apparently showed limited clinical benefit one year after the intervention and less effect on T2D risk reduction [136]. Issues regarding how to translate knowledge from experimental studies to primary health care settings have been explored [137]. It was necessary to determine the possibility of replicating the research results concerning the effectiveness of lifestyle interventions when performed in primary health care settings [138]. Meeting this demand for applying and implementing the experimental studies in primary health care settings [137] has been attempted in some countries. Finland [137, 139], the Netherlands [140], Australia [141] and China [142] have successfully tried out lifestyle interventions in their local primary health care settings. The primary health care systems of various countries differ greatly, including as to the resources that are allocated for those experimental studies reporting the reduction in T2D risk and weight reduction of people with overweight, obesity and T2D [138]. The content, intensity and duration of each lifestyle programme depends on the resources allocated for the local primary health care setting where the programme is offered. It is also a question whether it is possible to achieve the same results in differing cultures, regions and age-groups; the impact of variations of co-operation among segments of society, of people's awareness of lifestyles and of the social inequalities in health are also factors to explore [138].

In Norway, although the local municipalities differ greatly in resources and size, they all have the same primary health care system. The municipalities health care system are responsible of the public health through health promotion and disease prevention.

1.4. Public Health actions; health promotion and disease prevention

Taking care of the “Public Health” requires action from two different perspectives: health promotion and disease prevention. These two overlap, complement and reinforce each other [143].

Health promotion is a process that enables people to increase their control over their health and improve it in an attempt to reduce risk factors or causes of diseases within populations [144]. In the mid-1980s, the WHO launched strategies to accommodate the shift in the global health picture from infectious diseases to lifestyle-related diseases [145]. The Ottawa Charter was the first political document at the international level to be written in response to the increase in lifestyle-related diseases; it became the primary political foundation for promoting health, resulting in a new public health movement around the world [146]. The main aim of the Charter was "action / measures to achieve health for all by the year 2000" [146] through reducing health inequalities, strengthening local social and physical environment structures in order to promote individual health [146].

Disease prevention has been described both in terms of high-risk and public health approaches [143]. Diseased prevention as a high-risk approach, identifies and focuses exclusively on individuals at the highest risk of developing diseases [143]. Prevention involves applying advanced measures to counteract something possible or probable. Prevention in medicine has been divided into three stages – primary, secondary, and tertiary [147].

Primary prevention keeps the disease process from becoming established by eliminating causes of disease or increasing resistance to disease. It also involves the dissemination of knowledge about how to prevent disease thus fostering wellness in general and, non-specifically, reducing the likelihood of disease, disability, and premature death. Interventions are aimed to reach all, e.g. information campaigns

against smoking, and education about diet. An important supplement to primary prevention is to stimulate the increase in social environments that promote preventive behaviour [147].

Secondary prevention interrupts the disease process before it becomes symptomatic, uncovering disease or disease risk before it symptoms of disease develop, management of pre-symptomatic disease, as well as reduction of the impact of disease once it has been diagnosed [147].

Tertiary prevention limits the physical and social consequences of symptomatic disease by addressing the consequences of disease and disabilities that engender additional problems for those concerned [147].

1.5. The Norwegian health authorities Public Health initiatives

Over the last two decades, the Norwegian health authorities have increased their focus on public health care. Reductions in physical activity and increases in high-caloric food intake were among the most important public health changes in the Norwegian population from 1986 to 2010 [148]. The Norwegian public health is generally excellent, but there are differences according to SES, with lower SES being associated with lower health status [149].

Disease prevention and health promotion have become high political priorities in Norway, particularly in terms of enabling people to make lifestyle-related changes. The first follow-up of the Ottawa Charter in Norway was a 1991 political report with a target aim to increase the population's number of good years of life and create primary prevention strategies to reduce diseases, injuries, social problems and mortality and to reduce risk factors [150]. In addition, the report suggested action to improve quality of life, well-being and opportunities to master the challenges and workloads of daily life [150]. However, the health promoting and disease preventing work was poorly rooted in practice and seemed to be based primarily on idealism and volunteer efforts.

Then, in 2002, the Norwegian Government ("Bondevik II") released the 16th report to Parliament, "Prescription for a Healthier Norway" in order to systematize and improve health-promotion and the prevention of lifestyle-related diseases [151]. The "prescription" involved preventive health care, aiming for similar changes as the

Ottawa Charter – more years of good health, reduced health disparities in the population [151]. It proposed four main strategies to reach those aims: first, to strengthen people's prerequisites for taking responsibility for their own health; second, to build alliances and infrastructures within public health; third, to prevent more and fix less; and, fourth, to apply experienced-based knowledge more. In accordance with the prescription, the Minister of Health at that time, Dagfinn Høybråten, introduced a tariff scheme called "Green Prescription" as secondary prevention. This encouraged general practitioners (GPs) to offer advice about diet and physical activity to patients with hypertension and/or T2D as an alternative to medical treatment. Follow-up of the advice was at the patients' own initiative [151]. It was intended to stimulate the offering of guidance, and move treatment of lifestyle-related diseases away from medical interventions and toward lifestyle changes.

Evaluation of the "Green Prescription" found that the GPs considered the prescription to be inadequate, in part because they lacked appropriate referral possibilities for people needing such follow-ups as physical activity classes and nutritional advice [152]. After this evaluation, the Norwegian Directorate of Health funded five of the 19 Norwegian counties (i.e. 32 municipalities) to try out local lifestyle interventions for people in need of them. The programmes had a "Prescription Plan" involving a variety of approaches to change physical activity, diet and tobacco usage. Evaluation of those programmes found that 80% of the GPs and 90% of the participants were satisfied, and that 70% of the participants completed the interventions [153].

In 2009, the Health Minister at that time, Bjarne Håkon Hansen, released the "Coordination Reform: Right Treatment - Right Place - at the Right Time". It was enacted in 2012 and aimed to improve public health and to better the health services in a sustainable way through a strategy of preventing diseases and treating persons early and close to where they live [7]. In the same time period, from 2009-2012, various political white papers and guidelines shifted the focus towards cross-sector cooperation, aiming to strengthen public health through anchoring it more to the prevention than to the treatment of diseases [7, 154, 155]. As part of the national strategy for preventing lifestyle-related diseases, a law regarding public and municipal

health care was published [156] as well as a national health care plan [155]. These documents increased the demands made on the municipalities.

The Municipal Health Service Act (§ 1-29) states that:

> The municipality shall, through health promotion, well-being and good social and environmental conditions, seek to prevent and treat disease, injury or disability. It shall disseminate information about and increase interest in what the individual and the public can do to promote their own well-being, health and the public health [155].

1.5.1. Norwegian Healthy Life Centres (HLCs)

In 2011, in order to address the new legal acts and requirements and as a way to organize the municipal health care, the Norwegian Directorate of Health recommended that all municipalities establish Healthy Life Centres (HLCs).

The first HLC had actually been established in Modum in 1996. Among the 498 Norwegian municipalities, 43 HLC had such centres in 2008, while in 2012 there were approximately 200 HLCs in municipalities, inter-municipalities and in parts of major cities [157].

The HLCs function is to improve health within the municipalities and to bridge the gap between health care and public health through including health promotion and preventive medicine. The Norwegian Directorate of Health prepared an instruction manual to help the municipalities organise and develop HLCs, outlining common principles for content and practice. HLCs are defined as individual and group-oriented lifestyle programmes to promote health and to enhance social communities [158].

The HLCs serve as a low-threshold health service and Norway's public health insurance covers the cost of participation [158].

HLCs are to target people aged 18-70 years with the aim of contributing to changes in lifestyle, primarily regarding physical activity, diet, and tobacco use [158]. GPs, other health personnel and the Norwegian Labour and Welfare Administration (NAV) may refer individuals to an HLC, and individuals may contact the HLC themselves. The intention is that participants at an HLC go from being in need of help for health related issues to coping with their health on their own [158] (**figure 4**).

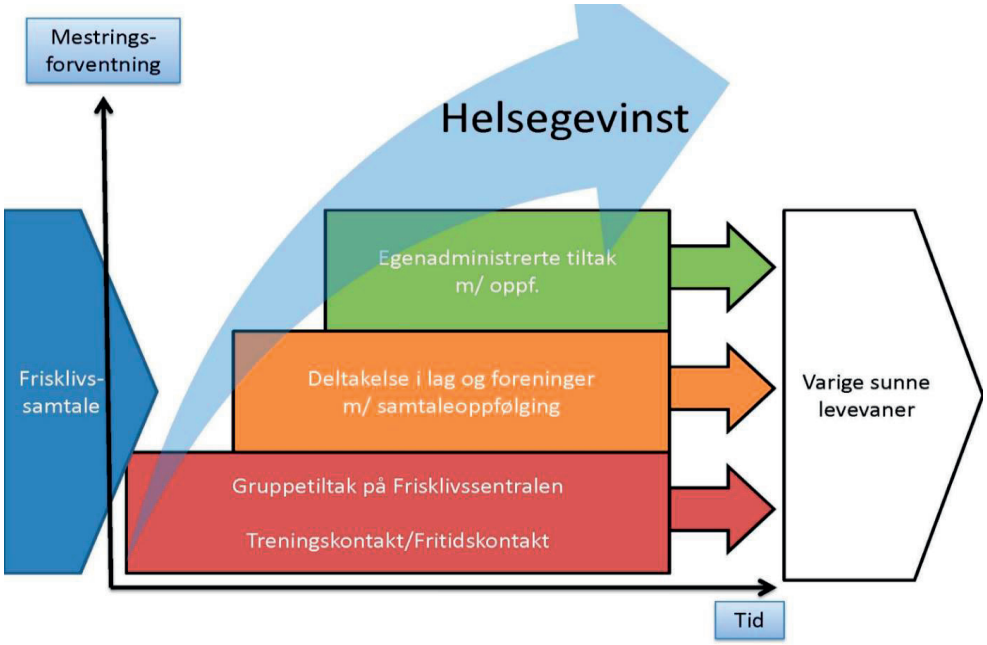

Figure 4: The HLCs step model for participants to achieve long-lasting, healthy habits. The Health Conversation provides a basis for determining measures to take based on participant's wishes and expectations concerning their own coping with changes in health behaviour. Red box is regular contact with the HLC. Orange box shows follow-up of participants who have sporadic contact with HLC. Green box illustrates that those who are ready to embark on self-administration actions are being monitored by the HLC. Reproduced with permission from the *The Norwegian Directorate of Health* [158].

The establishment of HLCs is based on local resources and executive work in each municipality in Norway. The organisation of HLC services is largely shaped at the community level by local framework conditions and priorities. There is to be a collaboration with other health services and voluntary groups where appropriate [159]. It is recommended that the Norwegian HLC lifestyle programmes apply a Salutogenic approach [158, 160] with the aim of helping participants gain confidence in their own coping skills and increase their ability and resources to change their lifestyle [159].

1.5.2. Healthy Life Centres lifestyle (HLCs) programmes

The lifestyle programme at an HLC starts with an individual health conversation to clarify the participants' resources, motivation as well as to set goals (**figure 5**). Each HLC lifestyle programme lasts for twelve weeks, with the option to repeat the programme an additional three times.

Figure 5: An overview model of the HLCs intervention programme. The programme period starts with a "Healthy Life Conversation". On the basis of the plan agreed upon, various initiatives are carried out involving physical activity, diet and smoking cessation. The programme period ends with another "Healthy Life Conversation", where the need for a new period is considered. One goal is for the HLC participants to enrol in various activities in the local municipality or engage in self-administered activities. Reproduced with permission from the *The Norwegian Directorate of Health* [158].

The health conversations are based on principles from Motivational Interviewing (MI) [161]. MI is a non-moralizing, empathetic and targeted approach where the purpose is to increase the participants' awareness of their own motivation for behavioural change [162]. The focus of the health conversation is the participants' views on their own situation [161]. The lifestyle programme ends with a second health conversation to evaluate the process and make plans for how to maintain healthy habits.

The physical activity offered by the HLC includes both indoor and outdoor options, two to four times a week, including group-based activities with a physical therapists or training physiologists. The physical activity is carefully and professionally conducted, safe and varied, following the national recommendations for physical activity [163]. The HLCs offer their own classes and some group sessions

may be carried out in cooperation with, or by, other local service providers. It is recommended that activities such cardio, interval and resistance training take place outdoors and require little equipment. Participants should become familiar with nearby hiking possibilities and relevant, locally available training offers. After the programme ends, the HLCs provide opportunities to receive social support and to expand their activity network in the local municipality ("Utslusningstiltak" **figure 5**).

The HLC's interventions and programmes regarding nutrition are based on national dietary advice [164]. The HLC uses individual health talks to address changes in eating habits including diet and nutrition. Also, a group-based nutrition course, "Good Food for Better Health" includes a total of ten one-hour sessions over ten days focusing on eating habits and food choices. The course is both theoretical and practical and is intended to provide a good start toward achieving sustainable changes in dietary and food habits. HLCs inform and encourage participants to take further action after the programme is finished, utilising other available resources such as cookbooks and online nutrition programmes ("Utslutningstiltak" **figure 5).**

A tobacco cessation programme (both snuff and smoking) is offered through individual sessions and group-based courses and is addressed in thematic seminars. The main approaches to tobacco cessation are counselling and drug therapy, and it is important that the HLCs cooperate with dental clinics, GPs, health care clinics and school health services. HLCs should inform and encourage participants to make use of available resources afterwards, such as websites and existing smoking cessation telephone support lines (Utslusningstiltak **figure 5**). The Norwegian Directorate of Health arranges certification courses for the HLC personnel who run "Good Food for Better Health" courses as well as courses on tobacco cessation and the use of MI.

1.6. A need for an expanded strategy for research into lifestyle change

Finding indicators that are favourable or unfavourable for lifestyle programmes can contribute to developing better practices in relation to the actual public health challenge of overweight, obesity and T2D.

Little is known about the participants or the effects of lifestyle programmes, such as HLC, held within Norwegian primary health care. In comparison, "Physical

Activity on Prescription" has been studied previously showing positive effects in Sweden [165] and Denmark [166]. Furthermore, prevention of T2D as mentioned in Chapter 1.3.3. has been found to be feasible within the primary health care services of some countries. However, there is only a limited amount of literature about the effects longer than three months after of the HLC programme or comparable lifestyle programmes [167].

The research into lifestyle programmes and lifestyle change has normally measured the changes in the physical body through an objective biomedical approach. Traditional research approaches may not be sufficient to avert the possible epidemic of diseases related to lifestyle [168]. As the public health issues with lifestyle-related diseases continue to rise despite the increase in evidence regarding what helps to reduce them, questions must be asked about the need for an expanded strategy.

Research could include more elaboration of social well-being [169]. As stated in the Ottawa Charter, individual changes are unlikely to last without social change [146]. Adults' social relationships might influence health outcomes: the most frequent factors influencing lifestyle change have been found to be "friends and family support" [170]. In 1988, Landis, and Umberson published a paper about social relationships' impact on health in *Science:*

> Social relationships, or the relative lack thereof, constitute a major risk factor for health—rivalling the effect of well-established health risk factors such as cigarette smoking, blood pressure, blood lipids, obesity and physical activity [171].

Lifestyle change touches upon several aspects of an individual's life, and there is a close relationship between lifestyle, life history, feelings and perceptions. It may seem as if lifestyle change success were something to be defined by researchers and health personnel [172]. Aims for success, however, might differ among the individuals making the changes, and the perception of lifestyle and of being at risk might also differ between individuals. Knowledge about how lifestyle programmes affect participants' health, and their own perception of lifestyle and risk may affect future lifestyle programmes. In addition, several factors might discourage individuals from attending lifestyle programmes, such as, broadly clustered, social, psychological and

practical barriers [173]. Information about those who refuse to attend lifestyle programmes might also have implications for future recruitment to lifestyle programmes. Nevertheless, given all the intervening factors that accompany an individuals' everyday life, there are challenges connected with doing research into lifestyle change within the primary health care setting, one in which individuals are not as controlled as they would be in a clinical experimental setting at outpatient clinics or hospitals (**figure 6**).

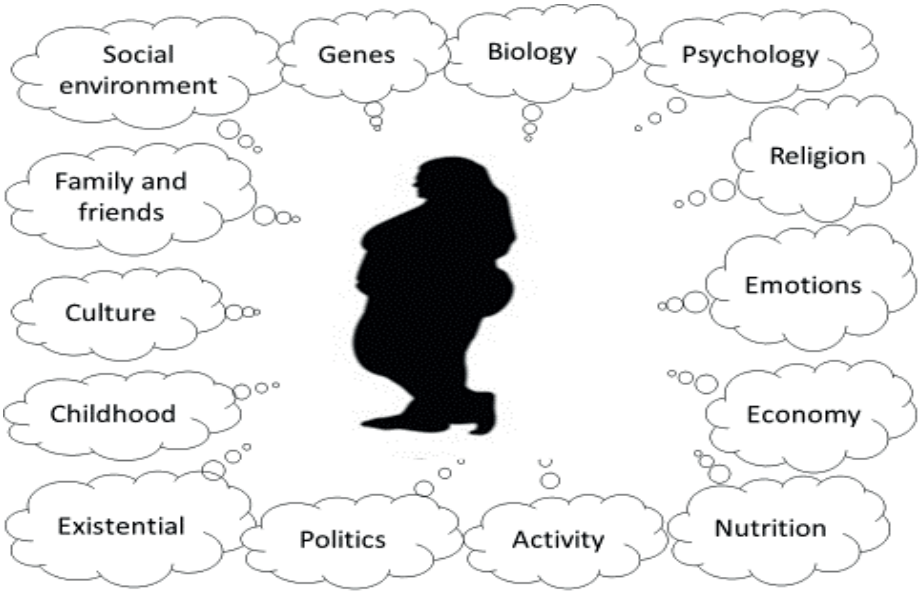

Figure 6: Fundamental aspects impacting in an individual's everyday life. The figure is made by the author, thus no publication permission necessary.

Use of qualitative methods may contribute to enrich our understanding of the participants' life situation and context. Such methods may be suited for interdisciplinary, behaviour-oriented treatment programmes, where new experiences make it clinically necessary to customise and individualise the programme along the way [174] and to generate knowledge from quantitative research variables that have not been explored previously [175]. When qualitative and quantitative methods

interact, it may be possible to develop an assessment procedure based upon research into key influences on lifestyle change and lifestyle programmes.

2. THEORETICAL AND CONCEPTUAL FRAMEWORKS

Both theoretical and conceptual frameworks are used in this thesis to interpret and understand the results.

Behavioural theories are useful to explain the mechanisms in the process of lifestyle change behaviour [176]. The common factors for behavioural change theories are social relations, attitudes, intention/stage of change and self-efficacy [177]. Behavioural change theories relevant for this thesis are the Health Belief Model (HBM), the Social Cognitive Theory (SCT), the Transtheoretical Model (TTM) and the Self-Determination Theory (SDT).

However, such behavioural change theories have not dealt specifically with emotional distress [178-180]. The conceptual frameworks "Allostatic Load" and "Habitus" are useful for understanding lifestyle change in relation to emotional distress and previous experiences. In addition, the concept/theory of Salutogenesis, on which the HLC lifestyle programmes are founded, is used to further understand the individuals' resources in the process of lifestyle change [158].

2.1. Behavioural change theories

2.1.1. The Health Belief Model (HBM)

HBM was developed in the 1950s by Social Psychologists Irwin M. Rosenstock, Godfrey M. Hochbaum, S. Stephen Kegeles, and Howard Leventhal, as a tool to help explain and to improve understanding of health-related behaviour [176].

HBM connects decision-making to people's health-related behaviours [181] and suggests that individuals' beliefs about health issues and their perception of the benefits of action as well as the impact of barriers to action, explain whether they do or do not engage in health-promoting behaviour [182]. A cue to action, must also be present in order to trigger the health-promoting behaviour [182]. HBM assumes that the health-promoting actions provided are likely to be adopted by the individuals, and that negative health effects are best avoided when the individuals believe in their ability to implement such actions related to the specific health behaviour change [176].

To explain health-promoting behaviour, six steps lead to the likelihood of engaging in health-promoting behaviour (**figure 7**).

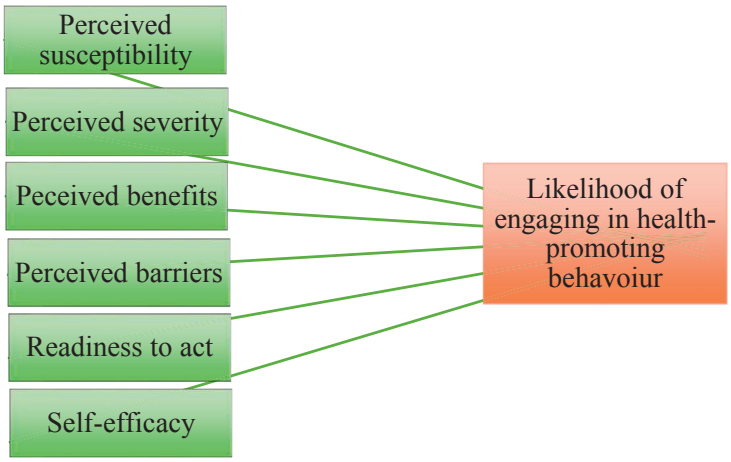

Figure 7: The six steps in HMB leading to health-promoting behaviour. The figure is modified and reproduced from online materials from *The Rosenstocks Historical Origins of the Health Belief Model* with permission [182].

HBM points to the relationship between perception of one's own health and one's actual health behaviour. The implication of HBM is that people will become aware of their own behaviour or investigate a health condition if they perceive that they are prone to a certain condition, that the condition causes serious consequences or that a behavioural change will be beneficial to either reduce risk or reduce the severity of the condition. Meanwhile, a behavioural change will only be made if the benefits are perceived to be greater than the barriers and costs of making such a change [176].

2.1.2. The Social Cognitive Theory (SCT)

SCT was introduced by the Stanford Psychologist Albert Bandura in 1977 [176]. SCT takes thought processes into account and acknowledges the role the thought process plays in determining if a behaviour is to be imitated or not. The core of SCT is involves five basic human capabilities: symbolizing, forethought, vicarious learning, self-regulation, and self-reflection [183].

Behavioural changes help situate people within authentic social practices with a focus on developing social proficiency and self-efficacy [184]. Self-efficacy is defined as how confident people are that they can exercise control over their own health and habits, which is presumed to have an impact on behaviour directly while other factors impact it indirectly [184]. Future behaviour is described in SCT as being based on self-efficacy, the confidence to achieve a wanted behaviour [185], and the assumption that a person's intention to change is the key determinant of change [184].

In SCT, the triangular relationship impact (**figure 8**) among the individual, the environment and the behaviour is not always symmetrical as to the strength of any bidirectional impact. Nor is the strength of the mutual impact of any two factors fixed regarding reciprocal causation [183].

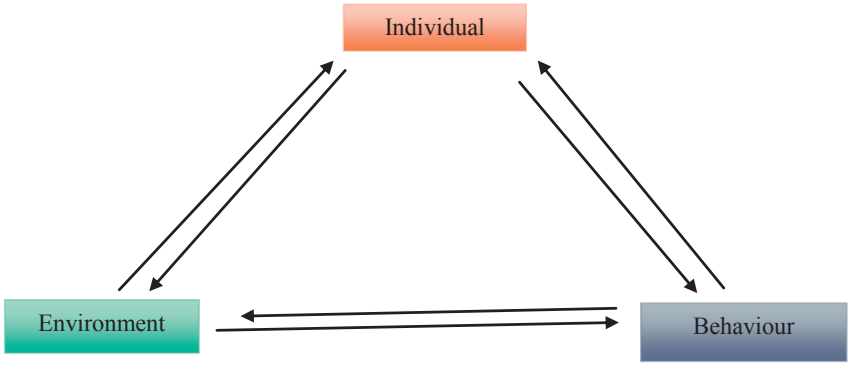

Figure 8: The triangular relationship impact in SCT. The figure is reproduced from non-copyrighted online materials regarding *Bandura's Social Cognitive Theory* with permission [186].

2.1.3. The Transtheoretical Model (TTM)

TTM was introduced by Prochaska & DiClemente in 1983 [176]. TTM describes feelings, such as being unhappy or disappointed, as creating critical situations that may tempt people to perform unwanted behaviours [187]. The time dimension is central to TTM, with the individual's change of action being a phenomenon that occurs over time. Changes over time involve processes that evolve in a stepwise progression through a series of stages. Often, however, they follow a more nonlinear progression

and an individual's behaviour may recycle through the stages, or regress to earlier stages [188].

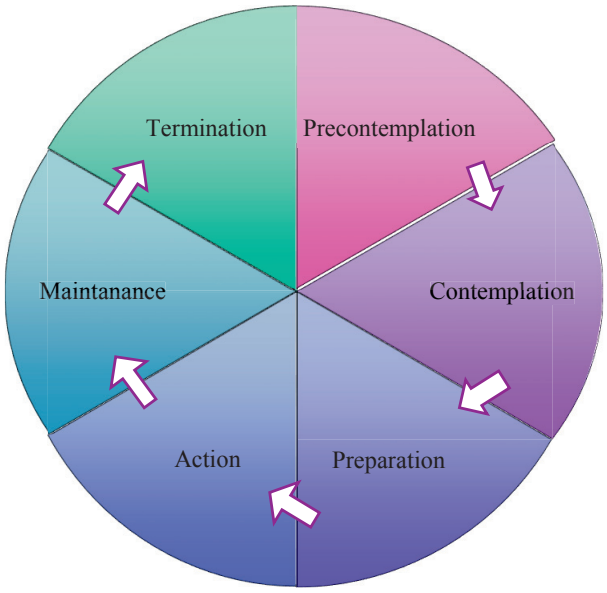

Figure 9: The six phases of the TTM. The figure is reproduced from *Prochascka et al* with permission. [188].

TTM posits six phases in the process of change (**figure 9**): pre-contemplation, contemplation, preparation, action, maintenance and termination. During the first phase, pre-contemplation, individuals tend to be resistant to change. They have often attempted to make changes earlier and have lost faith in their ability to succeed at actually making that change. Or, individuals may have no intention of changing and maintain a distance to focusing on their own behaviour. In the second phase, contemplation, they may be aware of both the benefits and the costs of making the changes. They may not be ready to make the change, but do intend to begin, maybe in half a year. An ambivalent attitude to change can leave them firmly planted at this stage for quite some time. In the third phase, preparation, people have a plan for how they will implement changes and are ready to act on it in the very near future, for example in a month. In the fourth, action phase, individuals make the planned changes. During the final six months, changes must be nearly sufficient to reduce the risk of disease. In the fifth phase, maintenance, new habits have to be held onto for more than

six months to avoid relapse. The sixth and final phase is termination, by which point the new habits have become a part of everyday life [188].

Examining a person's movement among these phases and the transitions between them provides insight and knowledge about the specific issues that may be helping or hindering that person's process of change [188]. Keys too replacing negative behaviour with alternative healthier behaviour include: boosting rewards for positive behaviour; reducing rewards for negative behaviour; seeking social support regarding the changes to be made; removing reminders of the negative behaviour; and, adding reminders that stimulate healthy behaviour [188].

2.1.4. Self-determination theory (SDT)

Developed by the Positive Psychology researchers Deci and Ryan in 1985, SDT is a broad framework for exploring individuals' motivation focusing on optimal functioning and motivation according to personality type. [189].

SDT seeks to explain three essential elements of how internal motivation and self-management facilitate behavioural change in terms of the need to govern oneself and make choices in accordance with one's own values [190]. The first is that individuals are inherently proactive in utilising their potential and mastering their inner forces (e.g. drives and emotions). Second, individuals have an inherent tendency toward growth, development and integrating functioning. Third, while optimal development and making actionable change are inherent, they do not come automatically [190].

SDT is centred on the theory called "inherent growth tendencies", the belief that human nature has persistently positive features that manifest repeatedly in human beings' exhibiting effort, agency and commitment in their lives. SDT suggests that, for various reasons and to a certain extent, people are driven to take action toward change [189].

According to SDT, three basic psychological needs must be satisfied to foster well-being, adequate functioning, growth and health: the need for autonomy, for competence [191], and for relationships [192] (**figure 10**). These are universal, innate and instinctive necessities that have been extant in all individuals throughout time

independent of gender or culture [193]. SDT takes into consideration the degree of motivation. It is closely related to motivational interviewing (MI) and can be seen to describe a continuum from a controlling motivation, i.e. “must do”, to an autonomous motivation, i.e. “want to do” [194].

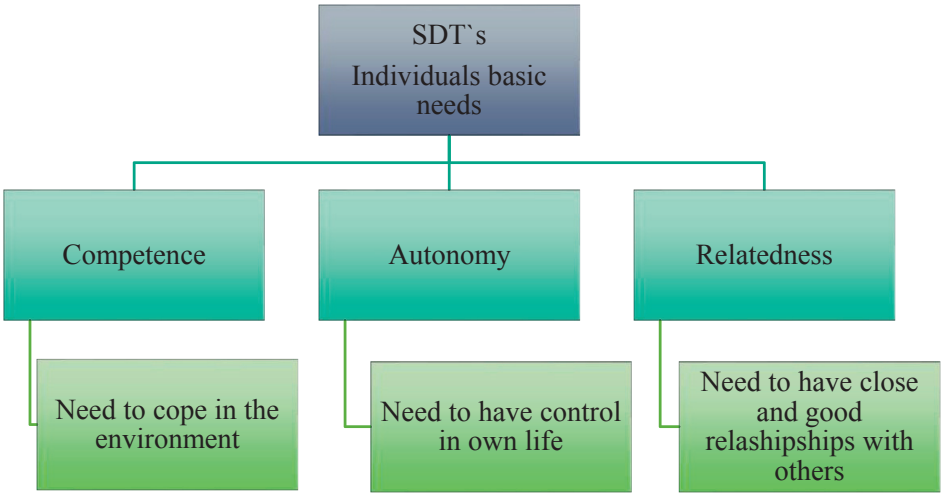

Figure 10: The three basic psychological needs in the SDT. The figure is reproduced from *Ryan and Deci, Self-Determination Theory and the Facilitation of Intrinsic Motivation,* with permission [189].

2.2. Conceptual frameworks

2.2.1. Allostatic load

The term “allostasis”, which means "stability modification", was introduced by Sterling and Eyer in 1988 [195]. McEwen and Stellar applied the concept of “allostatic load” in 1993 as a way to view health and disease as a multifaceted, mind-body approach; both psychopathological and pathophysiological research can use it to articulate dynamic processes that may destabilise and/or follow maladaptive trajectories [196].

The theoretical constructs of allostasis help explain how constantly changing social and environmental factors impact physiological functions and shape health and aging disparities [196]. Allostasis involves a biological feedback mechanism that affects the body's homeostasis [197]. It is the dynamic, adaptive, regulatory process that maintains homeostasis during exposure to physical and behavioural stressors [198] As it deals with the regulation of stress activation through social behaviour adaptation [199], it is of particular importance in stressful situations where one must act quickly, for example, during a life-threatening event [200]. When a person is exposed to a shock, he or she reacts with stress responses. These are learned behaviours, mobilised to survive danger. The primary, available behaviours are fighting, fleeing or stiffening (fight-flight-freeze) [201].

Also, mental stress increases the disparity between adaptation demands and coping resources. Mastery of psychological stress is defined as: "The continually adapted thought and behavioural efforts that the individual uses to deal with specific external or internal demands that are perceived as difficult or that exceed the person's resources" [180].

Stress experiences, however, may arise even when the requirements are less than the available coping resources since stress triggers an activation of the body's stress hormones, e.g. cortisol, epinephrine and norepinephrine [200, 202]. The brain is the central organ involved in the regulation of stress and adaptation to it, and both the social and physical environment have great influence on brain and body functions through the autonomic, neuroendocrine and immune systems [195]. The concept underlying allostasis involves the balance between Salutogenic, health-supportive factors and pathogenic influences ("wearing well vs. tearing down"). Thus, the "allostatic load" refers to the cumulative cost to the body of its allostasis [203]. If the allostatic load is chronically high, then pathologies develop [203].

Allostatic overload describes stress of a more chronic nature, corresponding to the critical homeostatic point of psychosocial overload from which serious pathophysiology can develop [203]. Secretion of glucocorticosteroids as well as the activity of other mediators of allostasis – the autonomic nervous system, CNS neurotransmitters, and inflammatory cytokines – all wax and wane according to the

allostatic load. One way of understanding allostatic overload clinically is that an individual has had too much of what is "tearing" and too little of what is "wearing well" [204] (**figure 11**).

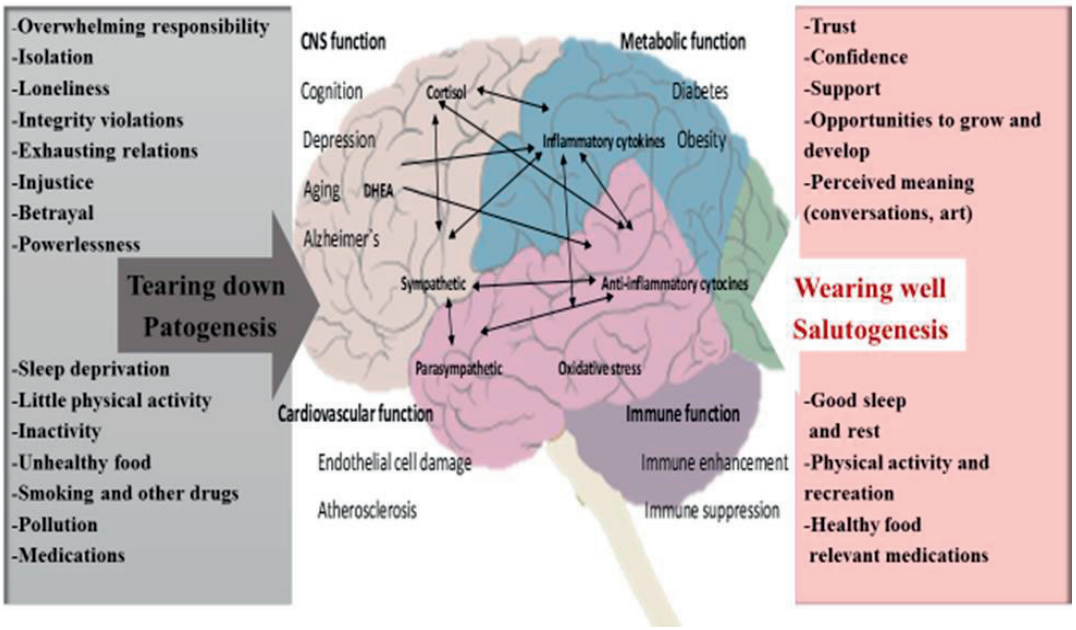

Figure 11: An overview of how pathogenic factors and Salutogenic factors may impact the system. The overview is inspired by picture from Trends in Cognitive Science [205]. The figure is drafted by the *Research Group for General Practitioners (AFE), NTNU* with permission.

Too much of what is tearing down (pathogenic) and too little of what is wearing (Salutogenic) may eventually exhaust the body's adaptation systems and affect the central nervous system, endocrine system and immune system [202]. When an individual is exposed to stress over a prolonged period, particularly during childhood, it will influence the body's biological systems and there will be a multi-system physiological dysregulation. This will increase health risks, including, for example, immunocompromised, cardiovascular disease and metabolic syndrome [87].

2.2.2. Habitus

The concept of "Habitus" originated with Aristotle as the term "hexis". Marcel Mauss and Maurice Merleau-Ponty referred to it, and in the 1960s, Pierre Bourdieu made the concept better known [206].

Habitus is seen to mediate the relationship between the individual as an actor and the setting as a structure. What people embody within themselves becomes their cultural capital on an individual level [207]; this then forms the connecting link for an analysis of the relationship between "mental structures" and "social structures" [208]. Habitus is considered to relate more too physical than consciousness structural conditions. It is explained as a system of fixed, although changeable, dispositions through which people perceive, assess and respond to the world.

Bourdieu elaborated his concept of the habitus while working with other ideas regarding how cognitive and generative schemes are dependent on history and human memory. Bourdieu also described habitus as the durable dispositions that shape behaviour and are a product of personalities and histories [207].

While the body's habitus is the medical term for physique, categorised into endomorphic (overweight), ectomorphic (underweight) or mesomorphic (normal weight), it may also be applied to the physical and constitutional characteristics of a person, especially as regards the tendency to develop a specific disease. Bodies reflect vehicle through which people live, experience and interact with others. Their bodies reflect people's ideologies and are also the means by which they can identify themselves and recognise each other. Uncomfortable emotions, such as shame, may arise if an individual experiences his or her body as being unlike that of other people. This may also be happen if their lifestyles differ and they are accused, for example, of being without self-control or being lazy. They may eventually internalise such societal prejudices [209].

2.2.3. Salutogenesis

The theory/concept of Salutogenesis was introduced in the 1970s by Aron Antonovsky, an American-Israeli Sociologist who based his stress theory on studies of Second World War concentration camp survivors [210]. Salutogenesis, literally, "the origin of health", is the study of what supports good health and is posited as being the opposite of pathogenesis [159].

Salutogenesis explores what causes positive health outcomes and a life view which helps in achieving mastery [210]. Salutogenesis is nuanced: one may not be either sick or healthy, but may be both sick and healthy at the same time. At any given time, people may be seen to be on a one-directional continuum from poor health toward good health, and may move upward toward the end of the continuum which is good health. In terms of Salutogenesis, people are continuously being exposed to external and internal stimuli. Salutogenesis explores factors that might contribute to pushing people upwards along the good health continuum [159].

According to Salutogenic thinking, the ability to use resources is termed a Sense of Coherence (SOC). It is a personal way of thinking, being and acting involving an inner trust, one which leads people to identify, benefit, use, and re-use the resources at their disposal.

Aron Antonovsky's explanation of the relationship between health and SOC is as follows:

> We are coming to understand health not as the absence of disease, but rather as the process by which individuals maintain their sense of coherence (i.e. sense that life is comprehensible, manageable, and meaningful) and ability to function in the face of changes in themselves and their relationships with their environment [159].

Implicit in SOC are three important factors that allow people to remain healthy despite their experiences and that determine whether their SOC is weak or strong. First, comprehensibility, the capacity to understand what is happening; second, manageability, the capacity to manage the situation alone or with significant others; and, third, meaningfulness, the capacity to find meaning in the situation [159]. The strength of one's SOC has direct psychological consequences that affect the health experience [210]. A person with a strong SOC will often make choices that benefit health, and can handle life in a way that does not impair his or her health in the long term [159]. A low SOC, on the other hand, may provoke feelings of being overwhelmed, of hopelessness or despair [159]. SOC is a crucial factor in explaining people's location along the continuum of health, and their movement toward the "healthy" pole. Differing SOCs are reflected in differing fundamental attitudes in the face of life events.

In terms of Salutogenesis, the foundation for how the SOC is how people build up their “resistance resources”. These play a key role along the path to good health and are important to how the person handles disease and stressful situations [210]. Good resistance resources are, for example, a good financial situation, a strong social network, a strong sense of affinity, high self-esteem and, for some, a strong connection to a religion. Resistance resources are to be found within people’s physical, socio-cultural and spiritual environments. The individual's resources will shape a variety of basic attitudes in the face of life events [159]. The key factor is not which resources are available but how to be able to use and re-use resources for the person’s intended purpose [210].

3. AIMS

The main aim for this thesis was to increase the understanding of the presumptions for lifestyle change for individuals attending Norwegian primary health care lifestyle programmes. Moreover, we wished to examine the potential effects of participation in a lifestyle programme on reducing overweight, obesity and preventing T2D.

Three approaches were used to explore the main aim. The first approach was to study a random selection of participants as they began a HLC lifestyle programme. The second approach was to explore selected participants among those at risk for T2D who were already attending a lifestyle programme to prevent their developing T2D. The third approach was to study the selected participants one year after the end of their participation in the programme and compare them, retrospectively, with non-participants.

The use of these three approaches provided an opportunity to investigate various aspects related to lifestyle change in Norwegian primary health care. The aims for the approaches were:

1. To study participants' previous life experiences as a factor impacting lifestyle change as they entered a newly established lifestyle programme in an HLC (paper I).
2. To study how participants attending an HLC lifestyle programme (the VEND-RISK Study) who had already been identified in the HUNT3 Survey as being at high risk of developing T2D experienced their own lifestyle and being at risk for T2D (paper II).
3. To study the effect of a one-year HLC lifestyle programme (the VEND-RISK Study) within Norwegian primary health care on participants at high risk for T2D one year after their participation in the programme had ended. Moreover, to investigate if and how the HUNT3 characteristics of those individuals who were at high risk for T2D and had accepted the invitation to participate in an HLC lifestyle programme (VEND-RISK Study) differed from those who had declined such an invitation (paper III).

4. METHODS

To meet these aims, both qualitative (paper I and II) and quantitative methods (paper III) were used based on two different studies (se **figure 12**).

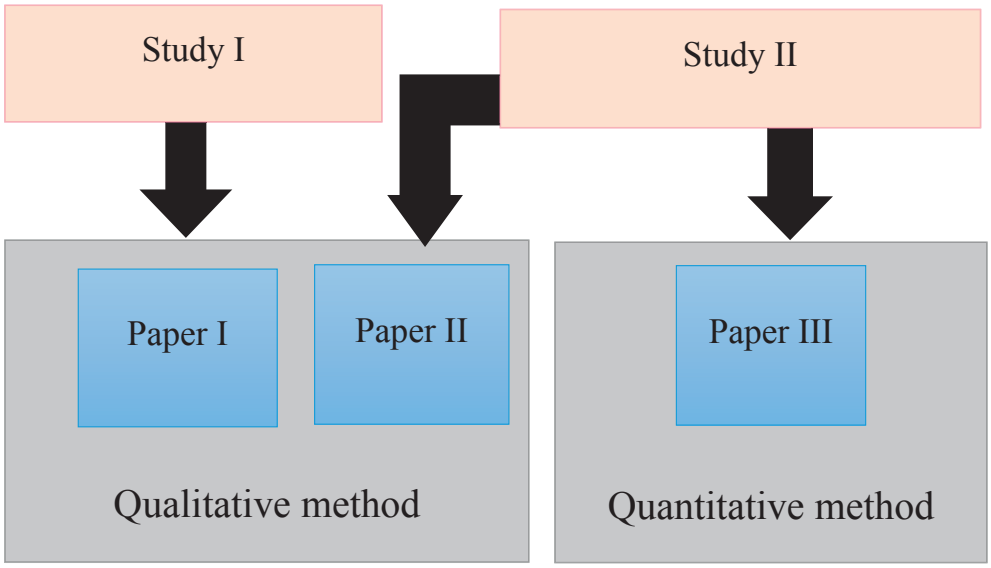

Figure 12: Flowchart showing which methods were used for the three papers and the two studies.

4.1. Qualitative method for papers I and II

Qualitative methods use a systematic and reflective process to elaborate on an individual's lifeworld [211, 212] through exploring experiences, emotions, perspectives, values and beliefs. The method focus both on the individual's actual perceptions [213] and on how the person extrapolates when perceiving their setting [214]. Qualitative methods provide rich descriptions of complex phenomena and produce findings from real-world settings where the "phenomenon of interest unfolds naturally" [215]. Utilising the contributions of the phenomenological approach, qualitative methods have been developed [216] to identify the significant "speech units" expressive of the collaboration between the researcher and the participant. A phenomenological approach was also used to interpret papers I and II as a way to

purposefully approach, observe and describe the meaning attributed to an experience, from the perspective of the consciousness of the person who is living it [217].

An interviewer approaching participants as they begin an HLC lifestyle programme is likely to encounter increased vulnerability. With the aim of building trust, emphasis was placed on being open and friendly, often beginning the interviews discussing everyday topics. The relationship between participant and interviewer has great impact on what emerges during the interview [211]. An openness to what the participant had to say was emphasized. To reduce the potential for developing relational asymmetry, an interviewer must be able to show respectful interest, to listen, to seek to know and understand the experiences of the individual. The quality of the interviewer's engagement helps evoke the inner essences of the stories shared.

Interviewing is an evolving process during which the researcher introduces the topic and then seeks to understand the participants' lifeworld and the meaning their experiences of the phenomena hold for them [212]. Having a phenomenological approach when meeting participants in interviews does not only involve seeing and accepting the participant, but also acknowledging the living body as the locus of expression of their lived life [218]. As such semi-structured interviews proceed, the researchers' informal observations can help them develop a keen understanding of which phenomena are of primary interest to the participant [219]. Thus, a challenge for the researcher is to explicitly acknowledge that embodied emotional orientations inevitably influence the research process, and to engage in those dialogues [220]. It is important to create an atmosphere in which the participant may talk freely and feel safe, while also respecting the person's integrity [212].

Somewhat paradoxically, it was the semi-structured approach to in-depth interviews, and utilising semi-structured interview guides that actually shaped the basic structure of the research. Semi-structured interviewing allowed informants the freedom to express their views in their own terms while the competence and preparedness of the interviewer remained apparent [219]. The interview guides helped to explain the aims for the interviews and the interviewers' intentions to all participants, clearly and consistently. A set of pre-determined yet open-end questions, and an openness to changing the sequence and form of those questions, facilitated

following up on the participants' specific answers and stories; this is the core material semi-structured interviews are used to elicit [212]. To ask questions from the interview guide and then listen to the answers also required that the interviewer simultaneously maintain a sense of his or her own self as independent of the participant [220]. The focus was on encouraging and allowing the participants` to speak freely about the main questions, and then to ask follow-up questions as they arose naturally. A rapport in the interview situation was sought so that the tension between the interviewers' questions and the participants' answers and experiences could be explored [220].

4.2. Quantitative method for paper III

Quantitative methods emphasise the statistical analysis of data collected through objective measurements, questionnaires and surveys [221]. Quantitative methods facilitate a systematic, empirical investigation focusing on gathering, analysing and quantifying data in order to identify associations and causal relationships, to gauge the effects of measures, and to generalise findings [214]. While quantitative methods are based on science as inspired by positivism and critical rationalism, the critical theory and pragmatism behind are nonetheless valuable for framing an overall understanding. Positivism emphasises the use of quantitative methods to empirically test hypotheses explaining why, what, where, how, and when phenomena arise [214].

Two quantitative designs were used in paper III.

First, a longitudinal, non-randomised, single-arm, observational, pre/post design was used to investigate the changes in health variables in participants with increased risk of T2D who participated in a HLC lifestyle programme (the VEND-RISK Study). This included assessments of baseline health characteristics both at the conclusion of the lifestyle programme and one year after each participant had finished the programme.

Second, a cross-sectional, quantitative design was used to explore if and how the characteristics of those at high risk for T2D as identified in the HUNT3 Survey, those who had been invited but had declined to participate in a lifestyle programme, differed from the assessments of those who had accepted that invitation and had participated.

4.3. Study I- Paper I

The study for paper I was performed in connection with the HLCs of the Levanger and Verdal municipalities. The HLCs were established in 2012, serving populations of 20,000 and 15,000 inhabitants respectively. The lifestyle programme at the HLCs in Levanger and Verdal followed the National Instruction Manual for HLCs, as described in Chapter 1.5.2. The personnel working with the HLCs included an educator, several physiotherapists, and two part-time nutritionists.

4.3.1. Recruitment and participants

The HLC personnel in Levanger and Verdal helped in recruiting participants to be interviewed. During the mandatory initial health conversation, the personnel asked eligible participants if they wanted to participate in the study. They also informed them that the interviewer was not an employee at the HLC.

The personnel offered potential participants interview appointment times, in consecutive order, either during or after health conversations. The intention was to gather a sample population that varied as to age and gender, and, on the first interview day, both genders and three different age groups were represented. The inclusion criteria for being interviewed for paper I was for participants to be aged 18-70 at the start of the lifestyle programme at the HLC in Levanger or Verdal, and competent to give their informed consent to participate. As fewer men were qualified to participate, all eligible men were interviewed. Nonetheless, the final sample included a predominance of women, which is typically the case for HLCs. The recruitment process continued until the data were saturated.

Twenty-three persons aged 18-70 years, the majority of whom were women (n=16), were interviewed. More than half of the participants had been referred to the HLC by their GP (52%), while the rest had contacted the HLC on their own (48%).

Participants reported lifestyle-related diseases such as overweight and obesity (83%) and T2D (22%), muscular and skeletal diseases (30 %), and psychological issues (26%). Multi-morbidity was present in almost all (91%) participants, ranging

from 0 - 8 different diagnoses, with the mean being three concurrent illnesses per participant.

One third of the participants had made prior attempts to follow their GP's advice regarding diet, smoking and physical activity, and/or had received help from municipal psychiatric nurses and/or physical therapists. In addition, one third of the participants reported participating unsuccessfully in various weight loss programmes at rehabilitation centres; two had had obesity surgery. Four of the participants were attending the HLC while awaiting approval for gastric bypass surgery or other specialised health services.

Over half the participants (57%) received benefits or help from the Norwegian Labour and Welfare Administration (NAV).

4.3.2. Data collection

Twenty-three in-depth interviews were conducted from February-April 2013, with participants beginning their HLC lifestyle programme in Levanger and Verdal municipality.

The interviews took place at the HLCs meeting rooms. The participants chose the location most convenient for them: sixteen participated at Levanger and seven at Verdal. The participants were offered coffee, tea or water before the interview started. The interviews were audio recorded digitally and lasted between 15 and 78 minutes, with the mean time being 42 minutes.

A pre-formulated, semi-structured interview guide with open-ended questions was used during the interviews. Having prepared semi-structured interview questions ahead of time supported the sense of the interviewers' professionality and competence and the interview setting's safety [219]. The questions were designed on the basis of the National Instruction Manual for the HLCs [158] and on dialogues held within the research group. The main questions in the interview guide were:

- "*Would you tell me what you think about attending an HLC?"*

- *"What expectations do you have when starting to change your lifestyle?" "What are your expectations of the personnel at the HLC?*
- *"How might you continue your healthy habits after the lifestyle programme?"*

To deepen the themes that were discussed, both follow-up questions and probing questions were asked during the interviews, such as, *"Would you tell me a little bit more about that?",* and, *"Would you describe this in more detail?"*. Notes were made during and after each interview to document the interviewer's immediate reflections on the interview situation, the participant and the conversation.

Each interview continued for as long as the participant had new information to share. Twenty to thirty interviews were planned, but after twenty had been held, little new information was forthcoming. It was assumed that a saturation of the data had been met.

4.3.3. Data analysis

During the spring and summer of 2013, all twenty-three recorded interviews were transcribed, chronologically and verbatim, in the official Norwegian written language (bokmål). The transcriptions yielded 234 typewritten pages.

The research group analysing the interviews consisted of people with different academic backgrounds: two registered nurses (the PhD. Candidate and the main supervisor, who holds a PhD) and one sociologist (PhD).

The analysis used was Malterud's modification [211] of Giorgi's systematic text condensation (STC) [218]. This phenomenological approach was applied to gain insight into how the participants experienced their lifeworld and as a real-world approach to understanding the phenomena of lifestyle change [218, 222].

During the transcription process, the first phase of the analysis, the words that had been spoken during the interviews were listened to and typed, bringing the interviewer closer to the material. Next, all material was read through to extract an overall impression. MindJet MindManager was used as a systematisation tool and mind maps

were made of the emerging themes and subthemes, with arrows marking the relationships between them. Drafting of the mind maps was begun during the transcription process. The research group read three interviews at a time and met to discuss them. Preliminary codes were assigned to the themes that had arisen which all three members of the research group considered to be important. The preliminary mind map, based on both the transcription process and the reading of what had been said, was used during the first meeting. More themes emerged there, and some of these were added to the mind map.

Second, the text was gone through thoroughly, and the material examined line by line to identify meaningful units, based on the previous step. Meaningful units were coded systematically to connect the common meanings with the themes from the first step. In this process, some themes were adjusted and/or renamed and some new themes were identified. This lifted the themes out of the material and helped in investigating them more thoroughly, along with other elements appearing in the material that contained information about the same issues [213]. All authors met and discussed the codes developed in this second phase, and the resulting 32 codes were then condensed to 25.

Third, each code was reviewed and sorted into themes. The content of the themes was condensed and quotations were selected and added. The participants' own words were used whenever possible, and the quotes that best illustrated the content of the specific themes were chosen. The programme QSR NVivo 10 was used as an organisation tool for codes and themes.

In the fourth and final phase, the pieces were reassembled, decontextualizing them. This decontextualization aimed at preventing reductionism and at assuring that the findings still reflected the situation in which they had been collected [213]. A summary of findings was written as a draft of the results section of paper I, adding descriptions of main themes and subthemes while still maintaining the connections to the field and the participants' descriptions. The content of each theme and subtheme was summarised and used, along with the relevant quotes, as the analytical text for each code. The draft of the results was checked against the transcriptions to validate the findings, checking particularly for data that might contradict the findings. During

the entire process, all the steps of the analysis were continuously checked against the transcription. The material was read several times during the analysis process to validate the findings and to identify and understand the meaning within the material's phenomena. The complete analysis process involved ten meetings plus discussions among the authors from May, 2013 to November, 2014. In order to assure the accuracy of the content's meaning, the Norwegian quotations were translated into English only once the analysis was complete.

4.4. Study II- Paper II and III

Study II was part of the VEND-RISK Study at the HLC in the Værnesregionen, established in 2010 and serving 44,000 inhabitants. The Værnesregionen consists of four municipalities: Stjørdal and Meråker in the county of Nord-Trøndelag, and Tydal and Selbu in the county of Sør-Trøndelag.

Study II's participants, however, were recruited solely from the Nord-Trøndelag Health3 Survey, based on their identified high risk for T2D (**figure 13**).

The Nord-Trøndelag Health Study (HUNT) is a large, total-population-based study which has made important contributions to knowledge regarding health and lifestyle in Norway. The HUNT Study addresses both somatic and mental disease as well as other health determinants. All inhabitants in the Norwegian county of Nord-Trøndelag ≥ 20-years or older had been invited to participate in three cross-sectional surveys during a 22-year period: HUNT1 (1984–1986), HUNT2 (1995–1997), and HUNT3 (2006–2008) [223]. The surveys included comprehensive questionnaires, interviews, clinical measurements, and the collecting of biological samples. In the HUNT3 Survey, 50,806 individuals (54.1% of those invited) participated between October 2006 and June 2008. Among these, 5,297 were identified as being at high risk of developing T2D over the next ten years, as deduced from the Finnish Diabetes Risk Score (FINDRISC) questionnaire [224].

The persons with a FINDRISC score of 15 or higher received oral and written information about their 30% risk of developing diabetes during the next ten years [92] and they were invited to attend the HUNT arm of an international, multicentre study,

the DE-PLAN study (Diabetes in Europe. Prevention through Lifestyle, physical Activity and Nutrition) [225]. The HUNT-DE-PLAN held information meetings from 2008-2010 all over Nord-Trøndelag regarding T2D and nutrition, during which they recommended that people at high risk for T2D exercise more and be more aware of weight gain.

In 2010, the VEND-RISK study was initiated with the goal of stimulating individuals at high risk of T2D to become more physically active and to follow a healthier diet by attending the HLCs lifestyle programme in the Værnesregionen.

The HUNT3 Survey had identified 332 residents of the two Værnesregionen municipalities of Stjørdal and Meråker as being at high risk for developing T2D. In 2012, letters inviting them to participate in the VEND-RISK Study and to join the lifestyle programme at the HLC in the Værnesregionen were sent out to them. The letter explained that they were being invited because of the high risk for T2D that HUNT3 had identified and included information about the HLC lifestyle programme. Of the 332 receiving the invitation, 45 agreed to participate in the VEND-RISK Study.

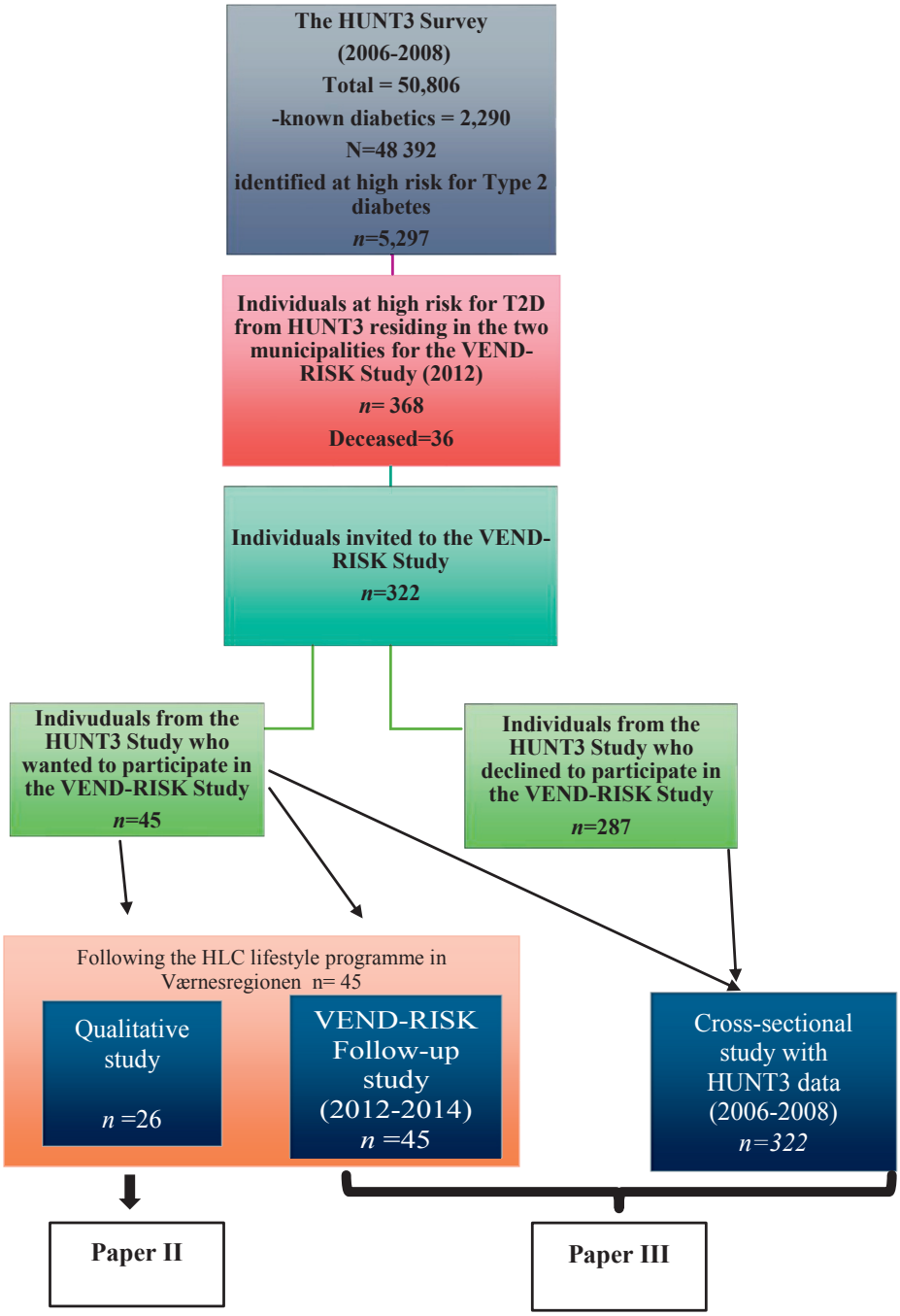

Figure 13: A flow-chart over recruitment of participants for study II, resulting in papers II and III.

4.5. Paper II

4.5.1. Recruitment and participants

Recruits for paper II were selected from the VEND-RISK study. One nurse involved in the study who worked at the HLC in Værnesregionen helped with the recruiting process, phoning the potential participants, informing them about the study, and inviting them to interviews. The nurse wrote a list of participants who had agreed to be interviewed. These were strategically invited to interviews based on gender since, in this sample also fewer men than women were eligible to participate. All men were interviewed. A schedule was made of interview times and dates. The recruitment process continued until the data were saturated.

The criteria for being interviewed included having been identified in the HUNT3 Survey as being at high risk of T2D, residing in the municipalities of Stjørdal and Meråker, attending the VEND-RISK Study, and being competent to give written informed consent.

Twenty-six ethnic Norwegian participants were interviewed, aged 59-75 years, with the mean age being 68. Of these, 15 were women and 11 were men. Of all participants, 20 were married or had a partner and six were divorced or widowed. Regarding their level of education, five had nine years or less of schooling, 14 had more than nine years of schooling, and seven held a Bachelor's Degree or higher. Four participants were working half-time, six were on disability leave, four were partially retired (< 50%), and 12 were fully retired.

According the participants' health measurements from the VEND-RISK baseline inclusion data, they had a mean BMI of 30.2 (Standard deviation (SD) 3.4). One participant was of normal weight (BMI 18.5-24.9 kg/m^2), 11 (42%) were overweight (BMI 25-29.9 kg/m^2) and 14 (54%) were obese (BMI ≥ 30 kg/m^2). A family history of T2D was present for 17 (65%) of the participants. Their mean FIND-RISC score was 17.0 (SD 3.2) and their mean HbA1c was 5.8 mmol/mol (SD 0.5). Mean waist circumference was 107.5 cm (SD 6.4) for men and 103.5 cm (SD 10.1) for women.

4.5.2. Data collection

In February and March, 2015, twenty-six in-depth interviews were conducted with participants attending the VEND-RISK Study in the HLC in Værnesregionen. Similar processes were followed with paper II as with paper I.

The interviews were audio recorded digitally and lasted between 14 and 73 minutes, with a mean time of 28 minutes. The interviews took place at Værnesregionen DMS in Stjørdal. The interviews were held in a relaxed atmosphere, in a "coffee break" room or a meeting room, depending on what the participants found most comfortable.

A semi-structured interview guide with open-ended questions was used during the interviews (appendix), allowing participants to speak freely about what they considered essential to their lifestyle and about being at increased risk of T2D. The main questions in the interview guide were:

- *"How has your health and lifestyle been throughout your life?"*
- *"How has the VEND-RISK lifestyle programme influenced your lifestyle?"*
- *"Did you make any changes based on learning about your T2D risk?"*
- *"What experience do you have with changing your habits regarding diet and exercise?"*

The interviews proceeded as a conversation, with follow-up questions such as, *"Would you tell me a little bit more about that?"* and *"Would you describe this in more detail?"* , with the aim of exploring what participants considered to be important.

Field notes were made by the interviewer during and after each interview. The relationship behaviour of the interviewer had same qualities as during the interviews for paper I. These interviews also lasted as long as new information was being shared. As for paper I, twenty to thirty interviews had been planned. Now, after 23 were held,

little new information was forthcoming and it was concluded that a saturation of the data had been met.

4.5.3. Data analysis

The interviews were transcribed verbatim by two different people (eleven and twelve interviews per transcriber). The raw data consisted of 398 pages, four of which were notes.

The same group of researchers as in paper I was involved in analysing the data with the addition of an endocrinologist (M.D.) and an occupational physician (M.D.).

The data were analysed using STC, the same as had been used for paper I.

The analysis was based on a phenomenological approach to help search for issues that affected the participants' responses as seen from their own perspective, to highlight the real-world approach to understanding lifestyle choices as well as the experience of being at high risk of T2D [211, 218].

In the first step of the analysis, both the transcribers listened to the interviews that the other had worked with and read each other's transcriptions without editing them. Then, all recorded interviews were listened to again. All the transcribed interviews and field notes were re-read in order to form an overall impression. A mind map was made using the program MindJet MindManager to register preliminary themes that seemed clear after the first reading.

In the second step, all meaning units that were derived from the material were sorted into codes. Codes were compared and categorised with QSR NVivo 10 being used to sort meaning units derived from the material into codes. Interview notes were also added using QSR NVivo 10. The authors' discussions of their varying conceptions of the codes resulted in 32 codes which were merged into two main themes with three subthemes each.

In the third step, themes and codes were summarized, read and discussed, aiming to find the essence in the material that reflected the participants' narratives. The authors arrived at a consensus as to the main themes and subthemes. The second and third authors read three interviews and a summary of the interviews and met with the first author in order to discuss codes and themes. After several meetings, the codes

and themes were adjusted and/or renamed, and the contents of the themes and subthemes were condensed.

In the fourth and last step, all findings were summarised and concepts within the themes and subthemes were grouped. The findings were continually checked against the transcriptions throughout the analysis and the discussions about the themes in order to validate them. The quotations selected from the text were translated from Norwegian to English only at the end of the analysis process to insure the accuracy of their content and meaning.

As the study design for paper II developed, the "Consolidated Criteria for Reporting Qualitative Research (Coreq): A 32-Item Checklist for Interviews and Focus Groups" was used to certify the appropriateness of the study methods, context, findings, analysis and interpretations, as well as the reporting of important aspects by the research team [226].

4.6. Paper III

4.6.1. Recruitment and participants

Participants for paper III were recruited from study II, i.e. the VEND-RISK Study and the HUNT3 Survey (**figure 13**), and were separated into two sample groups.

The first sample group consisted of the 45 participants. Inclusion criteria for this first sample group were that the participants had attended the HUNT3 Survey and been identified there as being at high risk of T2D, that they resided Stjørdal and Meråker municipalities in Nord-Trøndelag County. They also had to have agreed to participate in and attend the VEND-RISK Study.

The second sample group was composed of 322 participants. Inclusion criteria for this second sample group for paper III were that they had attended the HUNT3 Survey and been identified as being at high risk of T2D, that they resided Stjørdal and Meråker municipalities in Nord-Trøndelag county. These, however, was both those 45 in the sample group above who agreed to participate and those who declined the invitation to attend the VEND-RISK Study (see **figure 13**).

4.6.2. Intervention

The VEND-RISK Study intervention was to follow the HLC lifestyle programme offered in Værnesregionen during one year. The HLC lifestyle programme in Værnesregionen followed the national recommendations for HLC programmes as described in Chapter 1.5.2. The personnel who worked in the HLC in Værnesregionen included two nurses, several publically employed physiotherapists, and a half-time clinical nutritionist.

The study included annual surveys, blood sample tests and physical activity tests for prospectively five years from when their participation in the intervention had begun.

4.6.3. Data collection and measurements

In the first part of paper III, the follow-up data for participants who had accepted invitations to the VEND-RISK Study's included their baseline data, data at the end of the (one year) intervention period, and then data one year after the end of their intervention period.

For the second part in paper III, data from the HUNT3 Study and HUNT DE-PLAN Study (education variables) were applied for and received from the HUNT Databank. The VEND-RISK participants had been labelled only with their birth identification numbers and sent in to the HUNT Databank.

Measures in both HUNT3 and VEND-RISK

The socio-demographic characteristics included were age, gender, education and work participation. Education was assessed by the asking, "How many years of education have you completed?" The work data question asked for a "yes" or "no" answer to, "Are you working?"

The anthropometric measures included were height and weight (for BMI)) and waist circumference. Trained nurses measured waist circumference with a measuring tape [227]. BMI was calculated as weight divided by height squared (kg/m^2). Height

and weight measurements were taken following a standardised procedure during which participants wore light clothes and no shoes.

The diabetes risk measurements included were the FINDRISC questionnaire responses and fasting serum glucose load to assess diabetes risk.

The cardiovascular status was measured in terms of triglycerides, total cholesterol and HDL cholesterol.

Measures only in VEND-RISK

Diabetes risk measurements and cardiovascular health were also obtained using Haemoglobin A1c (HbA1c) and LDL cholesterol.

Aerobic fitness status was assessed through measuring maximal oxygen uptake ($VO2_{peak}$).

Physical activity was measured using the questionnaire COOP/WONCA Functional Assessment Charts and with the question, "What level of physical activity can you maintain for at least 2 minutes?" The five-point scale response options included: "very heavy" (fast running), "heavy" (light running), "moderate" (fast walking), "easy" (regular walking), and, "very easy" (slow walking). These were dichotomized into "heavy" and "light, with "moderate" being included in the "light" category.

Self-reported health was measured using the Dartmouth Primary Care Cooperative Information Project/ World Organisation of National Colleges, Academies, and Academic Associations of General Practice/Family Physicians (COOP/WONCA) questionnaire. The COOP/WONCA was developed for use in general practice to screen patients' level of functioning [228] and is recommended for use in HLC. The instrument has been translated into Norwegian [229]. We used the COOP/WONCA overall health question, "During the last two weeks… How would you rate your health in general?" Answers were along a five-point scale from "very good" to "very poor". We also asked, "During the past two weeks… Has your physical and emotional health limited your social activities with family, friends, neighbours or

groups?" Answers were along a five-point scale from "not at all" to "extremely".

Measures only in HUNT3

Sedentary behaviour (total sitting time) was measured by asking, "About how many hours do you sit during an average day (include work hours and leisure time)?"

Physical activity was measured using three questions: "How often do you exercise?"; "If you exercise as often as once or several times a week, how hard do you exercise?"; and, "How long do you exercise each time?" These answers were recoded into metabolic equivalents (METs) and divided into three different MET scores based on frequency x duration (METs) x intensity/minutes: 1= 0 – 8.3 MET-h/wk (0-500 MET-min/wk); 2= 8.4 – 16.6 MET-h/wk; and, 3= >16.6 MET-h/wk. A score of 1 is lower than the recommended amount of physical activity while scores of 2 and 3 meet the recommendations for physical activity [230].

Self-reported health information was obtained by posing the question: "How is your health at the moment?" The four-point response scale was subsequently dichotomized into "poor" and "good" [231]. The second question, "Has your physical or emotional health influenced social relations with family and friends over the last four weeks?" is from the SF-8 Health Survey and has been widely used internationally [232]. Here, the five-point scale responses included: "not at all", "a little", "some", "a lot", and "all the time". These answers were also dichotomized so that "not at all" was classified as "no" while all the other answers were classified as "yes" [233].

4.6.4. Data analysis

Data sets from HUNT3 and VEND-RISK including the characteristics of participants were analysed using the IBM Statistical Package for Social Sciences (SPSS) version 23.0. Prior to the analyses, the data were checked for outliers and missing data. A research nurse punched in the VEND-RISK data to reduce the chance of misclassification of variables or outcomes. The normality of the variables was

measured using the Shapiro-Wilk test (p-value ≥ 0.05), and with visual inspection of histograms, normal Q-Q plots and box plots.

The baseline characteristics both of participants in the follow-up study and of those who participated in HUNT3 but not in VEND-RISK, were described with mean ± SD. To see the changes in the main variables for the participants' follow-up in the VEND-RISK Study – from baseline to the end of the one-year lifestyle programme and a year after the end of lifestyle programme – we used a paired t-test for normally distributed data and a Wilcoxon non-parametric test for non-normal data. Binary logistic regression was applied to calculate an odds ratio (OR) with a 95% confidence interval (CI) to see what if any differences there were between participants and non-participants. All analyses were separated according to gender, and adjusted for age (yrs.). For strength calculations, a 5% significance was selected and an 80% strength.

4.7. Ethics

4.7.1. Approvals and registration

Approval from the Regional Committee for Medical Research Ethics, Central Norway was obtained (REK nr. 2012/1755) for paper I. All participants received oral and written information about the study and were required to give informed consent in writing before completing the interview. They were informed that participation was voluntary and that they could withdraw from the study at any time.

For papers II and III, all participants received oral and written information to enable them to make an informed choice about participating in the study, and all gave written informed consent. The Regional Committee for Medical and Health Research Ethics (REK) in Central Norway approved our study and our interviewing of participants for paper II (REK nr 2015/188). They also approved the VEND-RISK Study (REK nr 2010/696) for paper III. Participants had received oral and written information enabling them to sign an informed consent form in the HUNT3 Survey, which had also been approved by the Committee.

The VEND-RISK Study was registered on ClinicalTrials.gov on April 26, 2010, with the registration number NCT01135901.

The transcribed data, audio and SPSS files that were collected were anonymized and confidentiality was upheld. All data were stored on a private, password-protected computer. The transcribed data, a disc containing audio files, and the signed consent forms for papers I and II were stored in a locker in a locked office. The data are to be stored until 2020.

4.7.2. Considerations for the qualitative papers (I & II)

When applying qualitative methods, researchers play a close and active role in the project, thus acquiring considerable influence [211]. By putting into words the understanding, as well as expectations regarding the research results, one become more aware of own preunderstandings ("bracketing"), which helps prevent preconceptions from tainting the empirical data [211]. Before the recruitment and interviewing process began, these preconceptions were clarified and written down.

A preunderstanding that emerged regarding paper I was that the group of participants in HLCs would not necessarily meet the criteria for receiving specialist health care treatment and thus would have fewer health issues and problems. The assumption was that participants would be more capable of making lifestyle changes and implementing them in their daily lives than would those seeking specialised health care assistance. The revised policy law had stated that primary health care should target participants who needed assistance to make lifestyle changes, with the mandate being to become less disease-oriented and more focused on health promotion [158]. Since it is a low-threshold, municipal lifestyle programme, the preconception was that HLC would be more likely to assist participants to implement lifestyle changes into their daily lives than would a stay at a rehabilitation centre; the expectation was that, returning to their homes after such a stay, it would be more difficult not to revert to their established habits. The preunderstanding based on a sample from primary health care was that a group in need of preventive strategies would have fewer diseases and a less complex medical profile than people receiving specialist health care.

A preunderstanding before performing the interviews for paper II was that selecting a sample from among the participants in two other studies would yield a group of people who would be highly motivated to make lifestyle changes that benefitted their health. In addition, as they had accepted the invitation to the VEND-RISK Study and had previously participated in the HUNT3 Survey, it could be presumed that they were more aware of their own health. The thought was that these participants as a group might provide important insight into what resources and perceptions furthered the aim of preventing the development of T2D. What they would emphasise as being important for making lifestyle changes now that they knew they were at high T2D risk, was expected to influence their ability to actually make such changes. The preunderstanding included the presumption that these people had become more concerned about their lifestyle once they learned that they were at risk of T2D.

5. RESULTS

Paper I for study I, revealed two main themes with respectively five and four subthemes each (**figure 14**). The first main theme affected the second main theme, which in turn affected the first main theme that again made it hard to initiate a change.

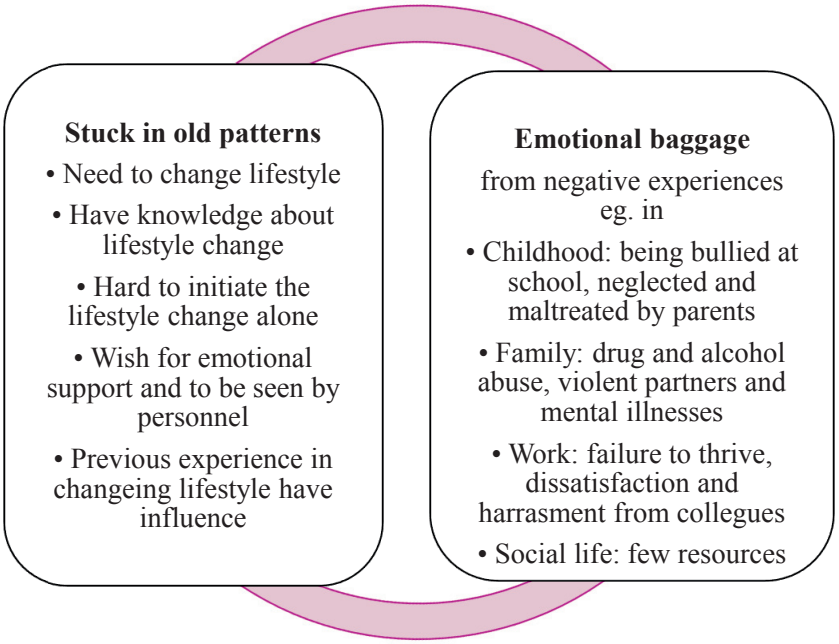

Figure 14: An overview of the main results in paper I.

Stuck in old patterns described the situation the participants faced in the beginning of the HLC lifestyle programme. They needed to change their lifestyle because their lives were adversely affected by their health behaviours. Lack of knowledge was not the reason for failing to change their lifestyle on their own, but that the barrier was knowing how to start a change that lasted. They asked for emotional support and to be seen by the HLC personnel.

Emotional baggage, included negative experiences` in childhood like being bullied at school and being neglected or maltreated by parents. Hard feelings and emotional distress linked to childhood memories made their adult life difficult. There were also other family and social experiences like substance abuse, violent partners and mental illnesses that was part of their emotional baggage that hindered them from

initiating changes. Criticisms from current-day surroundings and social life was experienced debilitating, i.e. negative experiences with family, friends, fellow students and colleagues. This could take form of failure to thrive, dissatisfaction and harassment at work. Their social life did not contain many resources.

Paper II studied a selected sample of participants in study II. They had accepted invitation to attend the HLC programme in the VEND-RISK Study based on having been identified in HUNT3 Survey as being at high risk of T2D. From exploring their perception of how they experienced their own lifestyle and being at high risk of T2D the results revealed two main themes with three subthemes each (see **figure 15**). The first main theme was presented by the participants as connected to how they handled their high risk for T2D in the second main theme.

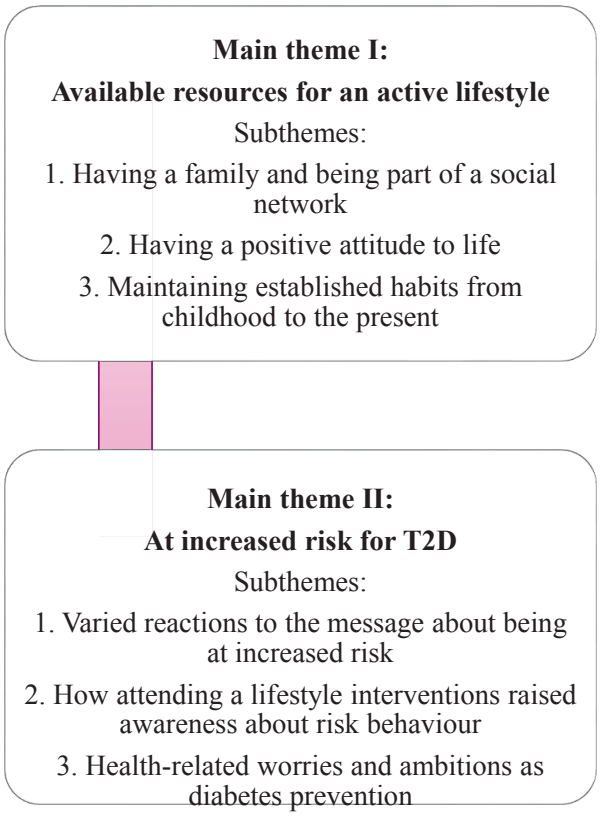

Figure 15: An overview of the main results in paper II.

Available resources for an active lifestyle included having a family with children, grandchildren and siblings nearby, as well as being part of a social network. They turned to their families and social networks to get through difficult life experiences, traumatic episodes and negative health conditions. They accentuated that they had a positive attitude to life, and saw themselves as responsible for their own happiness. They told they had formed habits during their childhood through an active lifestyle and healthy eating, and had continued these established habits into adulthood.

Being at high risk for T2D was described by a variation of reactions from the participants after they had gotten the information about high risk for T2D at the HUNT3 Survey. Participants told they focused on a healthier behaviour after being included in the VEND-RISK Study, but to varying degrees. However, even if there was variation in awareness about high risk for T2D, their stories showed an increased focus on being more active. Those with T2D in the family were more worried about their high risk and getting T2D, and especially those with complications such as nephropathy, retinopathy and immobility. They emphasized family history of T2D and their ambitions to stay healthy as long as possible as more important for their lifestyle than the information about their high risk alone.

Paper III, part I studied the follow-up of participants one year after attending the one year intervention in study II. Their mean age baseline in the VEND-RISK Study was 64.2 years. All participants met for the follow-up one year after ended intervention (45/45, 100% responder rate). For the total sample, the mean BMI changed slightly from 30.2 kg/m^2 at baseline to 29.7 kg/m^2 at one year follow-up. HbA1c decreased significantly (-0.2 mmol/l) and none developed T2D one year after ended intervention. For women, a significant decrease of 4 cm was found in waist circumference from baseline to the follow-up one year after the intervention ended ($p<0.00$).

In paper III-part II, 287 of the 332 (86%) invited individuals declined to participate at the VEND-RISK Study, after being identified at high risk of T2D at the HUNT3 Survey. Totally, 59% were women with a mean; age of 60 years, BMI of 31 kg/m^2 and FINDRISC score of 16.9. All had high risk of CVDs, with elevated lipids. None of

non-participants health measurements; i.e. socio-demographic, anthropometric, diabetes risk, CVD risk and physical activity level were different from the participants. The non-participating women was significantly different from women who participated in that they reported fewer years of education ($p< 0.00$) and more unemployment ($p=0.05$). They also reported more frequently that physical and emotional health affected their social relations the last 14 days ($p=0.04$). For men, no differences were seen between those not participating and those who participated.

6. DISCUSSION

6.1. Discussion of key results

In paper I study I, for which the inclusion criteria were broader than for study II (paper II and III), the participants expressed having emotional baggage from negative experiences with family and social networks, which they told, contributed to their remaining stuck in old habits.

The participants in paper II were selected among those who had chosen to attend the VEND-RISK Study. They reported having supportive families and social network as well as personal individual resources available to help them choose a healthy lifestyle.

The HLC participants in paper III who had accepted an invitation to attend the VEND-RISK Study maintained stable BMI and did not develop T2D. Based on their HUNT3 data, women who had declined the invitation to attend the VEND-RISK Study had a lower SES, and reported that their health affected their social relations more often as compared to those who attended the VEND-RISK Study.

6.1.1. Negative life experiences' influence on lifestyle change

Being stuck in old patterns

In paper I, participants described feeling stuck in old patterns despite needing to change their lifestyle. They reported that they had the necessary knowledge regarding lifestyle change, but that it was hard to implement such lifestyle changes on their own.

According to the HBM theory, benefits must be of greater import than barriers to initiate a change. In the findings from other studies, it appears that everyday life tends to get in the way of implementing healthy habits [234], and that it may be difficult, even for individuals who explicitly want a healthier lifestyle, to consistently make the right choices and change their habits [235]. Another study did find that, as physical activity and healthy diet became part of participants' ingrained habits, they less often described themselves as being stuck in old patterns, and their new habits became more a part of their everyday life [236].

However, the processes of changing and integrating change are demanding. Both the SCT and SDT theories emphasise that improving one's coping abilities and self-efficacy is important for change. Thus, for participants in paper I, they did not know how to begin the change. From TTM's perspective, changing unhealthy habits inevitably involves transiting through a variety of phases. In paper I, we did not track the phases the HLC programme participants went through; they expressed that they wanted change but simply did not know how to implement it. At the same time, they felt that the emotional baggage they carried from negative experiences hindered their changing.

Emotional baggage due to current and prior negative experiences

Participants in paper I reported that negative experiences in everyday life, in their surroundings and social lives, left them with emotional baggage that made it more difficult for them to change their lifestyle.

According to other studies, participants who failed at making life style changes reported more prior experiences of loss and more psychosocial crises, such as grief, serious illness and personal or family difficulties [237, 238]. Difficulties with lifestyle change is found to be associated with experiencing stressful life events or rating one's life as stressful [239]. Living with serious challenges and a sense of pressure in everyday life may lead over time to the development of chronic stress and alter the body's biological systems; hormones associated with a high chronic stress can, in the long run, cause changes in the brain and body that can lead to disease [202]. Thus, when attempting lifestyle change, factors that increase one's allostatic load may affect the body's mechanisms in way that makes it harder to lose weight [240].

The participants in paper I reported negative experiences from their childhood and adolescence, such as being tormented and bullied by their schoolmates. Over time, the types of conflicts within families and social networks that our participants described may elevate the level of the appetite-controlling glucocorticosteroid [203] leading, in turn, to an increase in food consumption and thus potentially triggering even more stress-induced eating [203].

Other studies have found that experiences in early life have great formative impact on the body and brain, which endure throughout life, influencing behaviour, brain function and increasing the risks for a number of physiological and mental disorders [241].

Several studies have reported that adverse experiences during childhood and adolescence, such as sexual abuse and maltreatment, play an important role in the development of overweight, obesity [56, 242, 243] and T2D [55, 244]. Adverse experiences during childhood may lead to mental and emotional disturbances, maladaptive coping responses, stress, inflammation and metabolic disturbances [243]. It is suggested that a dose response system exists such that the more adverse experiences a person has been subjected to during childhood, the higher their rate of morbidity as adults [57, 245]. A study from HUNT3 investigating self-reported childhood difficulties, retrospectively, showed a general, graded association between childhood difficulties and multimorbidity in adulthood [246]. We need also to consider that the studies on adverse childhood experiences were based on a middle class population [247]; there may thus exist additional less-explored factors which act as early life stressors. It is also important to underline that these studies do not imply that all overweight and obese people have had an adverse childhood, nor that all who have had an adverse childhood will develop overweight or obesity as adults [243].

Adverse childhood experiences may lead to the development of negative coping behaviours and the suppression of negative emotions [248]. Our participants in paper I described their negative experiences as being emotional baggage that kept them stuck in old habits. Psychological distress from childhood experiences may have a negative influence on the one's ability to change [202]. Social Cognitive Theory (SCT) considers prior experiences to be key factors regarding self-efficacy [185]. Previous negative life experiences are known to reduce self-efficacy and to have a negative impact on the ability to change health behaviour [184]. As a result, as we heard from participants at the start of HLC lifestyle programmes, lifestyle change is difficult.

The results for paper I support the findings that, to help people achieve and maintain a healthier lifestyle, it is important to identify and resolve the negative experiences that may underlying their lifestyle issues [54, 247].

Biological inscriptions of prior negative experiences

In addition to participants' in paper I pointing out that their emotional baggage and prior negative experiences were obstructing their lifestyle change, they also had on-going medical, psychological and social problems.

Chronic stress stemming from negative experiences may lead to alterations in the body's biological systems [202]. "Experience" is, however, a subjective phenomenon, associated with and evoked by specific situations, and in a specific atmosphere [249]. In recent research on people's lifetime health, an examination into both prior and present life conditions and experiences has deepened the understanding of these relationships [250].

"Life experiences" are the cumulative impact of all the intrinsic and extrinsic factors that affect people, from cultural to genetic conditions [202]. Each new experience is affected by and integrated with previous experiences [249]. Accordingly, an individual's personal biography is a description of how that person has interpreted and adapted his/her perceptions of life events and experiences [251]. Individuals are shaped by life experiences that are written into the body, so to speak, in the form of a specific physiological preparedness [252]. The results of this formative process are often described as a narrative script, a "psycho-biological" basic "setting" and "mentality" that determines a person's level of allostatic load – from well-being to crisis management [253]. The concept of allostatic load helps in identifying the effects of emotional distress and adaptation from a life-course perspective. For example, high stress levels can cause a dysregulation in the hypothalamic–pituitary–adrenal axis and increase cortisol, ghrelin, insulin and pro-inflammatory cytokines levels [254, 255].

Emotional distress may also occur when the coping resources that are available are less than the resources required to handle the specific situation. Allostatic overload may result when a person experiences that the capacities available to meet a specific situation are inadequate or unsatisfying [256].

6.1.2. Resources important for lifestyle

Family and social network

In paper II, we report having found that the selected participants attending the VEND-RISK Study had had positive experiences with family and social network, in direct contrast to what the participants in paper I described. The participants in paper II said they were part of a social network and a family that helped them to be active and maintain healthy habits.

A review of qualitative studies regarding what was considered important for lifestyle change programmes found that a majority of the studies had focused on the importance of physical activity and diet. The review also mentioned that support from friends and family could be considered a core element for success [257], which coincides with our findings from paper II.

Families may represent a potential source of support for making behavioural changes [258]. Having good social relationships in connection with exercise is seen as an important motivator for change [259]. Having social support, being joined by family and friends in physical activities [260], are related to successful weight reduction among people with overweight and obesity [261]. Also, weight management was improved by having friends and co-workers who encouraged their healthy eating [260]. A study of participants in a T2D prevention programme found that good family and community relationships were related to successful behavioural change [141].

The participants in paper II expressed that attending cultural and physical activities, where bonding with family and friends was important, was part of what they described as “activity” and “being active”. Attending cultural activities has been found by others to be associated with better health [262]. Furthermore, according to the concept of Salutogenesis, meaningful activities, which promote health, have a positive impact on one’s sense of coherence (SOC) [210].

Others have reported that the companionship of significant others may be part of an effective intervention strategy to promote behaviours that are important for weight loss [263]. Thus, based both on our findings and those of several other studies [141, 259, 264], adequate social relationships seem important for a healthy lifestyle.

Including an assessment of participants' family and social network resources could provide indications as to how best to improve the outcomes of lifestyle intervention programmes. A sense of belonging and a perception of being supported and acknowledged may also contribute to strengthening or restoring health [265]. A recent study elaborated on the two poles of family influence on behavioural change [266]; the degree to which people's familial and social relationships either support or sabotage their making and maintaining lifestyle changes should be addressed [266].

Individual resources

The participants in paper II reported having a positive attitude toward life, in the face of and in spite of life's difficulties. They felt they could turn to their family and friends as resources when they experienced problems.

From a Salutogenetic perspective, how we experience ourselves and our surroundings is also influenced by our history [159]. Having the belief that the necessary resources, both the internal and external, for coping with difficulties are and will be available provides a higher SOC [210]. A successful change in lifestyle depends in part on the participants' ability and willingness to utilise and rely on their own internal coping resources [267]. Furthermore, when people experience finding meaning in handling difficulties, they also develop a higher SOC, and, consequently, improve both their coping abilities [159, 210] and sense of self-efficacy [132]. Another ability that seems essential to adopting a healthier behaviour was seen among some participants in paper II. They experienced that the challenges they faced were not merely burdens but also opportunities to confirm their ability to make the best of difficult situations. Though we have not performed comparative analyses of the participants in papers I and II, it seems as if important internal coping resources were more apparent among participants in paper II than those in paper I. While support is important, previous experience of one's own capacity to cope also has a positive impact.

6.1.3. Effect of lifestyle programmes on T2D risk and BMI

In paper III, part I, the small reduction in the BMI of participants within the selected sample of older adults was not significant – a mean BMI decrease from 30.2 at baseline to 29.7 kg/m^2 one year after the end of the programme. Their mean $HbA1_C$, however, did decrease significantly. Also, the women' mean waist circumference had decreased 4 cm as of one year after finishing the programme.

A BMI range of 23.0-29.9 kg/m^2 is associated with optimal longevity for older adults [268, 269]. Older individuals at risk for T2D appear to have lower expectations and less clarity regarding lifestyle changes [270]. Other studies have found that aging in itself is an independent risk factor for metabolic changes leading to impaired glucose tolerance [271, 272]. Thus, the small changes in the BMIs of older participants in the present study should be interpreted as positive since the aim of the VEND-RISK Study was to prevent further development of overweight, obesity and T2D. From the time of the HUNT3 survey until one year after the VEND-RISK Study, none of the participants in our study developed T2D.

Other studies besides the VEND-RISK Study have found that T2D can be prevented through individuals at high risk attending lifestyle programmes [120, 121, 135]. The resulting lifestyle change has also been sustained, suggesting a long-term prevention of the progression to T2D [124]. There is a need to replicate long-term, experimental studies in primary health care settings to examine the feasibility of lifestyle programmes, as well as the resources required and the optimal level of intensity, necessary to prevent T2D. During the past five years, several studies have transferred T2D prevention interventions from RCT settings to local primary health care settings [139, 273-275]. This reallocation has been found to be feasible and to yield successful results regarding the risk of T2D [139, 273-275]. However, studies are needed also to evaluate the long-term effectiveness of prevention of T2D within the primary health care setting.

The contents of each lifestyle programme will depend on the available resources of the local primary health care system where the programme is offered. Paper III aimed to include participants with a high risk for T2D who had attended the

HLC lifestyle programme in accordance with National Norwegian recommendation. The first paper ever to focus on participants in a Norwegian HLC programme was published in 2013 [276]. That study investigated physical capacity and COOP/WONCA scores and found that both had increased as of one year after the programme ended [276]. Unlike the present VEND-RISK study, however, that HLC study did not investigate T2D risk, nor other clinical measures.

6.1.4. The influence of low socioeconomic status (SES) on lifestyle

The second part of paper III focuses on the 86% of the people invited to participate in the VEND-RISK Study who had declined; they had all been identified as being at high risk for T2D according to the baseline HUNT3 Survey. We compared them to the remaining 24%, also at high T2D risk, who had accepted the invitation and had participated in the programme. The women in our results who had declined to participate had reported (in HUNT3) completing fewer years of education and were more frequent unemployed. More than the women who participated, furthermore, the women who declined to participate reported that their health affected their social relations.

In the general HUNT3 Survey it was found that those who did not participate had a lower SES, and a higher prevalence of chronic diseases as compared to those who did participate [277]. The participation rate in HUNT3 among Nord-Trøndelag inhabitants > 20 years was 54% [277]. As we found in our study, non-participants in a comprehensive CVD lifestyle intervention trial reported having lower levels of education and were more likely to be unemployed than were participants [278]. Thus, we cannot yet know how well-suited the VEND-RISK Study is for lower SES participants, even if thought they are equally in need of lifestyle-related disease prevention. Others researchers have suggested that unemployed people should be specially targeted for participation in lifestyle programmes [279], as we also conclude in paper III. Based on paper I, for which the inclusion criteria were broader than for participation in papers II and III, we should expect more psychosocial and health related issues. A strategy more specifically targeting coping resources in order to

achieve long-term lifestyle changes might be advisable. The participants in paper I and II are carrying different baggage (see **figure 16**).

People with low SES, including low levels of education and/or work status, tend to engage more in higher health-risk behaviours [280]. In HUNT3, the incidence of overweight, obesity and T2D was found to be higher among people with low SES [281]. An increased prevalence of disharmonic family environments has been found among lower SES families, characterized by violence, neglect, abuse, parental addiction, harsh parenting methods, negative belief systems and a lack of family cohesion [282]. Others have also reported that SES disadvantages are linked to emotional distress [283], and experiencing years of lower SES may contribute to allostatic overload [203]. A causal model of weight gain has been published underlining that the disadvantages of SES, with the accompanying emotional distress, comprise a starting points for a cascade of events leading to disrupted energy homeostasis, which then leads to weight gain [284].

The results from our three papers highlight that more attention should be paid to people with greater baggage and fewer resources, allocating more resources to them than to others in HLC lifestyle programmes.

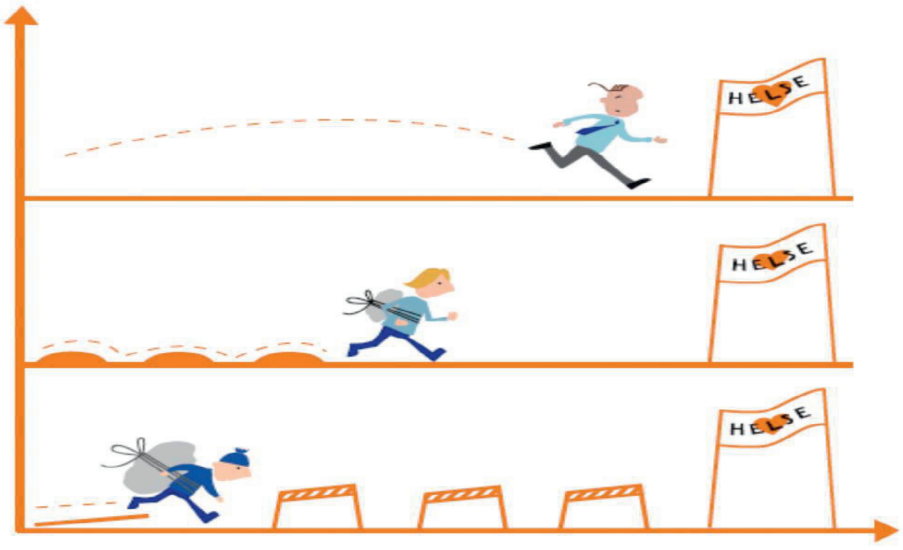

Figure 16. A model showing that some people carry more baggage on their way to health. The figure is reproduced with permission from *The Norwegian Ministry of Health* ILLUSTRATØRENE v/Elisabeth Moseng [285].

6.2. Methodological considerations

Two qualitative papers (I and II) and one quantitative paper (III) were included in the present thesis. The qualitative and quantitative research approach methods involve essentially different paradigms [286] and thus must be considered for discussion separately. Qualitative research seeks to illuminate, understand, and extrapolate phenomena and situations, while quantitative research aims to identify associations and causal relationships, predictions and generalization of findings [287].

6.2.1. Considering the qualitative research approach (papers I and II)

The intention behind these papers was to grasp and describe the meaning that the participants ascribed to their experience [217]. In accordance with recommendations for qualitative analyses, we aimed to reach a deeper understanding of the phenomena under study involving people attending an HLC lifestyle programme. Thus, their histories as told by them, the way they expressed their presuppositions and experiences, as described in their own words and from their perspective, were analysed using a phenomenological approach. For paper I, we examined how the participants described their previous life experiences in relation to changing lifestyle. For paper II, we looked both at how they experienced their lifestyle plus their experience of being at increased risk for T2D. The findings were discussed in relation to theoretical and/or conceptual frameworks [212], and also relative to previous studies.

When communicating qualitative research findings, it is important to convey and represent the research process in an accurate and detailed manner. For papers I and II, we pursued our aim for transparency by applying a reflective and systematic process that involved an assessment of its rigour, trustworthiness and transferability, in order to evaluate the quality of the findings [213, 288].

Rigour

The criteria for rigour include that the aims be clear, the background and setting adequate, the material precisely described, and the analysis well-documented [213].

Initially, the aim for paper I had been to study the participants' expectations as they started attending an HLC lifestyle programme. Unexpectedly, the participants began spontaneously to share their prior experiences and reveal the emotional baggage they carried, which they considered to be central phenomena in relation to lifestyle change. The researchers chose to follow the themes the participants raised as being important when attending a lifestyle programme; thus, the very aim of the study was altered. This shift in focus was not elaborated on in the published paper, although recounting it might have contributed to higher transparency. It was discussed in the research group and the shift was described in the feedback to the reviewers of paper I. The original aim for paper II included what the researchers considered relevant for the participants, and it remained unchanged throughout the process of data collection and the writing of the paper.

The aim in using a semi-structured design for the in-depth interviews in papers I and II was to elicit descriptions of the participants' life-world in order to interpret the meaning which the phenomena they described held for them. The interview guide was intended to assure that the interviewers would remain open-minded, without the questions being standardised. Semi-structured interviews were conducted since the participants' stories and their views, from their own perspective, were considered to be most important. A dialogue aim gaining insight into the participants' world view became a source of learning and an arena for understanding, and to help elaborate on the phenomena to be studied. Consequently, the topics raised by the participants were pursued and the interview guide for paper I was modified to include the new topics.

We do not know if focus group interviews or observational designs might have afforded as much or even better insight than did the individual in-depth interviews and the other perspectives in our papers. For paper I, we doubt that other designs would have yielded equally nuanced information. Such information is not easy to access using observational methods. Also, it involved information that was highly sensitive and difficult to speak about under any circumstances, but particularly in groups where participants do not know each other. In addition, we included the participants consecutively, immediately after they began at the HLC, to find out their expectations and experiences as early as possible. That would have been difficult to accomplish

using focus group interviews. For paper II, focus groups rather than individual interviews might have worked. Individual interviews, however, allowed us to arrange the time and place to accommodate each of the participants. Individual interviews also contributed to our collecting a saturated material thus insuring us sufficient insight and depth.

In Chapter 4.3.3. and 4.5.3. we described as thoroughly as possible the steps involved in performing the analyses. The computer program MindJet Mindmanager was applied during the transcription process for both papers to help organise the data systematically. QSR NVivo 10 was used for coding and to get an overview of themes, subthemes and related themes. The program was quite helpful; one could listen to the interviews while simultaneously reading and sorting out meaning units and codes. It is important to keep in mind, however, that the program is only a tool. The analysis was thought through as described in the steps in the Methods.

Trustworthiness

In the interview setting, a friendly and empathetic approach was emphasized. When meeting the participants, we aimed to build trust as well as to ensure an equitable balance of power. No attempt was made to manipulate the conversations toward any particular phenomena of interest [215] and unexpected topics arose during the interviews. In paper I, we altered the aim of the study in response to the strong interest the participants had in sharing how they perceived their life experiences. This may imply good credibility. During the interviews for paper I, the informants were unexpectedly open about their personal stories, and the interviews were much more emotionally touching than expected. Some said during the interviews that they were talking about things they had not talked about for years. Some even said they had never before told anyone about those things. Other researchers have postulated that high-quality data may emerge when participants reveal something deeply personal about themselves [289]. However, as an interviewer, one had to maintain professionality, even, or perhaps especially, in moments when the informants were upset. The interviewer had experience working with patients in clinical settings regarding overweight and obesity, and were used to talking with participants in both

clinical and research settings – but not in a face-to-face interview setting. The use of body language and eye contact became important in meeting participants' expressions of feelings. The interviews succeeded in helping the interviewees feel safe enough to continue to speak, despite how emotional the topics they were speaking about were. The same process was followed for paper II, though the interviews were not as highly charged emotionally, and the participants were also speaking more often about more positive feelings.

Transferability

The researchers' backgrounds and positions impacted on the approach used for this study. Our values must also be considered, particularly regarding our inquiry into the meaning of the data [213]. Thus, to ensure transferability, preunderstanding were written down before the interviews (Chapter 4.7.2.). For papers I and II, the research group consisted of people with different academic backgrounds and clinical experience; thatbrought a variety of perspectives to the analysis of the results. For paper I, all three research group members read the same interviews, by the time the main themes were to be drafted, there were differing views as seen from different angles. For paper II, there were also diverging views when the summary of the findings was to be made. This underpinned the reflexivity of the results. To validate and consolidate transferability, the transcripts were checked and rechecked throughout the process of analysis to verify that the final themes were rooted in the data. The transcripts for both paper I and paper II were also appraised critically.

Also important for establishing study transferability is the richness of the data collected [290], which is dependent on the complexity of the phenomena studied and the quality of the data [288]. Interviews for both papers I and II were continued held until no new themes arose and we could conclude that the data were saturated. In all, there were 234 pages of transcribed interviews for paper I and 398 pages for paper II.

6.2.2. Strengths and limitations of the quantitative method (paper III)

Study design and sample

For the first part of paper III, a longitudinal, non-randomized, single-arm, observational pre-post design was used to investigate the effect on changes in the health characteristics of participants in a HLC lifestyle programme (the VEND-RISK Study). Measurements were taken first to establish a baseline, then at the end of the lifestyle programme, and, finally, one year after the programme ended.

Longitudinal design is a quasi-experimental research design that involves repeated observations of the same variables to permit drawing comparisons over long periods of time [291]. The design used here was aimed at helping to detect developments or changes in the characteristics of the sample from baseline through follow-up.

Longitudinal, non-randomized, single-arm studies may involve the same individuals. Unlike cohort-studies, the differences are observed within the groups, before (pre) and after (post) the intervention, and are less likely to be the result of cultural or generational differences [292].

However, RCTs, for which the selection of participants in two or more interventions is random and not determined by the characteristics of the participant, are considered to be the gold standard for determining whether or not an intervention works [221]. Single-arm studies are useful for assessing the effect of novel regimens for which it may not be feasible, or desirable, to use an RCT. Single-arm studies are often used before performing larger scale RCTs.

The lack of a control group for the follow-up of our study weakens the generalizability of our findings and might represent a systematic bias, especially regarding the motivations of the sample. Randomizing participants into a treatment scheme that focuses solely on lifestyle change, without their overt consent, perhaps even against their will, risks leading to very low compliance.

Also, there are few studies that evaluate the effects of lifestyle programmes similar to the HLCs more than three months after the programmes have ended [167]. As such, these can not address the programmes' long-term impact. We believe that one

strength of our study is having follow-up data from one year after the programme ended. In addition, the VEND-RISK Study was not adjusted to fit a research programme. The duration of the programme, with its data collection and implementation through the HLC in the primary health care setting, was longer (one year) than the three months other HLC programmes normally schedule. Data were not gathered regarding comorbidity as the programme was focused on participants at risk for T2D, but the effects implicit in that information would have been interesting to study.

The longitudinal study sample size was limited and the statistical power was low. To compare participants in HLC with non-participants, we performed multiple logistical regression analyses, adjusting only for age and gender, instead of using a more advanced model to adjust for all potentially relevant variables. We performed multiple comparisons, which may have increased the risk for type 2 errors; we could have lowered the significance level from 0.05 to 0.01 to avoid such risks. However, others have stated that not making adjustments for multiple comparisons may in turn lead to fewer errors of interpretation when the data under evaluation are not random numbers but actual observations from nature [293], as was the case in our study.

In the second part of paper III, a cross-sectional design based on the HUNT3 data was used to distinguish participants' in the VEND-RISK Study from non-participants. Cross-sectional design is used in observational studies. Its defining feature is that data are collected from one or several groups at a single point in time. A cross-sectional design provided us the possibility to compare the groups. However, it could only yield information about associations [292] and it offered limited help in elucidating causal relationships.

Validity

Validity is divided into those inferences that pertain to the subjects of the study, i.e. the internal validity, and the degree to which the results are applicable to other samples, i.e. the external validity [292].

For paper III, we assumed that the participants we included were engaged in healthy behaviour. The observation that individuals who volunteer to participate in a

study have better health than individuals not volunteering to participate is called a "healthy volunteer bias" [294]. The temporary change in behaviour that might occur when the participants know they are in a study and are being observed can lead to a bias called the "Hawthorne effect" [295]. Though this effect is likely to have faded by one year after the intervention ended, had the study been two-armed, the effect could have been avoided entirely.

Internal validity

A research nurse collected all information for the first part of paper III and an exercise physiologist measured aerobic capacity with the maximal oxygen uptake (Max VO_2). The knowledge and experience they both had using international standards and procedures in research was expected to increase the internal validity of the study. However, the low sample size and missing information of Max VO_2 from follow-ups reduced the internal validity of the study. However, we were not able to evaluate intervention effectiveness using Max VO_2 as we had intended, there were other measures of physical activity. Furthermore, Max VO_2 is a demanding resource, and is not normally used in HLC settings to evaluate effects.

Increasing internal validity further, both the VEND-RISK Study and the HUNT3 Survey measured height, weight and waist circumference according to international standards [223, 281], which are considered by others to give far more precise results than self-reporting [296]. In self-reported studies, persons with overweight and obesity have been found to underestimate their weight [297, 298].

6.3. Ethical discussion

People with overweight, obesity and T2D may be vulnerable to stigmatisation in the general society, which might also be reflected in health care and other settings.

6.3.1. Trust

It was emphasized in the interview situations for papers I and II that the participants were of primary of importance. Nonetheless, one may have to improvise when

interviewing and use one's own judgement to establish trust, in that specific situation and in that intersubjective relationship which involves that particular participant.

The person in the position of researcher interviewing people in lifestyle programmes might not manage to keep the participants' equality as human beings in the foreground; participants may experience themselves as inferior in a research situation, and feel powerless. Nonetheless, the researcher's own individuality in the relationship with the participant needs to be emphasized; people recognise themselves while acknowledging others. In the interview situation, people are equal though different. Our similarities enable us to understand each other and ourselves. In the dependency on each other that we carry as part of our collective humanity, the relational person stands at the centre [299]. This was of utmost importance in the research setting: to acknowledge the participant as a fellow human being and to value all participants, both for being there, for their appearance just as it was, and for sharing their stories.

6.3.2. Shame

In paper I, ethical issues were involved when meeting participants who had previously attempted to lose weight and change their lifestyle, and who described not having succeeding as being yet another layer of negative experience.

Shame can arise from experiencing a pervasive pattern of societal condemnation, and as a response to one's failure to live up to a certain standard. In today's society, it is expected that we all take responsibility for our own body and health by exercising and eating healthy food. The great myth that more and more self-discipline and willpower will win in the end may well sabotage motivation. People who have attempted self-management of their lifestyle change time and again without success may run into the motivational roadblock of shame. The emphasis placed on personal responsibility for being overweight or obese can intensify feelings of shame [300].

As participants in paper I explained, their weight gain was triggered initially by emotional distress; then, the stigma they may experience in society and/or among health personnel may exacerbate that distress, sending them deeper into a spiralling

cycle of negative emotions about themselves and their bodies. In part, being overweight and obese might be an unconscious attempt to solve other problems dating back to their earliest years, though obscured by time, shame and social taboos against revealing and exploring certain areas of life experience [54].

The desire and ability to seek to understand participants such as those in paper I as fellow human beings in need of changing their lifestyle is an implicit prerequisite for performing a qualitative study with a phenomenological approach. As previously seen with participants in a lifestyle change process, and as studies have pointed out, people who seek help for their overweight and obesity usually have a negative self-image as relates to their body and they are often victimise and/or blame themselves for the condition [301]. In addition, health care professionals (GPs, nurses, psychologists) have been found to hold negative attitudes towards people with overweight and obesity [302].

Most participants in paper I were in a vulnerable situation; the majority had a body size that caused them to seek help. The participants wishing for change must act on the basis of resources embodied in their habitus; the body can not be understood as an entity separable from the mind and consciousness [208]. The lived body serves as the foundation of our perspective, and constitutes our inter-subjectivity [303]. As participants in paper I wished to have understood, feelings are not merely some phenomena "hidden behind the body's facade". Rather, there is a concurrency between the body and the emotions [304].

In the data collection for both papers I and II, neither the participants' body size or weight were relevant to the aim of the study: elaborating on the phenomena we intended to explore while acknowledging the participants as fellow human beings was the main focus. In the interview situation, seeing participants, trying to understand their vulnerability, and showing empathy when listening to their stories, came spontaneously.

The importance of embracing the needs of people living with overweight and obesity with appropriate sensitivity regarding weight and body size are yet to be adequately addressed.

7. CONCLUSION AND IMPLICATIONS

7.1. Implications for practice in lifestyle programmes

Wide differences in the effectiveness of lifestyle programmes have been reported. This may be indicative of differences in the participants, the programmes' content and/or the people conducting the programmes. Others have suggested that how programmes are delivered by health personnel may be crucial for their efficacy [305]. The profound importance of having adequate help and guidance from health personnel when starting lifestyle change must not be underestimated [236]. Health personnel can make the situation more comprehensible to the participant, drawing attention to resources and contributing to the participants' customising of their goals in line with their capacity [306]. By learning more about which factors influence lifestyle change, health professionals will more able to offer an approach based on the individual's needs [173].

The results from the papers I, II and III indicate that each individual's experiences should be assessed in order to locate where more effort is needed to facilitate that individual's process of lifestyle change. Unfortunately, the potential exists for encouraging individuals to enter self-defeating cycles of negative health behaviours. Attempting to motivate people who struggles with feelings of shame is more than likely to be counterproductive and unsuccessful. The struggles a person may experience when trying to make a lifestyle change can become enormously frustrating over time, which can cause or worsen psychological issues [29]. Failure to recognize, acknowledge and address underlying causes, complications and barriers is likely to result in poor compliance and high rates of recidivism, making the psychological and social consequences of their lifestyle an even greater source of shame and blame. In general, internalization of negative weight-based stereotypes may result in further decreased motivation to engage in efforts to implement lifestyle change [209].

Helping individuals who need to strengthen their capacity to utilise available resources might be important in improving outcomes of lifestyle intervention

programmes. Emphasizing what works well in the participants' lives, and asking questions that increase their awareness of the resources they have at their disposal, should be a priority [307]. Through talking about feelings and options, their life history and situation, people may be even more likely to come up with good solutions for themselves, as well as becoming more amenable to receiving advice [308]. Strengthening the Salutogenic factors for participants, acknowledging the meaning for them of what had caused their need for lifestyle change to begin with, are also important (**figure 17**). Personnel working with lifestyle programmes should acknowledge that every person has a story, one that helped to put the person into the position of having issues related to lifestyle.

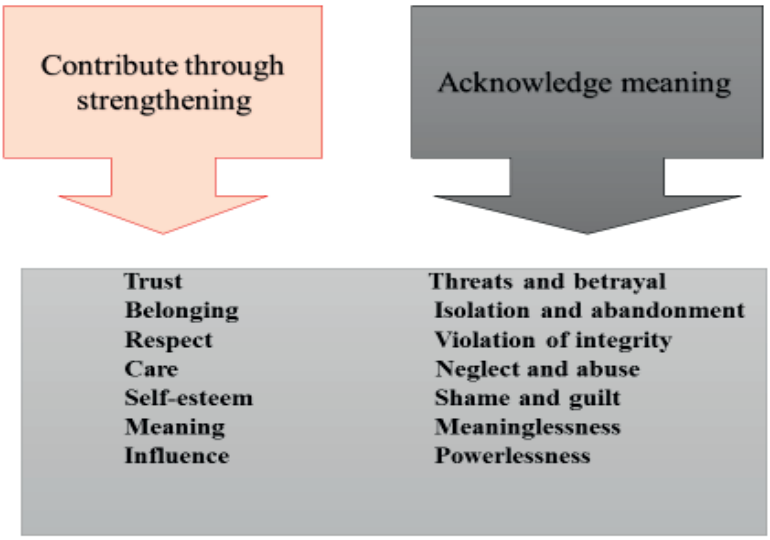

Figure 17: Potential topics to explore to help participants with emotional distress examine previous positive and negative experiences. The figure was drafted by *The Research Group for General Practitioners (AFE), NTNU* and used with their permission.

7.2. Political actions

As the public health picture has changed globally, health authorities and researchers have acknowledged the need to intervene in the epidemic of people becoming overweight and obese [8, 14, 309] and developing T2D [310]. However, any programme to prevent overweight, obesity and T2D, must be comprehensive [311,

312]. Sustainable, on-going interventions on multiple levels of health promotion and prevention over the course of several years would be required [313].

The Norwegian white papers, laws, instructions and guidelines require primary health care to act to prevent disease [7, 11, 154-156, 314]. The HLC programmes will be an important element in future work regarding health promotion and disease prevention [156]. Experiences from the HLCs may provide the basis for further development and the establishment of more such programmes.

From a *health promotion perspective*, to prevent a further increase in overweight, obesity and T2D there should be a sector change within shops, agriculture, food services, education, transportation and urban planning [313]. In addition, it is important that policy makers become knowledgeable about the evidence documenting the health consequences resulting from weight stigmatization, and then encourage the development of policies to counter such stigmatizing, in schools, workplaces, and medical settings [315]. *Primary prevention* should include campaigns in kindergartens, schools, local environments and workplaces. *Secondary prevention* involving GPs and public health nurses is important for the task of identifying those who may need help regarding lifestyle issues, and also recognising those whose life histories, such as adverse events, may impact their health behaviour. *Tertiary prevention* should address individual behaviour change and/or group programmes, both in the primary and secondary health care [313].

7.3. Future research

Based on our findings, future research could:

- Explore indicators that promote lasting change and see what characteristics persons who succeed at purposefully making long-lasting lifestyle changes have in common.
- Investigate the effect of lifestyle programmes on other age groups for prevention of overweight, obesity and T2D.
- Study follow-up data of the health measurements of the participants and non-participants in the VEND-RISK Study in the next HUNT4 Survey in

2017-2019, to track the changes over time and both whether and how attending the lifestyle programme had affected health outcomes.

- Explore how health personnel in HLCs perceive and experience working with participants pursuing lifestyle change.
- Performing a systematic review of primary health care lifestyle programmes to prevent T2D.
- Use qualitative methods to study unselected participants in HLCs through a series of interviews over time in order to elaborate on the understanding of their experiences with HLC.
- The VEND-RISK Study's measurements of the two, three and four year post-intervention follow-ups have not yet been examined.

7.4. Closing remarks

The main purpose of this thesis was to increase the understanding of individuals' presumptions for lifestyle change when attending lifestyle programmes in the Norwegian primary health care, and to see if participation in such a lifestyle programme could contribute to reduction in overweight, obesity and preventing T2D.

These thesis results raise questions about how health services should handle lifestyle change and who is most likely to benefit from lifestyle programmes. The recommendation to "eat less and exercise more", which has been the main advice offered to people with overweight and obesity since the time of Hippocrates, is apparently not optimal. It seems clear that overweight, obesity and T2D is not simply an issue of will power or self-control.

The importance of prevention programmes at a population-based level, such as health promotion strategies that target all individuals, should be highlighted in the future. Most essential: the existential needs for feeling a sense of belonging and for self-worth should take precedence over physical activity and nutrition.

Epilogue

While working on this thesis, I have included topics from it in the teaching I do in "Obesity and Health" for MSc students at NTNU, in "Public Health" for postgraduate students and in "Physical activity" for BSc students, both at Nord University. I have also had the privilege of giving presentations to GPs and other researchers/health personnel that have allowed me to spread my findings, and increase engagement in this PhD work.

Papers I and II from this thesis were used in the new National Instruction Manual for HLCs that was revised in October, 2016. I sincerely hope this thesis can help build understanding of participants' presumptions for lifestyle change and encourage further work with prevention of overweight, obesity and T2D in the Norwegian primary health care.

I have been looking back at the beginnings of my work with this thesis. I came to it from the field of specialist health care, where I worked with research on overweight and obesity and was on the lookout for ways to prevent of lifestyle-related diseases within primary health care. It did not turn out quite as I thought. Sometimes, our most important lessons are the ones we learn the hard way. Entering deeply into the stories of the participants in paper I, I uncovered and learned to cope with painful negative emotions in myself. After that experience, I wish even more that people with lifestyle issues had less stigma to cope with and were met with more understanding of the reality that it is not necessarily as simple as "eating less and exercising more". When I think of about what could be done, I remember what one of our participants said: *"I only want to be seen for who I am, not my weight or HbA1c. That someone who knows my story, why I am here, still smiles at me and gives me a pat on the back. I have been starved for that my whole life..."*

List of figures and tables

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Paper I-III

Paper I

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Previous experiences and emotional baggage as barriers to lifestyle change - a qualitative study of Norwegian Healthy Life Centre participants

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Abstract

Background: Changing lifestyle is challenging and difficult. The Norwegian Directorate of Health recommends that all municipalities establish Healthy Life Centres targeted to people with lifestyle issues. Little is known about the background, experiences and reflections of participants. More information is needed about participants to shape effective lifestyle interventions with lasting effect. This study explores how participants in a lifestyle intervention programme describe previous life experiences in relation to changing lifestyle.

Methods: Semi-structured qualitative in-depth interviews were performed with 23 participants (16 women and 7 men) aged 18 – 70 years. The data were analysed using systematic text condensation searching for issues describing participants' responses, and looking for the essence, aiming to share the basis of life-world experiences as valid knowledge.

Results: Participants identified two main themes: being stuck in old habits, and being burdened with emotional baggage from their previous negative experiences. Participants expressed a wish to change their lifestyles, but were unable to act in accordance with the health knowledge they possessed. Previous experiences with lifestyle change kept them from initiating attempts without professional assistance. Participants also described being burdened by an emotional baggage with problems from childhood and/or with family, work and social life issues. Respondents said that they felt that emotional baggage was an important explanation for why they were stuck in old habits and that conversely, being stuck in old habits added load to their already emotional baggage and made it heavier.

Conclusions: Behavioural change can be hard to perform as psychological distress from life baggage can influence the ability to change. The study participants' experience of being stuck in old habits and having substantial emotional baggage raises questions as to whether or not Healthy Life Centres are able to help participants who need to make a lifestyle change.

Keywords: Primary healthcare, Health behaviour, Lifestyle change, Multi-comorbidity, Overweight, Qualitative research

Background

Lasting lifestyle change requires a substantial time investment. Individuals who want to take part in interventions that will enable them to change their lifestyle may encounter barriers to starting the process. Over the last few decades, there has been increasing interest in Norway in enabling people to make lifestyle changes [1–3]. In 2011, the Directorate of Health recommended that all municipalities establish Healthy Life Centres [4].

Healthy Life Centres are a service offered by the primary health care system that target people who need to change their lifestyle in terms of physical activity, diet and tobacco use to improve their health or prevent unhealthy lifestyles [4]. The background for creating Healthy Life Centres was to counteract the growth in lifestyle-related disease in the Norwegian population. The increase in individuals that are overweight, obese and have type 2 diabetes, coincident with reductions in

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physical activity and increased high-caloric food intake, are among the most important changes in the Norwegian population from 1986 to 2010, as measured by the population-based HUNT study [5]. In spite of these developments, there has also been an improvement in the overall health of the general population, but health behaviour varies systematically with social background [6]. Lifestyle-related diseases show a clear social gradient, where social inequalities represent a growing problem [7]. Studies that examine interventions to reduce lifestyle-related diseases have shown little effect on primary outcomes, such as for type 2 diabetes [8] and are burdened with high dropout rates [9]. The results from a Healthy Life Centre study in Norway [10] were in line with international findings [11, 12], although participants had increased their physical capacity and health-related quality of life when the intervention ended [10].

The theoretical foundation for Healthy Life Centres is a salutogenic approach that aims to help participants gain confidence in their own resistance resources and increase their ability to change their lifestyle [4]. Lifestyle change depends on individual behavioural factors. Multiple individual factors as social, psychological and practical barriers can make lifestyle change hard to perform [13]. Performing lifestyle change and adherence to change is a continuous process and contains several different phases [14]. Behavioural change theories have not in particular dealt with psychological or emotional distress [15–17], although they present several are common factors that are important for lifestyle change: social relations, attitude, stages of change and self-efficacy [18]. Individual barriers to lifestyle change may be countless and they can be hard to address by health care providers [19]. Previous negative life experiences could cause psychological or emotional distress [20] and are known to negatively affect the ability to change lifestyle [21]. Addressing psychological and emotional distress as barriers to lifestyle change may help improve outcomes from lifestyle change programs. To the best of our knowledge, the relevance of background characteristics of participants, including their life experiences, intentions and expectations, has not been previously explored. The aim of this study is to examine how participants in a lifestyle intervention programme describe previous life experiences that are important for lifestyle change when they entered Healthy Life Centre intervention programmes.

Methods

Design

A qualitative study was designed to explore how participants described previous life experiences that they identified as important for lifestyle change upon entry into a Healthy Life Centres intervention programme.

Interviews and interview guide

Individual in-depth interviews were conducted from February 2013 to June 2013 at two Healthy Life Centres in Central Norway. The interviews lasted between 15 and 78 min, with a mean time of 42 min. The first author performed the interviews. The interviewer wrote down additional notes and reflections right after each interview.

A semi-structured interview guide was used to ensure that all aspects addressing the questions in the study objective were covered. The interview guide included the participants' reasons for attending Healthy Life Centres, their previous lifestyle and their expectations upon starting an intervention programme for lifestyle change.

Healthy Life Centres

Healthy Life Centres offer physical activity as both in- and outdoor optional activities two to four times a week, and as either individual or group-based activities with a physical therapist. The centres also offer a healthy diet course composed of five, two-hour sessions. A tobacco cessation programme is offered both as individual sessions and group-based courses that are run six times. Healthy Life Centre personnel practice principles of motivational interviewing with a focus on exploring ambivalence and helping participants to change. An intervention period lasts for three months, with the ability to extend the period two additional times for a total of nine months altogether. General practitioners can refer patients to a centre, or participants can contact a Healthy Life Centre themselves. Healthy Life Centres serve as a low threshold health service, and Norway's public health insurance covers the cost of participation in centre programmes.

Recruitment and participants

All Healthy Life Centre participants were eligible for the study, although there was a preference for individuals who had just begun attending an intervention programme. Personnel working at the Healthy Life Centres helped in the recruiting process. A strategic sample of informants, based on their age and gender were invited to the study at a mandatory health conversation. The personnel informed the participants that they helped recruiting and that they as personnel were not part of the study. The personnel also told that if they participated in the study or not, it would not affect the participants period at the Healthy Life Centre. Recruitment proceeded continuously until data saturation.

Altogether, twenty-three participants aged 18–70 years, with a majority of women, participated (see Table 1). More than half of participants received a referral from their general practitioner to the centre (52 %), while the rest had contacted the Healthy Life Centre on their own (48 %). Multi-comorbidities were common (91 %) among participants, with a range from zero to

Table 1 Informant characteristics

Characteristics	Number of informants
Gender	
Females	16
Males	7
Age	
18–29	4
30–39	4
40–49	5
50–59	5
>60	5
Ethnicity and language spoken	
Norwegian	23
Civil status	
Single/Separated	9
Partner/Married	14
Education level	
Some college	4
No high school diploma	4
High school graduate	11
Bachelor's degree or higher	4
Work status	
Not working[a]	13
Working < 50 %[b]	4
Studying or working > 50 %	6
Previous attempts to change lifestyle	
Specialist health care interventions	7
Primary Health care interventions[c]	8 (+7)
On their own[d]	8 (+8 + 7)
Started at the Healthy Life Centre	
Less than three months ago	15
Three months ago	7
Six months ago or more	1

[a]Three were retired at the age of 62 years or more
[b]The percentage varied from 13 % to 50 % in workload
[c]Those who had been in specialist health care [7] interventions had previous tried interventions with their general practitioner or other primary health care personnel
[d]Those who had been in specialist health care [7] interventions and those who had tried primary health care interventions [8] had earlier attempts on their own to change lifestyle

eight different diagnoses. Participants frequently reported lifestyle-related diagnoses such as overweight and obesity (83 %) and type 2 diabetes (22 %). These illnesses were prevalent and multiple diseases were often found concurrently in the same individual. Participants also reported muscle- and skeletal diseases (30 %) and psychological issues (26 %).

Participants had previously tried to follow advice from their general practitioner regarding diet, smoking and physical activity. In addition, participants commonly reported unsuccessfully participating in different kinds of weight loss programmes at rehabilitation centres, or with the help of community psychiatric nurses, physical therapists, and general practitioners. Four of the participants were attending the Healthy Life Centre while were waiting for approval for a gastric bypass or other specialized health service. Fifty-seven per cent received benefits or help from the Norwegian Labour and Welfare Administration.

Ethics

All participants received both oral and written information so they could make an informed choice about participating in the study. All participants signed an informed consent form before the interview started. The Regional Committee for Medical and Health Research Ethics in Central Norway approved the study (REK nr 2012/1755).

The interviewer aimed to be friendly and non-judgmental during the interview. This is an important way of creating trust and a good relationship during the interview situation [13]. The interviewer used many interaction strategies to create friendly feelings and intimacy, especially with respect to sensitive questions and themes [22]. All participants were offered to read their transcribed interview. Only three participants accepted, and none had any comments to the transcript. Participants were also offered to know more about the content of the analysis, but none was interested

Data analysis

Audio recordings of all 23 interviews were transcribed verbatim. MindJet MindManager 2012 was used as a systematization tool during the transcription process to identify themes. Interview notes were added to the mind map. The data were analysed using systematic text condensation with a search for issues that described the participants' responses. The systematic text condensation were performed by looking for the essence, and thereby aiming to share the basis of the informants life-world experiences as valid knowledge [23]. The first author read all of the material, transcribed interviews and interview notes. The co-authors read three interviews, then met and discussed preliminary themes from each interview. This approach was used to assemble different opinions and perspectives, and to allow question to arise regarding differing interpretations of what the material meant [24]. The material was examined and broken down into codes, and then the codes were compared, conceptualized and categorized. NVivo 10.0 was used to sort meaning units derived from the material into codes. Material with the same content in the text was coded together. The mindJet MindManager mapping with preliminary themes that arose during transcription were added

during the coding process. The authors discussed, compared and merged codes. Different conceptions of the codes were also discussed, and then the codes were reorganized until authors came to a consensus on the main themes and sub themes. The quotations in the text have been translated from Norwegian to English.

Results

The participants' perceptions of barriers to lifestyle changes were categorized into two main themes: they were stuck in old behaviours and habits (main theme 1) and that they were burdened by emotional baggage from previous experiences (main theme 2). Interrelated content was included in sub themes (see Fig. 1). Participants who came to a Healthy Life Centre also said they found it hard to know where to begin to change when there were so many difficult elements in their lives.

Main theme 1: stuck in old habits

The theme "stuck in old habits" described the situation the participants faced when they began attending the intervention programme. Participants described old habits as barriers to change, including behaviours such as unhealthy food habits, being sedentary, being addicted to tobacco, and often choosing unhealthy behaviours in everyday life. They needed to change their lifestyle because their lives were adversely affected by their behaviours, which in turn affected their surrounding environment, including their children, grandchildren and work. They said they felt their lifestyle had gone in a direction that led them to ask for help to change. Participants also used the phrase *"I should have..."* several times during the interviews:

> *"Why do we have these kinds of habits? I have to try to find the key to change the bad habits I have gotten into. I should lose some weight. I should quit smoking. I should work out more. Everything I do is wrong. I have to start somewhere..."* Woman *40–49 years*

A common sentiment among participants was the appreciation for being able to get help from the Healthy Life Centre. They also commonly expressed the hope that they could turn their negative health behaviours around. The personnel's friendliness was also mentioned. Participants who had lifestyle diseases said they wanted to have a healthier life and lose weight. Those few who did not have any lifestyle diseases were concerned about gaining weight and developing cardiovascular disease and type 2 diabetes.

Knowing, but not doing

The participants said that lack of knowledge was not the reason for failing to change their lifestyle on their own, but that the barrier was knowing how to start a change that would last. They found it paradoxical that they knew what to do, but were unable to act. They expressed hope and had the motivation to change their lifestyle, but did not initiate changes on their own. They saw the Healthy Life Centre intervention as a solution for their need for help and an opportunity to get started with activities that could work for them. One said:

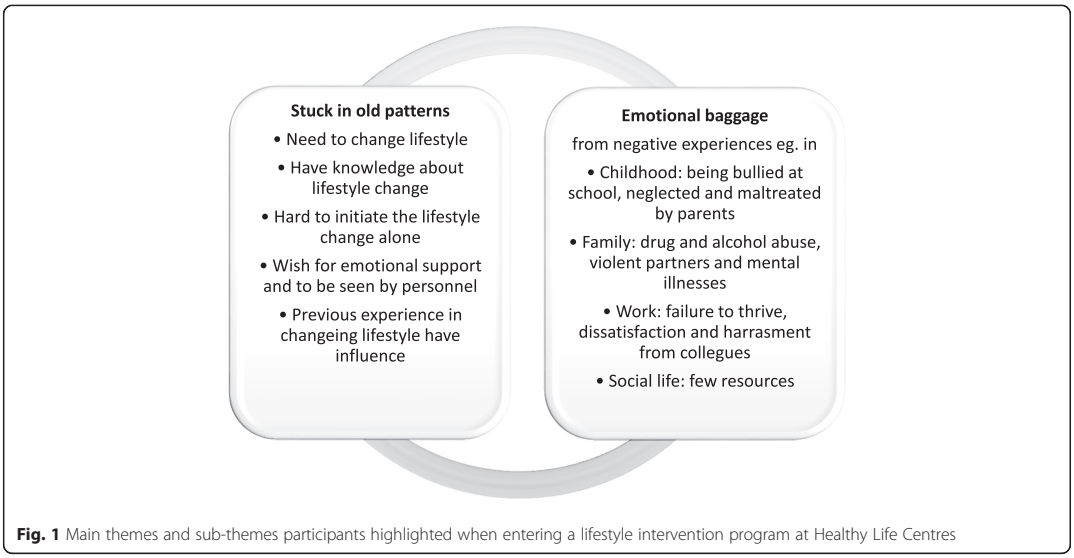

Fig. 1 Main themes and sub-themes participants highlighted when entering a lifestyle intervention program at Healthy Life Centres

"I know a lot about good habits and things like that. I'm not clueless as to why I am so big. I know that I do not exercise, I eat unhealthy food, I know it and I know that it is not good for me. But I struggle with why I cannot do the right things when I know all this." Woman 18–29 years

Previous experiences in changing lifestyle

The participants' previous attempts to change their lifestyle became barriers to new attempts to change without supervision. At the same time, the previous attempts made them realize that at the beginning of earlier interventions they had expected the change to provide visible results quickly. Without any visible or measurable changes, they lost motivation after only a short period of trying. The participants found that there were no easy solutions to making lasting lifestyle changes. They stated their desire for long-lasting, permanent change, and said they did not want a temporary solution that would ultimately fail.

"I have started cures and programmes for exercising and dieting numerous times, but I expected everything to happen quickly. Now I am more aware that I need to start at the beginning and take one step at time. I want this to be a permanent change…." Woman 40–49 years.

The participants highlighted the importance of knowing that breaking from a newly changed good habit did not mean that the whole "good habit" pattern was destroyed. They asked for emotional support and to be seen by the Healthy Life Centre staff. These experiences were seen as important in giving them the courage to start and to continue gradually with healthy changes, and to be helped over time to make a long-lasting lifestyle changes. Most of them said that three months was too brief for them to succeed in permanently changing their lifestyles, given their starting point, and expressed the need to extend the intervention.

Main theme 2: Baggage from previous life experiences as a barrier to change

Participants explained that they were "stuck in old habits" because of previous life experiences that prevented them from initiating changes. Participants highlighted previous trauma or long-lasting bad circumstances as contributing to their need for a lifestyle change. Their emotional baggage included negative childhood experiences as well as other family and social experiences, which were accompanied by medical, psychological and social problems. One participant exemplified this complexity:

"I have so much emotional baggage from my life that explains this bad pattern I have gotten into. I have been used as a doormat all my life. I don't want this anymore. I had problems at my work where my colleagues harassed me, and I had problems in my private life and with bad childhood experiences. Then I lost my job. I struggled with migraines, and after all of these experiences, I was very tense. My general practitioner said that he assumed that I was depressed, and I was given medications, which caused me to gain weight, and I was somewhat overweight before. Now I have to lose weight and I can't do this by myself, I need help…"Woman 40–49 years

Childhood experiences

Several participants described childhood problems as a part of the explanation as to why they were needed help with lifestyle issues. These participants commonly described difficult childhood experiences. Some mentioned bullying at school during their childhood and youth and they said that they had had a hard childhood because their peers had tormented them. Another common problem was parents who were not affectionate or who were verbally abusive or dissatisfied with them. Hard feelings and emotional distress linked to childhood memories made their adult life difficult. One participant said that ever since she started school and on into her adolescence, her father had told her how stupid she was. She said that the feeling of not being good enough had stayed with her all her life. Another individual described the difficulties caused by an overly critical parent:

"When I hear his name I get tears in my eyes. All I have wanted my whole life is for him to be happy with me. He has always criticized me, everything I've ever done has been wrong…" Woman 30–39 years

Participants had clearly not come to terms with the burdens of their life experiences and the accompanying feelings from childhood; this lack of closure influenced participants' everyday life and burdened them, which in turn made making a lifestyle change hard to initiate and demanding to pursue.

Family, work and social life

Participants said they found criticisms from their current-day surroundings and social life to be debilitating. They commonly described negative experiences with family, friends, fellow students and colleagues. This could take the form of harassment at work, mental problems within their family, and violent partners. Some had histories of being bullied at their present workplace. Table 2 presents the issues participants listed concerning their family and social life.

These experiences affected participants' current life, and as they explained it, were a part of the reason why

Table 2 Quotes on life burdens

Participant	Quotes on family, work and social issues
Female 40–49 years	"I was bullied at my work place by almost all colleagues. I was also bullied in younger years. I think it makes me more vulnerable, all those memories from earlier bullying came alive with this new bulling at my work place. I have been crying a lot…"
Female 40–49 years	"I don't have any contact with my parents. I ended up with an abusive man. When I found myself a new man it was also a violent relationship...." In addition, one of my children have ADHD and I have been struggling a lot with all these things…"
Female 40–49 years	"My daughter is struggling in the same way as me with psychological problems and suicidal thoughts. I have several suicide attempts behind me. My daughter and I like to be at home by ourselves and I think that because of our problems we do not socialize much…"
Male 50–59 years	"When I first got married it turned out my wife was an alcoholic and her doctor said that she had little left time to live if she continued drinking like that. So with all the uncertainty with my wife being an alcoholic it all got messy. But I have to help her and be there for here, I cannot just run away…"
Male 50–59 years	"My daughter is a drug addict and I have tried to help her many times, knowing she would take all my money and run away again as she always does. Now I have not seen her in a while…"
Female > 60 years	"My daughter was abused as a child and she had many problems growing up, but it was as an adult she came forward and told me what had happened. She is mentally ill because of what happened and I have to be there for her and help her as she is often hospitalized. I have been feeling a lot of guilt and I do not understand that the abuse could have happened without me not knowing…"
Female >60 years	"I moved from my first husband because he was violent. I felt that it was better for the children to grow up with only their mother. Then I got a new husband and he had mental problems, which was demanding. I have now lost my husband and I also lost my boy, he became a drug addict …"

they were stuck in old habits. The continuing problems added to the heavy emotional baggage they already struggled with, which in turn made it hard to initiate a lifestyle change.

Discussion

The participants who entered intervention programmes at Healthy Life Centres were stuck in old habits; making unhealthy choices with food, activity and tobacco in their everyday life, which affected themselves and their environments negatively. They wanted to improve their lifestyle but were not able to act on the knowledge they possessed about healthy habits. Previous failed experiences with lifestyle change held participants back from making new attempts on their own, and made them realize that it takes time to establish lasting changes in habits and lifestyle. In their experience, there were no easy solutions. In addition, we found that participants had significant emotional baggage from being bullied in childhood and harassed at work, not having supporting parents, having violent partners and children with drug problems. This emotional baggage was an important reason for why they were stuck in their old habits and inversely, being stuck in old habits added to their already substantial emotional burden.

Establishing new habits in everyday life

Participants in lifestyle intervention programmes that are focused on nutrition and physical activity often go back to old habits after the intervention period [15, 16]. It appears that everyday life tends to get in the way of maintaining healthy habits [25, 26], and that it can be difficult for individuals who explicitly want a healthier lifestyle to consistently make the right choices and habits [27]. When physical activity and healthy diet became ingrained habits, participants could define themselves as successful, and the habits and their improved self image became a part of their new everyday life [28]. However, other studies have shown that many obese individuals still rely on 'quick fix' strategies in their struggle for permanent change [29]. The participants in our study saw the need for long-term lifestyle change, in part because several of the participants had made numerous previous attempts to lose weight. To get a referral from the general practitioner to the Healthy Life Centre, as half of the participants had gotten, may have had implication for these participants readiness for change [30]. The other half who had contacted the Healthy Life Centre themselves could acknowledged their lifestyle problems, and thereby be readier to perform lifestyle change.

Our participants told about the importance of not relapsing from a changed habit, known in behaviour change theories staged that those who have performed lifestyles changes are working to prevent relapse [31]. Three months with intervention was said by participants to be to short time to make a lasting change, and the time aspect of incorporating changed behavior is important [31]. Help from health personnel is important to achieve long-lasting lifestyle change [32]. Participants in our study were also thankful that the Healthy Life Centre and accompanying personnel had been established to help. Another study found participants who had tried to change eating and/or activity habits several times felt unable to do so by themselves without any support, and that they wanted someone such as their primary health care providers to help them with the process of change [29].

Emotional baggage

Studies have found that psychological and emotional overload from childhood can lead to negative coping behaviours and the suppression of negative emotions [33]. Furthermore, several studies have found associations between childhood mistreatment and unhealthy lifestyles as adults [34–38]. Childhood mistreatment can include neglect as well as physical, sexual, and emotional abuse [34, 37]. In our results, participants described different difficulties in childhood. Verbal abuse and lack of affection from parents were among the difficulties mentioned. In a person who lacks adequate emotional resilience, adverse childhood experiences can increase the risk of psychological and emotional distress with internal problems that may eventually cause a psycho-emotional overload [39]. Chronic stress over a long period, especially during vulnerable life stages, may have biological consequences in the long term [20]. Psychological distress from previous experiences in childhood can influence the ability to change negatively [20]. Previous experiences are key factors for self-efficacy [40]. Thus, experiences, which are negative, as they were for our participants, the self-efficacy, may be low. Consequently, the behavioural change gets harder to perform. A fundamental source of life satisfaction and emotional well-being is social support [41]. People with partners, family and friends who provide psychological and material support have better health than people with less social connections [42]. Studies have shown associations between social support and mental and physical health and variables for better health, such as physical activity, smoking and blood pressure [43]. Other studies found that those who failed to make lifestyle changes had more psychosocial crises such as grief, serious illnesses and personal or family difficulties [44].

Changing ingrained habits

The complexity of the etiology in lifestyle issues may have been neglected in the past. We found psychological and emotional barriers for participants as important to change their habits when they were starting a lifestyle change program. Given the Healthy Life Centres' salutogenic foundation, it is important to plan, act and intervene in accordance with the participants' resistance resources [45]. Differences in resistance resources have implications for how participants handle health difficulties, diseases and negative life events [45]. Participants need to strengthen their resistance resources during the intervention period at Healthy Life Centres. Strong resistance resources are associated with high self-worth, inner strength, belief of being in control of change, social networks with a strong degree of affinity and good economic situations [45], which may not characterize this study's participants. A successful change in lifestyle depends on the participants' ability to use and rely on their resistance resources [45]. The outcome after an intervention period depends on whether Healthy Life Centres have strategies to enhance the resistance resources so that participants can change ingrained habits.

Strengths and limitations

The strengths of the current study include the semi-structured interview form, where unexpected themes could arise. Participants themselves focused on their life stories and personal information to explain their situation, and thus, this became central to the study. In the study of complex human phenomena, qualitative interviews allow for ambiguity [15]. Lifestyle is an issue that affects so much of participants' lives that it was important that the interviews allowed for such ambiguity.

The variation in age and gender in our study reflects the population that uses the Healthy Life Centres in the region. Then again, because Healthy Life Centres are a primary health care service, their challenge is embracing a large and differentiated user group with a broad range of participants in terms of lifestyle issues. If we had relied on a more selective sample, such as women aged 50–60 years, we might have had more focused answers, but the utility of our results in a clinical setting would be questionable.

Conclusion

In Norway, Healthy Life Centres offer help in preventing and reducing lifestyle diseases. In our study, we found that participants who started a lifestyle intervention programme were stuck in old habits and had heavy emotional baggage. They wanted to change their old habits, but were unable to do so, even though they knew had information about healthy behaviours. Childhood and/or family, work and social life experiences were obstacles for lifestyle change. Previous negative experiences with accompanied psychological distress can influence the ability to change as self-efficacy may be low, which can make behavioural change hard to perform. Healthy Life Centres ought to consider the emotional burdens and previous life experiences of their clients as they work with participants to change old habits. However, our findings raise questions as to how health services should handle lifestyle change. Future studies should examine how lifestyle interventions in the Norwegian primary health care system are organized and how personnel can help participants with and promote lasting lifestyle changes. It remains to be seen who actually can benefit from Healthy Life Centres intervention programmes, and who will need other approaches to lifestyle changes, such as social or psychological interventions, or specialized health care treatment.

Competing interests
The authors declare that they have no competing interests.

Authors' contributions
ISF designed the study, with guidance from ASH. ISF performed the data collection and was responsible for the analysis. MS and ASH analysed parts of the data with ISF and all authors worked out the main results together. ISF drafted the manuscript and MS and AHS have continually revised the text and critically commented on the manuscript. All authors have given final approval to the manuscript.

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Paper II

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RESEARCH ARTICLE Open Access

Exploring lifestyle and risk in preventing type 2 diabetes-a nested qualitative study of older participants in a lifestyle intervention program (VEND-RISK)

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Abstract

Background: Lifestyle intervention may reduce the development of type 2 diabetes among high-risk individuals. The aim of this study was to explore how older adults perceived their own lifestyle and being at increased risk for type 2 diabetes while they participated in a lifestyle intervention programme.

Methods: A nested qualitative study was performed with 26 participants (mean age 68 years) in the VEND-RISK Study. Participants had previously participated in the HUNT3 Study and the HUNT DE-PLAN Study, where their risk for developing type 2 diabetes (FIND-RISC ≥ 15) had been identified. The data were analysed using systematic text condensation.

Results: Two main themes were identified. The first theme was having resources available for an active lifestyle, which included having a family and being part of a social network, having a positive attitude toward life, and maintaining established habits from childhood to the present. The second theme was being at increased risk for type 2 diabetes, which included varied reactions to the information on increased risk, how lifestyle intervention raised awareness about risk behaviour, and health-related worries and ambitions as type 2 diabetes prevention.

Conclusions: Assessing a participant's resources could improve the outcomes of lifestyle intervention programmes. Both family history and risk perception could be used in preventive strategies to enhance changes in lifestyle.

Trial registration: The VEND-RISK Study was registered in ClinicalTrials.gov on April 26, 2010, with the registration number NCT01135901.

Keywords: Type 2 diabetes risk, Lifestyle, Lifestyle intervention, Salutogenesis, The HUNT study, Qualitative research, Semi-structured interviews

Abbreviations: BMI, Body mass index; DE-PLAN, Diabetes in Europe prevention through lifestyle, physical activity and nutrition; FIND-RISC, The finnish diabetes risk score questionnaire; HUNT3, The Nord-Trøndelag health study 3; REK, The Regional Committee for Medical and Health Research Ethics in Central Norway; SD, Standard deviation; VEND-RISK, The lifestyle intervention programme in two municipalities in North-Trøndelag

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Background

Type 2 diabetes has increased rapidly over the last thirty years, as has prediabetes in middle-aged and older adults [1]. Of all diseases measured in years lived with disability, type 2 diabetes has increased the most from 1990 to 2013 [2].

Several studies have shown that type 2 diabetes can be prevented when individuals at increased risk make lifestyle changes [3–6], even with modest clinical efforts [5]. The World Health Organization has estimated that 90 % of type 2 diabetes can be prevented through changes in diet, physical activity and smoking habits [7]. In order to prevent type 2 diabetes, it is important to develop tools and strategies to help individuals at high risk to make lifestyle changes [8].

A healthy lifestyle is associated with keeping risk factors at low levels [9]. Intervention programmes for healthier lifestyle offered by primary health care services have been found to be feasible and effective for individuals at high risk for type 2 diabetes [10]. During the last ten years, health authorities in Norway have recommended municipalities to establish services for people with unhealthy lifestyles, highlighting the need for preventing type 2 diabetes [11]. Lifestyle intervention programmes in municipalities are recommended to be based on a salutogenic theoretical approach [12]. The main essence of the salutogenic theory is sense of coherence, which refers to the ability to use one's own resources [13], including the ability to understand what is happening, the ability to manage the situation alone or with the help of significant others, and to find meaning in the situation [14]. A high sense of coherence is associated with better future health [14, 15]. In individuals at risk for type 2 diabetes, a high sense of coherence is found to be associated with lifestyle change [16]. However, such associations are contested. A study that included individuals aged 50 years or older at increased risk for type 2 diabetes found no association between a high sense of coherence and developing type 2 diabetes [17].

How information about risk is processed and understood may depend on social and psychological factors, including both family history and present lifestyle [18]. Several quantitative studies have elaborated on type 2 diabetes prevention [3–6, 10] and risk perception in relation to lifestyle [19–22]. One study found that individuals at high risk for type 2 diabetes did not have a higher awareness about the importance of diet and weight management as a means to prevent type 2 diabetes than those without risk [19]. Another study found that a higher age of those at risk was associated with lesser expectations and lower readiness for lifestyle change [20]. However, interventions that involved and changed risk perceptions successfully, regardless of age, seemed to change towards a healthier behaviour [21, 22].

Despite numerous quantitative studies on type 2 diabetes, lifestyle and risk [3–6, 10, 19–22], there is still a need for qualitative studies on these issues. Qualitative studies are well suited to explore and provide rich descriptions of complex phenomena [23]. Previous studies have explored perceptions of risk for type 2 diabetes and lifestyle change from individuals at increased risk [24–26]. These studies have found that people with prediabetes were surprised about their risk [24, 25]. A study of participants' experiences with screening for type 2 diabetes found that those who were at high risk were relieved to see that they were only at risk, but had no intention to change their lifestyle [26]. Perceptions of risk for type 2 diabetes may change during a stepwise method developed to help individuals adapt psychologically to their risk [25]. However, little is known about how those at increased risk for type 2 diabetes understand their lifestyle and how they perceive their risk when they choose to attend a lifestyle intervention programme. Thus, the aim of this study was to explore how older adults who are participants in a lifestyle intervention programme experience their own lifestyle and being at increased risk for type 2 diabetes.

Methods

This study used a nested qualitative approach with individual semi-structured in-depth interviews. The design enabled us to obtain rich data about informants' perceptions about their lifestyle and being at increased risk for type 2 diabetes, contextualized in the setting of attending a lifestyle intervention programme (the VEND-RISK Study). As a theoretical framework for our explorative analysis, we used the main concept sense of coherence from the salutogenic theory [14, 15].

Sample size and recruitment

The sample selection goes retrospectively back through three studies: the Nord-Trøndelag Health Study 3 (HUNT3), the HUNT DE-PLAN Study and the VEND-RISK Study.

The HUNT Study is a large population study in the county of Nord-Trøndelag in Norway with three surveys over the last 30 years [27]. The third HUNT Study in 2006-08 identified about 5000 people as being at a high risk (>30 %) of developing type 2 diabetes over the next ten years, based on the Finnish Diabetes Risk Score (FIND-RISC) questionnaire. The questionnaire includes eight questions about traditional risk factors for type 2 diabetes and is considered the best screening tool to use in a Caucasian population [28, 29]. A FIND-RISC score of 15 or more with an index from 0–26 means having at least 30 % increased risk of developing type 2 diabetes during the upcoming ten years [30]. Individuals without

known diabetes and a score of >15 received oral and written notices about their risk.

Furthermore, these individuals identified at increased risk for type 2 diabetes were eligible participants for the HUNT arm of an international multicentre study, the DE-PLAN Study (Diabetes in Europe. Prevention through Lifestyle, physical Activity and Nutrition). They received a letter and a phone call from a study nurse inviting them to attend the DE-PLAN Study [31]. The first step of the DE-PLAN Study was an oral glucose tolerance test, identifying some people who had already contracted diabetes. These were referred to their own physician for diagnostic follow-up and treatment, and they were not invited to further follow-up in DE-PLAN. The DE-PLAN Study offered participants the opportunity to attend informational meetings including the importance of avoiding type 2 diabetes, and how this could be prevented through simple nutritional advice. Also, the meetings addressed how to be more active and participants were informed about physical activities in their local communities. Furthermore, it was recommended that the individuals avoid gaining weight.

In 2012, the VEND-RISK Study was initiated in two of the municipalities were the HUNT DE-PLAN had taken place. All participants who had been involved in the HUNT DE-PLAN (n = 322) received an information letter about participation in the VEND-RISK Study. Eligible participants' names and addresses were retrieved from the HUNT DE-PLAN participant list for these two municipalities. The VEND-RISK Study included a more intensive lifestyle intervention programme provided by the primary health care services in local municipalities. VEND-RISK was designed for overweight people at increased risk for type 2 diabetes, with the goal of stimulating participants to be more physically active and to eat a healthier diet. VEND-RISK offered various physical activities lead by physiotherapists twice a week, and nutritional courses with a nutritionist. In addition, information meetings with themes relevant for type 2 diabetes risk were held once a year. The study also included annual surveys, blood sample testing and physical activity tests for five years. Altogether 45 out of 322 DE-PLAN participants from the two municipalities agreed to be involved in the VEND-RISK Study, and were eligible for selection to participate at interviews in this present study. Figure 1 illustrates the timeline for the sampling process for participants included in the present nested qualitative study.

One nurse working with the VEND-RISK Study helped in the recruiting process. The nurse phoned potential participants, starting at the top of the alphabetical list of the 45 individuals eligible for the study. Appointments were made one week before each interview. During the phone-call, the nurse informed participants about the qualitative study and everybody who were invited accepted to be interviewed. Recruitment proceeded continuously until 26 participants had been interviewed, at which point the interviews brought no new information. All interviews were conducted during a period of six weeks. The 26 participants that were interviewed were similar regarding age and gender for all 45 eligible participants. The 19 participants not being interviewed continued the lifestyle program in the VEND-RISK Study as planned, together with the 26 participants that were interviewed.

Informants

Twenty-six ethnic Norwegian informants aged 59–75 years (mean age 68) were interviewed. The informants' health measurements at VEND-RISK baseline inclusion showed a mean body mass index (BMI) of 30.2 (Standard Deviation (SD) 3.4) with a mean FIND-RISC score of 17 (SD 3.2). Sociodemographic variables and health measurements of informants are described in Table 1.

Interviews and interview guide

Individual in-depth interviews were conducted over six weeks in spring 2015 at a local outpatient care facility that served the two municipalities. Interviews lasted between 15 and 73 min (mean duration 28 min). The first author conducted all interviews. Additional notes and reflections were written down immediately after each interview.

The interview guide was semi-structured with open-ended questions, allowing informants to speak freely about what they considered essential to their lifestyle

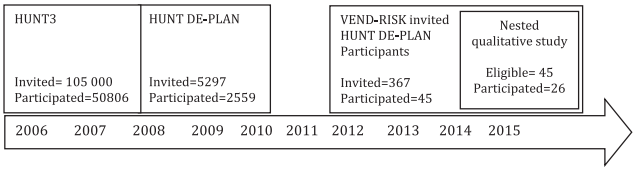

Fig. 1 Timeline showing the sample selection from the HUNT3 Study, the HUNT DE-PLAN Study and the HUNT DE PLAN participants who were involved in the VEND-RISK Study, which were eligible informants for the present study

Table 1 Informants characteristics

Characteristics	Total (*N* = 26)
Sociodemographic variables	*N* (%)
Gender	
Female	15 (58)
Male	11 (42)
Age	
59–64	4 (16)
65–69	17 (65)
≥ 70	5 (19)
Civil status	
Partner/married	20 (77)
Divorced/widowed	6 (23)
Highest level of education	
Nine years or less of school	5 (19)
More than nine years of school	14 (54)
Bachelor degree or higher	7 (27)
Work status	
Disability leave	6 (23)
Partly retired (1–49 %)	4 (16)
Working 50 % or more	4 (16)
Retired (100 %)	12 (46)
Essential health measures	
Family history of type 2 diabetes	
Present	17 (65)
Not present	9 (35)
Weight Categories[a]	
Normal weight (BMI 18,5–24,9 kg/m^2)	1 (4)
Overweight (BMI 25–29,9 kg/m^2)	11 (42)
Obese (BMI ≥30 kg/m^2)	14 (54)
Waist Circumference (cm)	Mean (SD)
Men	107.5 (6.4)
Women	103.5 (10.1)
HbA_{1c} (mmol/mol)	5.8 (0.5)

[a]Weight category definitions are based on the World Health Organizations (WHO) Body Mass Index (BMI) cutoffs

and being at increased risk. Main interview questions were: "*How has your health and lifestyle been through your life?*", "*How did you react to the information about being at risk for type 2 diabetes?*" and *"How has the VEND-RISK intervention programme influenced your lifestyle?"* . The interviews proceeded as a conversation, with follow-up questions *"Did you do any changes based on the knowledge about your risk?" and "What experience do you have with changing habits in diet and exercise?"*, with the goal of exploring what informants considered to be important.

Data analysis

Audio recordings of all 26 interviews were transcribed verbatim. Systematic text condensation based on a phenomenological approach were used in the analysis [32, 33]. In the first step of the analysis, the first author read all transcribed interviews and interview notes to get an overall impression. A mind map was made for preliminary themes that were identified during the first reading. In the second step, all meaning units derived from the material were sorted into codes. Codes were compared and categorized into main themes and subthemes. In the third step, themes and codes were summarized, read and discussed, with the goal of finding the essence in the material that reflected the participants' narratives. The second and last author read three interviews and a summary of the interviews and met to discuss codes and themes with the first author. After several meetings, codes and themes were adjusted and renamed, and the content of themes and subthemes was condensed. In the end, all findings were summarized and concepts in the themes and subthemes were grouped. The findings were continuously checked against the transcription for validation during the analysis and discussions of themes. NVivo 10.0 was used as a systematization tool.

All quotes presented in the results section are translated from Norwegian to English and anonymized.

Results

The study revealed two main themes with three subthemes each (see Fig. 2). The first main theme was "Available resources for an active lifestyle". Subthemes were "Having a family and being part of a social network", "Having a positive attitude to life", and "Maintaining

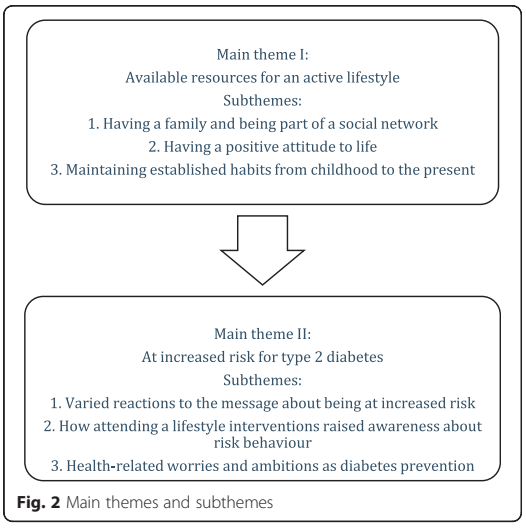

Fig. 2 Main themes and subthemes

established habits from childhood to the present". The second main theme was "Being at increased risk for type 2 diabetes". The subthemes were "Varied reactions to the message about being at risk", "How lifestyle intervention (VEND-RISK) raised awareness about risk behaviour", and "Health-related worries and ambitions as type 2 diabetes prevention".

In the stories, the first main theme was presented as a foundation that affected the second main theme.

Main theme I: available resources for active lifestyle

Having a family and being part of a social network

In the informants' narratives, having a family with children, grandchildren and siblings nearby was essential for an active lifestyle. In addition, being part of a social network was seen as important for their activity habits. They highlighted being engaged in organizations and local community groups, exemplified by political engagements, senior groups, company sport groups and voluntary work. The social aspect of being occupied with different activities was emphasized in their stories, as typified by one informant:

> *I attend the health association every Monday and the knitting club every Tuesday. I also go bowling once a week. I have to go out to see people so this social aspect is most important for me. Woman, age 63*

Having a positive attitude to life

Informants accentuated that they had a positive attitude to life. They saw themselves as responsible for their own happiness and quality of life. They asserted that it was important to be engaged in life and activities, and emphasized that there was nothing to be gained by feeling sorry for themselves. They were grateful for what life had given them. In spite of traumatic episodes and negative health conditions, they said that they would not let sadness ruin their lives. It became apparent that they turned to their families and social networks to get through difficult life experiences. To acknowledge their resources, to be able to use them and to have a positive attitude was essential for staying active, in spite of life difficulties. One participant said:

> *I lost my wife a year ago. I had no desire to sit thinking about this. I have a positive attitude. I go travelling with friends, go to concerts and go out dancing… I cannot just sit at home and feel sorry for myself that is not beneficial. Man, age 66*

Maintaining established habits from childhood to the present

According to the informants' narratives, they had formed habits during their childhood through an active lifestyle and healthy eating. They told that they as children, after a normal school day, helped out at home or played outside. They walked or bicycled to get around, a habit that continued through their adult life. As described in their stories about childhood eating habits, food was made with natural ingredients. In the views of the study participants, food habits from their upbringing continued into adulthood, and they told that they still considered regular meals and a low sugar intake as important for a healthy lifestyle.

Not many had been involved in organized sports as children and adolescents, but they were used to being out hiking, skiing, ice skating and walking in the woods. When talking about exercise in their adult life, some informants described going to fitness centres, while others attended organized sport activities. Participants said it was common for them to go for walks with their family on the weekends. They perceived the recommendation for 30 min of daily physical activity as healthy behaviour for maintaining an active lifestyle.

Being active was important for their quality of life. However, their stories described more than just physical activity. Activities involving family and friends were highlighted as important, whether going to a concert or the swimming pool. In addition, they described everyday activities such as housework and garden work as important. One said:

> *I am active with daily activities. I go skiing in the winter, I shovel snow, I chop wood and I have a house to keep clean. I pick berries in the woods. I cook for my family and I have my loom, so I do not sit in a chair. Woman, age 67*

Main theme II: at increased risk for type 2 diabetes

Varied reactions to the information about being at increased risk

The informants' stories varied along a continuum in terms of the consequences the risk information had on their lifestyle. They felt that receiving the information about being at increased risk for type 2 diabetes from the HUNT3 study was valuable. Some informants remembered being told that their established food habits and the fact that they already met activity recommendations were good strategies for continuing their lives without needing to be worried about their increased risk. Others were surprised about being at increased risk and talked about having reduced their sugar intake after they were given this information. However, most informants thought little about making lifestyle changes because of the risk information provided by the HUNT3 survey (see Table 2). They described themselves as being active individuals, which made their increased type 2 diabetes risk less of a concern. Informants recalled very little about attending the HUNT DE-PLAN Study.

Table 2 Informants' remarks regarding the second main theme, an increased risk for type 2 diabetes

Varied reactions to the information about being at increased risk (HUNT 3):
"It was okay to get the information and to learn about my health status." Man, age 66
"It was good to get the message, but I can't go around being afraid of getting type 2 diabetes." Woman, age 59
"I stopped wanting to eat sweets when I learned I was at risk for type 2 diabetes." Woman, age 65
"Actually, I thought it was strange that I was at risk, but I am glad that I found out about it." Woman, age 65
How attending a lifestyle intervention (the VEND-RISK Study) raised awareness about risk behaviour:
"Now I have the chance to start prolonging my life and improving my health." Man, age 65
"I thought, now I have to start; I walked before but now I walk at least two hours a day." Woman, age 74
"I want to learn more about eating healthier to prevent further disease and I want to lose some weight." Woman, age 63
"I have become far more conscious about the importance of activity and diet." Man, age 65
"I think it's easier to stay on track and focus on good habits with the VEND-RISK tests follow-up. It is important to get some objective feedback. It would be much easier to slip back if we did not have the measurements." Man, age 64
"It is like a carrot to have the VEND-RISK study measurements." Man, age 63
Health related worries and ambitions as diabetes prevention:
"My husband has diabetes, and he has had to have both legs amputated, and that makes me think about my lifestyle." Woman, age 66
"My mother went blind because of diabetes, and died young. At that time there was not much known about preventing diabetes." Man, age 67
"My mother had diabetes and she was obese. She struggled with pain in her joints and just sat in a chair. Because of that I try to take precautions, I ate a lot of sweets before, but now I think more about what I eat and the consequences." Woman, age 65
"After my father got type 2 diabetes I've been very aware of my risk … Also, one of my aunts had to have both legs amputated and that scared me." Man, age 63
"I don't want to take medication, so when I learned I was at risk for diabetes I just had to do something and focus more on diet and exercise." Woman, age 67
"I want to improve my health to stay well as long as possible." Man, age 66
"It is not too late to do something about your diet and exercise habits; I do not want to sit on a couch and watch television for the rest of my life." Man, age 65

How attending a lifestyle intervention programme (VEND-RISK) raised awareness about risk behaviour

The informants considered the invitation to the lifestyle intervention programme (VEND-RISK) to be a reminder of their increased risk. They focused on a healthier behaviour after being included in VEND-RISK, but to varying degrees. Some had started at fitness centres and others were more aware of their diet. One informant had been to a diabetes training programme at the local hospital to learn more about type 2 diabetes. For those who participated in physical activity, established self-initiated activities were preferred over the activity interventions provided by VEND-RISK. However, even if there was variation in awareness about risk and in the efforts made by informants to have a healthier lifestyle, the stories they told showed an increased focus on being more active. Furthermore, they described that results from blood samples and physical measurements at the annual VEND-RISK tests as motivation for being more active. They also expressed the feeling that they had a social responsibility to contribute to research (see comments in Table 2).

Health-related worries and ambitions as type 2 diabetes prevention

Informants with diabetes in the family were worried about getting the disease themselves. Those who had family members with complications from diabetes such as nephropathy and retinopathy were more anxious. Some had obese parents with diabetes, some of whom also had obesity-related pain and reductions in mobility. The prospect of finding themselves in similar situations led to the desire to prevent the disease. They emphasized that they did not want to end up like their parents or relatives. Also, some informants mentioned medicines, needles and injections as being so frightening that they had shifted to a healthier lifestyle to avoid this kind of future for themselves. The focus on preventing type 2 diabetes had been strengthened from the time when they were given the first information on risk to the present, in part because they had grown older.

They emphasized their ambitions to stay healthy as long as possible in their stories. A family history of diabetes and ambitions of having a healthy life seemed to have had a greater influence on informants in terms of determining whether or not they had a healthier lifestyle than information about their risk alone. The informants also contradicted themselves, describing themselves as active on the one hand, while also saying that diabetes-related worries helped motivate them to make lifestyle changes.

Discussion

This study explores the experiences of a sample of older adults who attended a lifestyle intervention programme with respect to their own lifestyle and being at increased risk for type 2 diabetes. The sample was selected from individuals who had participated at the HUNT3 Study and the HUNT DE-PLAN Study, and who were currently participating in the VEND-RISK Study. The first main theme that emerged was having resources available to live an active lifestyle, including having a family and being part of a social network, having a positive attitude to life, and maintaining healthy habits from childhood to

the present. The second main theme that of being at increased type 2 diabetes risk, included varied reactions to the risk information, attending a lifestyle intervention programme (VEND-RISK) raised awareness about risk behaviour, and health-related worries and ambitions as type 2 diabetes prevention.

Importance of resources and the ability to use them

In this study, the resources of having a family and being part of a social network were important in maintaining an active lifestyle among this selected sample of individuals at increased risk for type 2 diabetes. Another qualitative study on individuals in lifestyle programs showed that a negative experience with family and social life was debilitating and a barrier to making lifestyle changes [34]. Several studies have found that having a good social network is a protective factor against morbidity [35]. In addition, according to the salutogenic theory, social belonging is important for a positive health outcome [15]. People with partners, family and friends who provide psychological and material support have better health than people with poor social connections [36]. Furthermore, the motivational aspects of social relationships are associated with increased activity [37–39].

In our data, informants described themselves as active and having a positive attitude to life and considered themselves as persons who did not give up when they faced difficulties. These characteristics provided by our sample coincided with the salutogenic theory where individuals with a high sense of coherence have an ability to manage difficult situations alone or with the support of significant others [15]. To find meaning in a situation, for example through activities, is also an important part of the sense of coherence concept [14]. Thus, high sense of coherence affects an individual's health positively over time in helping them handle stress and adapt to a healthier lifestyle [15]. Strengthening the sense of coherence for individuals in need, could play a role in trying to help them handle type 2 diabetes risk [17]. Focusing on and assessing sense of coherence may be useful in improving the outcome of lifestyle interventions [16]. Individuals with few available resources could be in need of more intensive follow-up from health personnel to help them make lifestyle changes than those with more resources.

Perceived risk related to family history

Our results revealed different reactions to the risk information and differences in actions taken to live a healthier life. The informants described themselves as active, and continued with established lifestyle habits without making an effort to prevent type 2 diabetes. This is in accordance with one study that found risk perception among individuals with type 2 diabetes to be based on non-modifiable factors, suggesting they underestimated the impact of behavioural factors [40]. From a theoretical perspective, perception of risk itself is not sufficient to motivate an individual to make a change [41]. Nevertheless, increasing a perception of risk may result in some kinds of healthier lifestyles [21, 22, 42].

Individuals at risk with a family history of diabetes may worry more about developing the disease, compared to those without diabetes in the family [43]. Furthermore, those with the most negative secondary experiences with type 2 diabetes can construct excessive cognitive and emotional responses to the disease [43]. Studies have shown that when health care providers have information and knowledge about a person's family history of diabetes, this can have a temporary effect on behavioural changes in individuals at risk of type 2 diabetes [44]. Other studies suggest that the usefulness of family history may however depend on the way information about risk is understood and perceived by those with increased risk [18, 45]. Nevertheless, in preventive strategies, a family history of diabetes may be of importance [46], and health personnel are open to using family history for such purposes [47]. In our study, a family history of diabetes was experienced more important than risk information in regard to participants' perceiving a need for lifestyle change.

We recommend future intervention programmes to assess each individual perception of risk, with the goal of finding people who need more knowledge about the importance of modifiable factors in lifestyle change. Furthermore, even if health personnel initially focus on family history to initiate lifestyle change, an individual's understanding of risk may be more important in helping with lifestyle improvements.

Strengths and limitations

A qualitative design may provide insight to complex phenomena. Our selected sample of participants from HUNT DE-PLAN and VEND-RISK would have been difficult to recruit without using a nested design. Adding interviews to a quantitative study (VEND-RISK) adds independent knowledge about lifestyle change for individuals at increased risk for type 2 diabetes.

Using only one researcher to collect all data could be a limitation [48]. In the present study the first author conducted all interviews. In order to minimize potential biases, the co-authors (ASH and MS) read three interviews and a summary of all interviews. ASH and MS also analysed and discussed the data with ISF until they reached consensus on the results. The present study may be affected by recall bias since there was a gap of eight years between the information on risk that was provided at HUNT3 and participation in the VEND-RISK Study. Also, participants had attended two lifestyle

intervention (HUNT DE-PLAN and VEND-RISK) studies before being interviewed. The HUNT DE-PLAN Study and the VEND-RISK Study had similar content, but differed in their locations and the intensity of their interventions.

Informants in the present study were selected because they were individuals at increased risk for type 2 diabetes and could be different from those from the HUNT DE-PLAN Study who chose not to participate when invited to the VEND-RISK Study. Also, they could differ from those who did not attend the HUNT DE-PLAN from HUNT3. We assume that the participants we included were engaged in improving health and avoiding type 2 diabetes. However, the aim of the study was to explore these engaged participants' perceptions when attending a lifestyle intervention, as they also had been previous participants in a lifestyle intervention study. Other studies have found that people who choose not to participate in lifestyle intervention studies might be those who would have benefitted the most from the intervention [49]. In addition, the informants' ages limit the transferability of the findings to all individuals at increased risk of type 2 diabetes who participate in lifestyle intervention programmes. However, these results are an important supplement to knowledge about older adults' experience of lifestyle and increased type 2 diabetes risk.

Conclusions

Having access to individual and social resources was shown by this study to be important for an active lifestyle. For this reason, helping individuals who need to strengthen their resources and the ability to use resources might be important in improving the outcomes of lifestyle intervention programmes. Concerns related to family history of diabetes and ambitions for a long and healthy life were more important in inducing lifestyle changes than information about risk. Our study indicates that improving an individual's understanding of risk as a supplement to using family history in preventive strategies might be helpful in inducing lasting lifestyle changes. As there is a growing need to prevent type 2 diabetes, these results are important when planning and improving lifestyle interventions and health promotion programmes.

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Availability of data and materials

The raw data supporting the findings in this article can be found at the Department of Health Sciences, Nord University, Levanger, Norway. Due to the Regional Committee for Medical and Health Research Ethics in Central Norway regulations, we have to secure the anonymity of the participants. In the raw data it is possible to identify the participants, and restrictions therefore apply to the availability of these data.

Authors' contributions

KM conducted the HUNT DE-PLAN Study and BK was responsible for the VEND-RISK Study. ISF and ASH had the research idea for the present study. ISF designed the present study and performed the data collection, with guidance from ASH. ISF, ASH and MS were responsible for the analysis. ISF drafted the manuscript with comments from ASH, MS, BK and KM. All authors read the final version. All authors read and approved the final manuscript.

Competing interests

The authors declare that they have no competing interest.

Consent for publication

Not applicable.

Ethics approval and consent to participate

All participants signed an informed consent form after they had received oral and written information to enable them to make an informed choice about participating in the present study. The Regional Committee for Medical and Health Research Ethics in Central Norway approved the study (REK nr 2015/188). The baseline HUNT3 Survey and the HUNT DE-PLAN Study were also approved by the Committee. Approval was also obtained for the VEND-RISK Study (REK nr 2010/696).

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Paper III

Individuals at high risk for type 2 diabetes — the VEND-RISK Study follow-up and the HUNT Study characteristics of participants and non-participants in a lifestyle programme

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ABSTRACT

Objective: Prevention of type 2 diabetes mellitus is possible through lifestyle programmes, but the effect depends on the programme's content, resources, and setting. This study aimed to investigate the effect of a lifestyle programme in a Norwegian primary health care setting on individuals at high risk for type 2 diabetes. Furthermore, the study aimed to explore characteristics of individuals at high risk for type 2 diabetes invited to a lifestyle programme to see if those who participated differed from those who declined to participate.

Research Design and Methods: Individuals identified at high risk for type 2 diabetes during the third survey of the Nord-Trøndelag Health Study (HUNT3) from two municipalities (N=322) were invited to attend a lifestyle programme (the VEND-RISK Study). A longitudinal design was used to see if the lifestyle programme had an effect on the participants' characteristics 12 months after the programme ended. A cross-sectional design was used to explore if the participants' characteristics differed from those who declined to participate.

Results: $HbA1_c$ decreased significantly for all participants ($p<0.00$) and waist circumference decreased by 4.0 cm for women ($p<0.00$) 12 months after the lifestyle programme ended. Of all individuals at high risk for type 2 diabetes invited to the lifestyle programme, 86% (287/322) declined to participate. Women who declined to participate had fewer years of education ($p<0.00$), were more frequently unemployed ($p=0.05$) and reported more often that their health affected social relations ($p=0.04$), compared to women who participated.

Conclusions: Future research regarding individuals at high risk for type 2 diabetes in the primary health care should focus on how to promote participation among those with low socio-economic status, especially women.

Significance of the study

What is already known about this subject?

It has been shown that lifestyle programmes in primary health care settings can prevent or delay the onset of type 2 diabetes for individuals at high risk for type 2 diabetes. However, lifestyle programmes are often confronted with high non-participant rates and many drop-outs.

What are the new findings?

The primary outcomes for each of this study`s two aims were: Firstly, the effect of a 12 month lifestyle programme for participants at high risk of type 2 diabetes resulted in a significant decrease in $HbA1_c$ and none developed type 2 diabetes 12 months after the lifestyle programme ended. Secondly, women who declined to participate lifestyle programme had lower socio-economic status i.e. fewer years of education and was more frequent unemployed, and they reported more often that their health affected social relations, compared to women who participated.

How might these results change the focus of research or clinical practice?

To prevent type 2 diabetes using the Norwegian primary health care system, lifestyle programmes for individuals at high risk for type 2 diabetes should focus on recruitment of individuals with low socio-economic status, especially women

INTRODUCTION

The global type 2 diabetes epidemic will overwhelm health care resources if preventive strategies are not urgently implemented [1]. The number of people with type 2 diabetes is also increasing in Norway [2]. The importance of preventing type 2 diabetes has been highlighted over the last ten years [3] and several studies have shown that type 2 diabetes can be prevented when individuals at high risk make changes in diet and physical activity habits [4-6]. The Norwegian Health Authorities have recommended that all municipalities establish lifestyle programmes at Healthy Life Centres as part of the primary health care system to serve individuals who need to make changes in diet, physical activity and tobacco use [7].

The Finnish Diabetes Prevention Study (DPS), the Diabetes Prevention Programme (DPP), and the Da Qing Study showed that type 2 diabetes can be prevented when individuals at high risk make lifestyle changes have been conducted in comprehensive experimental settings [4-6]. However, there are questions concerning how best to translate knowledge from experimental settings to local primary health care settings [9]. Studies that have transferred the interventions on preventing type 2 diabetes from experimental settings to local primary health care settings have shown successful results, assuming that it is possible to prevent type 2 diabetes in local primary health care settings [9-12]. However, the content of each lifestyle programme depends on the resources in the local primary health care system where the programme is offered. There has been a call to replicate long-term studies in primary health care settings to examine the feasibility of lifestyle programmes and the resources and level of intensity they require to prevent type 2 diabetes [9]. In Norway, there has been a demand for documentation of the long-term effect of lifestyle programmes in preventing type 2 diabetes in primary health care settings, such as municipal Healthy Life Centres.

Unfortunately, lifestyle programmes are often confronted with many drop-outs and low participation rates [13]. The individuals who choose not to participate in lifestyle programmes might be those who would have benefitted most from the programmes offered [14]. Reasons given from potential

participants for not participating in lifestyle programmes are usually health-related [15]. However, in studies it is found that non-participants are more likely to be from rural areas [16], with a lower level of education [17-19], lower socio-economic status and more often men [17, 18, 20]. Women are generally more likely to contact the health care for health-related problems than men are [21]. In addition, studies have reported that women have a higher prevalence of high risk for type 2 diabetes than men [22, 23]. The characteristics of women and men choosing or declining to participate in lifestyle programmes could differ somewhat. Identifying the characteristics of women and men who decline to participate in a lifestyle programme can add useful knowledge about where efforts should be targeted to recruit women and men to lifestyle programmes to prevent type 2 diabetes.

This study's first aim was to investigate the effect of a 12-month lifestyle programme in the Norwegian primary health care service for participants at high risk for type 2 diabetes 12 months after the programme ended. The second aim was to study if the characteristics of women and men at high risk for type 2 diabetes who were invited to a lifestyle programme (the VEND-RISK Study) and participated differed from those who declined to participate.

RESEARCH DESIGN AND METHODS

Study design and settings

A non-randomized, single-arm, pre-post examination was used to investigate the effect on changes in of participants in the lifestyle programme (the VEND-RISK Study) with assessments at baseline, at the end of the lifestyle programme and 12 months after the programme ended.

A cross-sectional design was used to explore if the characteristics of those at high risk for type 2 diabetes but who declined to participate after being invited to a lifestyle programme (the VEND-RISK Study) differed from those who participated.

Recruitment of participants at high risk for type 2 diabetes

The Nord-Trøndelag Health Study (HUNT) is a large population-based study in Norway, with three waves of data collection [24]. The present study uses the

third wave, the HUNT3 Survey (2006-2008), for its baseline risk factor assessments. In HUNT3, 5297 out of a total 48 392 individuals were identified as being at high risk of developing type 2 diabetes over the next ten years [25]. The Finnish Diabetes Risk Score (FINDRISC) questionnaire (range:0-26) was used to identify individuals at high risk, where a score of 15 or more indicated at least a 30% high risk of developing type 2 diabetes during the next ten years [26]. Individuals with a score of 15 or more received oral and written notices about their high risk through an invitationto attend the HUNT arm of an international multicentre study, the DE-PLAN Study (Diabetes in Europe. Prevention through Lifestyle, physical Activity and Nutrition) [27].

In 2012, the VEND-RISK Study was initiated in two municipalities in Nord-Trøndelag with the goal of stimulating individuals at high risk for type 2 diabetes who were overweight or obese to be more physically active and to eat a healthier diet by following the lifestyle programme at the Healthy Life Centre. The individuals identified at high risk for type 2 diabetes in the HUNT3 Survey who lived in the two municipalities (N=332) were invited by letter to attend the VEND-RISK Study and then follow the lifestyle programme at the Healthy Life Centre. The letter explained that they were invited because of their high risk for type 2 diabetes and that the lifestyle programmes aimed to motivate to lasting lifestyle change and prevent the development of type 2 diabetes. The letter also provided information about the lifestyle programme at the Healthy Life Centre, with opportunity to attend individual or group-based physical activities, a group-based nutrition course, individual health conversations with health personnel, and testing through physical measurements, blood samples and questionnaires.

The Healthy Life Centres' lifestyle programme

Individual health conversations are undertaken in the beginning and the end of the Healthy Life Centres lifestyle programme [8]. The health conversations is based on motivational interviewing principles to promote change [28].

The Healthy Life Centres lifestyle programme offered physical activity classes ,as both indoor and outdoor optional activities, two to four times a week. These were either individual or group-based with physical therapists or training physiologists. The activities classes had both cardio and resistance

training. Participants also learned to be familiar with walks, hiking possibilities and relevant training in the local environment. The lifestyle programme also provided information about activities in the local municipality after the lifestyle programmes period.

The Healthy Life Centres also offered a group-based nutrition course, "Good food for better health" that focused on eating habits and food choices based on national dietary advice. The Norwegian Directorate of Health had developed the course that was composed of one hour-long sessions over ten days with different themes for each session. The course was both theoretical and practical, meant as a good start to achieve sustainable changes in nutrition habits. All participants received a cookbook made for the course from the Norwegian Directorate of Health at the course. . "Good food for better health" was based on motivational interviewing aiming to inspire for healthy food choices and good dietary habits. The Healthy Life Centres further informed and encouraged participants to use online nutrition programmes.

Healthy Life Centre personnel consists of a physical therapist, nutritionist and a nurse, The VEND-RISK Study's participants followed the lifestyle programme at Healthy Life Centres over one year.

Measurements

The socio-demographic characteristics included in VEND-RISK and HUNT3 were age and gender. Information about education and work participation was also obtained for HUNT DE-PLAN. Education was assessed by the question "How many years of completed education do you have?" and work data questions included "Are you working?" with the answer categories of yes and no.

The anthropometric measures included in VEND-RISK and HUNT3 were height and weight (for Body Mass Index (BMI)) and waist circumference. Height and weight followed a standardized procedure where participants wore light clothes and no shoes. BMI was calculated as weight divided by height squared (kg/m^2). Trained nurses measured waist circumference with a measuring tape [29].

The FINDRISC questionnaire and fasting serum glucose load were used to assess diabetes risk in VEND-RISK and HUNT3. Hemoglobin A1c ($HbA1_c$) was also measured in VEND-RISK.

Triglycerides, total cholesterol and HDL cholesterol were measured to assess cardiovascular status in VEND-RISK and HUNT3, while LDL cholesterol was also measured for VEND-RISK.

Aerobic fitness status was measured in VEND-RISK using maximal oxygen uptake ($VO2_{peak}$). However, the number of measurements decreased for every measurement period (baseline N=40, end of programme N=24 and 12 months after the programme ended N= 23).

The COOP/WONCA Functional Assessment Charts were used to measure physical activity for VEND-RISK with the question "What was the most enduring physical activity you could do for at least 2 minutes?". The five-point scale answers of very heavy (fast running), heavy (light running), moderate (fast walking), easy (regular walking) and very easy (slow walking) were dichotomized to heavy and light, where moderate was included the light category.

The HUNT3 Survey included variables for sedentary behaviour (total sitting time) and self-reported physical activity. Sedentary behaviour was measured by asking "About how many hours do you sit during an average day (include work hours and leisure time)?". Physical activity was measured using three questions, "How often do you exercise?", "If you exercise as often as once or several times a week, how hard do you exercise?" and "How long do you exercise each time?". These answers were recoded into metabolic equivalents (METs). The METs scores were divided into three different MET scores (frequency x duration (METs) x intensity/minutes): 1= 0 – 8.3 MET-h/wk (0-500 MET-min/wk), 2= 8.4 – 16.6 MET-h/wk and 3= >16.6 MET-h/wk. A score of 1 is below the recommendations for physical activity, while scores of 2 and 3 fulfil the recommendations for physical activity [30].

Self-reported health status was measured in VEND-RISK by the COOP/WONCA Functional Assessment Charts question "During the last two weeks… How would you rate your health in general?" on a five-point scale from very good to

very poor and “During the past two weeks… Has your physical and emotional health limited your social activities with family, friends, neighbours or groups?” with respondents answering on a five-point scale from not at all to extremely.. HUNT3 obtained this information by posing the question: “How is your health at the moment?” with a four-point response scale that was subsequently dichotomized to poor and good [31] and “Has your physical or emotional health influenced social relations with family and friends over the last four weeks?”, with answers on a five-point scale composed of not at all, a little, some, a lot and all the time. These answers were also dichotomized so that not at all was classified as no and all the other answers were classified as yes [32].

The VEND-RISK Study measurements were collected at baseline (2013) and at the end of the 12-month lifestyle programme (2014) and 12 months after the programme ended (2015). In the HUNT3 Survey, all measurements were obtained at one point (2006-2008). **Figure 1** shows the sample selection, time when the lifestyle programme was offered and measurement points.

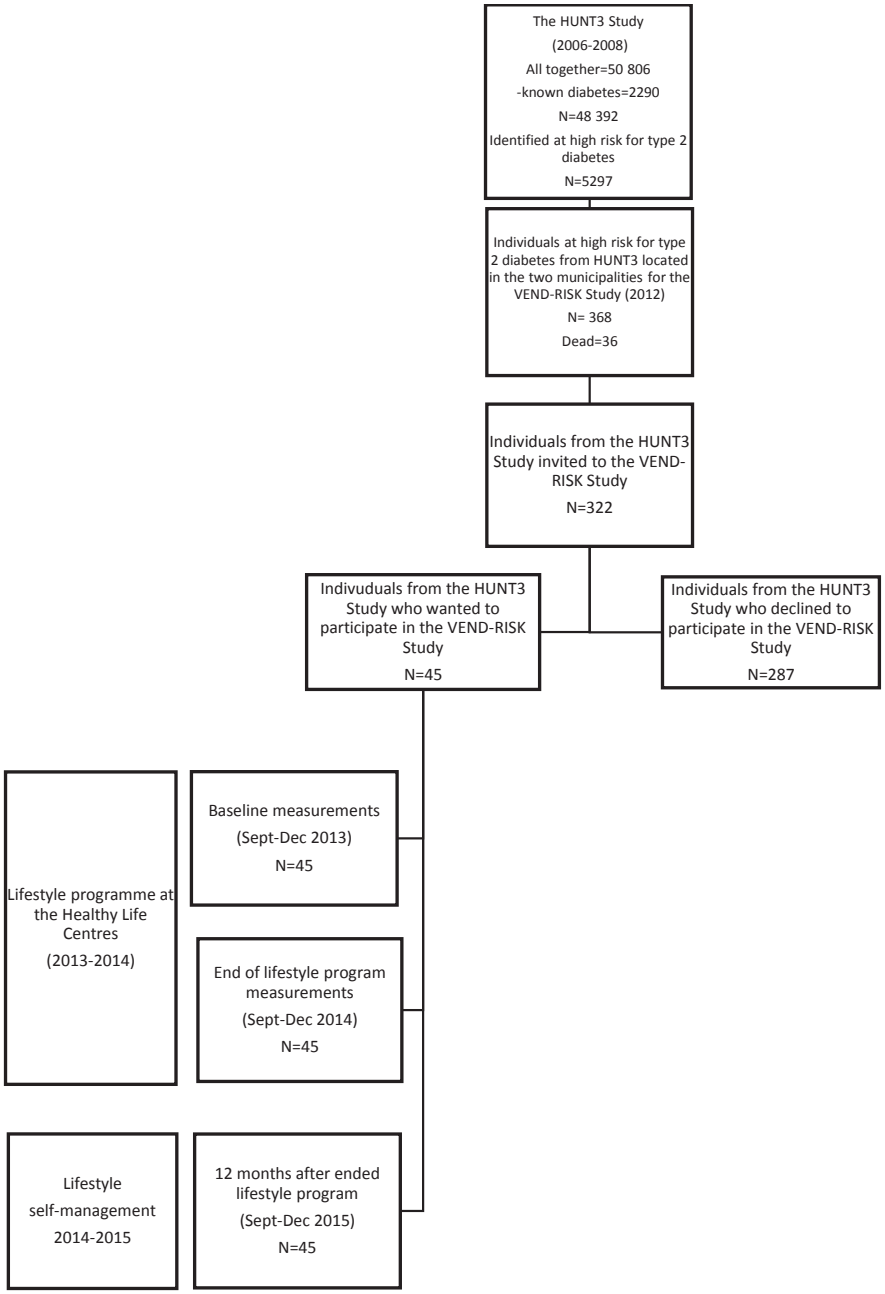

Figure 1: The study's overview from the beginning, in which individuals who were identified at high risk for type 2 diabetes at the HUNT3 Study in 2006-2008 and who were also located in the two municipalities for the VEND-RISK Study were invited to participate in the lifestyle programme at Healthy Life Centres in 2013.

Ethics

Participants in the VEND-RISK Study received oral and written information to enable them to approve and sign an informed consent form. The Regional Committee for Medical and Health Research Ethics in Central Norway approved the VEND-RISK study (REK nr 2010/696). The Regional Committee also approved the HUNT3 Survey and the HUNT DE-PLAN Study, where participants received oral and written information to enable them to approve and sign an informed consent form.

Data analysis

Datasets with the characteristics of participants were analysed using the IBM Statistical Package for Social Sciences (SPSS) version 23.0. Prior to the analyses, the data were checked for outliers and missing data. Variables were tested for normality by the Shapiro-Wilk test (p-value above 0.05), and with visual inspection of histograms, normal Q-Q plots and box plots.

The baseline characteristics of participants in the follow-up study and the characteristics of participants from HUNT3 who participated and did not participate in the lifestyle programme were described with mean ± standard deviation (SD). For normally distributed variables, we used a paired t-test and for non-normal variables we used a Wilcoxon non-parametric test to see the changes in the main variables from baseline to the end of the 12-month lifestyle programme and 12 months after the end of lifestyle programme for the participant's follow-up in the VEND-RISK Study. Binary logistic regression was applied to calculate an odds ratio (OR) with a 95% confidence interval (CI) to see if there were any differences between participants and non-participants. All analyses was separated by gender, and adjusted for age (yrs.). For strength calculations a 5% significance was selected and 80% strength.

RESULTS

Participants' changes at follow-up to the VEND-RISK Study

The participants' mean age at baseline in the VEND-RISK Study was 64.2 years, and all of these attended the follow-up 12 months after intervention (45/45, 100% responder rate). **Table 1** presents the participants'

characteristics at baseline, and the mean changes in characteristics from baseline to the end of the lifestyle programme and 12 months after the lifestyle programme ended. For the total sample,, $HbA1_c$ had decreased significantly (-0.2 mmol/l) and none developed type 2 diabetes 12 months after the lifestyle programme ended. The mean BMI changed slightly from 30.2 kg/m^2 at baseline to 29.7 kg/m^2. Waist circumference in women showed a significant decrease of 4 cm, from the baseline to 12 months after the lifestyle programme ended ($p<0.00$).

Table 1 Participants mean ± SD characteristics at the VEND-RISK Study baseline measurements and mean changes ± SD from baseline to the end of lifestyle programme and to 12 months after the end of the lifestyle programme.

	Baseline means ± SD	**Changes baseline-end of programme means ± SD**	***P* value***	**Changes baseline-12 months after ended programme means ± SD**	***P* value***
Weight (kg)					
Women	83.0 ±12.4	-1.0 ± 3.9	0.22	-1.4 ± 5.8	0.22
Men	97.2 ± 11.9	-0.3 ± 3.4	0.68	-0.9 ± 6.3	0.53
BMI (kg/m^2)					
Women	30.3 ± 4.2	-0.4 ± 1.4	0.21	-0.6± 2.1	0.21
Men	29.9 ± 2.8	-0.1 ± 1.1	0.72	-0.2 ± 1.9	0.59
Waist Circumference (cm)					
Women	102.4 ± 9.5	-2.7 ± 3.9	0.00*	-4.0 ± 5.4	0.00*
Men	107.1 ± 6.1	-0.5 ± 3.8	0.60	-1.7 ± 6.2	0.20
FINDRISC Score					
Women	16.8 ± 2.6	-1.1 ± 2.8	0.08	-1.2 ± 3.2	0.09
Men	16.3 ± 3.8	+0.5 ± 2.8	0.36†	-0.2 ±2.8	0.69†
HbA1$_c$ (mmol/mol)					
Women	5.8 ± 0.3	-0.2 ± 0.2	0.00*†	-0.2 ± 0.2	0.00*†
Men	6.0 ± 0.6	-0.2 ± 0.2	0.00*	-0.2 ± 0.4	0.03*
Fasting blood glucose(mg/dL)					
Women	5.6 ± 0.7	-0.2 ± 0.6	0.18†	-0.1 ± 0.5	0.24†
Men	5.9 ± 1.3	+0.0 ± 0.6	0.44†	+0.3 ± 0.4	0.03*
Total-cholesterol (mg/dL)					
Women	5.4 ± 0.9	+2.0± 0.6	0.00*	+0.1 ± 0.8	0.42
Men	4.9 ± 1.1	+1.5 ± 0.5	0.00*	-0.2 ± 0.6	0.25†
HDL- cholesterol (mg/dL)					
Women	1.8 ± 0.9	-0.2 ± 0.9	0.06†	-0.2 ± 0.9	0.86†
Men	1.3 ± 0.3	-0.0 ± 0.1	0.95	-0.0 ± 0.1	0.95
LDL- cholesterol (mg/dL)					
Women	3.3 ± 1.1	+0.0 ± 0.4	0.81	+0.2 ± 0.8	0.19
Men	3.1 ± 1.0	-0.2 ± 0.4	0.06	-0.1 ± 0.6	0.68
Triglycerides (mg/dL)					
Women	1.2 ± 0.5	+0.1 ± 0.5	0,93†	+0.2 ± 0.4	0.06
Men	1.3 ± 0.7	-0.1 ± 0.3	0.14†	+0.1 ± 0.2	0.13†
COOP/WONKA Physical activities as hard					
Women	23.1 %	-0.1 ± 0.4	0.13†	+0.1 ± 0.5	0.78†
Men	42.1%	-0.1 ± 0.6	0.28†	+0.0 ± 0.6	0.63†
COOP/WONKA Overall health as good					
Women	76.9%	+0.1 ± 0.5	0.41†	-0.0 ± 0.6†	0.71†
Men	52.6%	-0.2 ± 0.5	0.18†	-0.1 ± 0.5†	0.10†
COOP/WONKA Health impact on social activities					
Women	19.2%	-0.0 ± 0.4†	1.00†	+0.1 ± 0.4†	0.32†
Men	0.0%	+0.1 ± 0.2†	0.32†	+0.1 ± 0.2†	0.32†
VO_2max					
Women	34.6 ± 5.1	+0.6 ± 2.4	0.43	+0.91 ± 4.2	0.44
Men	27.8 ± 6.1	-0.5 ± 3.0	0.18	-0.21 ± 3.3	0.85

Kg= Kilograms, Cm=Centimetre
VO_2max=Maximum oxygen uptake
*Significant p<0.05
† Wilcoxon test used

Characteristics of participants' vs non-participants

Of the 332 individuals with high risk for type 2 diabetes identified from the HUNT3 Survey (2006-2008) invited to the VEND-RISK Study, a total of 287 (86%) declined to participate. **Table 2** presents the characteristics of the participants and non-participants. The socio-demographic, anthropometric, diabetes risk, cardiovascular (CVD) and physical activity level measurements for participants were not different from the non-participating men and women. In both groups of participants and non-participants, 59% were women with a mean age of 60 years, a mean BMI of 31 kg/m^2 and a mean FINDRISC score of 16.9. Both groups of participants and non-participants were at high risk for CVDs with elevated lipids. The women who declined to participate diverged significantly from women who chose to participate in that they reported fewer years of education ($p<0.00$) and more unemployment ($p=0.05$). They also were more likely to report that physical and emotional health affected their social relations in the last 14 days ($p=0.04$). For men, no differences were seen between those who declined to participate and those who participated.

Table 2 Characteristics (means ±SD) and comparison (OR 95% CI) between participants and non-participants from the baseline HUNT3 Survey (N=332).

	Participants (n=45)	Non-participants (n=287)	OR (95% CI)	*P* value*
Variables[a]	**Means ± SD**	**Means ± SD**		
Age (yrs)				
Women	58.5 ± 9.5	60.1 ± 9.8	1.0 (0.9-1.1)	0.23
Men	59.5 ± 5.8	59.5 ± 9.3	1.0 (0.9-1.1)	0.99
FINDRISC score				
Women	16.4 ±1.9	16.9 ±2.0	0.8 (0.7-1.1)	0.22
Men	17.2 ±1.9	16.9 ±2.3	1.1 (0.8-1.3)	0.65
Years of education				
Women	12.6 ± 3.1	10.7 ±3.1	1.2 (1.1-1.4)	0.00*
Men	12.7 ± 3.2	11.7 ± 3.2	1.1 (0.9-1.3)	0.22
Working				
Women	65.4%	44.7 %	2.3 (1.1-5.5)	0.05*
Men	66.7 %	57.6 %	1.5 (0.5-4.2)	0.47
BMI (kg/m^2)				
Women	30.6 ± 3.8	31.0 ± 4.4	1.0 (0.9-1.1)	0.64
Men	31.3 ± 3.2	31.3 ± 3.3	1.0 (0.9-1.2)	0.98
Weight (kg)				
Women	83.5 ± 10.6	83.5 ± 13.5	1.0 (0.9-1.0)	0.99
Men	100.9 ± 12.4	98.4 ± 11.7	1.0 (0.9-1.1)	0.39
Waist Circumference (cm)				
Women	101.0 ± 7.9	101.0 ± 12.4	1.0 (0.9-1.0)	0.99
Men	109.0 ± 8.2	108.0 ± 8.4	1.0 (0.9-1.1)	0.59
Triglycerides (mmol/L)				
Women	1.8 ± 0.9	1.8 ± 1.0	1.1 (0.7-1.6)	0.77
Men	2.0 ± 1.1	2.2 ± 1.2	0.8 (0.5-1.4)	0.84
Total cholesterol (mmol/L)				
Women	6.0 ± 1.2	5.8 ± 1.0	1.2 (0.8-1.8)	0.28
Men	5.4 ± 1.1	5.5 ± 1.1	0.9 (0.6-1.5)	0.68
HDL cholesterol (mmol/L)				
Women	1.4 ± 0.4	1.4 ± 0.4	0.9 (0.3-2.8)	0.94
Men	1.1 ± 0.3	1.2 ± 0.3	0.4 (0.1-2.8)	0.37
Serum glucose (mmol/L)				
Women	5.5 ± 0.7	5.8 ± 1.3	0.8 (0.5-1.2)	0.27
Men	5.9 ± 1.1	6.2 ± 1.8	0.9 (0.6-1.3)	0.57
Sitting time (hrs a day)				
Women	6.2 ± 3.7	5.9 ± 2.7	1.0 (0.8-1.2)	0.68
Men	6.2 ± 3.5	6.1 ± 3.0	1.0 (0.8-1.2)	0.87
Physical Activity (hrs/wk)				
Women	5.8 ± 3.4	5.4 ± 4.4	1.0 (0.9-1.1)	0.70
Men	6.5 ± 5.4	6.6 ± 5.4	0.9 (0.9-1.1)	0.90
Self-perceived health (SWB) Good				
Women	65.4%	57.6%	1.9 (0.7-5.3)	0.17
Men	61.1%	64.4%	0.8 (03-2.2)	0.65
Physical or emotional health impacts on social relations the last 14 days				
Women	19.2%	40.6 %	0.3 (0.1-0.9)	0.04*
Men	22.2 %	28.0 %	0.7 (0.2-2.3)	0.57

Yrs= Years, BMI= Body Mass Index, Hrs a day= Hours a day

*Significant p<0.05

OR are adjusted by gender

CONCLUSIONS

In this study, a follow-up of participants in a 12-month Healthy Life Centre lifestyle programme in the Norwegian primary health care setting (The VEND-RISK Study), participants' diabetes risk decreased and none had developed type 2 diabetes 12 months after the lifestyle programme ended. BMI had decreased slightly and for women, waist circumference decreased significantly. Of all those who were identified as at high risk for type 2 diabetes and were invited to the VEND-RISK Study, a total of 86% (287/322) declined to participate. Women who declined to participate had fewer years of education, were more likely to be unemployed and reported more often that their health affected social relations compared to women who participated.

Follow-up of participants in the lifestyle programme

The present study found no changes in the self-reported physical activity level or health status (COOP/WONCA) at the end of the 12-month lifestyle programme, nor 12 months after the programme ended. A qualitative study that explored a smaller segment of this study's sample found that the participants already saw themselves as active and that they had resources to undertake lifestyle change on their own [33]. Those who increased their physical activity in a lifestyle programme reduced their weight by 3.6 kg, their waist circumference by 3.6 cm, along with their total cholesterol, low-density lipoprotein/high-density lipoprotein ratio and fasting glucose load compared to those who did not increase their physical activity [34]. However, there could be other mediating factors explaining this change other than physical activity level. As in the present study, $HbA1_c$ decreased significantly for all participants and waist circumference decreased significantly for women despite no change in physical activity level.

Participants at high risk for type 2 diabetes in this study were older adults who slightly decreased their mean BMI from 30.2 at baseline to 29.7 kg/m^2 at 12 months after the lifestyle programme ended. The higher age of individuals at risk for type 2 diabetes has been found to be associated with lower expectations and lower clarity regarding lifestyle changes [35]. People at high

risk for type 2 diabetes are older compared to people who are not at risk for type 2 diabetes [36]. However, a BMI range of 23.0-29.9 kg/m^2 is associated with optimal longevity for older adults [37, 38]. Other studies have found that being older, inactive and obese are independent risk factors for metabolic changes leading to impaired glucose intolerance [39, 40]. Being obese has been found to be associated with higher mortality across all ages, but not in older adults [37]. Thus, the small changes in the present study in the BMIs of participants, but significant reduction in $HbA1_c$ should be interpreted as positive, as the aim of the VEND-RISK Study was to prevent type 2 diabetes and the further development of overweight and obesity in participants.

In addition to significant reduction in participant's $HbA1_c$ and waist circumference, the changes was maintained 12 months after ended lifestyle programme. The results also showed a greater improvement 12 months after ended programme than directly after completing the programme. The maintenance of changes is often discussed as one of the greatest challenges in the behavioral treatment of overweight, obesity and its metabolic complications [41].

Characteristics of non-participants

In the present study, non-participating women had fewer years of education and were more often unemployed, and their health restricted social relations more often than participating women. Low education level and low socio-economic status are known to have a negative impact on health [42]. Much as in our study, non-participants in other studies are reported to have lower levels of education and were more likely to be unemployed than participants [43]. In contrast, however, another study found that those at high risk for type 2 diabetes were more likely to be employed compared to individuals without risk for type 2 diabetes [36]. However, it has been suggested that unemployed people should be targeted for participation in lifestyle programmes [44], as a higher prevalence of type 2 diabetes has been observed in groups of lower socio-economic status [45]. The HUNT Survey showed a higher prevalence and incident of type 2 diabetes among people with low socio-economic status [46].

Several individual factors can explain non-participation in lifestyle programmes, broadly clustered as social, psychological, practical barriers [47], and previous negative experiences [48]. Awareness of one's own unhealthy lifestyle, perception of susceptibility of disease and motivation to make lifestyle changes have been found to be associated with participation in lifestyle programmes [49]. Women tend to be more concerned about their health and utilize the health care more often than men do [21]. Even so, previous studies have questioned if individuals with unhealthy lifestyle are less likely to participate in primary health care interventions than those with better health [50]. Lifestyles are modified by socio-economic status. Some individuals at high risk for type 2 diabetes who are of lower socio-economic status may not understand the importance of how lifestyle affects their risk for type 2 diabetes. However, previous findings have showed that concerns about family history of diabetes was more important for lifestyle change than how lifestyle affected the risk for type 2 diabetes [33]. Women are found to recall a family history of diabetes better than men [51] that could explain the effect modification in gender for participants and non-participant for socio-economic status.

In light of our previous findings [33, 48], there may be a gap between the participants from the HUNT3 Survey presented in this study and those referred to lifestyle programmes at Healthy Life Centres in the primary health care system in Norway, in that the latter individuals may often already have developed different diseases related to their lifestyle choices.

The previous and present results raise questions as to who benefits from lifestyle programmes, and highlights the importance of prevention programmes at a population-based level, such as health promotion strategies that target all individuals.

Strengths and limitations

The VEND-RISK Study was undertaken through a lifestyle programme at the Healthy Life Centres in a Norwegian primary health care setting. There are few studies that evaluate the effects of long-lasting lifestyle programmes similar to those applied by the Norwegian Healthy Life Centres for more than three months after programmes have ended [52]. We believe that having

follow-up data from 12 months after the programme ended is a strength. However, there was no control group for the follow-up. Participants who are randomized against their will to treatment that solely involves lifestyle change may result in very low compliance. The lack of a control group weakens the generalizability of our findings, and can be a systematic bias, especially regarding motivation for the sample.

A limitation of the study is the relatively small number of participants and the resulting low statistical power. Thus, when comparing participants in the lifestyle programme with non-participants we performed multiple logistical regression analyses only adjusted for age for men and women instead of one separate logistic analyses for men and women adjusting for all potential relevant variables. We could have lowered the significance level from 0.05 to 0.01 due multiple comparisons, but it would have increased the chance of missing a genuine effect. Not making adjustments for multiple comparisons may lead to fewer errors of interpretation when the data under evaluation are not random numbers but actual observations on nature, like in our study [53].

The cross-sectional design used to describe non-participants versus participants allows us to compare the two groups, but the design is limited in its ability to elucidate causal relationships. Follow-up data of health measurements of the non-participants could be obtained in the next HUNT Survey (HUNT4) in 2017-2019. However, those participating in the HUNT3 Survey may differ from those in the general population who did not participate in the HUNT3 Survey at all.

The present study contributes to knowledge about lifestyle programmes in the Norwegian primary health care system, a venue that must take active steps to prevent the development of type 2 diabetes in the population. The study suggests that individuals with low social status in Norway should be targeted in primary health care settings for recruitment to programmes to prevent type 2 diabetes.

Contributors

BK planned and was responsible for the VEND-RISK Study. KM conducted and organized the HUNT DE-PLAN Study. ISF, BK and AHS designed the present

study together with KM and VR. ISF analysed the data and interpreted the results, together with ASH and BK. ISF drafted the manuscript with comments from ASH, BK and VR. All authors read the final manuscript.

Competing interests

The authors declare they have no conflicts of interest.

Ethical approval

The Regional Committees for Medical and Health Research Ethics (REK), Norway (REK nr 2010/696) approved the study.

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Data sharing statement

No additional data are available

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Appendices

Appendix 1: Information and declaration of consent paper I and II

Appendix 2: Interview guides paper I and II

Appendix 3: FIND-RISK questionnaire used for inclusion for study 2

Appendix 4: Invitation letter for paper III

Appendix 5: Invitation letter and declaration of consent for HUNT3

Appendix 1

Information and declaration of consent paper I and II

Forespørsel om deltakelse i forskningsprosjektet

«Gammel vane- vond å vende»
Hvordan kan helseatferd bedres hos personer med ikke smittsomme sykdommer?- en studie av brukernes perspektiv under oppstarten av kommunale frisklivstilbud

Bakgrunn og hensikt
Dette er et spørsmål til deg om å delta i en forskningsstudie for å få brukerperspektivet i oppstart av Frisklivssentralen i Innherred Samkommune. Formålet med studien er å se på hva en Frisklivssentral kan bidra med for at personer med livsstilsproblematikk skal klare å endre levevaner og opprettholde det. Vi ønsker å finne nærmere ut hvilke krav og forventninger dere som brukere har til Frisklivssentralen. Vi ønsker å se på personer som har behov for å endre sine levevaner sine forventninger, erfaringer og behov når det startes opp frisklivstilbud ved Innherred. Denne studien er del av et doktorgradsprosjekt ved Høyskolen i Nord-Trøndelag, Helseundersøkelsen i Nord-Trøndelag og Institutt for Samfunnsmedisin ved NTNU. Studien utføres i samarbeid med Innherred Samkommune.

Hva innebærer studien?
Det vil bli utført individuelle intervju med varighet på mellom 40-90 minutter. Intervjuene blir tatt opp med digital diktafon og lydformatet blir senere gjort om til skriftlig format. Det vil lages sammenfatninger fra hvert enkelt intervju som kan leses gjennom av deg for å forsikre oss om at den informasjonen du har kommet med under intervjuet har blitt forstått riktig.

Mulige fordeler og ulemper
Fordelen med studien er at man vil være med på å legge til rette for at brukerperspektivet blir med når tilbudene ved Frisklivssentralen skal evalueres. Det er lite trolig at studien vil medføre ubehag.

Hva skjer med informasjonen om deg?
Informasjonen som registreres om deg skal kun brukes slik som beskrevet i hensikten med studien. Alle opplysningene vil bli behandlet uten navn og fødselsnummer eller andre direkte gjenkjennende opplysninger. En kode knytter deg til dine opplysninger gjennom en navneliste.

Det er kun autorisert personell knyttet til prosjektet som har adgang til navnelisten og som kan finne tilbake til deg. Koden vil kobles opp i mot Frisklivssentralens register. Informasjonen som innhentes vil lagres ved Høyskolen i Nord-Trøndelag og vil slettes innen 01.01. 2020.

Det vil ikke være mulig å identifisere deg i resultatene av studien når disse publiseres.

Frivillig deltakelse
Det er frivillig å delta i studien. Du kan når som helst og uten å oppgi noen grunn trekke ditt samtykke til å delta i studien. Dette vil ikke få konsekvenser for din videre deltakelse ved Frisklivssentralen. Dersom du ønsker å delta, undertegner du samtykkeerklæringen på siste side. Om du nå sier ja til å delta, kan du senere trekke tilbake ditt samtykke uten at det påvirker din øvrige deltakelse ved Frisklivssentralen. Dersom du senere ønsker å trekke deg eller har spørsmål til studien, kan du kontakte Ingrid S. Følling på telefon: 928 55 412 eller e-post: ingrid.folling@hint.no

Ytterligere informasjon om studien finnes i kapittel *A* *– utdypende forklaring av hva studien innebærer.*
Ytterligere informasjon om biobank, personvern og forsikring finnes i kapittel B *– Personvern, biobank, økonomi og forsikring.*

Gammel vane-vond å vende – Hvordan bedre helseatferd hos personer med overvekt som er i risiko for å utvikle type 2 diabetes?- en studie av kommunale frisklivstilbud – 10.09.2012

Samtykkeerklæring følger etter kapittel B.

[Gammel vane- vond å vende– Kapittel A og B – 10.09.2012]

Kapittel A- utdypende forklaring av hva studien innebærer

Kriterier for deltakelse

- Deltakere i Innherred Frisklivssentral avd. Levanger eller Verdal
- Menn og kvinner
- 18-65 år
- Samtykkekompetent

Bakgrunnsinformasjon om studien

En av dagens store helseutfordringer er kroniske sykdommer relatert til levevaner. Bare en av fem nordmenn er tilstrekkelig fysisk aktive i forhold til å oppnå god helseeffekt. En stillesittende livsstil er assosiert med overvekt, som er et av vår tids store folkehelseproblemer Andelen overvektige og nordmenn med type 2 diabetes har økt betraktelig i Norge de siste tretti årene. Både den norske befolkningen og helsemyndighetene i Norge har i løpet av de siste årene kommet med et økende krav om at kommunene bør opprette tilbud til personer med livsstilsproblematikk. Studier viser at det går an å forebygge diabetes type 2 med endring av levevaner inkludert kostendringer, fysisk aktivitet og vektreduksjon. Likevel er forebygging av overvekt og diabetes type 2 et forsømt område og det finnes for få behandlingstilbud i forhold til det økende behovet i Norge. Sentrale dokumenter signaliserer en økt satsing på folkehelsearbeid. I Nord-Trøndelag er HUNT undersøkelsen et dokumentert behov for å iverksette folkehelsetiltak innen fysisk aktivitet, kosthold og mestring. I 2011 kom Helsedirektoratet med anbefaling om at det burde opprettes frisklivssentrale i alle kommuner eller i interkommunalt samarbeid i Norge. Det er begrenset med dokumentasjon omkring Frisklivssentraler. Det trengs ytterligere kunnskap som kan gi implikasjoner for oppbygging og praksis av Frisklivssentraler for en brukergruppe med behov for endring av levevaner for å unngå sykdom. Denne studien er en av fire delstudier som til sammen utgjør et doktorgradsprosjekt, Formålet med doktorgradsprosjektet er å søke etter å finne svar på hvordan kommunale tilbud kan bidra til endring av levevaner og reduksjon av risikoprofil hos personer med overvekt og/eller med risiko for å utvikle diabetes type 2. Doktorgradsprosjektet skal bidra til å finne indikatorer som er gunstige for å lykkes med å endre levevaner, og den kan således være med på å legge premisser for hvordan vi i Norge intervenerer i forhold til vår tids store folkehelseutfordring. Denne delstudien ønsker å se på brukernes forventninger og tanker under oppstarten av en frisklivssentral.

- **Alternative prosedyrer eller behandling deltakeren får dersom personen velger å ikke delta i studien**

Deltakere vil følge vanlig tilbud i frisklivssentralen, men vil bli rekruttert parallelt med oppstart av tilbud

- **Tidsskjema – hva skjer og når skjer det?**
  Individuelle intervju vil bli avhold i perioden januar 2013-juni 2013. Hvert intervju vil være på cirka 40-90 minutter. Intervjuene vil foregå ved Innherred Frisklivssentral avd.Verdal eller Levanger, avhengig av den enkelte deltakers tilhørighet. Intervjuene vil bli tatt opp med digital diktafon (olympus) og vil bli gjort om til skriftlig format i etterkant.
- **Mulige fordeler**

Fordelen med å være med på studier er å kunne bidra med informasjon som kan være til nytte under oppstart av Frisklivssentral.

- **Mulige bivirkninger**

Det er lite trolig at denne studien vil ha noen former for bivirkninger eller ubehag.

- **Studiedeltakerens ansvar**
  Deltakeren må møte til avtalt intervju med forsker
- **Forskers ansvar ovenfor studiedeltaker**

[Gammel vane- vond å vende– Kapittel A og B – 10.09.2012]

Studiedeltakeren vil bli orientert så raskt som mulig dersom ny informasjon blir tilgjengelig som kan påvirke villighet til å delta i studien, og deltakere vil bli informert om endringer i forhold til deltakelse på intervju.

Kapittel B - Personvern, biobank, økonomi og forsikring

Personvern
Opplysninger som registreres om deg er lydbåndopptak av intervju, transkriberte intervju; det vil si lydbåndopptaket i skriftlig form, samt notater som blir gjort under intervjuet.
Høyskolen i Nord-Trøndelag ved dekan ved helsefag er øverste databehandlingsansvarlig.

Utlevering av materiale og opplysninger til andre
Hvis du sier ja til å delta i studien, gir du også ditt samtykke til at prøver og avidentifiserte opplysninger utleveres til Høyskolen i Nord-Trøndelag, Norge.

Rett til innsyn og sletting av opplysninger om deg og sletting av prøver
Hvis du sier ja til å delta i studien, har du rett til å få innsyn i hvilke opplysninger som er registrert om deg. Du har videre rett til å få korrigert eventuelle feil i de opplysningene vi har registrert. Dersom du trekker deg fra studien, kan du kreve å få slettet innsamlede prøver og opplysninger, med mindre opplysningene allerede er inngått i analyser eller brukt i vitenskapelige publikasjoner.

Økonomi og Helsedirektoratets rolle
Studien er finansiert gjennom Høyskolen i Nord-Trøndelag for å gjøre et doktorgradsprosjekt i samarbeid med Innherred samkommune.

Forsikring
Pasientskadeloven gjelder ved deltakelse i studien da studien forutsetter deltakelse i Frisklivssentralen som ligger inn under helsetjenesten.

Informasjon om utfallet av studien
Som deltaker i denne studien har du rett til å få informasjon om utfallet/resultatet av studien.

Samtykke til deltakelse i studien

Jeg er villig til å delta i studien

(Signert av prosjektdeltaker, dato)

Jeg bekrefter å ha gitt informasjon om studien

(Signert, rolle i studien, dato)

Forespørsel om deltakelse i forskningsprosjektet

«Gammel vane- vond å vende»
Hvordan kan helseatferd bedres hos personer med ikke-smittsomme sykdommer?

Bakgrunn og hensikt
Dette er et spørsmål til deg om å delta i en forskningsstudie for å se hvilken betydning det har hatt for deg å få avdekt risiko for å utvikle type 2 diabetes og om du har gjort noen endringer i forhold til din livsstil med bakgrunn i dette etter HUNT 3. Formålet med studien er å se på hvordan man kan endre levevaner på lavterskelnivå med de tilbudene som ble gitt gjennom HUNT DE-PLAN for å se på hva som kan bidra til at personer skal klare å endre levevaner og opprettholde det. Vi ønsker å intervjue deltakere fra HUNT DE-PLAN som har gjort endringer etter at de fikk vite at de var i risiko for å utvikle type 2 diabetes i de nærmeste ti årene. Studien er del av et doktorgradsprosjekt ved Høgskolen i Nord-Trøndelag og Institutt for Samfunnsmedisin ved NTNU. Studien utføres i samarbeid med Helseundersøkelsen i Nord-Trøndelag.

Hva innebærer studien?
Det vil bli utført individuelle intervju med varighet på mellom 40-90 minutter. Intervjuene blir tatt opp med digital diktafon og lydformatet blir senere gjort om til skriftlig format. Det vil lages sammenfatninger fra hvert enkelt intervju som kan leses gjennom av deg for å forsikre oss om at den informasjonen du har kommet med under intervjuet har blitt forstått riktig.

Mulige fordeler og ulemper
Fordelen med studien er at man vil være med på å bidra til å finne indikatorer som er gunstige for å lykkes med å endre levevaner, og den kan således være med på å legge premisser for hvordan vi i Norge intervenerer i forhold til ikke-smittsomme kroniske sykdommer, på hvilket nivå intervensjonen bør være, på hvilke individuelle forutsetninger som ligger til grunn for å gjøre endring og hvordan helsevesenet og samfunnet kan imøtekomme disse. Det er lite trolig at studien vil medføre ubehag.

Hva skjer med informasjonen om deg?
Informasjonen som registreres om deg skal kun brukes slik som beskrevet i hensikten med studien. Alle opplysningene vil bli behandlet uten navn og fødselsnummer eller andre direkte gjenkjennende opplysninger. En kode knytter deg til dine opplysninger gjennom en navneliste.

Det er kun autorisert personell knyttet til prosjektet som har adgang til navnelisten og som kan finne tilbake til deg. Informasjonen som innhentes vil lagres ved Høgskolen i Nord-Trøndelag og vil slettes innen 01.10. 2021.

Det vil ikke være mulig å identifisere deg i resultatene av studien når disse publiseres.

Frivillig deltakelse
Det er frivillig å delta i studien. Du kan når som helst og uten å oppgi noen grunn trekke ditt samtykke til å delta i studien. Dette vil ikke få noen konsekvenser. Dersom du ønsker å delta, undertegner du samtykkeerklæringen på siste side. Om du nå sier ja til å delta, kan du senere trekke tilbake ditt samtykke. Dersom du senere ønsker å trekke deg eller har spørsmål til studien, kan du kontakte Ingrid S. Følling på telefon: 928 55 412 eller e-post: ingrid.folling@hint.no

Ytterligere informasjon om studien finnes i kapittel *A* *– utdypende forklaring av hva studien innebærer.*

Gammel vane-vond å vende – Hvordan bedre helseatferd hos personer med overvekt som er i risiko for å utvikle type 2 diabetes?- en studie av HUNT DE-PLAN deltakere

Ytterligere informasjon om biobank, personvern og forsikring finnes i kapittel B – *Personvern, biobank, økonomi og forsikring.*

Samtykkeerklæring følger etter kapittel B.

[Gammel vane- vond å vende– Kapittel A og B – 10.09.2012]

Kapittel A- utdypende forklaring av hva studien innebærer

Kriterier for deltakelse

- Deltatt på HUNT DE-PLAN (Deltakere i HUNT 3 som fikk avdekt risiko for å utvikle type 2 diabetes i løpe av de neste ti årene)
- Menn og kvinner
- 18-75 år
- Samtykkekompetent

Bakgrunnsinformasjon om studien

En av dagens store helseutfordringer er kroniske sykdommer relatert til levevaner. Bare en av fem nordmenn er tilstrekkelig fysisk aktive i forhold til å oppnå god helseeffekt. En stillesittende livsstil er assosiert med overvekt, som er et av vår tids store folkehelseproblemer Andelen overvektige og nordmenn med type 2 diabetes har økt betraktelig i Norge de siste tretti årene. Både den norske befolkningen og helsemyndighetene i Norge har i løpet av de siste årene kommet med et økende krav om at kommunene bør opprette tilbud til personer med livsstilsproblematikk. Studier viser at det går an å forebygge diabetes type 2 med endring av levevaner inkludert kostendringer, fysisk aktivitet og vektreduksjon. Likevel er forebygging av overvekt og diabetes type 2 et forsømt område og det finnes for få behandlingstilbud i forhold til det økende behovet i Norge. Sentrale dokumenter signaliserer en økt satsing på folkehelsearbeid. I Nord-Trøndelag er HUNT undersøkelsen et dokumentert behov for å iverksette folkehelsetiltak innen fysisk aktivitet, kosthold og mestring.
Formålet med dette doktorgradsprosjektet er å søke etter å finne svar på hvordan kommunale tilbud kan bidra til endring av levevaner og reduksjon av risikoprofil hos personer med overvekt og/eller med risiko for å utvikle diabetes type 2. Doktorgradsprosjektet skal bidra til å finne indikatorer som er gunstige for å lykkes med å endre levevaner, og den kan således være med på å legge premisser for hvordan vi i Norge intervenerer i forhold til vår tids store folkehelseutfordring.

- **Tidsskjema – hva skjer og når skjer det?**
  Individuelle intervju vil bli avhold i perioden januar 2015-mars 2015. Hvert intervju vil være på cirka 40-90 minutter. Intervjuene vil foregå tilpasset etter deltakeres ønsker, avhengig av den enkelte deltakers tilhørighet. Intervjuene vil bli tatt opp med digital diktafon (olympus) og vil bli gjort om til skriftlig format i etterkant.

- **Mulige fordeler**

Fordelen med å være med på studien er å kunne bidra med informasjon som kan være til nytte til videre oppbygging av kommunale tilbud til personer med livsstilsproblematikk.

- **Mulige bivirkninger**

Det er lite trolig at denne studien vil ha noen former for bivirkninger eller ubehag.

- **Studiedeltakerens ansvar**
  Deltakeren må møte til avtalt intervju med forsker
- **Forskers ansvar ovenfor studiedeltaker**

Studiedeltakeren vil bli orientert så raskt som mulig dersom ny informasjon blir tilgjengelig som kan påvirke villighet til å delta i studien, og deltakere vil bli informert om endringer i forhold til deltakelse på intervju.

Kapittel B - Personvern, biobank, økonomi og forsikring

[Gammel vane- vond å vende– Kapittel A og B – 10.09.2012]

Personvern
Opplysninger som registreres om deg er lydbåndopptak av intervju, transkriberte intervju; det vil si lydbåndopptaket i skriftlig form, samt notater som blir gjort under intervjuet.
Høgskolen i Nord-Trøndelag ved dekan ved helsefag er øverste databehandlingsansvarlig.

Utlevering av materiale og opplysninger til andre
Hvis du sier ja til å delta i studien, gir du også ditt samtykke til at prøver og avidentifiserte opplysninger utleveres til Høgskolen i Nord-Trøndelag, Norge.

Rett til innsyn og sletting av opplysninger om deg og sletting av prøver
Hvis du sier ja til å delta i studien, har du rett til å få innsyn i hvilke opplysninger som er registrert om deg. Du har videre rett til å få korrigert eventuelle feil i de opplysningene vi har registrert. Dersom du trekker deg fra studien, kan du kreve å få slettet innsamlede prøver og opplysninger, med mindre opplysningene allerede er inngått i analyser eller brukt i vitenskapelige publikasjoner.

Økonomi og Helsedirektoratets rolle
Studien er finansiert gjennom forskningsmidler fra Høgskolen i Nord-Trøndelag.

Forsikring
Det er ikke aktuelt med forsikring i forbindelse med studien.

Informasjon om utfallet av studien
Som deltaker i denne studien har du rett til å få informasjon om utfallet/resultatet av studien.

Samtykke til deltakelse i studien

Jeg er villig til å delta i studien

(Signert av prosjektdeltaker, dato)

Jeg bekrefter å ha gitt informasjon om studien

(Signert, rolle i studien, dato)

Appendix 2
Interview guides paper I and II

Gammel vane vond å vende

- Hvordan kan helseatferd bedres hos personer med ikke-smittsomme sykdommer?
- en studie av brukernes perspektiv under oppstarten av kommunale frisklivstilbud

Intervjuguide
Tid: 40-90 min
Bruk av hjelpemidler: Digital diktafon

Hensikt med studien: Både den norske befolkningen og helsemyndighetene i Norge har i løpet av de siste årene kommet med et økende krav om at kommunene bør opprette tilbud til personer med livsstilsproblematikk. Frisklivssentraler er noe Helsedirektoratet i 2011 anbefalte etablering av i alle landets kommuner eller i interkommunalt samarbeid. Høyskolen i Nord-Trøndelag har i samarbeid med Helseundersøkelsen i Nord-Trøndelag og Institutt for Samfunnsmedisin ved NTNU fått midler fra Helsedirektoratet til gjennomføring av et doktorgradsprosjekt i samarbeid med Innherred Samkommunes Frisklivssentral. Bakgrunnen for dette er at kunnskapen om kommunale Frisklivssentraler og tilbud for personer med behov for endring av levevaner er lite utforsket i Norge. Det trengs ytterligere kunnskap som kan gi implikasjoner for oppbyggingen av og utøvelsen ved Frisklivssentral. Denne studien ønsker å se på brukeres perspektiv og forventninger i oppstarten av tilbud.

Intervjuet: Intervjuet vil foregå som en dialog i forhold til dine forventninger og tanker knyttet opp i mot ulike tema som er forberedt på forhånd. Intervjuguiden skal sikre at samme tema blir omtalt under intervjuet, samtidig som muligheten for å slippe til med egne meninger holdes åpen og er veldig viktig.

Anonymitet: Intervjuene tas opp på bånd og skrives siden ut. Om ønskelig kan du i etterkant få en utskrift av intervjuet til gjennomlesning. Opplysningene vil bli behandlet konfidensielt og anonymiseres. Samlet sett vil intervjuene systematisk settes sammen og analyseres i lys av egnet teori og oppsummeres i en artikkel. Det vil ikke være mulig å identifisere deg i resultatene når studien publiseres.

Frivillighet: Det er frivillig å delta i studien. Din deltakelse er basert på at du, på bakgrunn av den informasjonen du har fått, har gitt ditt samtykke til å delta i studien.

Spørsmål?

Intervjuguidens struktur er som følger:

1. ***Bakgrunn:***

Jeg ønsker innledningsvis at du forteller litt om deg selv og din bakgrunn:

- Alder:
- Arbeidsforhold:
- Familie:
- Bakgrunn for frisklivsresept:

2. ***Hovedspørsmål:***

- Kan du fortelle meg om hva du tenker rundt å skulle delta på Frisklivssentral?
- Hvilke forventninger har du til deg selv når du skal starte opp?
- Hvilke forventninger har du til dine meddeltakere?
- Hvilke forventninger har du til behandlerne og tilbudene ved Frisklivssentralen?
- Hvordan kan kommunale tilbud bidra til at du kommer i gang med endringer i livsstilen og at du fortsetter med disse endringene også etter at tilbudet er ferdig?

3. ***Oppsummering:***

- Gitt det vi har snakket om i dette intervjuet, er det andre spørsmål som du savner?
  Hvis ja, hvilke?
- Er det noe annet du vil meddele før vi avslutter i forhold til det vi har snakket om?

Jeg takker så mye for din velvillighet og at du stilte opp!

Ingrid S. Følling
Phd. Stipendiat
HiNT, HUNT, ISM, NTNU i samarbeid med Innherred Samkommune

Gammel vane vond å vende

- Hvordan kan helseatferd bedres hos personer med ikke-smittsomme sykdommer?

Intervjuguide

Tid: 40-90 min

Bruk av hjelpemidler: Digital diktafon

Hensikt med studien: Både den norske befolkningen og helsemyndighetene i Norge har i løpet av de siste årene kommet med et økende krav om at kommunene bør opprette tilbud til personer med livsstilsproblematikk. Kunnskapen om kommunale tilbud for personer med behov for endring av levevaner er lite utforsket i Norge. Det trengs ytterligere kunnskap som kan gi implikasjoner for oppbyggingen av tilbud for personer som har behov for å endre levevaner. Denne studien ønsker å se på personers som har deltatt i Helseundersøkelsen i Nord-Trøndelag og deres erfaringer med å ha fått avdekt risiko for å utvikle type 2 diabetes og deres tanker om å endre levevaner gjennom kommunale tilbud, som ble tilbudt i etterkant for disse personene i risikogruppen. Studien er en del av et doktorgradsprosjekt ved Høgskolen i Nord-Trøndelag og Institutt for Samfunnsmedisin, NTNU.

Intervjuet: Intervjuet vil foregå som en dialog i forhold til dine forventninger og tanker knyttet opp imot ulike tema som er forberedt på forhånd. Intervjuguiden skal sikre at samme tema blir omtalt under intervjuet, samtidig som muligheten for å slippe til med egne meninger holdes åpen og er veldig viktig.

Anonymitet: Intervjuene tas opp på bånd og skrives siden ut. Om ønskelig kan du i etterkant få en utskrift av intervjuet til gjennomlesning. Opplysningene vil bli behandlet konfidensielt og anonymiseres. Samlet sett vil intervjuene systematisk settes sammen og analyseres i lys av egnet teori og oppsummeres i en artikkel. Det vil ikke være mulig å identifisere deg i resultatene når studien publiseres.

Frivillighet: Det er frivillig å delta i studien. Din deltakelse er basert på at du, på bakgrunn av den informasjonen du har fått, har gitt ditt samtykke til å delta i studien.

Spørsmål?

Intervjuguidens struktur er som følger:

1. ***Bakgrunn:***

Jeg ønsker innledningsvis at du forteller litt om deg selv og din bakgrunn:

- Alder:
- Arbeidsforhold:
- Familie:

2. ***Hovedspørsmål:***

- Kan du fortelle meg om hva du tenkte da du fikk avdekt risiko for å utvikle type 2 diabetes?
- Hvilke erfaringer har du med livsstilsendring (enten før eller i etterkant av HUNT 3)?
- Hvordan kan kommunale tilbud bidra til at du kommer i gang med å endre livsstil/ levevaner?
- Hvordan kan man bevare livsstilsendringer etter at tilbudene er ferdig?
- Hvordan får man gode vaner inn i hverdagen?

3. ***Oppsummering:***

- Gitt det vi har snakket om i dette intervjuet, er det andre spørsmål som du savner?

Hvis ja, hvilke?

- Er det noe annet du vil meddele før vi avslutter i forhold til det vi har snakket om?

Jeg takker så mye for din velvillighet og for at du stilte opp!

Ingrid S. Følling

Phd. Stipendiat

HiNT, HUNT, ISM, NTNU i samarbeid med Innherred Samkommune

Appendix 3
FIND-RISK questionnaire used for inclusion for study 2

FinnRisk

1. Alder
    a. 45-54 år (2 poeng)
    b. 55-64 år (3 poeng)
    c. > 64 år (4 poeng)
2. BMI
    a. < 25 kg/m^2 (0 poeng)
    b. 25-30 kg/m^2 (1 poeng)
    c. > 30 kg/m^2 (3 poeng)
3. Midjemål (rett under ribbena, vanligvis ved navlen)
    a. < 94 cm (menn) eller < 80 cm (kvinner) (0 poeng)
    b. 94-102 cm (menn) eller 80-88 cm (kvinner) (3 poeng)
    c. > 102 cm (menn) eller > 88 cm (kvinner) (4 poeng)
4. Trener eller mosjonerer du hver dag en halvtime eller mer i fritiden o/eller på jobb (inkludert hardt fysisk arbeid)?
    a. Ja (0 poeng)
    b. Nei (2 poeng)
5. Hvor ofte spiser du grønnsaker, frukt eller bær?
    a. Hver dag (0 poeng)
    b. Ikke hver dag (1 poeng)
6. Har du noen gang brukt blodtrykkssenkende medisiner?
    a. Nei (0 poeng)
    b. Ja (2 poeng)
7. Har du noen gang fått påvist høyt blodsukker (f.eks. ved helsekontroller, ved graviditet)?
    a. Nei (0 poeng)
    b. Ja (5 poeng)
8. Har noen i din familie fått diabetes?
    a. Nei (0 poeng)
    b. Ja, besteforeldre, tante/onkel eller søskenbarn (men ikke foreldre, søsken eller egne barn) (3 poeng)
    c. Ja, biologiske foreldre, søsken eller barn (5 poeng)

Appendix 4
Invitation letter for paper III

NTNU
Det medisinske fakultet
HUNT forskningssenter

hunt 3
Helseundersøkelsen i Nord-Trøndelag

Levanger, september 2012

Kjære deltaker i HUNT DE-PLAN-prosjektet etter HUNT3 i Meråker eller Stjørdal kommune

Tilbud om deltakelse i prosjektet *Vend Risk*

Den siste Helseundersøkelsen i Nord-Trøndelag (HUNT3) viste en sterk økning av type 2-diabetes og at svært mange i Nord-Trøndelag hadde en økt risiko for å utvikle diabetes. Takk for at du deltok i første del av oppfølgingsundersøkelsen (HUNT DE-PLAN) rettet mot risiko for diabetes og som pågikk fra 2008 til 2010, bestående av sukkerbelastningsprøver og en del informasjonsmøter.

Det er nå satt i gang et utvidet tilbud om oppfølging for dere som var med i HUNT DE-PLAN og som bor i Stjørdal eller Meråker. Dette er en del av frisklivsprosjektet *Vend Risk* som pågår i Værnesregionen.

Vi ved HUNT forskningssenter ønsker dette tiltaket velkommen og gir det vår anbefaling. Se vedlagt informasjonsskriv. Hvis du kunne tenke deg å være med eller høre mer om *Vend Risk,* så ta kontakt direkte med prosjektleder Monica Devle. Se vedlagt informasjonsskriv der telefonnummer og adresse er angitt.

Prosjektet *Vend Risk* er som HUNT3 godkjent av Regional komité for medisinsk og helsefaglig forskningsetikk i Midt-Norge (REK).

Vennlig hilsen

Kristian Midthjell
Leder for diabetesprosjektet
HUNT forskningssenter; Levanger

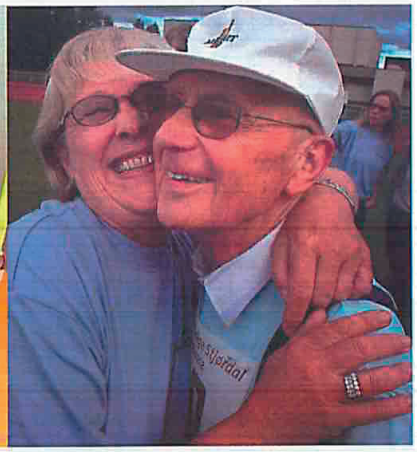
Postadresse	Org.nr. 974 767 880	Besøksadresse	Telefon	Professor dr.med
Forskningsv. 2	E-post: hunt@medisin.ntnu.no	Forskningsv. 2	74 07 51 80	Kristian Midthjell Tlf: 74 07 51 88
7600 Levanger	http://www.hunt.no	Levanger		Mobil 97657404

Appendix 5
Invitation letter for HUNT3

En time for bedre folkehelse

hunt 3

Helseundersøkelsen i Nord-Trøndelag



Hva er HUNT 3?

HUNT 3 er en folkehelseundersøkelse.
Når du deltar får du en enkel undersøkelse av din egen helse, og du gir et viktig bidrag til forskning.

HUNT 3 gjennomføres først og fremst for å øke vår kunnskap om store folkehelseproblemer som:

- Hjerte- og karsykdommer
- Lungesykdommer, andre luftveisplager og allergi
- Diabetes
- Muskel- og skjelettplager
- Hodepine
- Stoffskiftesykdommer
- Kreftsykdommer
- Psykiske plager
- Rusmiddelbruk
- Tannhelse
- Vektutvikling i befolkningen

Opplysninger, blod- og urinprøver som samles inn vil også bli benyttet til forskning om kvinnesykdommer, sykdommer i fordøyelsesorganer, urinveier, nervesystemet, sanseorganer og hud. Noen prosjekter vil undersøke hvordan livsstil, samfunn, levekår og miljø påvirker helse og trivsel. Det vil også bli forsket på arbeidsuførhet som følge av disse sykdommene eller tilstandene. Sammenhenger mellom arv, miljø og sykdom vil også være aktuelle tema. Til slike prosjekter vil det bli hentet ut DNA (arvestoff) fra blodprøvene.

Forskning

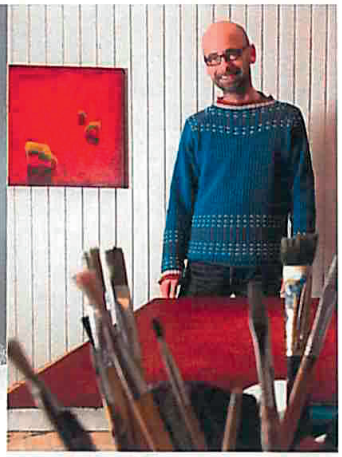
Det er allerede planlagt over 130 studier som skal benytte data fra HUNT 3. En liste over disse finnes på internett: www.hunt.ntnu.no. Hvis du ønsker å få listen tilsendt, kan du henvende deg til HUNT forskningssenter.

Samarbeidsprosjekt

HUNT 3 er et samarbeidsprosjekt mellom
- NTNU (Norges teknisk-naturvitenskapelige universitet)
- Helse Midt-Norge RHF
- Nord-Trøndelag fylkeskommune
- Kommunene i Nord-Trøndelag
- Nasjonalt folkehelseinstitutt
- Helse- og omsorgsdepartementet

HUNT 3 blir også støttet av
- NTE (Nord-Trøndelag Elektrisitetsverk)
- Sparebank 1 Midt-Norge
- Statoil

Noen delprosjekter støttes av næringsliv og ideelle organisasjoner. Bidragsyterne har ingen innflytelse på forskningen.



Vil du delta?

Du er invitert til å gi et viktig bidrag til forskning om hvordan sykdom kan forebygges og behandles.

Alle innbyggere i Nord-Trøndelag som er 13 år eller eldre, blir invitert til å være med i HUNT 3. Det er frivillig å delta. Du gir ditt bidrag ved å fylle ut det vedlagte spørreskjemaet og møte fram til en helseundersøkelse et sentralt sted i din kommune. Noen deltakere vil i ettertid bli invitert til videre undersøkelser. Hvis det gjelder deg, vil du få en ny invitasjon i posten. Du er ikke forpliktet til å delta selv om du er med i den første undersøkelsen.

Du er viktig!

Hver deltaker er like viktig, enten du er gammel eller ung, frisk eller syk. For å få gode forskningsdata er det viktig at alle er med. Hvis du har deltatt i HUNT tidligere, håper vi at du vil møte opp igjen.

Din helse

Etter undersøkelsen får du et brev med resultatene fra noen av dine prøver. Det gjelder blodtrykk, kolesterol, blodsukker og stoffskifte. Du vil bli anbefalt å kontakte din fastlege hvis noen av prøvene er unormale. Hvis du ikke ønsker å vite resultatene, kan du si fra om dette når du signerer samtykket. Hvis et prøveresultat er slik at det er nødvendig med rask legebehandling, vil du uansett bli kontaktet.

Verdens største

HUNT er verdens største folkehelseundersøkelse. To ganger tidligere har nord-trønderne møtt fram, første gang i 1984. Opplysninger fra HUNT 1 og HUNT 2 er benyttet i mer enn 300 vitenskapelige arbeider, og har gitt oss ny kunnskap om blant annet hjerte- og karsykdommer, lungesykdommer, diabetes, kreft og mental helse. Resultatene er publisert både nasjonalt og internasjonalt. Disse dataene er fortsatt verdifulle, og vil bli brukt i flere arbeider i framtiden. Forskning fører til ny kunnskap om forebygging og behandling av sykdom. Uten en innsats fra hver enkelt, hadde dette ikke vært mulig.

Slik foregår helseundersøkelsen

På forsiden av spørreskjemaet som du har fått, står det hvor du skal møte fram. Det er også foreslått et tidspunkt, men hvis dette ikke passer kan du selv velge når du vil møte. Den første delen av undersøkelsen tar omtrent en halv time.

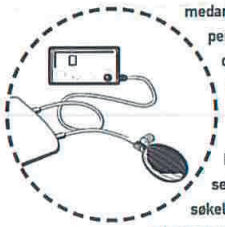
Påkledning

For at det skal gå raskt å måle blodtrykk, er det fint om du har på deg et kortermet plagg innerst. Når du skal veies må du ta av deg skoene, men ellers behøver du ikke å kle av deg.

Spørreskjema

Sammen med denne brosjyren har du fått et spørreskjema som du skal fylle ut og ta med til helseundersøkelsen. Der vil du få ett eller flere nye skjemaer. Disse er ulike for menn og kvinner og ulike aldersgrupper. Du kan fylle ut på stedet eller ta dem med hjem og returnere med post. Porto er betalt.

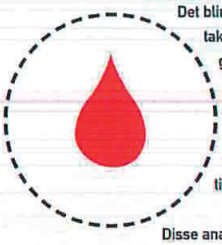
Undersøkelser



Du blir tatt i mot og registrert av HUNT 3-medarbeiderne, som alle er kvalifisert helsepersonell. Det blir målt høyde, vekt og omkrets av liv og hofter. Så gjennomføres et kort intervju og blodtrykket blir målt.

De fleste vil bli spurt om de kan tenke seg å delta i ytterligere én eller to undersøkelser. Hvilke undersøkelser det blir avhenger av kommunen du bor i, kjønn, alder og tilfeldig uttrekning.

Blodprøver



Det blir tatt blodprøve av alle deltakerne. Blodet fordeles på fem glass, men til sammen utgjør det ikke mer enn 40 milliliter, som er mindre enn en tidel av det en blodgiver gir. For de aller fleste vil det være tilstrekkelig med ett stikk.

Disse analysene blir gjort:

- Vanlige blodprøveanalyser som kolesterol, blodsukker og stoffskifteprøver.
- Det blir hentet ut DNA (arvestoff) som brukes i forskningsprosjekter som kartlegger sammenhengen mellom arv og miljø i sykdomsutvikling.
- Studier av hvite blodlegemer som deltar i kroppens forsvarsmekanisme mot sykdommer.
- Miljøanalyser, blant annet sporstoffer og spormetaller som bly og kvikksølv. Forekomsten i blodprøvene kan sammenliknes med mengden metaller som finnes i drikkevann og ellers i miljøet, for å finne ut mer om hvilke effekter det har på mennesker.
- Andre analyser vil også være aktuelle avhenging av forskningsprosjektene som blir satt i gang.

Kan vi be deg om litt til?

Etter at den første delen er gjennomført, kan du bli invitert til å delta i en eller to av følgende undersøkelser:

Pusteprøve

Pusteprøven er en enkel undersøkelse av lungefunksjonen. Du skal puste ut så kraftig som du klarer gjennom et munnstykke. Undersøkelsen er viktig for å studere mulige årsaker til lungesykdommer som astma og KOLS og forbedre behandling av disse. Det er viktig for resultatene at flest mulig av de inviterte, både med og uten lungesykdom, deltar. Tid: ca 5 minutter.

Beinmassemåling

Norge ligger på verdenstoppen i antall brudd, noe som trolig har sammenheng med lav beintetthet. Forskere ønsker å undersøke forskjeller i beintetthet avhengig av blant annet kjønn, alder, kosthold, fysisk aktivitet, sykdom og behandling av sykdom. Beintettheten vil enten bli målt i en underarm eller ved en mer omfattende måling i korsrygg, hofte og underarm. Stråledosen er svært lav, og målingen innebærer ingen risiko. Tid: ca 5 -10 minutter.

Ultralyd av hjerte

Personer som ikke har kjent hjertesykdom, kan delta i denne undersøkelsen. Hensikten er å kartlegge hvordan friske hjerter arbeider, noe som blant annet vil hjelpe leger og forskere til å skille mellom normale forskjeller og det som kan være tegn på sykdom. Du ligger på en benk mens undersøkelsen pågår. Du må være avkledd på overkroppen, men kan beholde bh. Gjennomføres for dem som bor i Steinkjer og Namsos. Tid: ca 20 minutter.

Ultralyd av lever og fettfordeling på kroppen

Det er stor variasjon mellom mennesker når det gjelder forekomsten av fett i leveren. Fordelingen av kroppsfett er også veldig ulik. Hensikten med undersøkelsen er å se på sammenhengen mellom fettavleiring i leveren og fettfordeling ellers på kroppen, blant annet for å undersøke om dette kan si noe om risikoen for hjerte- og karsykdom. Du ligger på en benk mens undersøkelsen pågår. Gjennomføres for dem som bor i Steinkjer, Namdalseid og Flatanger. Tid: ca 5 minutter.

Kondisjonstest

Fysisk aktivitet er viktig for god helse. Vi ønsker å finne ut mer om sammenhengen mellom kondisjon og helse, og hva som er årsaken til dårlig kondisjon. Derfor inviteres det til en test av blodårefunksjonen ved hjelp av ultralyd og en kondisjonstest på tredemølle. I kondisjonstesten skal du gå eller løpe til du føler at du anstrenger deg så hardt du kan. Testen avbrytes når du ikke klarer å yte mer, eller når du ønsker å stoppe.

Hvis du vil delta i denne undersøkelsen, må du være i stand til å gå eller løpe, ha på deg lette klær når du kommer til undersøkelse, og ha med deg joggesko eller andre sko som er gode å gå eller løpe i. Alder er ingen hindring for å delta, men hvis du har hjertesykdom skal du ikke være med. Gjennomføres for dem som bor i Stjørdal, Levanger, Verdal og Namsos. Tid: ca 20 minutter.

Urinprøve

Noen deltakere blir bedt om å avgi urinprøve når de møter til undersøkelse, eller hjemme etter undersøkelsen. Nødvendig utstyr blir delt ut.

Samtykke

Det er frivillig å delta i HUNT 3 og i andre folkehelseundersøkelser. Hver deltaker må gi sitt skriftlige samtykke for at opplysningene skal kunne brukes til forskning. Du blir bedt om å signere et samtykke når du møter fram. Opplysninger og prøver som du gir, blir oppbevart på ubestemt tid. I framtida kan de bli brukt i prosjekter som ennå ikke er planlagt, forutsatt at det er i samsvar med lover og forskrifter.

I framtida skal du få informasjon om nye forskningsprosjekter som bruker data fra HUNT. Slik informasjon finner du på internett www.hunt.ntnu.no. En gang i året vil det bli gitt ut skriftlig informasjon til befolkningen. Det vil også være omtaler av en del forskningsprosjekter i mediene.

Du kan når som helst etter undersøkelsen trekke tilbake ditt samtykke og be om at data om deg slettes eller at blod- og urinprøven blir ødelagt. Hvis du ønsker å trekke tilbake samtykket, kan du henvende deg til HUNT forskningssenter, Neptunveien 1, 7650 Verdal, telefon 74 07 51 80, faks 74 07 51 81 eller e-post: hunt@medisin.ntnu.no. Hvis det er et bestemt forskningsprosjekt du ikke ønsker at opplysninger om deg skal brukes til, vil det bli tatt hensyn til dette.

Nytt samtykke

Hvis det i framtida blir aktuelt å bruke opplysninger til å forske på nye spørsmål som ikke er beskrevet i denne brosjyren, kan det bli nødvendig å be om et nytt samtykke. Vi vil da sende deg et brev.

Du kan også bli spurt om et nytt samtykke hvis det blir aktuelt å samarbeide med private aktører om genetisk forskning. Slikt samarbeid vil være underlagt offentlig regulering og kontroll. Det vil ikke i noen tilfeller være aktuelt å selge blodprøver eller annet biologisk materiale.

Personvern og sikkerhet

Du kan være trygg på at informasjonen som du gir til HUNT 3 vil bli behandlet med respekt for personvern og privatliv, og i samsvar med lover og forskrifter. Så snart opplysninger, blodprøver og eventuelt urinprøver er samlet inn, blir de lagret uten å være merket med deltakerens identitet. Forskere som senere skal bruke opplysningene, har ikke tilgang til navn, fødselsdato eller personnummer. Alle medarbeidere i helseundersøkelsen har taushetsplikt.

Datatilsynet fører tilsyn med at lover og forskrifter om oppbevaring og bruk av helseopplysninger blir fulgt. HUNT 3 har konsesjon fra Datatilsynet.

Etisk godkjenning

Alle forskningsprosjektene skal godkjennes av en etisk komité. Komitéen er et frittstående organ som sikrer at de etiske sidene ved forskningsprosjekter blir vurdert. HUNT 3 er godkjent av Regional komité for medisinsk forskningsetikk, Midt-Norge. Alle framtidige forskningsprosjekter som benytter data fra HUNT, skal også godkjennes.

HUNT databank

HUNT databank består av opplysninger som er samlet inn gjennom HUNT 1, 2 og 3 gjennom spørreskjema, undersøkelser og analyser fra blod- og urinprøver. Hvis du deltok i HUNT 1 eller HUNT 2, vil dine data bli sammenstilt med opplysningene fra HUNT 3.

Genetisk materiale samles i HUNT biobank. Formålet med biobanken er at det i framtida skal være mulig å ta ut prøver, gjøre ulike analyser og sammenstille resultatene med øvrige data fra HUNT databank. På den måten vil det stadig komme nye data som legges til databanken.

Når forskerne får data fra HUNT databank er navn, fødselsnummer og andre kjennetegn fjernet, slik at de ikke kan vite hvem som har gitt opplysningene.

Sammenstilling med andre registre

For spesielle forskningsprosjekter kan det være aktuelt å sammenstille data fra HUNT med andre offentlige registre, for eksempel Reseptregisteret, Medisinsk fødselsregistrer, Kreftregisteret og Dødsårsaksregisteret. HUNT-data kan også bli sammenstilt med andre registre ved Statistisk sentralbyrå (SSB), for eksempel om miljø, befolkning, utdanning, inntekt, offentlige ytelser, yrkesdeltakelse og andre forhold som kan ha betydning for helsa.

I tillegg kan det være aktuelt å hente diagnoseopplysninger som for eksempel lårhalsbrudd, hjerteinfarkt, hjerneslag eller lungesykdommer hos primærhelsetjenesten, sykehusene i Nord-Trøndelag og St. Olavs hospital. For enkelte prosjekter kan det også være aktuelt å sammenstille opplysninger fra foreldre med opplysninger fra barn, søsken, foreldre og besteforeldre hvis disse også har deltatt i HUNT.

Alle slike sammenstillinger krever samtykke og/eller forhåndsgodkjenning av de offentlige instanser loven krever, for eksempel Regional komité for medisinsk forskningsetikk, Datatilsynet, Sosial- og helsedirektoratet eller Rikstrygdeverket. All informasjon vil bli behandlet med respekt for personvern og privatliv, og i samsvar med lover og forskrifter. Ingen av forskerne kan vite hvem som har gitt opplysningene.

Skadeerstatning

Det er svært liten risiko for at deltakere skal komme til skade som følge av undersøkelsen. Hvis det likevel skulle skje, kan man søke om skadeerstatning gjennom Norsk Pasientskadeerstatning (NPE). NPE behandler erstatningskrav for pasienter som er blitt påført skade innen det offentlige helsevesenet.

Ung-HUNT

Alle ungdommer i alderen 13-19 år i Nord-Trøndelag inviteres til å delta i Ung-HUNT. Prosjektet blir gjennomført på skolene, med utfylling av spørreskjema og kliniske undersøkelser i skoletiden. Ungdommer og foreldre vil få egen informasjon om Ung-HUNT via skolen.

Vil du delta?

Hvis du vil delta i HUNT 3, må du gi ditt skriftlige samtykke. Her er en kopi av dokumentet som du blir bedt om å signere når du møter fram til helse-undersøkelsen.

Samtykke til bruk av helseopplysninger i forskning

Helseundersøkelsen i Nord-Trøndelag 2006-08 (HUNT 3)

I brosjyren jeg har fått tilsendt har jeg lest om helse-undersøkelsens innhold og formål, og jeg har hatt mulighet til å stille spørsmål.

Jeg samtykker i å delta i undersøkelsen.

Dato _____

Signatur *Marianne Olsen*

Deltok du i HUNT 2?

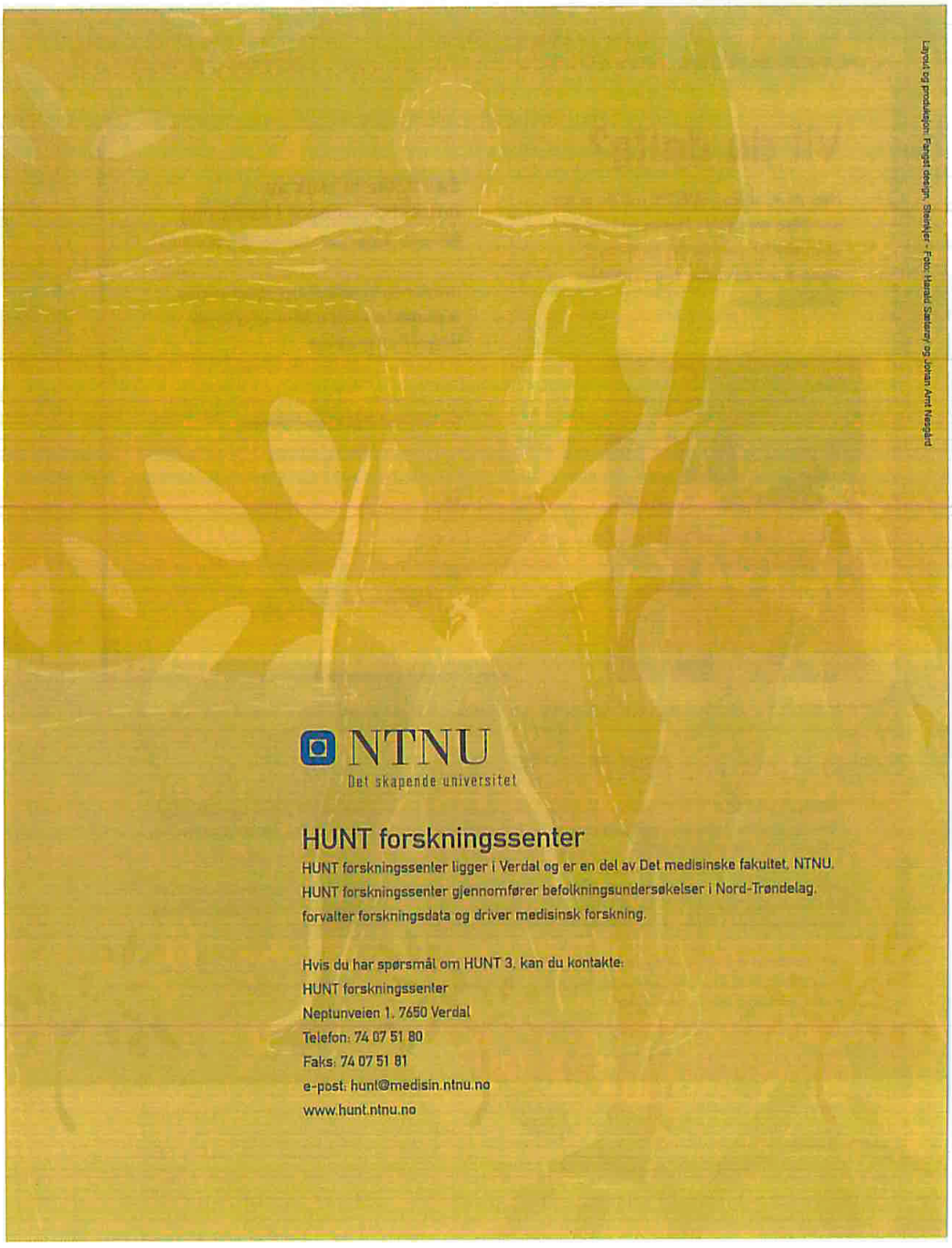
I etterkant av HUNT 2 (1995-97) ble det gjennomført flere undersøkelser der en mindre del av befolkningen deltok. Disse prosjektene hadde opprinnelig tidsbegrensede konsesjoner fra Datatilsynet, og avtalen var at opplysningene skulle slettes etter en bestemt dato.

I ettertid har det vist seg at opplysningene har stor verdi for framtidig forskning, og HUNT forskningssenter har derfor fått Datatilsynets tillatelse til å inkludere dem i HUNT databank. En liste over prosjektene som dette gjelder, finnes på internett www.hunt.ntnu.no. Du kan få listen tilsendt ved å henvende deg til HUNT forskningssenter.

Hvis du deltok i et av disse prosjektene og ikke ønsker at opplysninger om deg skal oppbevares videre, kan du ta kontakt med HUNT forskningssenter, Neptunveien 1, 7650 Verdal, og be om at opplysningene slettes. Det er ikke nødvendig å oppgi noen grunn til dette.

Deltok du i Ung-HUNT?

Hvis du deltok i Ung-HUNT i 1995-1997 eller 2000-01 vil disse opplysningene fra deg bli oppbevart og brukt på samme måte som opplysninger fra de voksne i tidligere HUNT-undersøkelser. Hvis du ikke ønsker at opplysningene skal oppbevares videre, kan du ta kontakt med HUNT forskningssenter, Neptunveien 1, 7650 Verdal, og be om at de slettes. Det er ikke nødvendig å oppgi noen grunn til dette.



NTNU
Det skapende universitet

HUNT forskningssenter

HUNT forskningssenter ligger i Verdal og er en del av Det medisinske fakultet, NTNU. HUNT forskningssenter gjennomfører befolkningsundersøkelser i Nord-Trøndelag, forvalter forskningsdata og driver medisinsk forskning.

Hvis du har spørsmål om HUNT 3, kan du kontakte:

HUNT forskningssenter
Neptunveien 1, 7650 Verdal
Telefon: 74 07 51 80
Faks: 74 07 51 81
e-post: hunt@medisin.ntnu.no
www.hunt.ntnu.no

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