healthintegrator

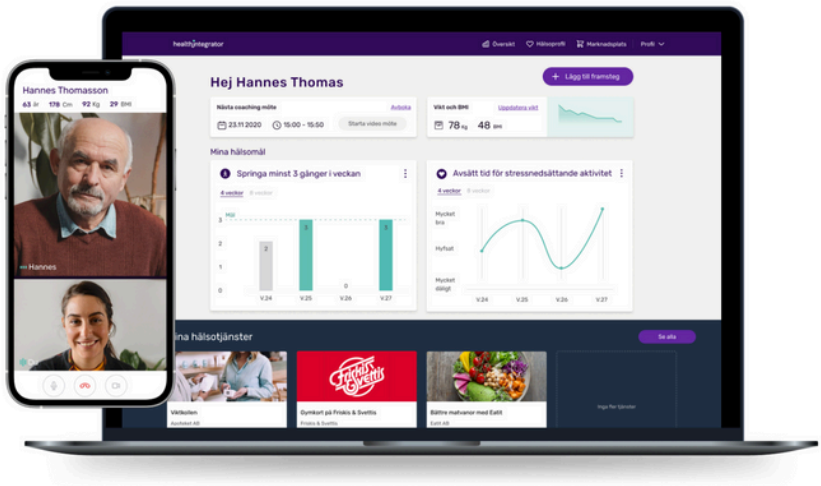
HEALTH INTEGRATOR -PREVENTION OF TYPE 2 DIABETES

24-monthreport

SEPTEMBER 2023

V1.21

CONTENT



1.VERSION HISTORY

This is the fourth version of the health programme report. The following were previously published (in Swedish, only 12 month in english):

18-month report

12-month report

6-month report

2.ABSTRACT

Backgrund

Region Stockholm's health care board has decided to test a model for more effective governance and financing of prevention initiatives. Among other things, the region wants to evaluate Health Integrator's preventive health programme, a prevention with significant digital elements to reduce the risk of type 2 diabetes. Previous scientific studies have shown that it is possible to halve the risk of type 2 diabetes with health-promoting lifestyle initiatives. Region Stockholm expects a health economic effect of SEK 1.4 billion per year at full scale-up to all pre-diabetics.

Aims and Objectives

The intervention aims to bring as many as possible (at least one third) of the participants from a prediabetes stage (HbA1c 42-47 mmol/mol) to a normal HbA1c (<42 mmol/mol) after two years of active intervention and maintain that proportion at the 3-, 4- and 5-year follow-up.

Participants and Methodology

Participants were mainly recruited through advertisements in social media and the daily press (both print and digital), newsletters to various companies and interest groups, and information sheets in waiting rooms at health centres. Interested participants were further screened using the FINDRISC form and blood tests where participants had to have an HbA1c between 42-47 mmol/mol to be included in the intervention. 925 participants were recruited from October 2020 to February 2022. The participants met with a health coach and together they planned different types of health goals to improve their lifestyle. Participants then booked health services and products using the Health Integrator digital platform.

Results

On 8 September 2023, 498 participants had passed 24 months follow up time point in the intervention, of which 358 have reported 24-month data. The results show that 54.2% (95% confidence interval 49.0%-59.3%) of participants at 24 months have a blood test showing an HbA1c <42 mmol/mol. There were 7.5% of participants who increased their HbA1c to meet the diagnostic criteria for diabetes, >=48 mmol/mol. The results show a statistically significant reduction in both HbA1c and BMI for the participants, p<0.001. The participants had on average spent SEK 5,460 on various health services and health products. 85% of the participants felt that the health programme has been a contributing factor to improved quality of life.

Conclusion

The results at 24 months show with statistical significance that the intervention has achieved its primary objective and more than half of the participants have reduced HbA1c to the point of leaving prediabetes status. The lifestyle intervention appears to be working and it also reduces the participants' BMI, with the effect occurring after six months and being sustained until 24 months. Only 7.5% of participants have developed an HbA1c indicative of type 2 diabetes over 2 years compared to 23% without lifestyle intervention.

3.INTRODUCTION

Today, the healthcare system is facing major challenges. Chronic and lifestyle-related diseases are increasing rapidly, the cost of medicines is rising, and we are living longer. The need for care for the sick appears to be increasing, but few efforts are being made to reduce the influx of new cases. The majority of health care resources in Sweden are currently spent on caring for those who are already ill. (Reference 1) Of the total cost of the health budget, chronic disease management accounts for about 80% of the total cost of the health budget. (Reference 2). On average, the cost of care for a person with type 2 diabetes is almost 4.5 times higher than for a person without type 2 diabetes. (page 6 in Hälsokontraktet, Reference 1)

With the right interventions, the trend can be reversed. Studies by the World Health Organisation (WHO) and others show that around 80% of chronic, lifestyle-related diseases worldwide could be prevented by health promotion. (Reference 3) Encouraging healthy behaviours such as exercise, diet, sleep, tobacco and alcohol consumption can prevent both physical and mental illness. Preventing disease will always be a win-win situation: for the individual, their families and society as a whole. (Reference 4)

Health Integrator's preventive health programme is the first initiative with a so-called health impact bond. (Reference 5), where the programme aims to support individuals at risk of developing type 2 diabetes to adopt healthy lifestyles in order to halt the progression of the disease. Region Stockholm has estimated that it could save SEK 1.4 billion per year in healthcare costs if it chooses to scale up and offer the intervention to all pre-diabetics in the region.(Reference 6)

This report presents the health programme design and results of the 24-month follow-up of the intervention/health programme.

3.1 BACKGROUND AND DESCRIPTION OF THE PILOT PROJECT

In May 2020, Region Stockholm's health care board decided to test a model for more effective governance and financing of prevention initiatives through a pilot with Health Impact Bonds. (Reference 6) Health Integrator's preventive health programme is one of three parts of service statement HSN 2019-1786 which reads as follows:

> **1. The Director of Health and Medical Services is instructed, in collaboration with AB Stockholm County Council's Internal Finance and FoUUI at the Regional Management Office, to carry out the development project Test of a model for more efficient governance and financing of prevention initiatives through a pilot with Health Impact Bonds. (Hälsokontrakt, se referens 1).**
> **2. The Director of Health is instructed to ask AB SLL Internfinans to execute the issue of a Health Impact Bond.**
> **3. The Director of Health and Medical Services is authorised to sign an agreement with Health Integrator AB during the project period.**

The background is that the region has called for models and processes to calculate the cost savings that arise if, at different levels of success, disease progression is averted and the need for care is avoided in different patient groups. The aim is to determine what is reasonable to pay for prevention, and to estimate the point at which the investment can be recouped.

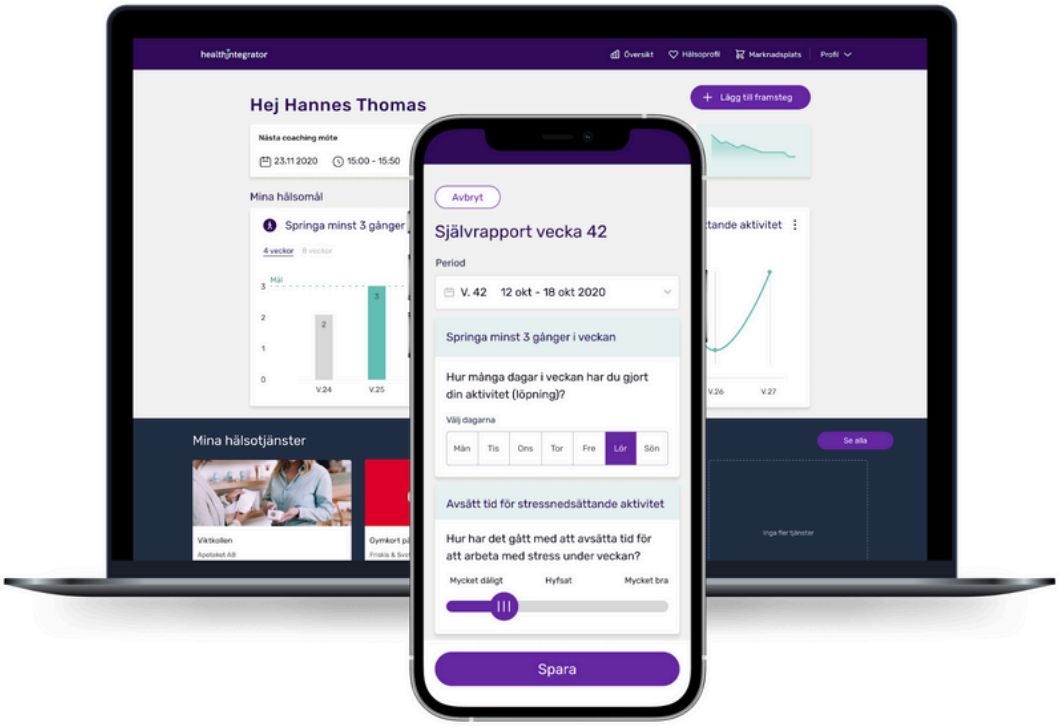
A challenge in the shift from reactive to preventive care is the need for liquidity during a transition period when the region pays for prevention while continuing to pay for the care of those who are already sick. It may be difficult to justify allocating a larger share of health care resources to prevention if more acute care needs continue to increase. Those who have fallen ill should be prioritised, while preventive measures can reduce the incidence of new patients. In the short term, increasing the proportion of resources devoted to preventive care would lead to increased costs, but in the longer term it is likely to generate substantial savings.

In addition to reductions in direct costs such as healthcare costs, there are also savings in indirect costs such as the absence of costs for any sickness benefit and loss of production. The opportunity cost of choosing not to invest in disease prevention is difficult to calculate, but it is obvious that it is financially unsustainable not to invest in prevention. According to the World Health Organisation (WHO), one krona invested in disease prevention results in a saving of six kronor in lost health care and social costs.

BACKGROUND AND DESCRIPTION OF THE PILOT PROJECT (CONTINUED)

To bridge the liquidity needs that arise in the transition period from caring for patients to increasing preventive treatment/intervention, outcome-based contracts can be used. This means that the financier is reimbursed based on the outcome of the prevention. This type of financing solution, a Health Impact Bond, forms the basis of the pilot project and Health Integrator's preventive health programme. More detailed information on the Health Impact Bond (Reference 6).

In the decision HSN 2019-1786; Test of a model for more efficient governance and financing of prevention initiatives through a pilot with Health Impact Bonds(Hälsokontrakt, se reference 1) describes that the primary care or other healthcare providers are not the optimal channel for reaching individuals at risk of disease, as these individuals are often not in the healthcare system as long as they are undiagnosed. Furthermore, it is considered that new channels and methods must be tested as a complement and thus also free up resources for primary care. A description of the recruitment and selection process for the Health Integrator health programme is described in Chapter 2.4.



3.2 Purpose and scope

The overall aim of the pilot project is to contribute to a systemic change in health care, moving from reactive care to preventive care. It contains three interlinked elements:

1) impact measurement
2) risk sharing through a new financial instrument
3) designing a prevention with significant digital elements.

This report aims to report on the status of the third point, design of a prevention programme with significant digital elements. Below is a description of the design of Health Integrator's health programme and the results of the 24-month follow-up in the prevention programme with regard to HbA1c and other outcome variables for the participants who had reported 24-month data at the time of data extraction in September 2023. The analysis of the health development of the participants and the conclusions drawn are Health Integrator's own and should be interpreted as an indication of the development of the participants rather than a full-fledged basis for evaluating the health programme as a whole. Health Integrator is the provider of the health programme on behalf of Region Stockholm.

According to previous scientific studies in diabetes prevention, a health-promoting lifestyle intervention over three years among people with glucose intolerance (blood sugar 6.0-7.0 mmol/l) can reduce the risk of diabetes by 58%, from 23% to 11%. (Reference 7, Reference 8). (Note that these studies did not use long-term blood sugar, HbA1c, as a basis for defining the study population.) This means that with a lifestyle intervention, Region Stockholm could prevent 12% (23%-11%) from developing type 2 diabetes over three years.

To prevent the development of type 2 diabetes, it is important to find and identify individuals at risk of type 2 diabetes before they become patients and are diagnosed with type 2 diabetes. (Reference 1) The measure used for the risk zone for prediabetes is long-term blood sugar, HbA1c = 42-47 mmol/mol. The diagnostic criterion for type 2 diabetes is HbA1c >=48 mmol/mol. A lifestyle intervention focusing on reducing HbA1c to <42 mmol/mol (normal level) can reduce the risk of this risk group developing type 2 diabetes.

The Health Contract defines a target value for the Health Integrator's health programme. To be considered successful, at least 300 out of 925 participants should reach a normal level of HbA1c at the last follow-up. (Reference 1). It is a direct measure of how many people are reversing the course of the disease. The intervention also measures HbA1c development in terms of the proportion of participants who are developing type 2 diabetes with an HbA1c >=48 mmol/mol. To match previous randomised studies with a risk reduction of 58%, 11% or less of the participants in this intervention should develop type 2 diabetes. However, it should be mentioned that there are differences in inclusion criteria compared to previous studies.

The impact will be evaluated after 24 months of the health programme and followed up annually for five years. The last follow-up of the participants is expected to take place in 2027, when all participants have passed the five-year follow-up. The health economic benefit of a risk reduction of type 2 diabetes has already been estimated. (Reference 6) by Region Stockholm and is estimated at 1.4 billion per year when fully scaled up to all pre-diabetics.

The aim of this non-randomised intervention is to evaluate the effectiveness of the health programme in bringing as many of the participants' HbA1c levels down to normal levels as possible, and as few as possible increasing their levels and developing type 2 diabetes.

3.3 HEALTH INTEGRATOR'S HEALTH PROGRAMME

Health Integrator's digital platform provides a digital marketplace that brings together providers of health promotion services and products that are considered helpful in tailoring a preventive health programme for individuals at risk of disease with the help of health coaches.

The health coach helps the individual to take a holistic approach to health, taking into account elements such as physical activity, diet, sleep, alcohol and tobacco consumption, mental health and stress. The health coach provides the participant with knowledge and understanding of the individual's current situation and establishes a health profile. On the basis of the health profile and with the guidance and support of the health coach, a customised health plan is created with planned and timed activities. These activities are based on the participant's needs and individual preferences for activities to increase adherence.

Each participant receives a health balance totalling SEK 6 250 per year for the first two years of the initiative. The health balance may be used for consumption of health services presented on the digital marketplace and for an increased number of counselling sessions with the health coach.

If the plan is not followed, the participant is contacted by the health coach for additional follow-up and support. All participants are invited to annual measurements and a follow-up meeting with their health coach.

After two years, the hope is that the participant has sufficient motivation and insight to pay for health services themselves or with the support of their employer. Any unused balance will be available for continued consumption during the total duration of the programme.

Health Integrator creates a digital ecosystem around users for better health , see more info (Reference 11 and Reference 12)

3.4 PILOT STUDY TO DEVELOP THE INTERVENTION PROGRAM

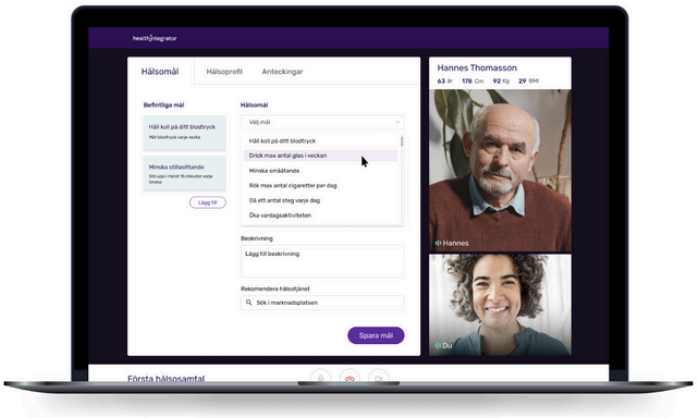
The health programme has been tested in a clinical pilot study. (Reference 9, Reference 10). The study was led by Ylva Trolle Lagerros, a physician and researcher employed by Region Stockholm and Karolinska Institutet with extensive experience in diabetes care and lifestyle for individuals living with diabetes. The study was a randomised, controlled parallel group study in which 209 individuals were recruited from four companies in Stockholm. Participants were healthy volunteers with a mix of salaried employees from insurance companies and pharmacies and workers from bus companies. Participants were randomised with equal chance to one of the following options for the three-month intervention:

1) Monthly health coaching calls and access to a digital platform, the precursor to Health Integrator's current platform, to record health goals. Over three months, participants were offered three health talks, two sessions and one follow-up.

2) Access to the digital platform but no access to counselling with a health coach.

3) Control group with neither access to the digital platform nor health coaching. However, they were offered access to the digital platform and counselling after the end of the study period.

The study showed that the health coaching and platform had a positive effect on the health of individuals compared to those in the control group in terms of waist size, BMI, and body fat. (Reference 10). The study shows that the functionality worked and that some effect on health can be achieved although this population is different from the one intended to be studied in this intervention, people at risk of diabetes.

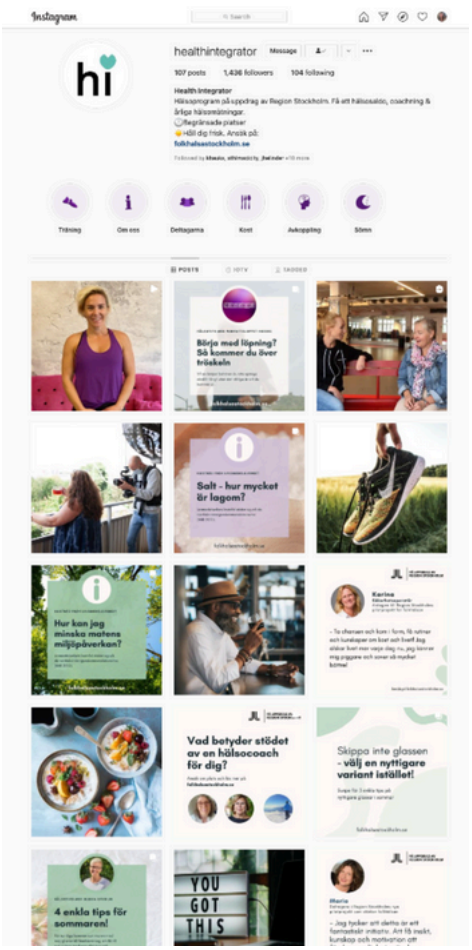


3.5 TARGET GROUP AND RECRUITMENT

The target group is people aged between 50 and 60 who live in the Stockholm region and have an increased risk of developing type 2 diabetes. The aim was to include as many men as possible and individuals from socio-economically disadvantaged areas. The target group is considered to have a very high probability of developing diabetes within a five to ten year period, based on analyses of the healthcare events in Region Stockholm's VAL database.

A total of 925 participants were recruited to the health programme over 16 months, from October 2020 to February 2022. The first health interview was conducted in February 2021.

Recruitment began by asking those who were interested to sign up for the programme. They were then asked to fill in a screening form, and those who qualified were invited for a blood test.



RECRUITMENT

Interested people were invited to apply for the health programme digitally on the application site www.folkhalsastockholm.se where they were asked to fill in contact details and a health form. The recruitment of participants to the health programme was done by Health Integrator through advertising in digital and analogue channels, resulting in more than 28,000 applications. The following channels were used for recruitment:

1. Social media on Instagram and Facebook. The advertisements were aimed at all geographical areas in Stockholm County, with repeated campaigns targeting the prioritised target group in socio-economically disadvantaged areas and with a particularly strong focus on men in these areas.
2. Editorial articles in newsletters to non-profit organisations and partners, including Blå Vagnen, Blodsockerkollen, the Facebook groups Diabetes Sverige, Viktminskning - Lifesum and Kaloriunderskott. Further, through newsletters and social media channels on the companies Apoteket, Skandia, SEB, Lloyd Apotek, Apohem, KGK, Nobina, Svenska Taxiförbundet, MTR, Lidingö Kommun, Friskis och Svettis, Järvafältet idrott, Bonava, TL Bygg, NCC, Wellobe and En Friskis Generation.
3. Paid adverts in both print and digital form in Aftonbladet, Svenska Dagbladet, Hemnet, Blocket, Mitti and LinkedIn.
4. Information about the initiative was distributed in the form of information sheets in waiting rooms in healthcare centres in Stockholm and on information sheets in connection with covid vaccination during the summer of 2021. A large part of the advertising was done in västerort, an area with low socio-economic status.
5. Collaboration with some influencers in social media who were judged to have a large number of followers in the target group.

All campaigns were conducted in Swedish, which limits the target group to a certain extent.

SCREENING

The screening was conducted outside of primary care because individuals with prediabetes in most cases have no diabetes-related contact with the health care system as they are undiagnosed. Screening outside of primary care also does not burden the healthcare system.

The screening was done in two stages. The first step was the application session at the www.folkhalsastockholm.se where the interested persons filled in a health questionnaire, FINDRISC, which is designed to identify individuals at risk of type 2 diabetes. FINDRISC includes questions about the individual's weight, height, exercise and dietary habits and more. Based on the answers in the form, a score is calculated that indicates a high (13 or more) or low (12 or less) risk of developing type 2 diabetes. Those deemed to be at high risk were invited for blood tests and those at low risk were informed about the recruitment process and that other applicants had been prioritised.

The second step in the screening process was blood testing. The applicants received an invitation via email asking them to order a blood test for long-term blood sugar (HbA1c) via 1177 with an invitation code given to them. Those who did not meet the inclusion criteria for age (between 50 and 60 years) or civil registration address (resident in Stockholm County) at the time of identification were denied the opportunity to order the blood test on 1177. Those who took the blood test and received a result within the range of HbA1c 42-47 mmol/mol were offered a place in the programme, where they were booked in with a health coach, until the intervention was fully recruited.

3.6 OBJECTIVES

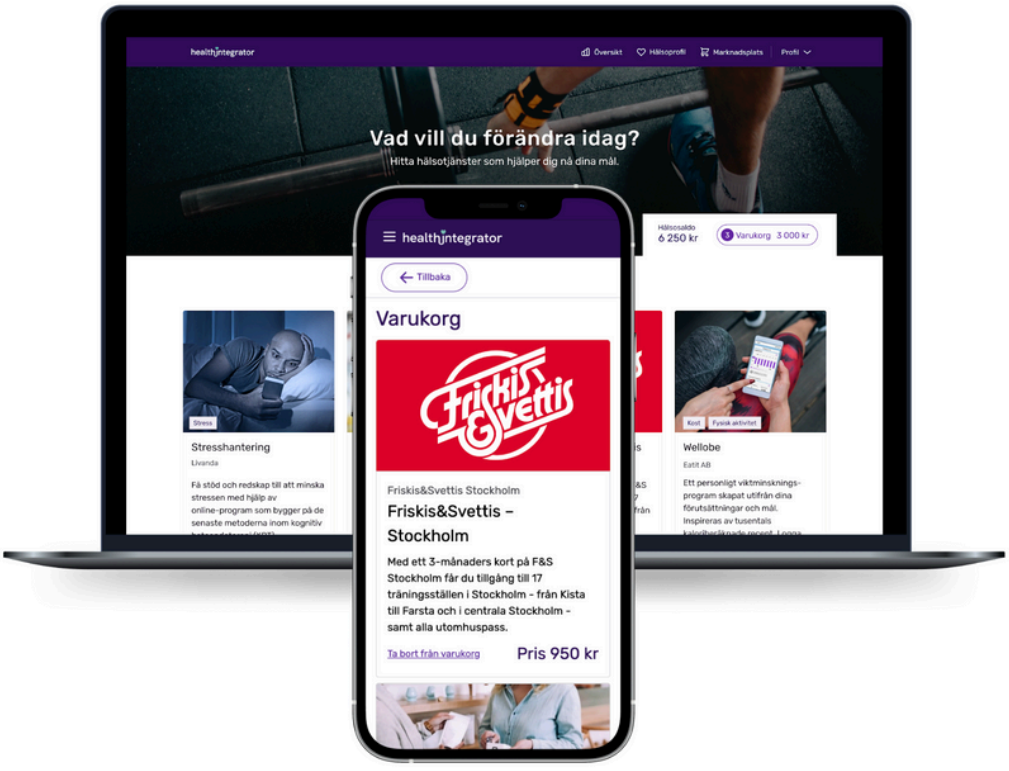
Primary objective

The primary objective is to reduce HbA1c among as many participants as possible and to move them from a pre-diabetic health state for type 2 diabetes with an HbA1c of 42-47 mmol/ml, to a normal value below 42 mmol/ml. Successful outcome is defined as at least 300 out of 925 participants achieving this goal.

Secondary objectives

Secondary objectives are to

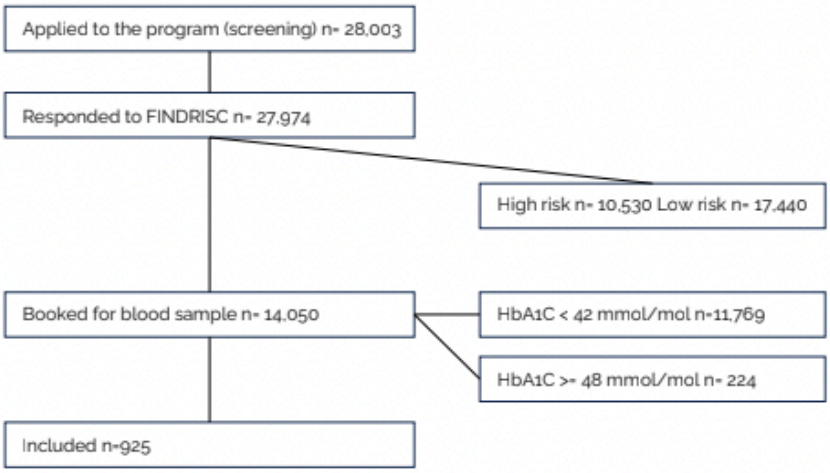
- Reduce HbA1c among as many participants as possible
- Reduce participants' BMI
- Proportion of participants who maintain <42 mmol/mol in HbA1c after 24 months.
- Participants improve their lifestyle



4.ENROLMENT OF PARTICIPANTS

Of the 28 003 applicants on folkhalsastockholm.se, all were invited to take a blood test for HbA1c. The first 925 consecutive applicants who met all inclusion criteria with respect to FINDRISC and HbA1c were included in the intervention. 224 of the applicants had a blood test result indicating that they already had diabetes and were referred to the health care system for further assessment and treatment.

Figure 1. Flow Diagram of the Recruitment of Participants.



Participants were recruited to the programme consecutively over 16 months. In February 2022, recruitment was closed as all 925 places were filled.

Since recruitment ended, 22 participants have actively chosen to drop out of the programme. Seven of these have dropped out due to moving to another location and 15 due to health or personal reasons.

Currently, 818 (88.4%) participants have reported 12-month data and 358 (41.2%) participants have reported 24-month data. The final non-response will be reported in the follow-up report next year.

DEVIATIONS FROM THE PLANNED IMPLEMENTATION OF THE HEALTH PROGRAMME

COVID-19 restrictions caused delays in the recruitment process as several of the applicants at high risk of type 2 diabetes who were invited for blood tests delayed their visit to the testing centre. Some applicants also opted to cancel their application as they did not want to spend time in public spaces among other people unnecessarily.

Other planning deviations that occurred included making information on the health programme available to reception and nursing staff at the sampling centres. A common misunderstanding was that the applicant was asked to show a referral at testing centres where they had technical problems getting the blood test order into their booking system. The applicant was then sent home, unnecessarily, as no referral was necessary to place an order for long-term blood sugar on 1177 with an order key. Because of this, some chose to cancel the process as they felt that it was too time-consuming to visit the sampling unit again. Many felt that Own sampling on 1177 was difficult to use and turned directly to Health Integrator for support instead of 1177.

As the operation was not fully recruited in January 2022, all applicants were invited to be sampled regardless of their FINDRISC score, i.e. also people at low risk according to FINDRISC. Among these, an additional 181 participants were recruited for the intervention.

The sample of participants is representative of society in general and no differences in geography or socioeconomics can be noted.

5.PRIMARY AND SECONDARY OUTCOME VARIABLES

Primary outcome variable:

- Proportion of participants with HbA1c <42 mmol/mol at 24 months.

Secondary outcome variables

- Proportion of participants with HbA1c <42 mmol/mol at 6, 12, 18, 30, 36, 42, 48, 54 and 60 months
- Proportion of participants who improved HbA1c at 6, 12, 18, 30, 36, 42, 48, 54 and 60 months compared to baseline.
- Mean change in HbA1c from baseline to 6, 12, 18, 24, 30, 36, 42, 48, 54 and 60 months.
- Mean change in BMI from baseline to 6, 12, 18, 24, 30, 36, 42, 48, 54 and 60 months.
- Proportion of participants with BMI classification of normal weight, overweight and obese at 6, 12, 18, 24, 30, 36, 42, 48, 54 and 60 months.
- Proportion of participants measuring and maintaining HbA1c <42 mmol/mol at 24 months
- Change in perceived quality of life

STATISTICS

All variables have been reported using descriptive statistics. For continuous variables, minimum, maximum, median, mean and standard deviation are presented. For category variables, frequency/number and proportion/percentage are presented.

Changes over time with respect to mean values are tested using a t-test with the null hypothesis: no change over time (=0).

The primary outcome variable, the proportion leaving pre-diabetes status, i.e. HbA1c <42 mmol/mol, is presented together with the associated 95% confidence interval. This proportion is tested against the null hypothesis that 0% have improved from baseline. A p-value <0.05 indicates a statistically significant proportion that has achieved an HbA1c <42 mmol/mol at 24 months.

STATISTICS (CONTINUED)

To analyse how much different factors are associated and discriminate against those participants who reached a normal HbA1c at 24 months, multivariate logistic regression was used, with age group, FINDRISC at baseline and gender included in the model.

Reporting of changes in quality of life was done with respect to the data reported at 18 months as they are collected annually starting at six months.

Statistics are calculated on observed values. No imputation for missing data has been done. Here, participants in the dropout group have been counted as having a negative outcome, i.e. having an HbA1c >42 mmol/mol.

The lost to follow up participants who were recruited and invited to report 24-month data is reported using descriptive statistics for baseline data.

REPORTED PROBLEMS WITH THE SYSTEM/EXPERIENCES OF INDIVIDUALS

The majority of participants were able to use the Health Integrator and the marketplace.
A few participants reported problems with purchases on the marketplace and problems with video calls, which were then resolved.

Participants reported requests for an Android or Apple app. In the planning of the intervention, an active choice was made not to develop dedicated mobile apps for a simpler user experience even though it would have meant a simpler technical implementation. The consequence was that it is not possible to automatically collect measures such as the number of steps per day. This is instead reported manually by the participant themselves.

6.OUTCOME OF PARTICIPANTS AFTER 24 MONTHS

6.1 PARTICIPANT FLOW AND BASELINE DATA

As of 5 September 2023, 498 participants have been invited to respond to the 24-month follow-up. Of these, 358 have reported data for the primary outcome variable, HbA1C. The largest proportion of non-responders is because they have just passed the 24-month reporting window and have not had time to respond.
For the 18-month follow-up, 577 participants have reported data for the primary outcome variable and the corresponding number for 12 months is 818 participants.

Baseline data for the entire intervention population is presented in Table 1. Data may differ from previous reporting as data has been cleaned from incorrect entries found since the 18-month reporting.

Table 1a. Descriptive Statistics Baseline.

		Valid N	Mean	Standard Deviation	Median	Minimum	Maximum
Female	Weight (kg)	611	90,3	19,1	88,0	51,0	167,8
Male	Weight (kg)	314	100,1	17,9	98,7	52,0	155,0
Total	Weight (kg)	925	93,6	19,2	91,8	51,0	167,8
Female	BMI	611	32,6	6,4	31,8	18,7	57,4
Male	BMI	314	30,9	5,1	30,4	18,0	52,0
Total	BMI	925	32,0	6,1	31,2	18,0	57,4
Female	Waist circumference (cm)	596	105,4	15,2	104,0	60,0	165,0
Male	Waist circumference (cm)	300	110,9	14,0	110,0	82,0	175,0
Total	Waist circumference (cm)	896	107,3	15,1	106,0	60,0	175,0
Female	Height (cm)	611	166,3	6,1	167,0	149,0	182,0
Male	Height (cm)	314	180,0	6,7	180,0	159,0	200,0
Total	Height (cm)	925	170,9	9,0	170,0	149,0	200,0
Female	Age	611	55,8	3,0	56,0	50,0	62,0
Male	Age	314	55,2	2,9	55,0	50,0	61,0
Total	Age	925	55,6	3,0	56,0	50,0	62,0
Female	Findrisc score	608	16,2	3,9	16,0	4,0	25,0
Male	Findrisc score	313	15,5	4,2	16,0	4,0	25,0
Total	Findrisc score	921	15,9	4,0	16,0	4,0	25,0

6.1 PARTICIPANT FLOW AND BASELINE DATA (CONTINUED)

Table 1b. Descriptive Statistics Baseline Categorical Variables.

			Count	Column N %
Female	Viktstatus	Normal (BMI<25)	57	9,3%
		Overweight (BMI 25-30)	177	29,0%
		Obesity class 1 (BMI 30-35)	181	29,6%
		Obesity class 2 (BMI 35-40)	117	19,1%
		Obesity class 3 (BMI>40)	79	12,9%
		Total	611	100,0%
Male	Viktstatus	Normal (BMI<25)	30	9,6%
		Overweight (BMI 25-30)	115	36,6%
		Obesity class 1 (BMI 30-35)	114	36,3%
		Obesity class 2 (BMI 35-40)	38	12,1%
		Obesity class 3 (BMI>40)	17	5,4%
		Total	314	100,0%
Female	Age	50-55 years	284	46,5%
		56-60 years	327	53,5%
		Total	611	100,0%
Male	Age	50-55 years	162	51,6%
		56-60 years	152	48,4%
		Total	314	100,0%

6.2 RESULTS OF PRIMARY AND SECONDARY OUTCOME VARIABLES

6.2.1 PRIMARY OUTCOME VARIABLE

There were 194 (54.2%, 95% confidence interval 49.0%-59.3%, p<.0.001) participants who met the criteria for the primary outcome variable at 24 months. This was slightly more for women than for men. The results are presented in Table 2a. There were more men (10.4%) than women (6.2%) who developed HbA1c levels qualifying for diabetes, >=48 mmol/mol at 24 months. HbA1c levels by age and FINDRISC score at baseline are presented in Tables 2b and 2c.

There was a similar proportion of normal HbA1c in both age groups. There was a greater proportion with normal HbA1c among those with a FINDRISC score <13 (low risk) (58.5%) at baseline than those with 13 or more (high risk) (53.7%) and there were more people with elevated HbA1c who met the diagnostic criteria for diabetes at 24 months in the high risk FINDRISC group (8. In the entire intervention population, 7.5% (95% CI: 5.1%-10.6%) met the diagnostic criteria for diabetes in HbA1c at 24 months.

Figure 2 illustrates the results for the primary outcome variable and the proportion leaving pre-diabetes at each follow-up point.

Table 2a. Primary Outcome Variable HbA1c by Gender.

		Months in Study									
		0		6		12		18		24	
		Count	Column N %	Count	Column N %	Count	Column N %	Count	Column N %	Count	Column N %
Female	Normal <42 mmol/mol	0	0.0%	241	49.1%	277	51.1%	203	52.9%	133	54.7%
	Prediabetes 42-47 mmol/mol	610	100.0%	220	44.8%	242	44.6%	167	43.5%	95	39.1%
	Diabetes >=48 mmol/mol	0	0.0%	30	6.1%	23	4.2%	14	3.6%	15	6.2%
	Total	610	100.0%	491	100.0%	542	100.0%	384	100.0%	243	100.0%
Male	Normal <42 mmol/mol	0	0.0%	122	47.7%	146	52.9%	91	47.2%	61	53.0%
	Prediabetes 42-47 mmol/mol	314	100.0%	123	48.0%	110	39.9%	82	42.5%	42	36.5%
	Diabetes >=48 mmol/mol	0	0.0%	11	4.3%	20	7.2%	20	10.4%	12	10.4%
	Total	314	100.0%	256	100.0%	276	100.0%	193	100.0%	115	100.0%
Total	Normal <42 mmol/mol	0	0.0%	363	48.6%	423	51.7%	294	51.0%	194	54.2%
	Prediabetes 42-47 mmol/mol	924	100.0%	343	45.9%	352	43.0%	249	43.2%	137	38.3%
	Diabetes >=48 mmol/mol	0	0.0%	41	5.5%	43	5.3%	34	5.9%	27	7.5%
	Total	924	100.0%	747	100.0%	818	100.0%	577	100.0%	358	100.0%

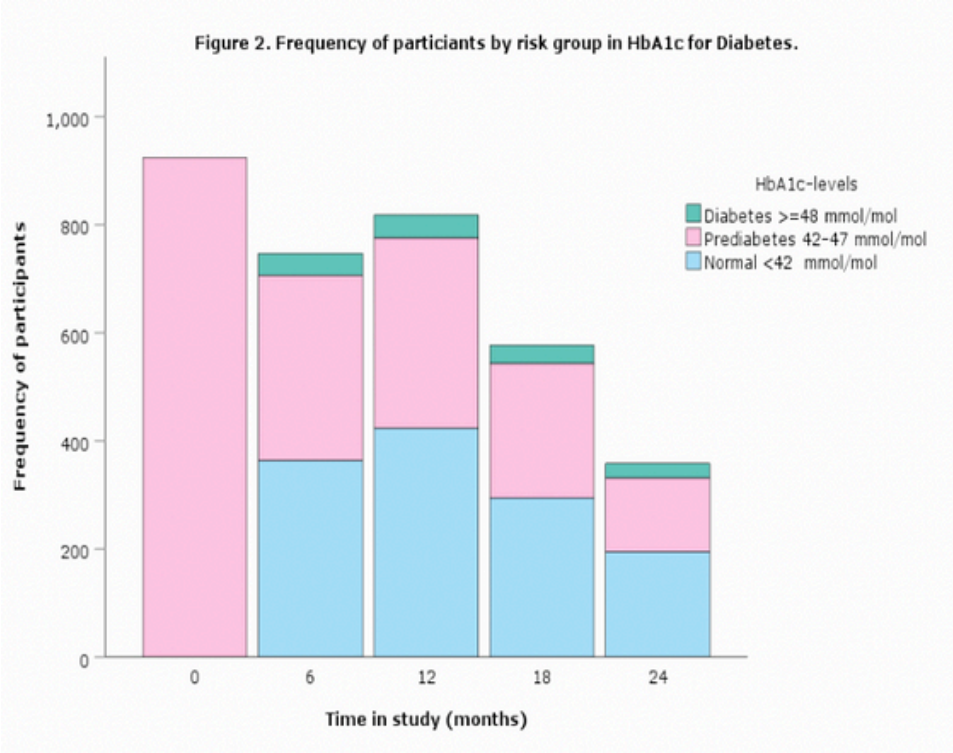
Table 2b. Primary Outcome Variable HbA1c by Age.

			Months in Study								
			0		6		12		18		24	
			Count	Column N %	Count	Column N %	Count	Column N %	Count	Column N %	Count	Column N %
-55 years	HbA1c	Normal <42 mmol/mol	0	0,0%	189	52,9%	210	53,3%	138	50,5%	93	53,4%
		Prediabetes 42-47 mmol/mol	446	100,0%	149	41,7%	159	40,4%	119	43,6%	71	40,8%
		Diabetes >=48 mmol/mol	0	0,0%	19	5,3%	25	6,3%	16	5,9%	10	5,7%
		Total	446	100,0%	357	100,0%	394	100,0%	273	100,0%	174	100,0%
>55 years	HbA1c	Normal <42 mmol/mol	0	0,0%	174	44,6%	213	50,2%	156	51,3%	101	54,9%
		Prediabetes 42-47 mmol/mol	478	100,0%	194	49,7%	193	45,5%	130	42,8%	66	35,9%
		Diabetes >=48 mmol/mol	0	0,0%	22	5,6%	18	4,2%	18	5,9%	17	9,2%
		Total	478	100,0%	390	100,0%	424	100,0%	304	100,0%	184	100,0%
Total	HbA1c	Normal <42 mmol/mol	0	0,0%	363	48,6%	423	51,7%	294	51,0%	194	54,2%
		Prediabetes 42-47 mmol/mol	924	100,0%	343	45,9%	352	43,0%	249	43,2%	137	38,3%
		Diabetes >=48 mmol/mol	0	0,0%	41	5,5%	43	5,3%	34	5,9%	27	7,5%
		Total	924	100,0%	747	100,0%	818	100,0%	577	100,0%	358	100,0%

6.2.1 PRIMARY OUTCOME VARIABLE (CONT)

Table 2c. Primary Outcome Variable HbA1c by FINDRISC score.

		Months in Study									
		0		6		12		18		24	
FINDRISC vid baslinje		Count	Column N %	Count	Column N %	Count	Column N %	Count	Column N %	Count	Column N %
<13	Normal <42 mmol/mol	0	0.0%	94	63.1%	112	65.9%	49	59.8%	20	58.8%
	Prediabetes 42-47 mmol/mol	181	100.0%	49	32.9%	50	29.4%	27	32.9%	13	38.2%
	Diabetes >=48 mmol/mol	0	0.0%	6	4.0%	8	4.7%	6	7.3%	1	2.9%
	Total	181	100.0%	149	100.0%	170	100.0%	82	100.0%	34	100.0%
>=13	Normal <42 mmol/mol	0	0.0%	268	45.1%	308	47.8%	243	49.4%	173	53.7%
	Prediabetes 42-47 mmol/mol	740	100.0%	291	49.0%	301	46.7%	221	44.9%	123	38.2%
	Diabetes >=48 mmol/mol	0	0.0%	35	5.9%	35	5.4%	28	5.7%	26	8.1%
	Total	740	100.0%	594	100.0%	644	100.0%	492	100.0%	322	100.0%
Total	Normal <42 mmol/mol	0	0.0%	362	48.7%	420	51.6%	292	50.9%	193	54.2%
	Prediabetes 42-47 mmol/mol	921	100.0%	340	45.8%	351	43.1%	248	43.2%	136	38.2%
	Diabetes >=48 mmol/mol	0	0.0%	41	5.5%	43	5.3%	34	5.9%	27	7.6%
	Total	921	100.0%	743	100.0%	814	100.0%	574	100.0%	356	100.0%



6.2.2 SECONDARY OUTCOME VARIABLES

The mean HbA1c at each follow-up occasion is presented in Table 3.

Table 3a. Mean HbA1c over Time by Gender.

			Months in Study				
			0	6	12	18	24
Female	HbA1c (mmol/mol)	Valid N	610	491	542	384	243
		Mean	43,4	41,9	41,6	41,5	41,5
		Standard Deviation	1,5	3,2	3,3	3,3	3,8
		Median	43,0	42,0	41,0	41,0	41,0
		Minimum	42,0	33,0	30,0	30,0	33,0
		Maximum	47,0	55,0	56,0	57,0	63,0
Male	HbA1c (mmol/mol)	Valid N	314	256	276	193	115
		Mean	43,5	41,7	42,1	41,8	41,5
		Standard Deviation	1,6	3,4	4,9	4,1	4,4
		Median	43,0	42,0	41,0	42,0	41,0
		Minimum	42,0	32,0	34,0	32,0	31,0
		Maximum	47,0	55,0	87,0	53,0	58,0
Total	HbA1c (mmol/mol)	Valid N	924	747	818	577	358
		Mean	43,4	41,9	41,8	41,6	41,5
		Standard Deviation	1,5	3,3	3,9	3,6	4,0
		Median	43,0	42,0	41,0	41,0	41,0
		Minimum	42,0	32,0	30,0	30,0	31,0
		Maximum	47,0	55,0	87,0	57,0	63,0

Mean HbA1c decreased from baseline to follow-up at six months by -1.5 (SD=3.0, 95% CI: -1.76;-1-33, p<0.001) mmol/mol and slightly more at 24 months -2.1 (3.3, 95% CI; -2.47:-1.67, p<0.001). The results are presented in Table 3c. The change was slightly greater for men than for women but no difference between age groups.

There was a 71% improvement in HbA1c from baseline to 24 months with a slightly greater proportion for women (72%) than for men (68%). There was no difference between age groups.
The results are presented in Table 4. The number of participants who improved in HbA1c is illustrated in Figure 3.

6.2.2 SECONDARY OUTCOME VARIABLES

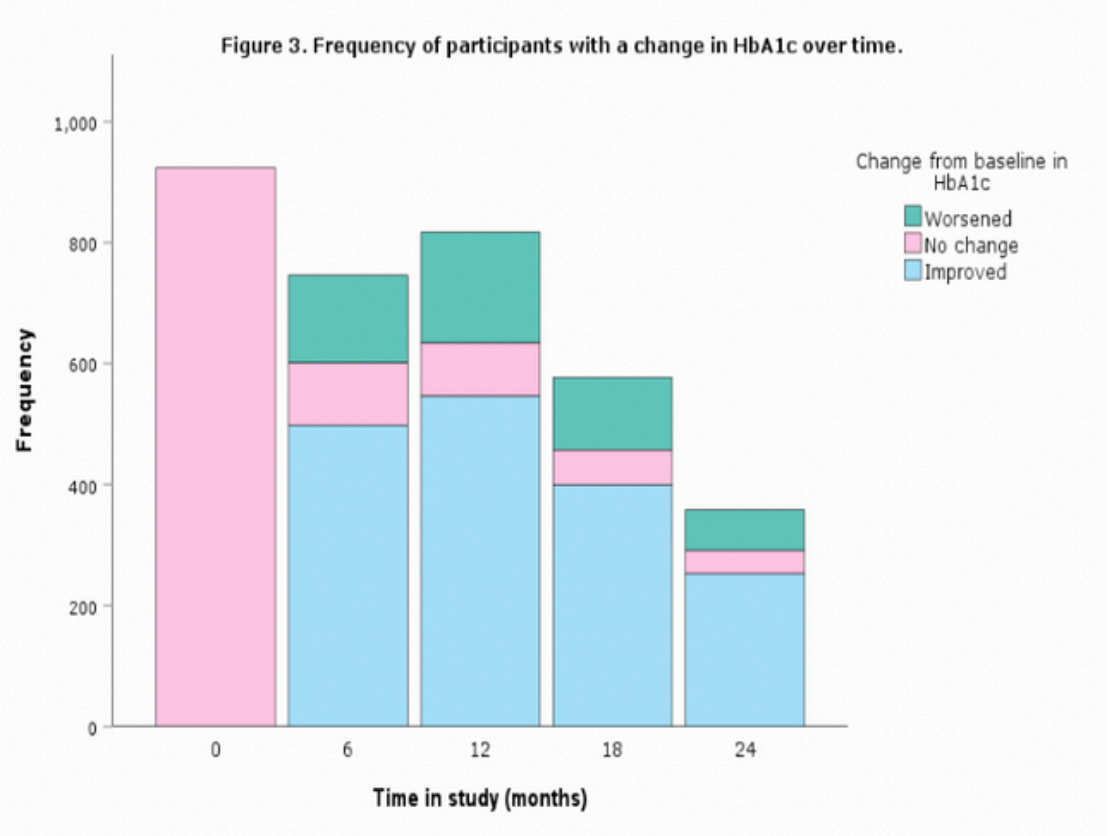
Table 3c. Mean Change in HbA1c over time by Gender.

			Months in Study				
		HbA1c	0	6	12	18	24
Female	Change from baseline	Valid N	610	490	541	384	243
		Mean	0,00	-1,41	-1,71	-1,82	-2,02
		95,0% Lower CL for Mean	0,00	-1,67	-1,97	-2,15	-2,47
		95,0% Upper CL for Mean	0,00	-1,16	-1,45	-1,50	-1,56
		Standard Deviation	0,00	2,84	3,05	3,22	3,62
		Median	0,00	-1,00	-2,00	-2,00	-2,00
		Minimum	0,00	-11,00	-14,00	-14,00	-13,00
		Maximum	0,00	12,00	14,00	13,00	21,00
Male	Change from baseline	Valid N	314	256	276	193	115
		Mean	0,00	-1,80	-1,44	-1,95	-2,19
		95,0% Lower CL for Mean	0,00	-2,21	-1,98	-2,49	-2,98
		95,0% Upper CL for Mean	0,00	-1,40	-0,90	-1,40	-1,40
		Standard Deviation	0,00	3,26	4,56	3,83	4,26
		Median	0,00	-2,00	-2,00	-2,00	-2,00
		Minimum	0,00	-11,00	-12,00	-14,00	-13,00
		Maximum	0,00	9,00	42,00	7,00	12,00
Total	Change from baseline	Valid N	924	746	817	577	358
		Mean	0,00	-1,55	-1,62	-1,86	-2,07
		95,0% Lower CL for Mean	0,00	-1,76	-1,87	-2,15	-2,47
		95,0% Upper CL for Mean	0,00	-1,33	-1,37	-1,58	-1,67
		Standard Deviation	0,00	3,00	3,63	3,43	3,83
		Median	0,00	-2,00	-2,00	-2,00	-2,00
		Minimum	0,00	-11,00	-14,00	-14,00	-13,00
		Maximum	0,00	12,00	42,00	13,00	21,00

6.2.2 SECONDARY OUTCOME VARIABLES

Table 4a. Proportion of participants with improvement in HbA1c by Gender.

				Months in Study									
				0		6		12		18		24	
				Count	Column N %	Count	Column N %	Count	Column N %	Count	Column N %	Count	Column N %
Kön	Female	Change from baseline	Improved	0	0.0%	324	66.1%	371	68.6%	273	71.1%	175	72.0%
			No change	610	100.0%	71	14.5%	56	10.4%	37	9.6%	29	11.9%
			Worsened	0	0.0%	95	19.4%	114	21.1%	74	19.3%	39	16.0%
			Total	610	100.0%	490	100.0%	541	100.0%	384	100.0%	243	100.0%
	Male	Change from baseline	Improved	0	0.0%	174	68.0%	175	63.4%	127	65.8%	78	67.8%
			No change	314	100.0%	32	12.5%	32	11.6%	20	10.4%	9	7.8%
			Worsened	0	0.0%	50	19.5%	69	25.0%	46	23.8%	28	24.3%
			Total	314	100.0%	256	100.0%	276	100.0%	193	100.0%	115	100.0%
	Total	Change from baseline	Improved	0	0.0%	498	66.8%	546	66.8%	400	69.3%	253	70.7%
			No change	924	100.0%	103	13.8%	88	10.8%	57	9.9%	38	10.6%
			Worsened	0	0.0%	145	19.4%	183	22.4%	120	20.8%	67	18.7%
			Total	924	100.0%	746	100.0%	817	100.0%	577	100.0%	358	100.0%



6.2.2 SECONDARY OUTCOME VARIABLES

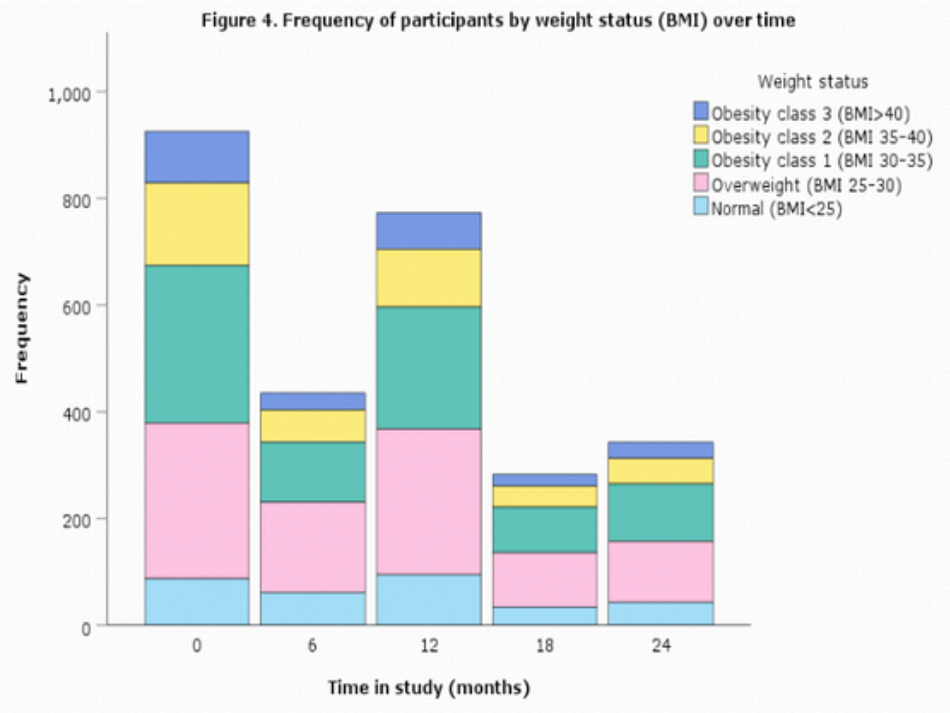
Change in weight status The proportion of participants at 24 months with obesity was 54.2%, with overweight 33.2% and 12.5% normal weight, see Table 5. There was a greater proportion among women with obesity (57%) compared to men (49%). However, men had a greater proportion with overweight (41%) compared to women (31%). For the whole population, the proportion with normal weight has increased from 9.4% at baseline to 12.5% at 24 months. The changes were similar in both age groups.
The change in weight status at each follow-up point is illustrated in Figure 4.

The mean BMI at each follow-up point is presented in Table 6.
The mean change from baseline to 24 months in BMI was -0.7 (SD=1.5, 95% CI; -0.9:-0.6, p<0.001). The results are presented in Table 7. The mean change was slightly smaller for men than for women.

Table 5a. Weight Status (BMI) over time by Gender.

		Months in Study									
		0		6		12		18		24	
		Count	Column N %	Count	Column N %	Count	Column N %	Count	Column N %	Count	Column N %
Female	Normal (BMI<25)	57	9.3%	39	13.9%	67	13.1%	25	13.4%	31	13.5%
	Overweight (BMI 25-30)	177	29.0%	98	34.9%	158	30.8%	59	31.6%	68	29.6%
	Obesity class 1 (BMI 30-35)	181	29.6%	70	24.9%	146	28.5%	55	29.4%	71	30.9%
	Obesity class 2 (BMI 35-40)	117	19.1%	46	16.4%	83	16.2%	29	15.5%	36	15.7%
	Obesity class 3 (BMI>40)	79	12.9%	28	10.0%	59	11.5%	19	10.2%	24	10.4%
	Total	611	100.0%	281	100.0%	513	100.0%	187	100.0%	230	100.0%
Male	Normal (BMI<25)	30	9.6%	22	14.3%	28	10.8%	9	9.5%	12	10.6%
	Overweight (BMI 25-30)	115	36.6%	71	46.1%	115	44.2%	43	45.3%	46	40.7%
	Obesity class 1 (BMI 30-35)	114	36.3%	43	27.9%	82	31.5%	30	31.6%	37	32.7%
	Obesity class 2 (BMI 35-40)	38	12.1%	14	9.1%	26	10.0%	10	10.5%	11	9.7%
	Obesity class 3 (BMI>40)	17	5.4%	4	2.6%	9	3.5%	3	3.2%	7	6.2%
	Total	314	100.0%	154	100.0%	260	100.0%	95	100.0%	113	100.0%
Total	Normal (BMI<25)	87	9.4%	61	14.0%	95	12.3%	34	12.1%	43	12.5%
	Overweight (BMI 25-30)	292	31.6%	169	38.9%	273	35.3%	102	36.2%	114	33.2%
	Obesity class 1 (BMI 30-35)	295	31.9%	113	26.0%	228	29.5%	85	30.1%	108	31.5%
	Obesity class 2 (BMI 35-40)	155	16.8%	60	13.8%	109	14.1%	39	13.8%	47	13.7%
	Obesity class 3 (BMI>40)	96	10.4%	32	7.4%	68	8.8%	22	7.8%	31	9.0%
	Total	925	100.0%	435	100.0%	773	100.0%	282	100.0%	343	100.0%

6.2.2 SECONDARY OUTCOME VARIABLES



6.2.2 SECONDARY OUTCOME VARIABLES

Medelvärdet för BMI för varje uppföljningstillfälle presenteras i tabell 6

Table 6a. BMI over time by Gender.

			Months in Study				
			0	6	12	18	24
Female	BMI	Valid N	611	281	513	187	230
		Mean	32,6	31,5	31,9	31,5	31,8
		Standard Deviation	6,4	6,2	6,6	6,0	6,6
		Median	31,8	30,1	30,7	30,7	30,8
		Minimum	18,7	19,4	19,1	19,7	20,0
		Maximum	57,4	51,4	57,5	47,3	57,8
Male	BMI	Valid N	314	154	260	95	113
		Mean	30,9	29,8	30,2	30,1	30,3
		Standard Deviation	5,1	4,7	4,7	4,6	4,8
		Median	30,4	28,9	29,2	29,4	29,8
		Minimum	18,0	20,0	19,1	20,0	20,3
		Maximum	52,0	45,1	47,0	41,1	44,4
Total	BMI	Valid N	925	435	773	282	343
		Mean	32,0	30,9	31,3	31,1	31,3
		Standard Deviation	6,1	5,8	6,1	5,6	6,1
		Median	31,2	29,8	30,4	30,2	30,4
		Minimum	18,0	19,4	19,1	19,7	20,0
		Maximum	57,4	51,4	57,5	47,3	57,8

Table 7a. Mean change in BMI over time by Gender.

			Months in Study				
			0	6	12	18	24
Female	Change in BMI	Valid N	611	281	513	187	230
		Mean	0,0	-0,9	-0,5	-1,0	-0,9
		95,0% Lower CL for Mean	0,0	-1,0	-0,7	-1,4	-1,3
		95,0% Upper CL for Mean	0,0	-0,7	-0,4	-0,7	-0,5
		Standard Deviation	0,0	1,5	2,2	2,5	3,1
		Median	0,0	-0,7	-0,3	-0,7	-0,4
		Minimum	0,0	-8,9	-16,2	-15,4	-12,4
		Maximum	0,0	1,8	22,4	10,9	27,2
Male	Change in BMI	Valid N	314	154	260	95	113
		Mean	0,0	-0,4	-0,2	-0,5	-0,3
		95,0% Lower CL for Mean	0,0	-0,7	-0,4	-1,0	-0,7
		95,0% Upper CL for Mean	0,0	-0,2	-0,1	-0,1	0,0
		Standard Deviation	0,0	1,3	1,5	2,0	2,0
		Median	0,0	-0,4	-0,3	-0,3	-0,2
		Minimum	0,0	-7,2	-6,3	-6,6	-9,1
		Maximum	0,0	3,2	10,7	4,9	4,7
Total	Change in BMI	Valid N	925	435	773	282	343
		Mean	0,0	-0,7	-0,4	-0,9	-0,7
		95,0% Lower CL for Mean	0,0	-0,9	-0,6	-1,1	-1,0
		95,0% Upper CL for Mean	0,0	-0,6	-0,3	-0,6	-0,4
		Standard Deviation	0,0	1,5	2,0	2,4	2,8
		Median	0,0	-0,5	-0,3	-0,6	-0,3
		Minimum	0,0	-8,9	-16,2	-15,4	-12,4
		Maximum	0,0	3,2	22,4	10,9	27,2

6.2.2 SECONDARY OUTCOME VARIABLES

Discriminant analys for a normalised HbA1c value at 24 months

The results of the logistic regression model show that gender is the strongest and a statistically significant factor associated with a difference among those who achieve a normalised HbA1c, with women having a higher odds of achieving a normal HbA1c than men, OR=1.56 (95% CI; 1.11-2.19, p=0.01). Other factors such as age and FINDRISC score at baseline did not show a statistically significant effect on who achieves a normal HbA1c value at 24 months.

Missing data analysis

Just over half (54%) of all participants (925) have been invited to report data for this 24-month follow-up. The others have not reached 24 months in the programme. There are 358 (72%) participants have reported the primary outcome variable HbA1c at this time.

The missing data analysis at 24 months is presented in Table 8 and shows that there is slightly greater missing data among men (29%) than among women (23%). The age distribution is approximately the same among both those who have reported and not reported. HbA1c at baseline was the same for those reporting 43.5 (1.7) and not reporting 43.6 (1.6) data at 24 months. They also had the same FINDRISC score at baseline, 16.0 (3.5) for those reporting and 16.9 (3.3) not reporting data at 24 months.

Table 8. Missing data analysis at 24 months, baseline data.

			Missing data group	
			Eligible at 24 months	Missing at 24 months
Gender	Female	Count	251	77
		Column N %	67,7%	60,6%
	Male	Count	120	50
		Column N %	32,3%	39,4%
Age	-55 år	Count	179	64
		Column N %	48,2%	50,4%
	>55 år	Count	192	63
		Column N %	51,8%	49,6%
HbA1c (mmol/mol)	Mean		43,5	43,6
	Median		43,0	43,0
	Standard Deviation		1,7	1,6
Findrisc score	Mean		16,9	16,9
	Median		17,0	17,0
	Standard Deviation		3.5	3.3

6.2.2 SECONDARY OUTCOME VARIABLES

Health goals

Among the participants who reported 24-month data, they had set between 1 and 21 health goals per participant by themselves or with the help of the coach during this period, with an average of 7.2 health goals per participant. The most common health goals that participants worked on during the period were exercise (322 participants), diet (182), stress management (32), sleep (23), beverages (12) and other activities (338).

The category "other activities" consists mainly of strategies to achieve a goal, mostly in the area of nutrition. See tables 9a and 9b. The average number of activities within each category of health goal is illustrated in Figure 6.

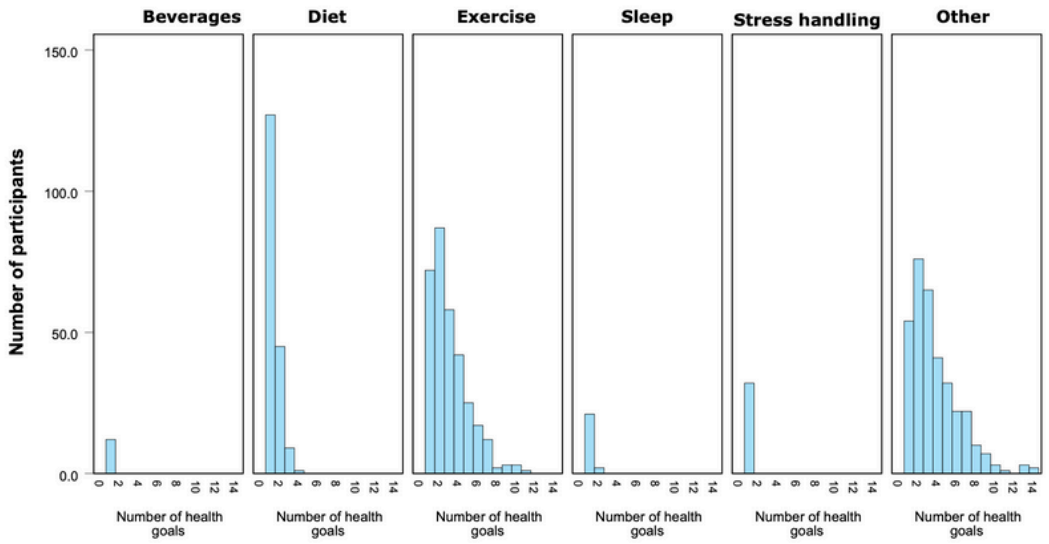
Table 9a. Number of health goals at 24 months.

	Valid N	Mean	Standard Deviation	Minimum	Median	Maximum
Health goals	358	7,2	3,4	1,0	7,0	21,0

Table 9b. Number of health goals by Activity at 24 months.

		Valid N	Mean	Standard Deviation	Minimum	Median	Maximum
Hälsomål	Beverages	12	1,0	0,0	1,0	1,0	1,0
	Diet	182	1,4	0,6	1,0	1,0	4,0
	Exercise	322	3,1	2,0	1,0	3,0	11,0
	Other	338	3,7	2,5	1,0	3,0	14,0
	Sleep	23	1,1	0,3	1,0	1,0	2,0
	Stress handling	32	1,0	0,0	1,0	1,0	1,0

Figure 5. Number of Health Goals by Activity.



6.2.2 SECONDARY OUTCOME VARIABLES

Health services and health products

All 925 participants reported that they spent a total of about SEK 3.9 million on health services and health products in the programme, and an average of SEK 4 211 (SD=2 896). There are large variations between individuals, partly because not all participants have passed 24 months in the programme. Among the 358 participants who reported 24-month data, they spent an average of SEK 5,459 (SD=2,969) per participant. They could spend a maximum of SEK 6,250 per year during the first two years, totalling SEK 12,500. Among those who reported the primary outcome variable at 24 months (HbA1c), the number of health products and services purchased in the first two years is presented, Table 10b, as well as the average number of health products and services that the participants spent money on per product, Table 10c. In descending order, participants spent the most on diet, equipment, courses and inspiration, health coaching, gym, sleep and stress and the least on products and services to reduce alcohol and tobacco consumption.

Self-perceived change in quality of life

85% of participants felt that the health programme has been a contributing factor to improved quality of life, see appendix 2, figures 6 + 7.

Table 10a. Money (SEK) spent on health-related products at 24 months.

	Valid N	Mean	Standard Deviation	Minimum	Median	Maximum
Money (SEK) spent	349	6482.8	3151.3	199.0	6511.0	13887.0

Table 10b. Number of health-related product spent at 24 months.

	Valid N	Mean	Standard Deviation	Minimum	Median	Maximum
Antal hälsoprodukter	349	12.32	6.67	1.00	12.00	35.00

Table 10c. Number of health-related products by product at 24 months.

	Valid N	Mean	Standard Deviation	Minimum	Median	Maximum
Diet (produkter)	329	4.14	2.48	1.00	4.00	13.00
Equipment and other	329	4.98	3.17	1.00	4.00	16.00
Courses and inspiration	282	3.13	2.41	1.00	3.00	15.00
Home-training	263	2.69	2.20	1.00	2.00	16.00
Health coach	205	1.57	0.83	1.00	1.00	5.00
Gym	194	3.65	2.82	1.00	3.00	15.00
Sleep and stress	119	1.93	1.36	1.00	2.00	10.00
Alcohol and tobacco	37	1.38	0.59	1.00	1.00	3.00

7 DISCUSSION

The 24-month results presented in this report are based on more than half of the intervention's participants (925). Among them, more than 70% have reported data for the primary outcome variable. This is a good reporting rate.

The results show that over half of the participants have left the pre-diabetes status in HbA1c. It is statistically robust as the 95% confidence interval shows that this proportion is somewhere between 49% and 59%. The results of the intervention show that it meets the set threshold for being classified as successful with 300 out of 925 (32.4%) participants having achieved a risk reduction for type 2 diabetes, as the confidence interval excludes this proportion. The estimated proportion is also statistically significantly greater than 32.4% with a p-value <0.001. This should also be strong evidence that the risk of developing diabetes in the long term, i.e. beyond 24 months, is greatly reduced. There is a slightly higher proportion of women than men who achieve the primary objective of the intervention. The intervention also shows that the lifestyle change effect starts at six months and is sustained, and the data suggests that it also increases slightly over time. This indicates that a significant proportion of participants have changed their lifestyle with this programme and that the intervention is sustained.

Previous studies have shown that the proportion of participants who develop type 2 diabetes after 3 years of lifestyle intervention is 11% compared to 23% in the control group, i.e. a risk reduction of 58%. This intervention shows that there were 7.5% who met the HbA1c criterion for type 2 diabetes, confidence interval 5.1%-10.6%, which corresponds to a risk reduction of 67%,

There is a greater proportion of men than women who reach a level of HbA1c corresponding to type 2 diabetes. It was found that it was more difficult to recruit men than women, which could explain the difference between men and women in the proportion who develop the diagnostic criterion for type 2 diabetes regarding HbA1c. It may also be due to other factors.

The results show that the intervention has had a statistically significant effect on reducing BMI from baseline to 24 months and that the proportion of participants who were obese at baseline has decreased and that more participants have normal weight at 24 months than at baseline.

DISCUSSION (CONTINUED)

The summary of how much the participants spent on health services and products shows that they have not used the full amount of SEK 12,500 they received. This may be because some have chosen to save an amount for the 3-5 year follow-up period, as the participants are offered that opportunity.

Among the choices of health goals that the participants planned together with the health coach, most have chosen exercise, which is positive. Many also chose to plan dietary activities, which is also seen in "other activities" where the majority were related to planned dietary strategies. It is a very small proportion of the participants, just under 10%, who chose to plan stress management, sleep and drink.

When evaluating which products and services the participants chose to spend their money on, almost all of them chose different options in nutrition and equipment, where courses and inspiration and home exercise products were common. Just over half chose to buy a gym card or other form of exercise card. Very few chose products to reduce alcohol and tobacco use. This could be interpreted to mean that there is not such a large proportion who consider themselves to have these problems and/or that they want to do other things that can improve their lifestyle to get a better HbA1c value and reduce the risk of type 2 diabetes. The intervention shows that of those who reported the primary outcome variable at 24 months, the vast majority have also used the money they were allocated to spend on health-promoting products and services.

Overall, 85% of participants felt that the health programme contributed to improved quality of life.

Limitations of the results include the fact that there is still a large proportion of participants who have yet to report 24-month data and the need to conduct a sensitivity analysis on how non-response can affect the results. However, the findings are so strong that there is little likelihood of this changing the results to any great extent.

A further limitation in the interpretation of the results is the lack of information on the contemporary medical and pharmacological treatment of the participants. The participants were recruited from outside the health care system but it is not unlikely that some may have been patients in the health care system for treatment of, for example, obesity. It may also be the case that some participants have been admitted to the healthcare system for treatment of obesity during the intervention. Some participants have started treatment for type 2 diabetes in the health care system during the intervention, as they met the diagnostic criteria for type 2 diabetes in HbA1c. Treatment in the health care system with drug use is a factor that may have increased the measured intervention effect. Theoretically, it would be possible to link data with the drug registry to measure the participants' drug consumption during the same time period. However, this is beyond the scope of the intervention.

8 CONCLUSION

The results in the 24-month reporting show with statistical significance that the intervention has reached the primary objective where more than half of the participants have reduced their HbA1c levels so much that they have left prediabetes status. Compared to previous studies, the proportion developing diagnostic criteria for type 2 diabetes in HbA1c was very low. It shows that the lifestyle intervention works and that it also lowers BMI and improves perceived quality of life. The effect comes already after six months and lasts until at least 24 months.

USER STORY

Maria N joined the RS programme in March 2021 and now, two years after the start of the programme, she is no longer at risk of diabetes. Her HbA1c value has decreased from 43 mmol/mol at the start to 40 mmol/mol today and she has also lost 8 kg.

Here are the benefits Maria has experienced from the health programme:

- Improved eating habits
- Better quality of sleep
- Increased energy
- Weight loss
- Change in lifestyle
- Positive impact on the whole family
- Reduced blood sugar levels and blood pressure
- Medication-free
- Holistic approach to health

"My health coach helped me understand how things are connected. She tried to get me to go at a reasonable pace, not to do a 180 degree turn, but to take it step by step. 'You shouldn't do a temporary change, you should do something you can live with.' That's how she coached me. The health coach has taught me to get to know myself, to start from what I feel and why and then see what I can do about it."

"In a sense, I have learnt to take care of myself in the long term and I will continue to live that way. I want to be active throughout my life. It has become my driving force; I think about quality of life now and it is important for me to have enough energy to do everything I want to do."

Read the interview with Maria N here

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APPENDIX

1. LISTA TABELLER OCH FIGURER

2. SUPPLEMENTARY TABLES AND FIGURES

Table 2d. Primary Outcome Variable HbA1c with Confidence Interval.

HbA1c		Months in Study 0	6	12	18	24
Normal <42 mmol/mol	Count	0	363	423	294	194
	Column N %	0.0%	48.6%	51.7%	51.0%	54.2%
	95.0% Lower CL for Column N %		45.0%	48.3%	46.9%	49.0%
	95.0% Upper CL for Column N %		52.2%	55.1%	55.0%	59.3%
Prediabetes 42-47 mmol/mol	Count	924	343	352	249	137
	Column N %	100.0%	45.9%	43.0%	43.2%	38.3%
	95.0% Lower CL for Column N %		42.4%	39.7%	39.2%	33.3%
	95.0% Upper CL for Column N %		49.5%	46.4%	47.2%	43.4%
Diabetes >=48 mmol/mol	Count	0	41	43	34	27
	Column N %	0.0%	5.5%	5.3%	5.9%	7.5%
	95.0% Lower CL for Column N %		4.0%	3.9%	4.2%	5.1%
	95.0% Upper CL for Column N %		7.3%	6.9%	8.0%	10.6%

Table 3b. Mean HbA1c over Time by Age.

			Months in Study 0	6	12	18	24
-55 years	HbA1c (mmol/mol)	Valid N	446	357	394	273	174
		Mean	43.3	41.6	41.8	41.6	41.4
		Standard Deviation	1.5	3.3	4.5	3.7	4.1
		Median	43.0	41.0	41.0	41.0	41.0
		Minimum	42.0	32.0	30.0	30.0	31.0
		Maximum	47.0	55.0	87.0	57.0	63.0
>55 years	HbA1c (mmol/mol)	Valid N	478	390	424	304	184
		Mean	43.5	42.1	41.8	41.6	41.5
		Standard Deviation	1.6	3.2	3.2	3.5	3.9
		Median	43.0	42.0	41.0	41.0	41.0
		Minimum	42.0	33.0	35.0	32.0	33.0
		Maximum	47.0	55.0	55.0	53.0	58.0
Total	HbA1c (mmol/mol)	Valid N	924	747	818	577	358
		Mean	43.4	41.9	41.8	41.6	41.5
		Standard Deviation	1.5	3.3	3.9	3.6	4.0
		Median	43.0	42.0	41.0	41.0	41.0
		Minimum	42.0	32.0	30.0	30.0	31.0
		Maximum	47.0	55.0	87.0	57.0	63.0

2. SUPPLEMENTARY TABLES AND FIGURES

Table 3d. Mean change in HbA1c over time by Age.

				Months in Study				
			HbA1c	0	6	12	18	24
-55 years	Change from baseline	Valid N		446	357	394	273	174
		Mean		0,00	-1,65	-1,58	-1,77	-2,01
		95,0% Lower CL for Mean		0,00	-1,97	-2,01	-2,20	-2,61
		95,0% Upper CL for Mean		0,00	-1,33	-1,16	-1,34	-1,42
		Standard Deviation		0,00	3,09	4,26	3,58	3,98
		Median		0,00	-2,00	-2,00	-2,00	-2,00
		Minimum		0,00	-11,00	-14,00	-14,00	-12,00
		Maximum		0,00	12,00	42,00	13,00	21,00
>55 years	Change from baseline	Valid N		478	389	423	304	184
		Mean		0,00	-1,46	-1,65	-1,95	-2,13
		95,0% Lower CL for Mean		0,00	-1,74	-1,93	-2,32	-2,67
		95,0% Upper CL for Mean		0,00	-1,17	-1,37	-1,58	-1,59
		Standard Deviation		0,00	2,91	2,92	3,30	3,69
		Median		0,00	-1,00	-2,00	-2,00	-2,00
		Minimum		0,00	-11,00	-12,00	-14,00	-13,00
		Maximum		0,00	9,00	8,00	7,00	11,00
Total	Change from baseline	Valid N		924	746	817	577	358
		Mean		0,00	-1,55	-1,62	-1,86	-2,07
		95,0% Lower CL for Mean		0,00	-1,76	-1,87	-2,15	-2,47
		95,0% Upper CL for Mean		0,00	-1,33	-1,37	-1,58	-1,67
		Standard Deviation		0,00	3,00	3,63	3,43	3,83
		Median		0,00	-2,00	-2,00	-2,00	-2,00
		Minimum		0,00	-11,00	-14,00	-14,00	-13,00
		Maximum		0,00	12,00	42,00	13,00	21,00

Table 4b. Proportion of participants with improvment in HbA1c by Age.

				Months in Study									
				0		6		12		18		24	
				Count	Column N %	Count	Column N %	Count	Column N %	Count	Column N %	Count	Column N %
Age	-55 years	Change from baseline	Improved	0	0,0%	241	67,5%	265	67,3%	191	70,0%	123	70,7%
			No change	446	100,0%	45	12,6%	41	10,4%	24	8,8%	20	11,5%
			Worsened	0	0,0%	71	19,9%	88	22,3%	58	21,2%	31	17,8%
			Total	446	100,0%	357	100,0%	394	100,0%	273	100,0%	174	100,0%
	>55 years	Change from baseline	Improved	0	0,0%	257	66,1%	281	66,4%	209	68,8%	130	70,7%
			No change	478	100,0%	58	14,9%	47	11,1%	33	10,9%	18	9,8%
			Worsened	0	0,0%	74	19,0%	95	22,5%	62	20,4%	36	19,6%
			Total	478	100,0%	389	100,0%	423	100,0%	304	100,0%	184	100,0%
	Total	Change from baseline	Improved	0	0,0%	498	66,8%	546	66,8%	400	69,3%	253	70,7%
			No change	924	100,0%	103	13,8%	88	10,8%	57	9,9%	38	10,6%
			Worsened	0	0,0%	145	19,4%	183	22,4%	120	20,8%	67	18,7%
			Total	924	100,0%	746	100,0%	817	100,0%	577	100,0%	358	100,0%

2. SUPPLEMENTARY TABLES AND FIGURES

Table 5b. Weight Status (BMI) over time by Age.

		Months in Study									
		0		6		12		18		24	
		Count	Column N %	Count	Column N %	Count	Column N %	Count	Column N %	Count	Column N %
50-55 years	Normal (BMI<25)	33	7.4%	26	12.0%	33	8.9%	13	10.1%	20	11.8%
	Overweight (BMI 25-30)	131	29.4%	87	40.1%	128	34.6%	43	33.3%	55	32.5%
	Obesity klass 1 (BMI 30-35)	147	33.0%	54	24.9%	115	31.1%	41	31.8%	53	31.4%
	Obesity klass 2 (BMI 35-40)	80	17.9%	32	14.7%	57	15.4%	21	16.3%	23	13.6%
	Obesity klass 3 (BMI>40)	55	12.3%	18	8.3%	37	10.0%	11	8.5%	18	10.7%
	Total	446	100.0%	217	100.0%	370	100.0%	129	100.0%	169	100.0%
56-60 years	Normal (BMI<25)	54	11.3%	35	16.1%	62	15.4%	21	13.7%	23	13.2%
	Overweight (BMI 25-30)	161	33.6%	82	37.6%	145	36.0%	59	38.6%	59	33.9%
	Obesity klass 1 (BMI 30-35)	148	30.9%	59	27.1%	113	28.0%	44	28.8%	55	31.6%
	Obesity klass 2 (BMI 35-40)	75	15.7%	28	12.8%	52	12.9%	18	11.8%	24	13.8%
	Obesity klass 3 (BMI>40)	41	8.6%	14	6.4%	31	7.7%	11	7.2%	13	7.5%
	Total	479	100.0%	218	100.0%	403	100.0%	153	100.0%	174	100.0%
Total	Normal (BMI<25)	87	9.4%	61	14.0%	95	12.3%	34	12.1%	43	12.5%
	Overweight (BMI 25-30)	292	31.6%	169	38.9%	273	35.3%	102	36.2%	114	33.2%
	Obesity klass 1 (BMI 30-35)	295	31.9%	113	26.0%	228	29.5%	85	30.1%	108	31.5%
	Obesity klass 2 (BMI 35-40)	155	16.8%	60	13.8%	109	14.1%	39	13.8%	47	13.7%
	Obesity klass 3 (BMI>40)	96	10.4%	32	7.4%	68	8.8%	22	7.8%	31	9.0%
	Total	925	100.0%	435	100.0%	773	100.0%	282	100.0%	343	100.0%

Table 6b. BMI over time by Age.

			Months in Study				
			0	6	12	18	24
50-55 years	BMI	Valid N	446	217	370	129	169
		Mean	32.6	31.3	31.9	31.9	31.5
		Standard Deviation	6.2	5.8	6.1	5.7	6.1
		Median	32.0	29.9	30.9	31.5	30.7
		Minimum	19.9	20.5	20.3	21.6	21.1
		Maximum	57.4	48.0	57.5	47.3	54.6
56-60 years	BMI	Valid N	479	218	403	153	174
		Mean	31.5	30.5	30.8	30.4	31.1
		Standard Deviation	5.9	5.8	6.0	5.5	6.1
		Median	30.8	29.7	29.7	29.8	30.1
		Minimum	18.0	19.4	19.1	19.7	20.0
		Maximum	57.1	51.4	57.1	46.8	57.8
Total	BMI	Valid N	925	435	773	282	343
		Mean	32.0	30.9	31.3	31.1	31.3
		Standard Deviation	6.1	5.8	6.1	5.6	6.1
		Median	31.2	29.8	30.4	30.2	30.4
		Minimum	18.0	19.4	19.1	19.7	20.0
		Maximum	57.4	51.4	57.5	47.3	57.8

2. SUPPLEMENTARY TABLES AND FIGURES

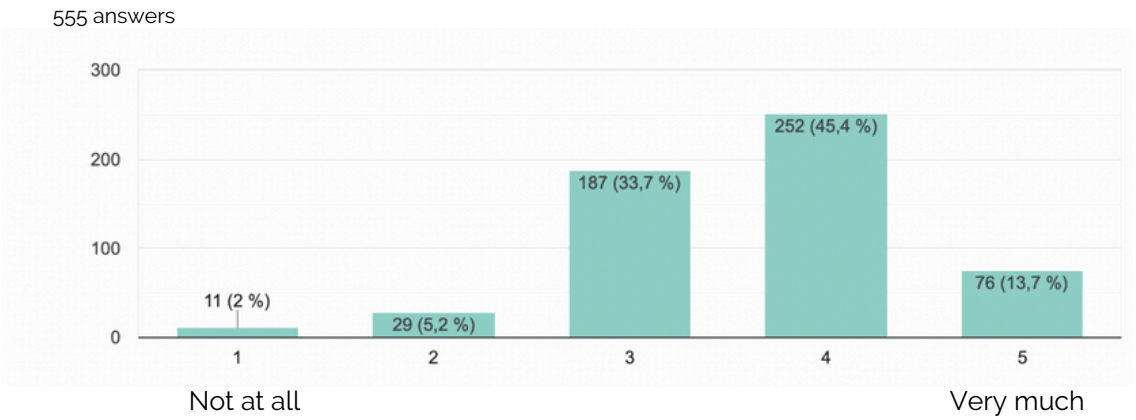
Table 7b. Mean change in BMI over time by Age.

			Months in Study				
			0	6	12	18	24
50-55 years	Change in BMI	Valid N	446	217	370	129	169
		Mean	0,0	-0,7	-0,5	-0,8	-0,8
		95.0% Lower CL for Mean	0,0	-0,9	-0,7	-1,2	-1,2
		95.0% Upper CL for Mean	0,0	-0,5	-0,3	-0,4	-0,5
		Standard Deviation	0,0	1,6	2,0	2,4	2,3
		Median	0,0	-0,5	-0,3	-0,6	-0,4
		Minimum	0,0	-8,9	-16,2	-15,4	-12,4
		Maximum	0,0	2,3	3,8	4,9	2,8
56-60 years	Change in BMI	Valid N	479	218	403	153	174
		Mean	0,0	-0,7	-0,4	-0,9	-0,6
		95.0% Lower CL for Mean	0,0	-0,9	-0,6	-1,3	-1,0
		95.0% Upper CL for Mean	0,0	-0,6	-0,2	-0,5	-0,1
		Standard Deviation	0,0	1,3	2,0	2,3	3,1
		Median	0,0	-0,6	-0,3	-0,6	-0,3
		Minimum	0,0	-7,1	-8,7	-11,1	-9,8
		Maximum	0,0	3,2	22,4	10,9	27,2
Total	Change in BMI	Valid N	925	435	773	282	343
		Mean	0,0	-0,7	-0,4	-0,9	-0,7
		95.0% Lower CL for Mean	0,0	-0,9	-0,6	-1,1	-1,0
		95.0% Upper CL for Mean	0,0	-0,6	-0,3	-0,6	-0,4
		Standard Deviation	0,0	1,5	2,0	2,4	2,8
		Median	0,0	-0,5	-0,3	-0,6	-0,3
		Minimum	0,0	-8,9	-16,2	-15,4	-12,4
		Maximum	0,0	3,2	22,4	10,9	27,2

2. SUPPLEMENTARY TABLES AND FIGURES

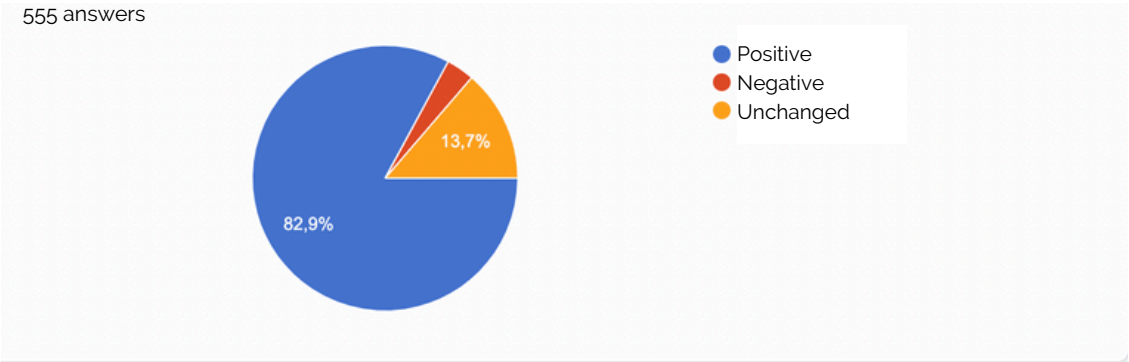
FIGUR 6

Has your quality of life changed since you joined the health program?



FIGUR 7A&B

In what direction has the change taken place?



Improved quality of life

Would you say that the health program has been a contributing factor to improved quality of life?