**Master Thesis** 

# Evaluation of SALUD: impact and experiences of people with T2DM



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### Evaluation of SALUD: impact and experiences of people with T2DM

How did people with Type 2 Diabetes experience the SALUD program and did it impact their Sense

of Coherence?

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# List of abbreviations

Abbreviation	Meaning
CLC	Certified lifestyle coach
GP	General practitioner
GRR	General resistance resource
PI	Principal investigator
SMH	Salutogenic Model of Health
SoC	Sense of Coherence
SRR	Specific resistance resource
T2DM	Type 2 Diabetes Mellitus
QoL	Quality of Life

# Abstract

**Background**: T2DM is a serious disease that can lead to various health complications, and the prevalence of this disease is increasing worldwide. Recent research shows that lifestyle intervention can play a role in lowering the burden of this disease, however, every-day life setting are not yet adequately taking into account. The SALUD program takes a salutogenic approach to promote health in people with T2DM, by strengthening important resources (including social support and self-identity).

**Aim**: The aim of this master thesis was to evaluate the SALUD program to determine its impact on participants Sense of Coherence (SoC). Furthermore, to gain a deeper understanding on why and how the program yielded those results, participants experiences and perceived effects of the intervention were analyzed.

**Methods**: SoC was measured with the SoC-13 questionnaire. The average change was compared between the intervention and control group and a general linear model, ANCOVA, was used to investigate the treatment effect. Focus groups were held to gain insights on participants experiences during the program. A thematic analysis of the transcripts provided information on re-occurring themes between the groups.

**Results**: The intervention group had a SoC change of 5,48 points(SD= 9,0), and the control group had an average change of 0,09 points (SD= 7,96). The change was significantly different between the intervention and the control group (P-value = 0.028). No significant effect of treatment was found. The focus group provided information on two main themes: perceived effects and participants evaluation. Overall, participants were enthusiastic about the program, experienced an improvement in their skills (e.g. reflection, awareness, control), were able to work on their goals and experienced social support from their peers and/or family. Furthermore, participants positively evaluated the program.

**Conclusion**: The SALUD program provided information on how salutogenic health promotion can lead to improved health for people with T2DM. Future research should focus on investigating the long-term effects of this study, to determine the sustainability of the results.

**Keywords**: Sense of Coherence, Salutogenic Model of Health, Type 2 Diabetes Mellitus, Randomized Controlled Trial, lifestyle intervention.

# **1** Introduction

Type 2 Diabetes Mellitus (T2DM) is a disease characterized by dysfunctional blood glucose level regulation, leading to elevated blood glucose levels that can impede vascular health (Bhattacharya & Roy, 2016; Kolb & Martin, 2017; Wu et al., 2014). Consequently, it leads to health complications, like diabetic neuropathy or retinopathy, and it is a major and independent risk factor for the development of cardiovascular diseases (Bhattacharya & Roy, 2016; Pandey et al., 2015; Wu et al., 2014).

T2DM is by far the most prevalent type of diabetes as it accounts for approximately 90% of all diabetes cases worldwide (Bhattacharya & Roy, 2016; Kaul et al., 2013; Wu et al., 2014). In the Netherlands alone, over a million people suffer from T2DM (Nielen et al., 2020). In the past few years, the prevalence of T2DM has increased significantly worldwide (Bhattacharya & Roy, 2016; Kolb & Martin, 2017). While it was estimated in 2004 that the total number of people suffering from diabetes in 2030 would be 366 million, more recent calculations show a significant higher estimate of 578 million (Lovic et al., 2020; Saeedi et al., 2019; Wild et al., 2004).

T2DM develops over time, and research suggests that this development can be reversed (Taylor, 2013; Wu et al., 2014). Development of T2DM is most likely attributable to changes in the environmental and lifestyle risk factors, of which obesity is the single most important (Bhattacharya & Roy, 2016; Hu et al., 2001; Kolb & Martin, 2017; Pandey et al., 2015; Wu et al., 2014). Although it is a reversible disease, this can only be achieved by either an invasive procedure (bariatric surgery) or losing an unhealthy amount of weight in a short amount of time or through strict dieting (Taylor, 2013). However, it is more suitable for people to gradually change their diet and physical activity (Wu et al., 2014).

One way to help people achieve these lifestyle changes, is through intervention programs. Recent research shows that lifestyle interventions are safer and have shown more profound effects than interventions based on medications alone (Bhattacharya & Roy, 2016). Furthermore, lifestyle interventions have fewer and less severe side-effects than pharmacological interventions (Gillies et al., 2007). More recent research on the effectiveness of diabetes nutrition theory, has recommended that people with prediabetes and obesity/overweight should be referred to an intensive lifestyle program, which includes individuals goal-setting components (Evert et al., 2019). Encouraging people with T2DM to eat more of certain food groups (e.g. legumes, whole grains, fruits, and dairy) and less of other food groups (red meat, processed meat, and sugar sweetened beverages) can decrease the risk of overweight or T2DM (Schlesinger et al., 2019; Schwingshackl et al., 2017). However, encouraging healthy eating in T2DM patients by only focusing on diet, without focusing on the social and contextual processes that go on during eating practices, did not lead to a long-term, significant change in weight or glycemic blood markers in previous T2DM interventions (Polhuis et al., 2021).

Dietary habits are formed throughout life (Swan et al., 2015), and people's understanding of healthy eating goes beyond food composition and health outcomes since it is a reflection of their personal, social and cultural experiences as well as their environment (Bisogni et al., 2012). Eating is something that is embedded in our social context (Raghoebar et al., 2019), therefor research and practice focused on promoting healthier eating habits needs to take the

social context into account. So far, research that has been conducted on this topic has not been optimized, since every-day life settings are not adequately taken into account (Polhuis et al., 2021). In order to support health-promoting behavior, a person's behavior within the dynamics of their environment needs to be considered (van Woerkum & Bouwman, 2014).

Salutogenesis is a theoretical model for health promotion, that focusses on strengthening a person's resources and capabilities (Lindström & Eriksson, 2005). Its main idea is that a person's health results from the way they cope with the environmental stressors of everyday life (Lindström & Eriksson, 2005; Mittelmark & Bauer, 2016; Polhuis et al., 2021). The key concept of salutogenesis is Sense of Coherence (SoC), which grasps a person's ability to view the world as comprehensible, manageable, and meaningful (Lindström & Eriksson, 2005; Mittelmark & Bauer, 2016; Mittelmark & Bauer, 2016; Mittelmark, M. B. et al., 2016).

A strong SoC helps to mobilize someone's available resources to successfully cope with stressors and manage tension (Bauer et al., 2020; Mittelmark & Bauer, 2016), and leads to better health (Lindström & Eriksson, 2005; Mittelmark & Bauer, 2016). According to Swan et al. (2015), SoC can be used in interventions as a means for improving nutrition behaviors and dealing with weight issues, and to enable resources that people have available to them to support a healthy weight.

Salutogenic nutrition research can aid in the development of more effective interventions, by looking at the dynamics between people and their environment and how health develops from this (Swan et al., 2015). Patterns and mechanisms are studied, to understand the interrelations between people and their environment and it is thereby more in line with how people experience eating and health in their everyday lives (Swan et al., 2015). The strength of this framework is that it allows to understand what creates health, which can be implemented in health-promotion research (Swan et al., 2015).

During the development of the **SALUD**-study (**Salu**togenic intervention for **D**iabetes Type 2) main principles of salutogenesis were utilized in a bottom-up approach to create a program that aims at improving important resources for healthy eating (Polhuis et al., 2021). This approach sets it apart from previously developed interventions, because of active involvement of stakeholders (i.e., people with T2DM, health care professionals, and scientist) during every step. This resulted in a 12-week, group-based intervention. For a more detailed description of how this program was created, see (Polhuis et al., 2021).

The aim of the SALUD intervention is to empower the participants, help them gain more control over their diets, and to support them in reaching their personal goals (Polhuis et al., 2021). Over the course of twelve weeks, participants in the intervention group followed twelve group sessions that are aimed at enabling resources which promote healthy eating. These interactive sessions focus on topics that are supported by scientific research and found important by the stakeholders in the review of the draft intervention (Polhuis et al., 2021).

The aim of this master thesis is to examine if this salutogenic approach in the SALUD program enhanced the SoC of the participants, and to evaluate how the participants experienced the program. Multiple methods are used to not only understand what the effect of the intervention was, but also how or why is has led to this effect.

# **2** Theoretical Framework

# 2.1 Salutogenesis

Salutogenesis is the complete opposite of pathogenesis (Lindström & Eriksson, 2005), instead of focusing on treating disease, the focus of salutogenesis is on people's resources and capacities to create health and wellbeing (Bauer et al., 2020; Lindström & Eriksson, 2005; Mittelmark & Bauer, 2016). It is not just about one individual, but about the interactions between people, and the structures of society (Lindström & Eriksson, 2005). As explained in the most recently updated Handbook of Salutogenesis: "*Health is understood as a multidimensional concept including physical, social, mental, and spiritual health. Health is regarded as a lifelong dynamic process with people as active participants in a context.*" (Mittelmark et al., 2022).

In salutogenesis, health is not seen as just the absence of disease (Mittelmark & Bauer, 2016). It is no longer a dichotomous outcome (ill or not ill) but in Antonovsky's Salutogenic Model of Health (SMH), health is imagined as a continuum. On one side there is ill-health and disease whereas on the other side there is health and ease, and the majority of people is somewhere in between the poles (Bauer et al., 2020; Mittelmark & Bauer, 2016). We move up and down this continuum throughout our lives as we face stressors (Mittelmark et al., 2022).

Stressors are changes or events that we are continuously exposed to during life, which have to be dealt with. Stressors can (temporarily) negatively impact our health, for example if they are major life events, such as changes in the family or in the workplace. However, these stressors can in the long-term also strengthen a person, as these experiences can be used in other situations to manage stress (Mittelmark et al., 2022). When faced with a stressor, three potential outcomes are possible: neutral (no movement), successful stress management (movement towards the positive side), and unsuccessful stress management (movement towards the negative side). Whether this management of a stressor is successful depends on a person's ability to utilize their resistance resources, both internal and external. This concept is emphasized within salutogenesis (Mittelmark et al., 2022).

Salutogenesis includes three main concepts: the SoC, general resistance resources (GRRs), and specific resistance resources (SRRs). A person's capacities and resources allow them to go from one side of the spectrum to the other, by either successfully or unsuccessfully dealing with stressors (Figure 1) (Bauer et al., 2020; Lindström & Eriksson, 2005; Mittelmark & Bauer, 2016).

### 2.1.1 Sense of Coherence

SoC is a key concept within the SMH, and it has been widely adopted in health promotion as it allows for practical measurements (Bauer et al., 2020; Mittelmark & Bauer, 2016; Uzdil et al., 2022). According to Antonovsky's model, SoC is a person's ability to comprehend life and their capacity to use the resources that are available to them (Bauer et al., 2020; Lindström & Eriksson, 2005; Mittelmark & Bauer, 2016). A strong SoC helps to mobilize someone's available resources in order to successfully cope with stressors and manage tension, thereby allowing them to move up the continuum (Figure 1) (Mittelmark & Bauer, 2016). It includes three key elements: comprehensibility, manageability, and meaningfulness (Bauer et al., 2020; Lindström & Eriksson, 2005; Mittelmark & Bauer, 2016; Mittelmark et al., 2020;

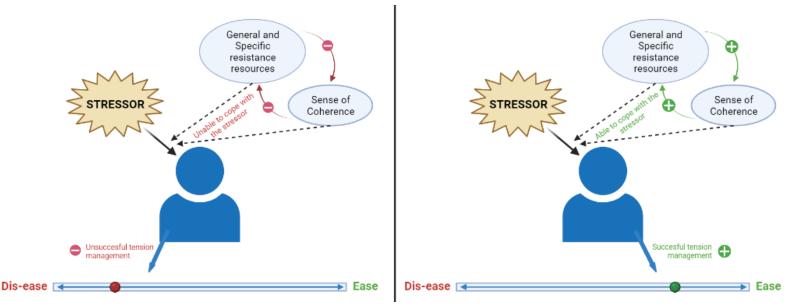


Figure 1: Visual representation of the relationship between a low (left) or high (right) SoC, GRRs, and SRRs, and tension management on the disease/ease continuum

Comprehensibility is the cognitive component of this concept. It refers to the extent to which stimuli (internal and external) that a person is confronted with, make cognitive sense. Meaning that this information is ordered, consistent, structured, predictable, explicable, and clear (Lindström & Eriksson, 2005; Mittelmark et al., 2022).

Manageability is the instrumental/behavioral component of this concept. It refers to the extent to which a person perceives that the resources that are available to them are adequate enough to meet the demands of the stimuli that they face (Lindström & Eriksson, 2005; Mittelmark et al., 2022).

Meaningfulness is the motivational component of this concept. It refers to the extent to which a person feels that problems in life are worth investing energy in, worthy of commitment and engagement, and seen as a challenge rather than a burden (Lindström & Eriksson, 2005; Mittelmark et al., 2022).

A strong SoC has frequently been associated with good mental and physical health (Mittelmark et al., 2022). This is explained by the fact that someone with a strong SoC is able to understand the situation they are in, find meaning to move towards a health-promoting direction, and have the capacity to do so (Mittelmark et al., 2022). Unfortunately, there is not a lot of specific research on the SoC and its relationship with diabetes yet, however a weak SoC has been associated with a 46% higher risk of diabetes in participants < 50 years old (Kouvonen et al., 2008). More research is needed on this topic to further investigate the association between SoC and diabetes.

### 2.1.2 GRRs and SRRs

General Resistance Resources (GRRs) and Specific Resistance Resources (SRRs) are assets that people have available to them, which can help to improve their health (Eriksson & Lindström, 2005; Idan et al., 2016; Mittelmark, Maurice B. et al., 2016).

GRRs are resources that are readily available at people's disposable and can be re-used. They do not apply to a specific situation and can be used in a wide range of circumstances (Lindström & Eriksson, 2005; Mittelmark et al., 2022). It is something that is created throughout life via different experiences (Lindström & Eriksson, 2005). GRRs can be genetic, constitutional, psychosocial, or material. Some examples are knowledge, childhood living conditions, marital

status (in men specifically), identity, coping strategy, and religion (Idan et al., 2016; Lindström & Eriksson, 2005).

SRRs, on the other hand, are resources that "*are optimized by societal action*" (Mittelmark, Maurice B. et al., 2016), meaning that these resources can also be provided by the government, through health promotion initiatives, or by the environment. These resources are only used when a specific type of situation occurs, for example the availability of a suicide telephone helpline, knowing healthy recipes, or a glucose meter (Mittelmark et al., 2022; Mittelmark, Maurice B. et al., 2016; Mittelmark, M. B. et al., 2016).

SoC and a person's ability to develop and utilize GRRs and SSRs are intertwined (Figure 1). By strengthening the GRRs and SRRs, a person's SoC can develop further. With a strong SoC, the available resources can also be better applied which can further promote health (Idan et al., 2016; Mittelmark et al., 2022; Mittelmark, Maurice B. et al., 2016).

To conclude this section, Lindström and Eriksson already reviewed salutogenesis and stated that it could have a more central position in public health and health promotion research and practice, contribute to the solution of some of the most urgent public health problems and create a solid theoretical framework for health promotion (Lindström & Eriksson, 2005). The next section will elaborate on how salutogenesis has been applied during the development of the SALUD-study, and why this is so valuable.

# 2.2 Theory applied

Most nutritional research has focused on studying risk factors related to poor dietary habits, which focusses on pathogenesis and biomedical pathways. However, these studies often do not consider the contextual factors that people encounter in everyday life (Swan et al., 2015), and they have faced a lot of critique because they are often not reproducible and do not offer proper solutions (Ioannidis, 2013).

The SALUD-intervention, on the other hand, is based on the theoretical SMH. The development of this study has been well documented and is published, which makes it very transparent. The intervention differs from the standard healthcare practices in the Netherlands for people with T2DM, as it is a holistic and pragmatic approach to support a healthier diet (Polhuis et al., 2022) The aim is to empower people to take control over their diets, and to support them practically, socially, and emotionally in reaching their personal health goals (Polhuis et al., 2022). This was done by strengthening participants GRRs, and focusing on important concepts like self-identity and social support (Polhuis et al., 2021).

The development of this program was conducted in two phases: *exploration and synthesis* (1), and *validation and adjustment* (2). During the development of the SALUD intervention, three important principles of salutogenesis were taken into account:

- 1. The participants as a whole;
- 2. The participant's active involvement;
- 3. The participants' individual learning process.

These principles resulted in a multi-component, supportive and evaluated program. During the first phase of developing the intervention, 17 T2DM patients were interviewed to uncover GRRs and SRRs for healthy eating (Polhuis, Vaandrager, et al., 2020), and the opinion of another 14 T2DM patients and 13 practice nurses regarding intervention setting and content

were investigated through interviews. The results from these studies, as well as the results from the systematic review (Polhuis, Bouwman, et al., 2020), led to the development of the first draft version of the SALUD intervention (Polhuis et al., 2021).

Based on these studies, it was concluded that self-identity and social support were the most important resources for healthy eating for this target group. Therefore, the main strategy of the SALUD study was to strengthen these resources. Within the salutogenic framework, self-identity is crucial, and needed to develop a strong SoC. Therefor it is hypothesized that strengthening the GRRs during the SALUD intervention would also increase the SoC of participants. Strengthening the resources instead of only focusing on the SoC, also allowed for "concrete and practical intervention strategies" (Polhuis et al., 2021).

During phase two, this draft version was presented to five T2DM patients, six health practitioners, and 39 scientists so they could provide their feedback. Based on this feedback, an individual intake meeting with the CLC and a booster session were included into the program. The results from the interviews showed that he intensity, duration, recruitment, setting, instructor, and delivery of the program was approved by most of the stakeholders and therefor the intervention was finalized (Polhuis et al., 2021).

### 2.3 Comparison with other lifestyle intervention programs

The SALUD program is not the only program that targets people with T2DM. Within the Netherlands, a program that specifically focuses on people with T2DM is the CooL, *Coaching op Leefstijl*, program. Two examples of programs outside of the Netherlands, are the Look AHEAD, *Action for Health in Diabetes*, and the DIRECT, *Diabetes Remission Clinical*, trial. Both of these programs are intensive lifestyle interventions, that focus on weight management (Leslie et al., 2016; Ryan et al., 2003; van Rinsum et al., 2019; Van Rinsum et al., 2018). This next section will explain some of the differences between these trials, and explain what differentiates the SALUD program from them.

Within the DiRECT trial, focus lies on weight loss and the program is categorized as a 'structured, intensive, weight management program' (Leslie et al., 2016). The total duration of the study is two years, and the focus of the program really lies on participants medication use and weight loss. The participants of this study included adults aged between 20-65 years with a BMI that varied between 27-45 kg/m<sup>2</sup>. During the trial, participants had to undergo a total diet replacement which consisted of a formula diet for 3-5 months (825-853 kcal/day), after which food was step-by-step reintroduced for eight weeks. Afterwards, participants received structured support for long-term weight loss maintenance (Lean et al., 2018). After two years, more than a third of the people with T2DM sustained remissions, which was linked to sustained weight loss in those participants (Lean et al., 2019). However, they reviewed how participants had experienced the intervention and noticed that the experience varied noticeably. During the first week, participants struggled with hunger and fatigue and unfortunately for some participants that feeling did not go away during the intervention. Furthermore, adherence to the program was challenging but participants were able to make modifications that made it easier to follow. During life events such as holidays or wedding, participants had trouble adhering to the strict diet. The participants within this trial needed a lot of support to deal with the challenges and setbacks during the program. Nevertheless, the rapid weight change and improved wellbeing did motivate the participants to continue, despite the challenges.

(Rehackova et al., 2022). Since the intervention is relatively new, future research can provide more insights on the durability of the intervention over a period of five, or even ten years.

The Look AHEAD trial is also an intensive weight loss program, that is delivered over a time span of four years. Participants have to decrease their caloric intake, and increase their physical activity. The primary outcomes of the Look AHEAD trial are focused on participants weight and cardiovascular diseases (Ryan et al., 2003). Recent studies have examined the long-term effect of the Look AHEAD trial, and although there have been positive outcomes, the researchers found that this type of intensive lifestyle intervention might be beneficial to some, but harmful to others (Wing, 2021). Almost a third of the participants did not reach the goal of losing 5% of their initial bodyweight within the first year of the program. Furthermore, on average, participants regained some of weight that they had lost in the first year (LookAHEADResearchGroup, 2014).

There is a clear difference between the approach of the two interventions mentioned above, and the SALUD program. Where these interventions take a very strict approach and are mainly focused on losing weight, the SALUD program is broader and is focused on increasing participants resources to promote health, but it still gives the participants freedom to work on their self-defined goals. The idea of the program was that it would fit into and is centered around the daily life of the participants, as too intensive and controlling interventions may only produce short-lived effects.

CooL is a combined lifestyle intervention, in which adults and children who are obese or at high risk of obesity, receive counseling by certified lifestyle coaches (CLC). Some key approaches within this program are goal setting, autonomy-supportive coaching, and celebrating (small) successes. This has some overlap with the main principles of the SALUD program, and both the SALUD and CooL intervention focus on goal setting (Philippens; & Janssen, 2018; Polhuis et al., 2022). For adults participating in the CooL study, medium to large effect sizes regarding cognitive and behavioral lifestyle factors, and weight were found. Furthermore, these improvements, although not completely maintained after 18 months, seem to be sustainable (Van Rinsum et al., 2018). As this study is relatively young, future research can provide more insight on how these effects are maintained over a longer period of time.

### 2.4 Research questions

Current intervention studies provide little insights on how they work and why. Within this thesis, the goal was to quantitatively and qualitatively look at the results from the SALUD program thereby gaining more insights into how the program has worked. Therefore, different types of analyses are done. To start, it was assessed if the SALUD program had led to a quantitative change in the SoC of participants. Furthermore, qualitative evaluation aimed to further investigate what the participants experienced during the program, and how they would evaluate the program This has led to the following research questions:

What is the effect of the SALUD intervention on the Sense of Coherence of people with T2DM compared to people with T2DM following the standard T2DM care?

What is the perceived effect of the SALUD intervention according to the participants?

How do the participants of the SALUD intervention evaluate the program?

It is hypothesized that by strengthening participants resources (i.e., social support and selfidentity), their SoC will increase. Furthermore, participants are expected to perceive multiple different effects of the program that relate back to the concept of manageability, meaningfulness, and comprehensibility. Since the program has been developed using a bottomup approach and by involving many different stakeholders, it is expected that the participants will positively receive the program.

# **3 Methods**

# 3.1 Study design and procedure

Data from the SALUD study was used, which was a two-arm, randomized controlled trial (RCT). The intervention lasted twelve weeks and the total duration of the study was 24 weeks. Data was collected at three points: baseline (T0), twelve weeks (T1), and 24 weeks (T2) (*Figure 2*).

### 3.1.1 Intervention

The aim of the intervention was to empower the participants to gain control over their diets. The SALUD-intervention consisted of an individual intake at the start, followed by twelve weekly group sessions, and a booster session at 24 weeks. This was given in addition to the standard care that is provided to people with T2DM in the Netherlands. Due to COVID-19 crisis in 2020-2022, all sessions were held online. There were various topics for discussion, which have all

been based on previous research and improved by *p* stakeholder input (Polhuis, Bouwman, et al., 2020; Polhuis,

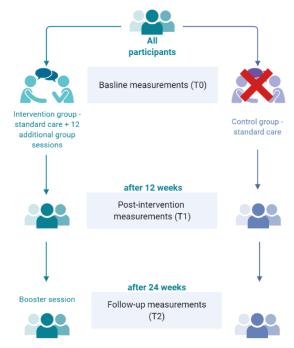


Figure 2 Time schedule of the SALUD-study including time points.

Vaandrager, et al., 2020; Polhuis et al., 2021). The sessions were guided by a CLC and when appropriate a dietician. A full overview of the goals and in-session activity of all the sessions can be found in the protocol (Polhuis et al., 2022), a brief summary is given in Appendix 1.

### 3.1.2 Control

Participants that were enrolled in the control group followed the regular care according to the Dutch General Practitioners Association (NHG, 2018) that is given to people with T2DM in the Netherlands. This includes three or four individual consults with a general practitioner (GP) or a practice nurse per year. That means that during the duration of the study, they would have had one or two visits to the GP. However, the exact frequency of the appointments depends on the specific agreements between the healthcare provider and the patient.

## 3.2 Study population

### 3.2.1 Participant recruitment and characteristics

Participants have been recruited by local GPs and practice nurses involved in the study, posters in GP practices, via social media, and regional newspapers. If an individual was interested, they could apply for more information on the SALUD website or contact the principal investigator (PI) directly per phone or mail. The participants were sent the information brochure and the informed consent, and an intake session was scheduled one week later. During the phone call, the PI explained the study and the participant could ask questions. If a person decided to participate, they signed the informed consent and sent it to the PI. Confirmation of participation was sent by e-mail and the participants were informed via e-mail whether they were allocated to the control or intervention group.

The study population consists of adult patients (18-75 years old) that have officially been diagnosed with T2DM in the Netherlands. Participants were excluded if: they are not fluent in

Dutch, currently (trying to get) pregnant, lactating, suffering from severe illnesses/conditions/comorbidities, have undergone bariatric surgery in the past, or if they suffer from an eating disorder.

After recruitment, participants were randomly allocated to either the intervention or the control group.

The study process and outcomes were both quantitatively (through questionnaire) and qualitatively (through focus groups) evaluated. First the quantitative methods and then the qualitative evaluation is described.

## 3.3 Quantitative evaluation of the Sense of Coherence

The first part of this thesis was aimed at quantitatively comparing the intervention and control group with each other, and see if there was a significant difference in their change in SoC. This was done through the administration of multiple questionnaires.

### 3.3.1 Variables

**Sense of Coherence (SoC-13):** Sense of Coherence was measured through the Orientation to Life Questionnaire (SoC-13), that consisted of thirteen items that cover how comprehensible, meaningful, and manageable the participants view the world (Appendix 2). The validity and reliability of this measure is extensively researched and the questionnaire is adapted in over 30 countries (Lindström & Eriksson, 2005). For this study, the translated Dutch version has been used. This version was found to have a Cronbach's alfa of 0.860, which is acceptable (Swan, n.d.). Answers were given on a 7-point Likert scale, ranging from 1 (very often) to 7 (almost never). Whether the scales are positive or negative was taken into account, and when needed the score was reversed. A total score was computed for each participant, as well as the scores on the three sublevels.

**Participant characteristics:** Participants demographics and clinical characteristics were measured through a questionnaire (Appendix 3). This included information on their age, gender, nationality (Dutch or non-Dutch), education (low, middle high), work situation (paid job, retired, other), living situation (alone, with partner, with partner and kids, with kids) and smoking habits. Smoking was assessed in two ways. First, it was determined whether someone has never smoked, was a current smoker, or a past smoker. When it was determined that someone was a past smoker, the years since they quit smoking were measured. This resulted in two variables for smoking. Lastly, two clinical characteristics were measured through this questionnaire, diabetes duration (years), and medication use (yes/no, type of medication).

**BMI**: BMI was assessed with the scale. The height of the participants was measured at the start of the study and the same height was used throughout the study. The weight of the participants was measured with the A&D Medical, type UC-411PBT-C scale. The scale was calibrated before use and placed on a flat surface. The measurements were done in a standardized method (Appendix 4). Prior to the measurement, participants age, height, and gender were entered into the scale. After weighing the participant, the scale calculated the BMI itself which was noted by the researcher.

To calculate BMI, the following formula was used (by the scale):

$$BMI\left(\frac{kg}{cm^2}\right) = \frac{Weight(kg)}{Height^2(cm)}$$

#### 3.3.2 Statistical analysis

All statistical analysis were executed in IBM SPSS Statistics 27. The demographic and clinical variables for the total sample, and the sample stratified by group were calculated and tabulated (Table 1). The values were given either as a percentage, (%(N)), or as mean with the standard deviation (mean  $\pm$  SD). Differences in characteristics between the two groups were investigated with the appropriate tests (Chi-Square, Fisher's exact or Likelihood's ratio test for categorical variables, and Mann-Whitney U tests for continuous variables) and corresponding P-values are presented in the tables.

Prior to running the models, a simple first inspection of the data was done. To check if there was a difference between change in SoC score, a new variable that calculated this change was computed and a table with the mean changes per group was drafted.

To investigate the difference between the two groups thoroughly, a univariate, general linear model (ANCOVA) was used. First, the assumptions were checked (a detailed description of this can be found in Appendix 7, all assumptions were met). The independent variable in all models was treatment allocation (defined as group), and the dependent variable was the SoC score post intervention (T1). The model was built step-by-step. The crude model was unadjusted for any variables, and only included SoC score post-intervention and group. The second model was adjusted for SoC score at baseline (T0). The third model was additionally adjusted for known confounding variables based on literature, which included age, gender, and BMI. This increased the comparability to other studies. The final model was additionally adjusted for the variables that were significantly different between the two group, and included smoking and medication use.

As the intervention was group-based, an extra analysis was performed to check whether the intervention effect was similar in all three subgroups (e.g., the Monday, Tuesday, and Wednesday group). The same model was run, but instead of using the variable Group as independent variable, the variable Subgroup was used. This allowed the researchers to check for differences between the three intervention groups, omitting the control group, to see if the three groups were comparable or if there were significant differences between them. Both on their characteristics, as their change in SoC.

### 3.4 Qualitative Evaluation : thematic analysis of the focus groups

The second part of this thesis was aimed at discovering how the participants perceived the intervention, and how they experienced the program. This was done to increase understanding on how the program (potentially) influenced participants SoC, and if their resources were indeed strengthened.

To gain insights in these questions, three focus groups were held with all intervention participants adjacent to the twelfth and final session of the intervention program. The CLC moderated the focus groups. The interview topic guide (Appendix 5) was followed by the CLC in all three intervention groups to ensure that the same questions were discussed. The goals of this session were to reflect on the program, to look ahead and ask participants how they are

going to continue the coming three months, and to ask for participants input on improving/further developing the program.

Prior to the focus group, the CLC asked whether the participants wanted their partners to be present during the final session. Only the Monday group wanted to involve their partners in the session/focus group. Permission to record the session was asked and given by the participants (and the partners of Monday group participants). The three recordings were transcribed by the MSc student, and used in the analysis. This part did not receive ethical approval beforehand, but the study has been retrospectively ethically inspected by the Social Ethical Committee of Wageningen University.

### 3.4.1 Thematic analysis

To investigate re-occurring themes between the groups, a step-wise, thematic analysis of the transcripts was done (Skovdal & Cornish, 2015). After familiarization of the data and writing down a story of each transcript, a preliminary list of codes that were expected to be needed during coding was drafted. After that, the transcripts were analyzed using ATLAS.ti and the coding network was further developed. When needed, new codes were created. After this initial coding, the transcripts were discussed between the PI and the MSc student. Based on these discussions, codes were merged, added, or removed. After this, the transcripts were checked again, and the coding list was finalized (see appendix 6).

Themes were identified by exploring how the codes relate to each other. Both the student and the PI independently drafted the primary relevant themes. The final themes are the result of multiple discussions between de PI and the MSc student. This resulted in two main themes, that each answered a different aspect of intervention: perceived health effects, and participants appreciation. The themes are displayed with relevant participant quotes (translated to English).

To provide maximal transparency in the current analyses, a summary of each of these themes was compared to the previously created stories, to confirm they overlap and share a similar message. Secondly, a tally was made of which participants provided information on each of themes.

# 4 Results I: Qualitative analysis of SoC

# 4.1 Participant characteristics

The demographic variables for the total sample, and the sample stratified by intervention group were calculated and tabulated (Table 1). The values were given either as a percentage, (%(N)), or as mean and the standard deviation (mean  $\pm$  SD).

The groups were quite comparable with each other, except for significant differences in past smoking, medication use, and baseline SoC score. In the control group, there were no current smokers, whereas in the intervention group 13% was a smoker. Additionally, the intervention group had a larger amount of past smokers than the control group (60,9% vs 36,4%; P-value=0.011). There was a difference in medication use, as fewer participants of the control group used diabetes medication (63,3% vs. 87%, P-value=0,019). Lastly, sense of Coherence score at baseline was significantly different between the two groups (P-value=0.027).

	Total (n=45)	Control (n=22)	Intervention (n=23)	
	% (N) or mean $\pm SD$	% (N) or mean $\pm SD$	% (N) or mean $\pm SD$	P-value
Women (%)	37,8% (17)	31, 8% (7)	43,5% (10)	0,420°
Age (y)	$63,\!38\pm9,\!73$	$66,05 \pm 7,82$	$60,83 \pm 10,82$	0.133 <sup>d</sup>
BMI (kg/m <sup>2</sup> )	$29,46 \pm 5,52)$	$29,43 \pm 5,17$	$29,48 \pm 5,99$	0,923 <sup>d</sup>
Nationality (%Dutch)	88,9% (40)	90,9% (20)	86,9% (20)	1,000ª
Education (%)				0,291 <sup>b</sup>
Low	15,6% (7)	22,7% (5)	8,7% (2)	
Middle	33,3% (15)	36,4% (8)	30,4% (7)	
High	51,1% (23)	40,9% (9)	60,9% (14)	
Work situation (%)				0,593 <sup>b</sup>
Paid job	40% (18)	40,9% (9)	39,1% (9)	
Retired	51,1% (23)	54,5% (12)	47,8% (11)	
Other	8,9% (4)	4,6% (1)	13,0% (3)	
Living situation (%)				0,682 <sup>b</sup>
Alone	24,4% (11)	18,2% (4)	30,4% (7)	
With partner	57,8% (26)	63,6% (14)	52,2% (12)	
With partner and kids	11,1% (5)	13,6% (3)	8,7% (2)	
With kids	6,7% (3)	4,5% (1)	8,7% (2)	
Smoking (%)				0,011 <sup>*b</sup>
Never	44,4% (20)	63,6% (14)	26,1% (6)	
Current	6,8% (3)	0% (0)	13,0% (3)	
Past	48,9% (22)	36,4% (8)	60,9% (14)	

Table 1: Participants characteristics

Quit smoking (y) <sup>+</sup>	$\textbf{23,28} \pm \textbf{16,05}$	$22,\!82\pm12,\!76$	$24,00 \pm 21,05$	0,877 <sup>d</sup>
Duration T2DM (y)	$9,\!17\pm7,\!02$	$8,76\pm6,38$	$9,56 \pm 7,71$	0,829 <sup>d</sup>
Medication (%yes)	75,6% (34)	87% (20)	63,6% (14)	<b>0,019</b> <sup>*d</sup>
SoC T0	69,96 ± 11,69	73,45 ± 11,4	66,61 ± 11,20	0,027 <sup>*d</sup>
SoC T1 <sup>#</sup>	$72,\!95\pm9,\!84$	$73,55 \pm 10,75$	72,33 ± 9,0	0,551 <sup>C</sup>

+: Excluding those who still smoke

\* : Significant, alfa=0.05

#: 2 dropouts are excluded from the intervention group

a: P-value based on Fisher's exact (assumption that all cells have a count >5 is violated) b: P-value based on Likelihood ratio (assumption that 20% of the cells have a count <5 is violated)

b: P-value based on Likelihood ratio (assumption that 20% of the cells have a count <5 is viol

### 4.2 Sense of Coherence

To provide a quick insight in the differences between the groups, Table 2 was drafted and shows the change in SoC score after three months (mean  $\pm$  SD). For the intervention group this change was 5,48 (SD= 9,0), and for the control group this change was 0,09 (SD= 7,96). The change was significantly different between the intervention and the control group (P-value = 0.028).

Table 2: Overview of the Sense of Coherence differences per group, after three months

	<b>Total</b> ( <i>n</i> =45)	Control (n=22)	Intervention <sup>+</sup> (n=23)	P-value
Change in Sense of	$2,72 \pm 8,28$	$0,09 \pm 6,68$	$5,48 \pm 9,03$	0,028*
Coherence	· · ·	0,07 = 0,00	0,.0 = 7,00	

\*: statistically significant with an alfa of 0.05 (NP Mann Withney U test)

To determine if following the intervention made a significance different on participants SoC, a model was built. The full table that depicts all the steps of building the model, and P-values can be found in Appendix 8. Here, only the crude and final model are shown.

The crude model did not show a significant effect (P-value: 0.691), and after adjusting for the relevant variables the final modal also did not show a significant result for the effect of the group (P-value=0.334). Thus, we cannot with certainty say that being allocated to the intervention group, is what caused the difference in SoC change between the participants. The final model had an R-squared of 0,417 (Table 3). As shown in Appendix 8, adjusting for SoC at baseline explained most of the data.

*Table 3: Overview of the SoC values for the intervention and control groups, and the corresponding P-values of the crude and final model as well as the R-squared* 

	Intervention (n=23 <sup>+</sup> )	<b>Control</b> ( <i>n</i> =22)	P-value crude model	P-value final model <sup>#</sup>	R-squared final model
<b>Soc at T0</b> mean ± SD	66,61 ± 11,20	73,45 ± 11,4	0 (01	0.224	0.417
Soc at T1 mean ± SD	72,33 ± 9,0	$73,55 \pm 10,75$	0.691	0.334	0.417

+: 2 dropouts are removed from the intervention group at T1

#: The final model is adjusted for SoC score at baseline, age, gender, BMI at T1, smoking habits, and medication use

#### 4.2.1 Differences between the subgroups of the intervention

Within the intervention group, the participants followed the sessions in one of three subgroups (also referred to as the Monday, Tuesday, or Wednesday groups). To compare these three groups, Table 4 was drafted (full table can be found in Appendix 9). Most noticeable is the age differences between the groups, where the Monday group is younger than the Tuesday and Wednesday group (resp.  $49,86 \pm 6,04$  vs  $67,57 \pm 5,03$  vs  $62,86 \pm 12,21$ ), and consequently also had a lower T2DM duration (resp.  $6,55 \pm 4,42$  vs  $11,57 \pm 7,21$  vs  $9,14 \pm 7,880$ ). Furthermore, the Monday group mostly consisted of participants who were still employed, while the Tuesday and Wednesday group mostly consisted of people who were retired. Lastly, the Monday group had one current smoker while the rest of the group never smoked, on the contrary the Tuesday and Wednesday group had more past and current smokers.

	Monday group (n=7)	Tuesday group (n=7)	Wednesday group (n=7)
	% (N) <i>or</i> mean ± SD	% (N) <i>or</i> mean ± SD	% (N) or mean ± SD
Women (%)	29% (2)	57% (4)	43% (3)
Age (y)	$49,\!86\pm6,\!04$	$67,\!57 \pm 5,\!03$	62,86 ± 12,21
BMI (kg/m <sup>2</sup> )	$28.52 \pm 5{,}61$	$26,92 \pm 4,54$	33,00 ± 6,68
Work situation (%)			
Paid job	86% (6)	29% (2)	14% (1)
Retired	0% (0)	57% (4)	71%(5)
Other	14% (1)	14% (1)	14% (1)
Living situation (%)			
Alone	14% (1)	43% (3)	29% (2)
With partner	43% (3)	57% (4)	57% (4)
With partner and kids	14% (1)	0% (0)	14% (1)
With kids	29% (2)	0% (0)	0% (0)
Smoking (%)			
Never	86% (6)	43% (3)	57% (4)
Current	14% (1)	14% (1)	14% (1)
Past	0% (0)	43% (3)	29% (2)
Quit smoking (y) <sup>+</sup>	n.a.	$29,50 \pm 22,75$	$17,67 \pm 19,14$
Duration T2DM (y)	$6,55 \pm 4,42$	11,57 ± 7,21	$9,14 \pm 7,88$

Table 4: Participant characteristics of the three subgroups of the intervention (removing the 2 dropouts so total n=21)

+: Excluding those who still smoke

Table 5 shows the mean SoC at baseline and post-intervention for each subgroup separately. In the Monday and Wednesday group there was a mean increase in SoC of >8 points, whereas in the Tuesday group there was no change in total SoC. Upon further investigation it was found that in the Tuesday group there was a change on the three different levels of SoC, manageability/ comprehensibility/meaningfulness, but they evened each other out in the total SoC. Although

there was an 8-point difference between the three subgroups, this difference was not significant (P-value=0,106). Therefor we can say that the intervention did not have a different effect in one of the three subgroups.

	<b>SoC at T0</b> mean ± SD	<b>SoC at T1</b> mean ± SD	<b>SoC Change</b> mean ± SD	P-value
Monday group (n=7)	62,57 ± 11,2	70,86 ± 13,4	8,29 ± 8,4	
Tuesday group (n=7)	$72,29 \pm 7,99$	$72,29 \pm 8,3$	$0,00 \pm 9,1$	0,106
Wednesday group (n=7)	$65,71 \pm 7,02$	73,86 ± 4,0	$8,14 \pm 8,1$	

Table 5: Overview of the SoC values at T0, T1 and the total change, per subgroup.

# **5 Results II: Thematic analysis of the focus groups**

The focus groups resulted in two main themes that provided information on different aspects of the intervention:

- 1. Perceived effects
- 2. Participants' evaluation

In theme one, the perceived effects of the SALUD program in participants' everyday life are described. Furthermore, this theme also discussed what (lifestyle) changes participants experienced during the program, and what had motivated them to make these changes. In theme two, the participants' evaluation of the SALUD program is described, including valuable features and areas for further improvement.

A summary of participants' answers and where to find them in the transcripts can be requested by contacting the MSc student. Table 6 provides a simplified overview of how each participant participated in the focus group and what they contributed by theme. Furthermore, participants were asked to bring an object that represented the program for them to the final session. An overview of all objects and reasoning behind them is given in Appendix 10, these objects were used to illustrate the results.

### 5.1 Theme 1: Perceived effects

#### 5.1.1 Grip

In all groups, participants generally emphasized that they experienced more 'grip' on their eating behavior and perceived health. For example, participant 12 mentioned that she had started to realize that she was responsible for her own body and actions, whereas participants 10, 14, and 20 all mentioned taking control over their own life.

"Because I have been doing this for a long period of time, but I do not yet have the self discipline. But, what I did gather from this [program], what I did gather is that I am responsible for my own life, and for my own body, so I should do it myself. And then you can make excuses, like this or that.., but. And I will work on it myself, so it is a different outlook on life." – Participant 18; group 3

However, there was considerable dispersion between the participants. Most participants expressed that they experienced more insight and grip on their eating behaviors, but they were not yet where they wanted to be eating-wise and health-wise. There were two extremes: one participant that stated he did not experience any change regarding his eating behaviors and health and, on the contrary, one participant that clearly and convincingly stated that he is completely were he wanted to be health-wise:

Participant 7: "I am where I want to be actually, so, that is nice."

Coach: "Keep maintaining this, right! "

Participant 7: "Yes, yes, and otherwise I will go back to measuring [his blood values] again." – Participant 7 & Coach-, group 1

		Theme 1: perceived effects				Theme	3: evaluation		
			Increased		Social	support	Realistic		
Group	Participant nr	Perceived grip	awareness of <b>the</b> <b>feasibility</b> of health behaviors	Reflective mindset	Peer support	Family support	goals / goals become part of daily life	Valuable features	Areas of improvement
	1	$\uparrow$		$\uparrow$		-			
	2	$\uparrow$	1		+	+/-	+	Setting & approach	General approach
	3	$\uparrow$		$\uparrow$					
Monday	4	1	Ť	<b>↑</b>	+	+		Setting & approach; content	Online format
	5	1	1	<b>↑</b>	+	+	+	Setting & approach; content	General approach; online format
	6	1	1	1		+	+	Setting & approach; content	Online format
	7	$\uparrow$	1	$\uparrow$	+	+	+	Setting & approach; content	Blood glucose measurements
	8	$\uparrow$	1	<b>↑</b>	+	+		Setting & approach	Online format
	9	1		<b>↑</b>	+	-		Setting & approach; content	General approach
	10	1	Ť	<b>↑</b>	+	+			General approach
Tuesday	11	1	1					Content	
	12	1	Ť		+			Setting & approach	General approach
	13	$\uparrow$	1		+	+		Setting & approach; content	General approach
	14	$\uparrow$	1	$\uparrow$	+	-		Setting & approach; content	General approach
	15	$\uparrow$	1	$\uparrow$	+		+	Setting & approach; content	General approach, Mindfulness
	16	$\uparrow$	Ť		+	+		Setting & approach	General approach, online format
	17	$\uparrow$	1	1	+	-		Setting & approach; content	Mindfulness; Blood glucose measurements
Wednesday	18	1	Î	1	+	+		Setting & approach; content	General approach, mindfulness, online format
	19	1	<u>↑</u>	↑	+	+		Setting & approach; content	General approach
	20	$\uparrow$		$\uparrow$				Setting & approach; content	General approach; online format
	21	$\downarrow$	1	1					Online format

Table 6: Overview of each participant's responses in the focus group; divided by the three main themes

 $\uparrow$  = experienced increase

↓ = experienced decrease
 + = perceived this aspect as something useful/positive

- = perceived this aspect as something not useful/negative

N.B.: when a cell is left empty, the participant did not express his/her opinion on this aspect

One participant (nr 21) noticeable differed from the other participants in the sense that he was the only participant not able to reach at least one of his goals (in contrary, he mentioned increased weight). His object also symbolized his deteriorated health (a scale that resembled increased weight and increased blood sugar). When the coach asked the group how your partner of family can help with keeping motivated and working on your goals, participant 21 replied:

Well by not, by not tempting. She [=his wife] should not bring things into the house that are, um, bad for me. And that, and she can eat that herself of course. But if she offers it to me, that is a step too far. I say do not do that, I say. So she has to get rid of that habit. Offering me something that is not good for me. ' – Participant 21; group 3

This is in contrast with how most other participants, since he answered the question quite negatively. Commonly, the other participants answered this question more positively and proactively by saying that they are responsible themselves.

Participants were able to experiment during the program (nr 1, 2, 6, 7, 10, 11, 15). Participant 7's blood glucose levels stabilized during the program, and he wanted to find out what unhealthy foods would do to his glucose levels. During his holiday he took the opportunity to eat more sugary foods and observe how his body reacted. He reported that his has helped him to understand his body more and he was able to reflect on the blood values. Participant 2, 11, and 15 specifically mentioned experimenting with food. For participant 2 this was experimenting with vegetables to increase her consumption of them. Participant 11 wanted to cook more salads, which he also symbolized through his object (a recipe book called '500 salads'). Participant 15 experimented by removing or replacing sugary products from his diet. He mentioned that prior to the intervention he would consume coffee with a lot of sugar, whereas if he were to drink coffee with that much sugar now, he would find it disgusting. This change in taste, participants experiencing products that they used to consume as too sweet, was also something that was mentioned by participant 5, 17, and 18.

### "And I could not imagine drinking that, coffee without sugar. But it's going well." – Participant 15; group 3

This increased feeling of 'grip,' or control, was also represented in the objects brought by the participants (Appendix 10). Participant 17 mentioned that during the three months of the intervention, she actively tried to find a balance in food, physical activity, and lifestyle in general. She symbolized this by the object that she brought, which was a notebook with the title "Revalue Balance". Two participants brought an object that symbolized taking control. Participant 10 brought a wheel and reported that he is in control of his own life, whereas participant 20 brought a golf ball to symbolize that you are the only one responsible for/in control of your progress.

"I play golf, and that is an individual sport. When it does not go well, you cannot blame someone else, right. It is always up to you. And it is the same for, for sugar (=diabetes), right." – Participant 20; group 3

This increased grip was not only reported by the participants, but it was also mentioned by the partners. Four participants of the Monday group brought their partner to the final session, and they actively participated in the focus group. All partners expressed that they observed significant changes in the participants' behaviors or mindset since the SALUD program. The

partner of participant 4 explained that participant 4 had consistently been working on his goals, and this had also been reflected in his blood values. This confirmation strongly motivated participant 4, as it provided tangible proof that the efforts he was making resulted in improved health. The partner of participant 5 explained that participant 5 had been less hesitant to 'get up and move', and had been more motivated to stay physically active than prior to the program. The partner of participant 6 explained that participant 6 had been taking more initiative to cook and buy groceries since the start of the study. Furthermore, she observed that participant 6 had a lot more energy. Finally, the partner of participant 7 mentioned that she had been telling a lot of the things covered in the program to participant 7 was also the participant who explicitly mentioned that he is where he wants to be, regarding his blood values, which was confirmed by his partner.

"I am really happy that he participated in this [= SALUD] program, because I have been saying some of these things [specifically the importance of vegetables] for years but it never seemed to land – Partner participant 7; group 1

#### 5.1.2 Social support

Participants expressed that experiencing social support in the SALUD sub-groups was an important factor for the participants to be able to work on, and achieve, their goals. Participant 4 explained why he found social support important for his health:

Participant 4: "Yes, that it is just eh, that you find out that you can change [...] but also that if you do that together with other people it is much easier".

Coach: "Beautiful, the social support yes".

Participant 4: "Yes, I think that if you do it alone, you know what to do and eh, but if you talk to each other like that and discuss it with friends or with your partner, then yes, it becomes more alive and then it is just easier". – Participant 4 & coach, group 2

They found this support either in each other during the sessions (peer support) or within their families and friends. All three groups emphasized that following the SALUD program in a peer group was important. It allowed the participants to connect with people who share similar experiences. This social connectedness was supported by the object of participant 2, which was a sugar packet to symbolize the connection that the participants were able to develop with each other, and that having sugar (e.g., diabetes) is what facilitated them make this connection. The participants felt like they could get a lot of support from each other, but also motivate each other through a form of social control. Being able to find people that could relate and understand what you experience was comforting for the participants (nr 2, 14, 16). In all three groups the participants appeared to have a high level of social connectedness and peer support, based on the positive and active interaction between them. For example, participants would give each other compliments or advice during the sessions.

Participant 8: "I would like to thank everybody for the kind way in which we interacted with each other, without having to constrain ourselves. Everybody

got to say what they wanted to say, and that is really cool. Because that is not so easy for everyone and ..."

Participant 9: "Oh [Participant 8's name], stop it. You were the one that during the first sessions invited everyone to see some nature, and I would like to take you up on that sometimes." - Participant 8 and 9, group 2

The peer support worked in two ways for the participants: motivating and learning. Participants explained that it was motivating to work in a group, because you get inspired by other people and feel supported by each other (nr 4, 5, 7, 8, 9, 12-17). Being part of a group also made the participants feel less alone. Moreover, being in a group motivated participant 5 to work on his goals, because he did not want to make a fool of himself.

"Being together is really nice. Being able to learn from each other's experiences and motivations." – Participant 7; group 1

Participants were able to learn from each other's experiences or practical skills, which was explicitly mentioned by a few participants (nr 2, 7, 12). Furthermore, the participants reported that they also learned from the role model that was invited in session 9 (nr 4, 12, 14). Participant 8 described this process as:

"Well look, everyone, from his or her position and background, can retrieve and share information. And eh you can extract very valuable moments from that that could be of help to that particular person and could bring them progress." – Participant 8; group 2

All three sub-groups had an active WhatsApp group, that was utilized for providing tips, experiences, and practical things like recipes with each other. All groups mentioned that they would like for this WhatsApp group to stay online, after the intervention ended. Multiple participants (nr 13, 14, 18) even mentioned the WhatsApp group as a future tool that they are planning to use, to motivate them if they would face future challenges regarding their health goals.

Besides support from each other, support from the family was also mentioned as important for being able to achieve their goals, as participants received motivation and support from their partners. Participant 5 frequently mentioned that his wife functions as a "big stick", because she motivates him when he is at a dead end. Some concrete examples of what the partners helped with were: walking together (nr 5, 6, 18), drinking more water (nr 6, 18), incorporating healthier foods into the diet (nr 2, 7), and helping the participant to avoid sugary foods (nr 18). Furthermore, participant 5 explained that getting a compliment from his partner is incredible rewarding and motivating for him:

"They [your partner] support you and say: 'You did well', that gives you a positive feeling and not like: 'Well, you finally did it and it's about time you did something'. So, but you see this positive approach, or you can give yourself a compliment, but if someone else does it, then it is often just that little bit more meaningful. It also gives you a good feeling that maybe next time it will be easier to do it yourself, or something like that." – participant 5, group 1 Some partners were very involved to the extent that the partners themselves also learned things form the SALUD program (nr 8). Participant 11 mentioned that he also pulls along this partner on his health quest as he persuades his wife to look at the nutritional value of products. Participant 13 mentioned 'the oil spill effects' of the SALUD program, meaning that other people see the positive effects of the SALUD program on her lifestyle and that this inspires relatives to work on their health as well

Nevertheless, there were some participants that expressed they did not feel the need to rely on their partners for support (nr 1, 2, 14, 17). Two participants mentioned that their partner also could have a negative influence. For example, some participants felt that their partner 'forced' them to eat more food, or stimulated them to eat unhealthy food (nr 14 and 21).

Lastly, the coach might have played a role in the experienced social connectedness in the group as she supervised the sessions and used her skills to facilitate the meetings. Participants expressed their appreciation for the coach and thanked her for her efforts.

#### 5.1.3 Increased awareness of the feasibility of health behaviors

Most participants brought up the fact that they have become more aware (nr 2, 4-8, 10-19, 21) of their lifestyle in general, but also specifically regarding their physical activity and eating habits. In Table 7, an overview on what participants gained awareness on, according to themselves, is given.

Participant nr	Life in general	Eating habits	Physical activity	Stress	Sleeping
/ topic	_	_			
P1					
P2					
P3					
P4					
P5					
P6					
P7					
P8					
P9					
P10					
P11					
P12					
P13					
P14					
P15					
P16					
P17					
P18					
P19					
P20					
P21					

Table 7 A tally of the topics that the participants became more aware on, and who it applies to

N.B.: When a cell is colored in, that means a participant mentioned gaining awareness on that topic. If a cell is not colored in, that means that the participant did not mention gaining awareness on that topic.

Most participants mentioned that they have become more aware in general, however some participants elaborated further and gave specific examples on what they have become more aware of and gave specific examples of some of the lifestyle changes that they made. This showed that they did not only start to think more about their lifestyle, but they were also motivated to change their habits. The topics could be categorized in four groups: eating habits, physical activity, stress, and sleeping.

Regarding eating habits, participants had become more aware of reading the nutrition labels, eating more vegetables, trying out healthier alternatives, drinking more water and consuming less alcohol. Furthermore, eating patterns and portion sizes were also discussed. Most participants started to actively read nutrition labels on food products which increased their nutritional knowledge and consumption behavior.

"I will never be able to look at a nutrition label without thinking of you (= the group)! [...]. And of course, I knew that, but yeah I never really looked at it that often. But now, now I am aware of it." – Participant 14, group 2

Secondly, the increased awareness on the importance of staying physically active was mentioned a few times. Participant 8 and 10 both mentioned that something that kept them aware of this, was their smartwatch.

"Also because of the smartwatch, because indeed it tells you that you have not done all your steps for today, so then I decide to go outside. "participant 10, group 2

Lastly, for a few participants the importance of stress and sleeping became clearer during the SALUD program. Especially the effect that it can have on your blood glucose levels. Gaining this insight is speculated to be a motivating factor to start working on improving your sleep and lowering your stress. This was supported by the object brought by participant 16, since she brought her mobile phone that simultaneously functioned as her alarm clock to show that she had been working on improving her sleep. This supported the idea that after gaining awareness on these topics, participants were motivated to start working on that aspect of their life.

"I have also learned that sleep is actually very important, more than I previously thought. Of course I knew that it was important, but that it influenced your sugar values this much is something that I did not expect." – participant 16, group 2

#### 5.1.4 Reflective mindset

The participants described the SALUD program as an inward journey or a self-discovery journey, which led to a more reflective mindset in daily life. The object brought by participant 5, a walnut, represented this. As he explained, on one side it symbolized the "happy nut", because the meetings with the group were fun. However, on the other hand it symbolized the "hard nut", because the participant was stimulated to think about what they want and what was good for they, which can be confronting but in a good way. Participants mentioned that they started to reflect more on their life and their daily actions (nr 1, 3-10, 14, 15, 17-21). Specifically reflecting on their goals, their eating behaviors, and emotions.

Reflecting on their goals was important, as it kept the goals achievable and relevant. However, it also showed that participants were actively involved in their learning process as they adapted the goal to fit in their current lifestyle. The participants explained that since the start of the study they have worked on their goals, reached goals, made new goals (nr 18), or intensified existing

goals (nr 10), and are planning to continue this way. The program motivated participant 5 more to think about his goals and what he wants, but also what he is capable of doing:

"Makes you think about your goals, what do I really want and eh you have to think about what can I do, what can I do, all that sort of thing. You really have to take a moment, a moment, a moment, you're really confronted with the facts of what, what exactly do you want, what, what, what would you keep up and that sort of thing so it is also, that's also very good for you – Participant 5, group 1

As participant 7 mentioned, it was important to keep adjusting the goals and he realized that even with small changes it was possible to book serious progress. Participant 8 mentioned that having the goals was important to get him started, and now he wants to continue this way. Participant 9 also said that by thinking about your goals every week, you stay on top of them. Which was also supported by participant 16, who mentioned that having weekly meetings ensures that your goals do not fade to the background:

# "Also because we get together every Wednesday on Zoom, it is kind of a reminder, keeping you aware of your goals." – Participant 16; group 3

Multiple participants reflected on their food choices, which was done in several different ways. Most of these have already been discussed, because it also showcased their new ability to experiment with eating and cooking. However, one more example of this was given by participant 2 who struggled to incorporate enough vegetables into her diet. However, she learned a new, fun way to experiment with vegetables from somebody else and realized that that helped her increase her vegetable intake.

Participant 2: "Well, vegetables are not very easy for me, and I figured well this is kind of intense, but I actually really liked it."

Coach: "Yes? And have you ever had it before?

Participant 2: Well, since I started this, I have kind of, kind of been experimenting. And somebody said that I should this this, so" – Participant 2 and the coach; group 1

Participants mentioned that they were eating more mindfully. Participant 4 and 19 specifically mentioned the mindful eating session as something that stuck with them and made them think about their way of eating. Furthermore, participants expressed that they were also more mindfully enjoying 'unhealthy' foods and not feeling guilty about it (participant nr 5, 6, 16, 19). Participant 6 explicitly mentioned that when he does eat something unhealthy, he is more in control than prior to the SALUD program, as he used to snack on multiple different food items:

"Right, where in the past I might have lost all control and thought: well, now I crave something sweet, and then something savory, and then this, which of course is terrible for your blood sugar. I have become much more aware of this, to really choose those moments." – participant 6; group 1

An important experienced consequence of the SALUD program was that several participants realized that they unconsciously were feeling ashamed for having T2DM when they are in social situations. For example, participant 16 realized this during the program and started to figure out

where this feeling came from. Several participants got rid of feeling ashamed of having T2DM and are no longer 'hiding' their disease for family and friends (participant 14, 16, 17).

The group also provided emotional support, which could have been used for reflection on these feelings. Furthermore, participant 8 mentioned that the sessions helped him to better deal with emotional situations. He explained that by talking to each other about it, he was able to reflect on those moments and minimize the emotional effect on him. In the future, he will use these insights to help reflect on these moments and minimize their impact on him.

"I am someone with a very emotional character [...], and I know that when everything in my head is clear than everything else, both physically as mentally, I feel better. [...]. Well, because of certain moments in my environment, I can, eh, respond very emotionally. And then it takes a day, and then it is over again and yes then I can give it a place. However, I have those moment quite frequently and that, that yes the sessions have motivated me to see if I can decrease those kind of moments. And for me that is a bonus point." – participant 8, group 2

#### 5.1.5 Realistic goals

The participants were encouraged to determine their own goals together with the coach, which ensured that everyone could work on the things they found most important or necessary. This also encouraged the participants to think about what was achievable for them (mentioned by participant 3-5, 7, 17-19) which directly links back to their reflective mindset and ensured that the participants were able to carry out the changes they wanted to make. However, the program was not meant to drastically change the life of the participants, but rather guide them into incorporating small, 'easy' and more healthier habits into their life. The participants positively received this:

"So that is, yes you notice that when you just, and that is indeed something important what we also said in the beginning, is that if you make your goals too difficult, than you are almost destined to fail and now it actually, actually every time it feels good that you achieved them. That you achieved your goals. But that it does not take too much effort and then, well you last longer, yes."-participant 5, group 1

Realistic goals were mentioned as an important factor by multiple participants (nr 5, 7, 10, 15). Participant 15 mentioned that the goals that he set for himself during this program, were more achievable than previous goals he had set. This is also reflected in the objects the participants brought to the focus groups: In total, eleven objects represented reaching or working on your goals (Appendix 10). Multiple participants (nr 2, 5, 6) mentioned that they noticed that the goals were starting to become a normal part of their day, instead of a challenging task they were obligated to do.

In total, eleven objects represented reaching or working on your goals (Appendix 10). One strong example of this is the object from participant 4. He explained that he was able to significantly minimize his alcohol consumption in order to work on his goals, which he symbolized with a bottle opener.

Participants expressed their desire to keep continuing this way and thus realized that although they have improved, they are not yet exactly where they want to be. Participants 14, 15, and 19 specifically mentioned that although they made progress, they still want to keep working on themselves after the program ended. Participant 15's objects explained this in a powerful way, as he brough one hiking shoe, instead of two, to reflect that although he has been able to work on his goal of physical activity, he is not yet where he wants to be:

"One shoe I have brought, not two, one. Because I am very well aware that I am not there yet, but that I want to go on, so I am halfway I think." – Particpant 15; group 3

### 5.2 Theme 2: evaluation of the program and future directions

#### 5.2.1 Valuable features

Overall, the participants found the program to be meaningful and believed that the program had a positive impact on their (mental) health. When the coach asked if they would recommend the program to others, all participants said that they would do so. In Table 8, a quick overview of what has been discussed in each of the three groups is displayed. This table shows that the participants appreciated the group-based format, and the broad and interesting topics.

Table 8: Overview of which participants (displayed as their numbers) mentioned one of the topics as a valuable aspect of the
program, separated per group

	Setting and approach			Content				
Group	Positive approach	Broad program	Group- based program	Broad and interesting topics	Role model & dietary advisor	One-on- one sessions	Reading nutrition labels	Mindfulness
Monday	5, 6	5, 6, 7	2, 4, 5, 7	5, 6, 7	4,7	7		5, 6
Tuesday		9	8, 9, 12, 13, 14	9	13, 14	14	9, 11, 14	
Wednesday	16, 17	15, 18, 20	15, 16, 17, 19	15, 18, 20			17	19

N.B.: If a cell is left empty, that means that this was not discussed between the participants of the focus group

**Setting & Approach**: The aspect the participants were the most enthusiastic about, was that the program was group-based. This allowed them to work on their goals collectively and support each other as discussed in the previous theme.

The participants appreciated the positive approach of the program, like celebrating small successes and giving compliments to each other. All participants agreed that the coach played a key role in the program. The participants explained that the coach managed to make them feel comfortable and create an environment in which they felt safe enough to be vulnerable and honest. Participant 17 elaborated on this and mentioned that the coach was positive towards the participants, while still being neutral in her advice/judgment:

"Well, what is important is that coaching that you do. So if there is a sequel to SALUD, it is important that there is an enthusiastic coach. And it is, yes, but well you were also really neutral [...]. And that really impressed me, that, well, you do not judge." – participant 17, group 3 In addition, participants appreciated that the SALUD program did not just focus on the biomedical outcome of health numbers (e.g., kilos) but also on the more intangible health outcomes (e.g. grip, awareness, wellbeing). This broad approach was appreciated by the participants (specifically mentioned by nr 5, 6, 7, 8, 9,18).

#### "The program is not a glorified diet program, but it is a lot broader. Also including mindfulness, stress management, awareness. Also the softer side [of health]." – Participant 6; group 1

**Content**: Every group mentioned that the program content was broad and interesting. Participants were pleased that the program provided information on different topics. The topics that are given during the program, are topics that the participants can further work on, on their own. As participant 18 said:

"The number of topics that we discussed, and also that you can investigate them further on your own [...]. But also, that everything is laid out clearly again and then, you get that beautiful English word 'awareness' in your head." – Participant 18; group 3

Regarding the specific topics of the program, multiple participants mentioned that the sessions which included the role model and dietary advisor were really helpful (nr 4, 9, 12, 14). Also, the one-on-one sessions, in which two participants were paired to separately talk/work on an exercise were appreciated (nr 7, 14). Lastly, the session on explaining how to read and interpret nutrition labels was mentioned by participants 12-19 as a valuable session.

For session 10, the participants chose their own topic. The Monday group requested additional information on pitfalls and temptations for your goal and how to achieve goals in times of stress. The Tuesday group chose an extra session with the dietician. The Wednesday group chose to have a cooking workshop together. All open sessions were positively received. Especially the cooking workshop; the participants enjoyed meeting each other in real life.

In some sessions there was additional time left, and the coach filled that up with extra material that was not officially part of the SALUD content. In the Tuesday group, the coach added instructions on how to read nutrition labels. This was a session that the Tuesday group felt was very valuable, and participant 9, 12, 13, 14 mentioned that it was something that should be included in the program. In the Wednesday group the coach provided a quiz to find out what kind of eater you are, and participant 17 mentioned that this could be something that more people could benefit from.

"You provided an extra, which I liked. With the questionnaire of what type of eater you are. Yes I think that would be good to include as well. As it provides more insights in what type of eater you are and how you eat." – Participant 17; group 3

#### 5.2.2 Areas for improvement

**General approach of the program**: Regarding the approach and content of the sessions the main suggestions were:

- including information on how to read nutrition labels (9, 12-19);
- providing an overview of the complete program (2, 5);

- having more one-on-one sessions in breakout rooms (9, 14);
- having the dietary advisor come in earlier and add a second session to reflect (9, 14);
- more information on stress, relaxation and sleep (17);
- including the quiz on what type of eater you are and the information on how to read nutritional labels as integral parts of the SALUD program (17);
- include something (e.g., a pamphlet) that provides general information on diabetes/ carbohydrates that can be read by those who do not have a lot of knowledge on it (20).

A few participants (nr 10, 16) raised their concern about having to continue on their own, now that the program has ended. In both the Tuesday and Wednesday group they came to the consensus that it would be nice to have something like a monthly meeting, for those who are interested, during the second phase of the program.

Finally, one of the partners also provided the coach with a suggestion. In group 1, partner 5 explained she would have liked to be included a little bit earlier in the program, to get an understanding of what was happening. However, none of the participants themselves responded to this suggestion, so it is not known whether they would appreciate this change.

**Mindfulness:** Although participants positively received the mindfulness session, it was mentioned by Participant 15 that it was noticeable that it was not an area of expertise for the coach. He suggested that in the future it might be better to invite a more experienced professional to give this session. Moreover, participant 17 mentioned that this was not a session that was suited to be given online and that it would be better to meet in real life for this topic.

**Online format**: Multiple participants mentioned that they would like the program to incorporate some real-life meetings as well (nr 4-6, 8, 13, 15, 18, 20). The participants mentioned several advantages of the program being fully online (nr 5, 9, 12) however, some participants also expressed that they would have liked to have a few sessions in real life. Besides the mindfulness session, the participants also felt like the nature walking session was one that could benefit from being in real life (nr 6).

According to the participants, having more real-life sessions could improve the social connectedness, especially during the first few sessions. After some discussion in group 1, they concluded that it would be ideal to have two sessions in real life to balance increasing the social connectedness but keeping the program easily accessible.

There were also some technical difficulties that resulted from the program being online. Most issues related to the camera or microphone not working properly, however some participants also experienced trouble logging into the meeting (specifically nr 16 and 21). Lastly, people's internet connections could also cause difficulties, and something the connection of participant 3 was insufficient which resulted in the conversation being cut off. Although nobody expressed these problems as troublesome, the researcher observed that it interfered with the natural flow of the conversations.

**Blood glucose measurements**: Multiple participants mentioned that it would be useful if the participants received a blood glucose monitor at the start of the program, to keep track of the changes in their blood glucose during the program (nr 7, 15, 17). The positive outcomes of tracking your blood glucose levels were mentioned by participants 4, 7, 8 and 17. Tracking your blood glucose can be motivating and provide feedback about the impact of nutrition and lifestyle changes.

# 6 Discussion

### 6.1 Answering the research questions

This thesis had two main objectives: (1) to investigate if the SALUD program had an impact on participants' SoC score, and (2) to gain more insights on how participants experienced the SALUD program and what they perceived as effects. Traditionally, the evaluation of programs has mainly been focused on the effectiveness or outcomes of a program, without an explanation or understanding on how these outcomes were produced (Salter & Kothari, 2014). Within this thesis, a broader approach was applied as both quantitative and qualitative methods were used to evaluate the data. This approach was expected to create a deeper understanding on the effect of the study, and how or why it has produced this effect.

The first part of the hypothesis, focused on the outcome, was partly confirmed by the study, as the change in SoC was significantly different in this intervention group (increase of 5,48 (SD=9,03) compared to the control group (0,09 (SD=6,68), P-value=0,028). However, it was unclear to what this difference could be attributed to, since the effect of the treatment/ intervention was not found to be significant. Therefor there could have been influences that were not accounted for that caused this change. Another explanation for not having a significant result, could be because the sample size of the intervention was too small. When you have a small sample size, you need a (very) large effect to show a significant difference. It would be interesting to see if future research can study this program on a larger scale and increase the power.

When adjusting the ANCOVA model for SoC at T0, R-squared drastically improved (Appendix 8; from 0.004 to 0.493). On the other hand, when all other variables were included in the model, R-squared only slightly increased. This might indicate that SoC score at the start of the intervention is a major predictor for SoC after the intervention.

It is important to note that the SoC score of the participants in the intervention group, was lower than that of the control group at the start of the intervention. This difference can partly be explained by the small sample size, and to prevent future studies from having this same situation it would be wise to increase the sample size. However, within this program it was not desirable to create the two groups on only their SoC-13 score, as the program was much broader than that and focused on different outcomes as well. Random allocation was the best approach to ensure equal distribution of all variables between the two groups, in the MSc students' opinion.

An interesting finding in the statistical analysis was that the Tuesday group had a mean change in SoC of 0.00 (SD=9.1), whereas the other two groups had a mean change around 8 points. An explanation for this is that the Tuesday group had a higher age. Recent research has shown that it is likely that SoC increases with age, but also remains more stable (Koelen et al., 2017). Another explanation could be that because the Tuesday group had a higher SoC score to begin with, they had "less to gain" from the program. According to a systematic review by Eriksson and Lindström in 2005, the means of the SOC-13 score range from 35.39 (SD 0.10) to 77.60 (SD 13.80) (Eriksson & Lindström, 2005). The SoC score of the participants in the Tuesday group was 72.29 (SD=7.99) at baseline, which is already at the upper side of that range.

This also raises the question if this program would be suited for everyone, or if for example there should be an age limit. However, the MSc students argues against this as (1) this was a

small study (the sub-groups only consisted of seven people each), and (2) it has not been studied what the effect of the SALUD program would be on a younger age group. Furthermore, although the focus of this thesis is mainly on the SoC-13 score, the SALUD program also takes other factors (i.e., food literacy, or self-efficacy) into consideration so no definite conclusions should be drawn from this individual finding. The Tuesday group was still very enthusiastic about the program during the focus groups, and participants mentioned many experienced benefits from the program.

The second part of the hypothesis, focused on the how or why, was also partly confirmed. It was expected that self-identity and social support would be the most important resources for healthy eating in this target group, and the SALUD program was designed to strengthen resources related to these topics (Polhuis et al., 2021). The thematic analysis revealed that the majority of participants gained more grip and awareness during the SALUD program, were able to better reflect on their life(style), and reach their realistic goals. Furthermore, participants gained/experienced a lot of social support during the program. It was one of the topics that was discussed frequently and in detail in all three sub-groups.

Social support, both from the group itself as from participants' family, was mentioned as a motivating and supporting factor. This is in line with existing research, as social support is a type of GRR (Koelen et al., 2017). However, it was expected that self-identity would also be an important resource that could be strengthened by the program, but the participants did not specifically discuss this during the focus groups. An explanation for this might be that the participants were already adults with an average age around 60 years old. Research has shown that the most important time-period for developing self-identity is adolescence (Flotskaya et al., 2019), and therefor this might be different in another age group. Nonetheless, the participants did mention that they felt capable to make changes in their life and take action, thereby realizing their own competence. This shows that the program did have a positive influence on their self-identity. Furthermore, social support and self-identity are closely related, as social relationships shape a person's self-identity (Langeland & Vinje, 2017). It is argued here that although the participants did not specifically mention that they gained new insights about themselves, their self-identity has changed. Perhaps the question that was asked during the focus group was too direct (e.g., did you learn something new about yourself), and in the future a more open question can be asked during the evaluation of the program to gain more insights on this.

## **6.2** Theoretical reflection

### 6.2.1 Theory-driven evaluation

The real world (outside of the scientific lab) is dynamic and complex. The salutogenic framework tries to take this into account, by also taking the interaction between individuals and their environment into account (Lindström & Eriksson, 2005). Findings from an intervention that has been conducted in a controlled environment, are not reliable to predict what the effect of that same intervention would be in an uncontrolled, real-life, setting. This is where theory-based, or theory-driven approaches can help to understand this black box (Marchal et al., 2012; Salter & Kothari, 2014).

A review by Marchal et al. (2012) argues that the advantages of the theory-driven inquiry are that by systematically deconstructing an intervention, it allows for understanding of what has

caused the observed outcome. This exposes the underlying mechanisms, but also in what context these results have been generated. This also means that transferability to other settings is increased. However, they stated that it remains challenging to fully grasp the underlying mechanisms (Marchal et al., 2012). Pawson and Manzano-Santaella (2012) suggest a balanced approach, which includes both quantitative methods to assess the outcomes and qualitative data to understand the context. This is exactly what has been done within this thesis, although, it was not the starting paradigm in which the results were analyzed. However, it is advised that future research take such a theory-driven approach, as it allows for deeper and more meaningful understanding of working mechanisms behind interventions.

#### 6.2.2 Salutogenic framework

Within the development of the SALUD study, and within this master thesis, a salutogenic approach to health promotion has been used. Within salutogenesis, the focus lies on a person's ability to use their available resources to cope with stressors. Within this framework, a person's *'view of life, and capacity to respond to stressful situations'* is defined as their SoC (Mittelmark et al., 2022). During the SALUD program, participants gained knowledge (e.g., about stress management) and learned practical skills (e.g., goal setting) to improve their ability to use available resources, thereby improving their health on the long term. A simplified overview based on what was discussed in the results, was created (*Figure 3*). Within this overview, the three key concepts of SoC (comprehensibility, manageability, and meaningfulness) are also depicted and on what part of the effect it played a role.

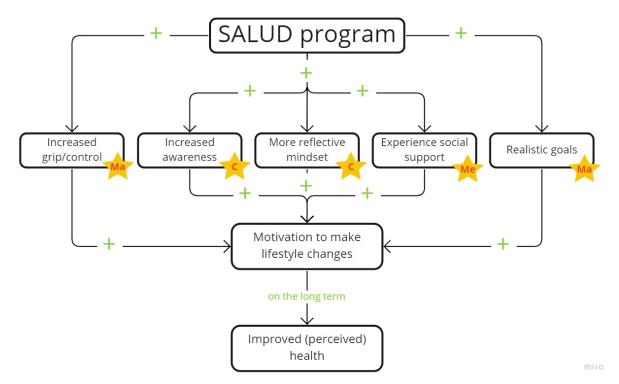


Figure 3: Schematic overview on a hypothesized scheme of how the intervention can lead to improved health (C= comprehensibility, Ma= manageability, Me= meaningfulness)

From the focus groups it became apparent that the SALUD program increased participants reflective mindset and their awareness, which can be related to the comprehensibility part of SoC. Furthermore, by having realistic goals participants did not feel too overwhelmed and were

more confident that they could reach these goals, thus increasing the perceived manageability they experienced. In addition, the participants expressed feeling more grip or control over their lives, which also directly links back to the perceived manageability. Experiencing social support increases the perceived meaningfulness and social support was frequently mentioned as a motivating factor. This simplified scheme was created to try and create a deeper understanding of how the program created the perceived effects, thereby opening up the black box. Future research can further work on such schemes to increase understanding on how the salutogenic framework can aid in intervention programs.

## 6.3 Comparison to existing literature

#### 6.3.1 Comparison to other programs

There are other lifestyle intervention studies that also focus on people with T2DM, as discussed in chapter 2. However, two of the discussed interventions are intensive lifestyle interventions in which participants have to drastically change their diets. SALUD participants, on the other hand, mentioned during the focus groups that they were relieved that the SALUD program was not a rigorous dieting program, but rather it included information on various topics that the participants then could further work on themselves. Multiple participants expressed that having to follow a strict diet was not maintainable for them.

Participants of the DiRECT trial needed a lot of additional support and guidance from health care providers to be able to successfully continue with the intervention, as they faced some challenges and setbacks. Furthermore, some participants mentioned that they would have liked to have had contact with other people following the program (Rehackova et al., 2022). This strengthens the finding that the fact that the SALUD study was a group-based program is a strong feature, as the DiRECT program lacked this, and participants expressed a desire for it.

The DiRECT trial showed promising results, however both the age and BMI of the population was a bit different than from the SALUD study (average age was lower, and average BMI was higher) (Lean et al., 2019). Furthermore, some participants of the SALUD intervention also had "healthy' BMIs, and for those participants following a strict program that is mainly focused on losing weight is not sensible. However, they can still benefit from following an intervention that is focused on strengthening resources, like the SALUD program.

The Look AHEAD trial is also an intensive weight loss program, that is delivered over a time span of four years. With this program participants also have to decrease their caloric intake, and increase their physical activity (Ryan et al., 2003). As mentioned in the theoretical framework, this program showed some mixed results and not all of the progress was maintained over a longer period of time. Therefor it is argued here if it desirable to implement these strict programs, when they do not seem to lead to beneficial results for all of the participants, while they do have a substantial impact on participants lives.

Both the SALUD and CooL intervention focus on goal setting (Philippens; & Janssen, 2018; Polhuis et al., 2022). A limitation of the CooL intervention is that it lacks a control group, therefor only effect sizes can be calculated within the participants and there is limited insight on the effectiveness of the intervention (Van Rinsum et al., 2018). However, results from this study and the SALUD study combined can complement each other and provide more reliable insights in the effectiveness and results of such lifestyle program within the Netherlands.

The most obvious difference between the SALUD study and other lifestyle interventions, is the time frame. Where SALUD has a duration of 6 months, these other programs have a much longer duration. The largest difference lies in the follow-up trajectory. For example, CooL last 24 months, where the first six to eight months are used for meetings and the next sixteen to eighteen months are focused on maintaining the progress/inspiring the participants (Philippens; & Janssen, 2018). Some participants of the SALUD intervention did express their desire for a follow-up trajectory, so this is something to take into consideration. However, participants are all enrolled in the WhatsApp groups and were free to continue utilizing those for support from the other participants. However, the initiative here lies with the participants themselves.

Both trajectories might have their own advantages. For example, starting a program that lasts for two or even four years takes a lot more commitment than starting a program that lasts six months. For people that might be motivated to make a change in their lifestyle, but do not want such a commitment right away, following the SALUD program can be ideal and provide them the skills to further work on their goals themselves. However, for someone who might need a little more support, following a longer program might work better. In the end, it is a very personal choice and there is no *one-size fits all* intervention.

What sets SALUD apart from these three other lifestyle interventions, is its transparent approach. Furthermore, the program was developed and improved by stakeholder feedback to ensure that the program would be suitable for people with T2DM. The analysis of the focus group showed that this approach has been appreciated by the participants. However, this program is still in its development phase, and findings from this study can be used to optimize it even more.

#### 6.3.2 Comparison to other literature

A recent meta-analysis concluded that: "*The majority of lifestyle weight-loss interventions in overweight or obese adults with type 2 diabetes resulted in weight loss <5% and did not result in beneficial metabolic outcomes.*" (Franz et al., 2015). This study showed that for a lot of people diagnosed with T2DM, weight loss might not be a realistic primary outcome to improve glycemic control. Rather, they should be encouraged to adapt a healthy eating pattern and increase their physical activity. Furthermore, the study concluded that focus should be on education and support (Franz et al., 2015). This is the same approach that the SALUD program takes.

Apart from comparing the SALUD program to other lifestyle interventions, it is also interesting to see how other RCTs interventions tried to increase SoC scores. Unfortunately, RCTs on increasing SoC in people diagnosed with T2DM were not found, so the search was expanded to see how SoC was achieved in other groups. Two of these studies will be discussed here. The first study was conducted in 2018 and looked at the influence of resistance training on older adults (aged 65 - 75) SoC score, and concluded that attending resistance training was beneficial for SoC. However, they also discussed that it seemed like SoC develops slowly, and their intervention needed to be longer than three months (Kekäläinen et al., 2018). The second study, which included older people (aged 60-85 years old) with a hip fracture did not show a change in SoC after a 12 week intervention on physical exercise (Pakkala et al., 2012). Both these studies suggest that to create a (sustainable) change in participants SoC, a program that lasts longer than three months might be beneficial.

## 6.4 Strengths and limitations

This design of this study is a RCT, therefor comparison with a control group was made which resulted in a higher internal validity as causality could be examined. There was almost no literature on increasing SoC through RCTs, and especially not when data specifically for people with T2DM was searched. This shows that this study is unique, and thus provides valuable insights on this topic. Future research is needed to further develop understanding of this topic.

The validity and reliability of the SOC-13 scale is extensively researched and the questionnaire is adapted in over 30 countries (Lindström & Eriksson, 2005). For this study, the translated Dutch version has been used, which was found to have a Cronbach's alfa of 0.860, which is acceptable (Swan, n.d.).

Qualitative research is susceptible to subjectivity, therefor it is important to understand the role of the researcher in constructing this knowledge (Sawatsky et al., 2019). To increase the trustworthiness of the findings, the process has been thoroughly documented and is as transparent as possible. For example, an overview on which quote was categorized within each of the themes was created and can be requested to see the reasoning behind the themes and the interpretation of the quotes by the MSc student. Although the coding was discussed closely between the student and the supervisor, both coded the transcripts separately with their own coding framework. The final themes were discussed on multiple occasions between the supervisor and MSc student to ensure that the conclusions which emerged from the focus group aligned with both their interpretations of the data.

A final strength of this intervention was the positive influence of the coach. The participants expressed their appreciation for the coach during the focus groups and described the coach of this program as enthusiastic and open-minded. Furthermore, the coach herself explained that she liked to coach people by standing next to them and work together, instead of standing above them and telling them what they have to do. The participants of this study clearly appreciated this approach. However, the role of the coach depends on several factors as the sessions are being conducted in a real life situation, and not in a controlled environment. Therefor it is impossible to completely replicate this coach. However, the profile sketched above of this coach can aid future programs in selecting appropriate coaches.

However, one of the limitations of this study, is that the coach conducted the focus group. This was done because the participants trusted the coach, which was expected to help them open up and provide honest answers to the questions asked. However, the coach is not a trained scientist, and her approach might have influenced the way in which participants responded to the questions. For example, in some instances the MSc student would have asked more follow-up questions to let participants elaborate more.

The study population was a small group of mostly Dutch adults. Therefore, the study cannot be generalized to other age groups or ethnicities, and it has a low external validity. More research on this topic is required to provide information for other age categories or ethnicities.

During the statistical analysis, BMI after the intervention was taken as a covariate, instead of the BMI at baseline. This was done in consultation with a statistics expert at the WUR. BMI at T1 says more about how a person is feeling at that point in time, than the BMI they had three months ago. However, one could also argue that the BMI at T0 had influenced how a participant is feeling throughout the entire process, thereby affecting their progress. To check that this did

not make a difference, the same model was run, but included BMI at baseline instead of BMI at T1. No difference was found.

Three months is not a very long period of time, and a longer follow-up period is needed to determine the sustainability of the program. This follow-up data was not collected within the appropriate timeframe of this thesis, but future research can provide more insights in this. With the current set-up of the program, data is only collected at baseline, after twelve weeks, and after 24 weeks. However, it is also advised to consider collecting data after multiple years to gain more knowledge on the effect a relatively short intervention can have over multiple years.

Finally, one last point of attention, is that it would be interesting to see how this program is received in a real-life setting. Due to the corona crisis in 2020-2022, the program was completely online which came with certain advantages and challenges. Participants gave some mixed opinions on which approach they preferred, and concluded that having a program that mixes real-life and online session would have been ideal. If future programs do indeed include these real-life sessions, it would be interesting to compare those results with the results of this study and see if they overlap or differ.

## **6.5 Practical implications**

Within this study the SALUD program was compared to the standard care that is given to people with T2DM in the Netherlands. Some participants mentioned that they learned valuable things, such as the importance of understanding nutrition labels or sleep and stress. However, this can be considered as relatively basic information. Therefor the student argues that these basic types of knowledge should be included in the standard care and a GP could for instance provide brochures on this topic. Of course, it is not certain that providing this information in that way, instead of through a coach, will have the same effect but it might be worth to research this further.

Current health care practices targeting people with T2DM might take lessons from this intervention and cooperate more information on the importance of social support and selfidentity for people with T2DM. For example, GPs could stimulate the participants to find a person they trust and confide in them. Furthermore, GPs might help participants to create realistic goals, and reflect on these goals during the regular check-ups. In that way, people with T2DM are encouraged to make active changes in their lifestyle. Finally, current practices should shift focus from treating T2DM mainly with medication, to helping people with T2DM gain more grip over their health and increase their capabilities to deal with the stressors of every-day life.

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## **Appendix 1: Overview of the intervention sessions**

In session one, the focus was on <u>building trust and disease acceptance</u>. This was done through an informal meeting that allowed participants to get to know each other while creating a safe environment. Furthermore, an informative presentation on T2DM as a disease and social issues that are related to it is given.

In session two, the focus was on <u>goal setting</u>. Participants were guided in formulating specific goals, and splitting these goals up in more manageable and concrete steps. The CLC helped participants to link their goals to intrinsic motivation, and to improve their reflection skill, every session started with an evaluation/reflection on their goals and their progression.

In sessions three and four, the focus was on <u>food literacy</u>. Participants were taught a number of topics that relate to healthier eating, cooking and grocery shopping. These included, amongst others: how to read nutritional labels, learn to find trustworthy resources on easy and healthy recipes, and advice on cheat days. Furthermore, cooking workshops were given to teach them how to cook healthier meals, and a network to share healthy recipes between participants was established.

In session five and six, the focus was on <u>stress management</u>. Stressors related to T2DM were discussed, as well as the fact that stress management is related to both external as internal changes. Mindfulness and the importance of nature were included in these sessions.

In sessions seven and eleven, participants <u>progress was evaluated</u>. In session seven, the participants discussed their experiences and they were motivated to find ways to stay on track after the intervention. Furthermore, local sport initiatives were brought to the participants attention.

In session eight, the focus was on <u>social support</u>. Participants could establish a social platform with each other, to share problems and request advice. Furthermore, participants were encouraged to bring a partner/friend to this session.

In session nine, the focus was on <u>self-identity</u>. Self-identity has already been strengthened by the weekly reflections, however, in this session specifically more attention was brought to how the mind works and how the environment influences behaviour. Furthermore, a role model was invited to share their experiences and allow the participants to ask them questions.

In session ten, the participants were allowed to choose what was going to be discussed. These topics varied per group.

Finally, session twelve was a <u>festive closure</u>. To celebrate the end of the intervention, participants were asked to bring an object that symbolized how they experienced the intervention. Furthermore, the group was encouraged to keep working on their goals and support each other.

After 24 weeks of the start of the intervention, a <u>booster session</u> was planned to reflect and share experiences. This session also focused on long-term commitment, and the insensitive of including this session is that it will hopefully result in more long-time results.

# **Appendix 2: SoC-13 questionnaire**

### Deel 3

De volgende 13 vragen gaan over de manier waarop u denkt over of omgaat met bepaaldeaspecten van uw leven. Geef bij iedere vraag aan wat u situatie **DOORGAANS** het beste weergeeft.

1	Hebt u het	gevoel da	at u niet echt l	bent geïnteress	seerd in wat e	r om u heen gebeurt?
0	0	0	0	0	0	0
Zee r						Zeer zelde
vaa k						n

2		Is het in het verleden wel eens voorgekomen dat u werd verrast door het gedrag vanmensen die u goed dacht te kennen?									
0			0	0	Ο	0	0	0			
	Altijd							Nooit			

3			s voorgek en vertrouv	omen dat u we ven?	rd teleurgeste	ld door mens	en op wie u
0		0	0	0	0	0	0
Al	ijd						Nooit

4	He	bt u tot nu	ı toe in uw le	ven			
0		0	0	0	0	0	0
	Totaal geen helder e doele n gehad						Zeer helder e doele n gehad

5	Hebt u het ge	evoel dat u	oneerlijk word	t behandeld?		
0	0	0	0	0	0	0
Zee r vaa k						Zeer zelden ofnooit

6		Hebt u u moet	-	/oel dat u	zich in een onb	ekende situat	ie bevindt en	niet weet wat
0			0	0	Ο	0	0	0
	Zee r vaa k							Zeer zelden of nooit

7	Uw dagelijk	se bezigheden	vormen			
	0 0	0	0	0	0	0
	Een bron van veel plezier en tevredenheid					Een bron van ellende en verveling

8	Zijn uv tegenstrij		voelens en	gedachten			
0		0	0	0	0	0	0
Ze r va k							Zeer zelden of nooit

9		Hebt u hebben?		lens die	u liever r	niet zou		
0			0	0	0	0	0	0
	Zee r vaa k							Zeer zelden of nooit

10		Hoe vaak	hebt u het ge	voel dat u in l	bepaalde situa	ities tekortsch	iet?
	0	0	0	0	0	0	0
	Zee r						Zeer zelden
	vaa						of
	k						nooit

11	Wann u	eer u ie	ts overkoi	mt, vindt u ove	er het algemee	en dat	
	0	0	0	0	0	0	0
	Het belang ervan ondersch atof						Het belang in de juiste proportie s
	overschat						ziet

12		Hoe vaak voorstelt?	hebt u h	et gevoel	dat uw	dagelijks	leven	maar	weinig	
	0	0	0	0		0		0		0
	Zee r vaa k									Zeer zelden of nooit

13		Hoe vaak he controle kanh	•	ns waarvan u	niet zeker w	eet of u ze o	onder
	0	0	0	0	0	0	0
	Zee r vaa k						Zeer zelden of nooit


# **Appendix 3: Measuring other characteristics**

## Intakevragenlijst

-	Contactgegevens (naam, adres) noteren op formulier 'contactgegevens' -
1. Wa	t is uw geslacht?
	Man
	Jrouw
$\Box$ A	Anders, namelijk
2. Wa	t is uw geboortedatum?
//	
3. In v	velk land bent u geboren?
 4. In v	velk land is uw moeder geboren?
•••	
5. In v	velk land is uw vader geboren?
6. Wa	t is uw hoogste, voltooide opleiding?
	Lagere school
	Aiddelbare school
	MBO
	HBO Jniversiteit
	Post-universitair
	Ike van de onderstaande categorieën beschrijft het beste uw <u>huidige</u> arbeidssituatie? ( g meer dan 1 antwoord invullen)

□ Betaald werk; ..... uur per week

- □ Vrijwilligerswerk (onbetaald),..... uur per week
- □ Geen werk, aan het zoeken naar werk
- □ Geen werk, NIET aan het zoeken naar werk
- □ Met pensioen
- □ Niet in staat om te werken (ziektewet, handicap)

#### 8. Welke onderstaande categorie beschrijft uw huidige thuissituatie het beste?

- $\Box$  Alleenwonend
- □ Samenwonend met partner/echtgenoot
- □ Samenwonend met partner en kind(eren)
- □ Samenwonend met kinderen
- □ Samenwonend met huisgenoot of huisgenoten (geen partner of kinderen)

#### 9. Hoeveel jaar geleden bent u gediagnosticeerd met diabetes type 2?

....

#### 10. Gebruikt u medicijnen voor diabetes type 2?

- 🛛 Ja
- □ Nee

#### 11. Indien ja, welke medicijnen gebruikt u voor diabetes type 2?

- □ Metformine (start 500-850 mg 1x per dag)
- $\square$  Metformine (850 mg 1000 mg 1 tot 3 per dag)
- □ Metformine + sulfonylureumderivaat (bijvoorbeeld gliclazide)
- □ Metformine + sulfonylureumderivaat (bijvoorbeeld gliclazide) + (middel)langwerkendinsuline (**1x per dag**)
- □ Metformine + sulfonylureumderivaat (bijvoorbeeld gliclazide) + (middel)langwerkendinsuline (meer dan 1x per dag)
- □ Metformine + sulfonylureumderivaat (bijvoorbeeld gliclazide) + DPP-4remmer of GLP-1-receptoragonist
- $\Box$  Anders:

.....

••••

#### 12. Rookt u?

- 🛛 Ja
- □ Nee

13a. Heeft u in het verleden gerookt?

- 🛛 Ja
- □ Nee

13b. Indien ja, hoelang geleden bent u gestopt met roken?

.....

Ruimte voor vragen of opmerkingen:

## **Appendix 4: Measuring weight and BMI**

# SALUD STUDIE Instructies meting gewicht en BMI

- Vraag deelnemer hun schoenen en sokken uit te doen, broekzakken te legen (sleutels, portemonnee) en dikke trui/vest/jas uit te doen. Eventueel horloges, sieraden af. Belangrijk dat elke proefpersoon bij elke opeenvolgende meting ongeveer evenveel kleren aan heeft.
- 2. Doe de weegschaal aan door het middelste knopje aan de bovenkant/zijkant van de weegschaal in te drukken. Er verschijnt nu een '1'
- 3. Druk nog een keer op het middelste knopje om gegevens bij meting 1 in te stellen. Je moet de **leeftijd, geslacht** en **lengte** in stellen. Met het knopje aan de linkerkant, stel je de waarde bij naar beneden, met het knopje aan de rechterkant stel je de waardes bij aan de bovenkant. Om een waarde te bevestigingen druk je weer op het middelste knopje.
- 4. Na het instellen van de lengte en de waarde van de lengte bevestigen, verschijnt de '1' weer. Laat de weegschaal los(!) en wacht tot het scherm op 0.00 staat. De weegschaal is nu ingesteld en geijkt en dus klaar om te gaan meten.
- 5. Vraag de proefpersoon op de weegschaal te gaan staan (met blote voeten). De hakken moeten op de onderste strepen staan, de zool van de voeten op de bovenste strepen. Armen langs het lichaam.
- 6. Wacht tot de piepjes en de metingen verschijnen op de display. Proefpersoon mag nu afstappen.
- 7. Noteer alle gegevens op het invulformulier.

## **Appendix 5: Interview topic guide** SESSIE 12 - kwalitatieve analyse (focusgroep duur 1.5 – 2 uur)

#### Intro

Dit is de laatste sessie van het intensieve deel van het programma. Met een ontspannen en vrolijke sfeer kijken terug op ieders persoonlijke reis tijdens dit programma. Ook wordt er vooruitgeblikt; hoe gaan de deelnemers nu zelfstandig verder met hun doelen/gezondheid de komende drie maanden?

#### Doelen

- Terugblikken/reflecteren op programma.
- Vooruit kijken.
- Plezier hebben en onderlinge verbondenheid voelen.
- Kwalitatieve analyse van programma (voor verdere ontwikkeling van het programma)

#### Lay-out

#### Check-in (20-30 min)

- □ Heet iedereen welkom, ook de dierbaren.
- $\Box$  Hoe is het afgelopen week gegaan?
- □ Leg uit wat we vandaag gaan doen: terugblikken en vooruitkijken naar de komende 3 maanden.
- Kwalitatieve analyse: Vraag of de deelnemers het goed vinden dat deze sessie wordt opgenomen en gebruikt wordt voor de wetenschappelijke evaluatie van het programma. In deze evaluatie/analyse worden geen namen genoemd of beeldmateriaal gebruikt --> het is daarom nodig dat je even formeel vraagt: 'gaat iedereen er mee akkoord dat deze sessie wordt opgenomen en wordt gebruikt voor wetenschappelijk onderzoek, namelijk de wetenschappelijke evaluatie van het programma?' en dat iedereen akkoord zegt op camera
- Start de opname

#### Thema (60 min)

- □ Welke **snack** heb jij gemaakt en waarom?
- □ Vraag aan iedere deelnemer uit te leggen welk object ze hebben meegenomen en waarom.
- □ Vraag deelnemers **terug te blikken** op het programma. Voorbeeldvragen:
  - Zijn er dingen veranderd in je dagelijks leven doordat je SALUD bent gaan doen? Wat dan?
    - dagelijkse activiteiten
    - omgang met anderen
    - hoe je tegen het leven aankijkt

- **Aan de dierbare:** merk je een verandering aan je vriend/partner/etc. sinds hij/zij meedoet aan het programma? Wat dan? Hoe is dat voor jou om te zien?
- Wat vond je waardevol? Wat heb je geleerd?
- Waar ben je meer over na gaan denken?
- Welke nieuwe inzichten heb je (over jezelf?) opgedaan?
- o Zou je SALUD aan andere mensen aanraden? Waarom?
- Als jij de baas was van SALUD, wat zou je anders doen? Wat is de reden?
- □ Vraag deelnemers **vooruit te blikken**:
  - SALUD is nu afgelopen: wat ga je komende 3 maanden doen?
  - *Hoe* ga je de volgende 3 maanden aan je doel werken?
  - Hoe kijk je tegen deze periode aan? (positief/negatief?)
  - Wat of wie gaat je hierbij helpen? En hoe?
  - Wat kan je doen als je het even moeilijk hebt?
  - **Aan dierbare:** zie je een kans om jouw vriend/familielid/partner te helpen bij zijn/haar doelen? En hoe?
  - **Onderlinge verbondenheid**: Bespreek of de groep gedurende die tijd contact wilt houden of niet en wat een goede manier hiervoor is.
- □ Ruimte voor vrij kletsen/vragen (10-15 min).

#### Check-out (15 min)

□ Leefstijlcoach geeft persoonlijk compliment aan elke deelnemer zodat de deelnemers zich gezien en gewaardeerd voelen.

# **Appendix 6: Final coding list**

Table 9: Final coding list that was used to code the transcripts of the three focus groups (alphabetically ordered)

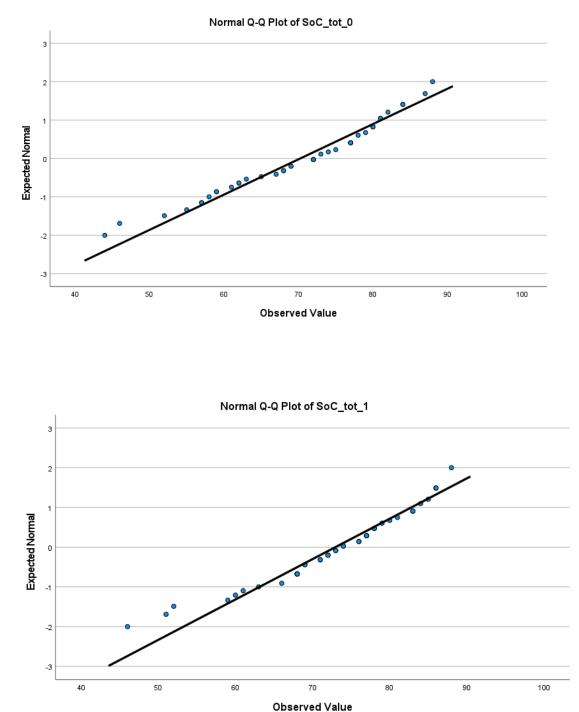
Code	Label				
Autonomy	Describes the (increased) capacity of the participants to act according to his/her motivations.				
Awareness	Describes developing or strengthening feelings of awareness, on all types of levels in the				
	participants				
Development resources	Describes the development of completely new resources				
Experiences	Describes how participants experienced the program in their own words or that of the coach				
Experiment	Describes experiments that the participants did as a result of the study, to see how their				
	body/environment/mind reacts (as a part of autonomy).				
Future	Describes future progression that the participant hopes to achieve				
Goals become part of	Describes how participants experienced working on their goals and if it became incorporated				
daily life	into their daily life				
Group dynamic	Describes how the group members interact which each other during the focus group				
Hindering influences	Describes outside factors that the participants experienced as hindering to their progress in				
from outside	the program, or future progress				
Impact on others	Describes the impact that following the program has had on the loved ones of participants				
Mechanism of action	Describes how the program led to a certain change/effect in the participants own perspective				
	or that of the coach				
Mobilizing resources	Describes the way in which participants utilize new or existing resources				
Object	Describes the object that the participants brought that reflected the program in their eyes				
Opinion on coach	Describes how the participants view the coach or experienced her coaching				
Opinion on the program	Describes participants opinions on the program in their own words or that of the coach				
Reflective mindset	Describes if and how participants were able to reflect on the choices they made in daily life				
Reasoning behind	Describes the reasoning behind the objects that the participants brought				
object					
Reasoning behind	Describes the reasoning behind the snack that the participants brought				
snack					
Short-term impacts	Describes a specific impact that was caused in the participants life, as a result from the				
0 1	program (or not)				
Snack	Describes the snack that participants brought to the last session				
Soc_Comprehensiblity	Describes the extent to which stimuli a person is confronted with make cognitive sense $O(1 + 1) = 1 - 2022$				
C	(Mittelmark, 2022)				
Soc_Manageability	Describes the extent to which an individual perceives resources that are available to them as				
See Meeningfulness	adequate enough to meet the demands of the stimuli they face (Mittelmark et al., 2022)				
Soc_Meaningfulness	Describes the extent to which an individual feels that problems in live are worth investing energy in and seen as a challenge rather than a burden (Mittelmark, 2022)				
Social Support	Describes the social relationships that participants or the coach mentions, that provide				
Social Support	support to the participant (or lack thereof)				
Stimulating influences	Describes outside factors that the participants experienced as stimulating to their progress				
from outside	in the program				
Strengthening	Describes the strengthening of already existing resources for the participants, as a results				
resources	from the program				
Suggestions SALUD	Describes specific suggestions that the participants provided to improve the SALUD				
000000000000000000000000000000000000000	intervention				
Technical difficulties	Describes whatever difficulties may arise from having the meeting online, instead of real				
	life. These things can possibly hinder the conversations.				
Valuable aspects of	Describes aspects that the participants found valuable about the SALUD intervention				
SALUD					

\* The highlighted codes are technically part of the same group, but were separated during coding to provide a more detailed overview.

## **Appendix 7: Checking the assumptions**

#### Normally distributed residuals

The first assumption that was tested, was if the residuals were (approximately) normally distributed for each category of the independent variable. This was done visually, through a Q-Q plot and tested with the Shapiro-Wilk test. This test for normality is most appropriate for a small (<50) sample size. Both SoC\_tot\_0 and SoC\_tot\_1 were not significant, which means that the residuals follow a normal distribution.

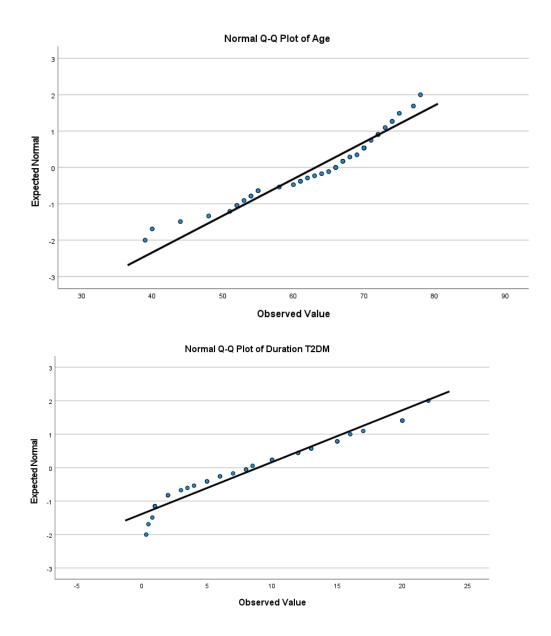


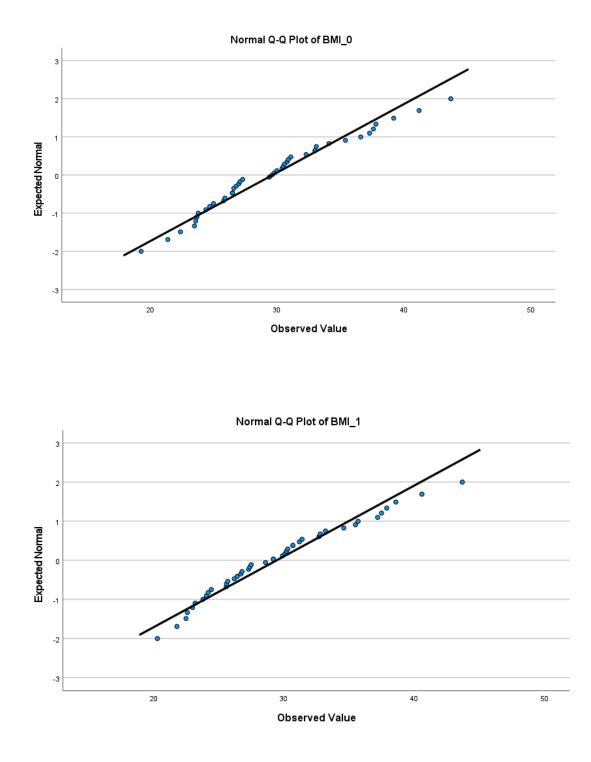
Tests	of N	orma	lity
-------	------	------	------

	Kolm	ogorov-Smir	Shapiro-Wilk			
	Statistic	df	Sig.	Statistic	df	Sig.
SoC_tot_0	,128	43	,073	,960	43	,135
SoC_tot_1	,121	43	,117	,948	43	,050

a. Lilliefors Significance Correction

Furthermore, the continuous variables were also checked with a Q-Q plot to see if they are normally distributed. Since they were not, the Mann Withney U test was done to assess differences between the groups.





#### Homogeneity of variances

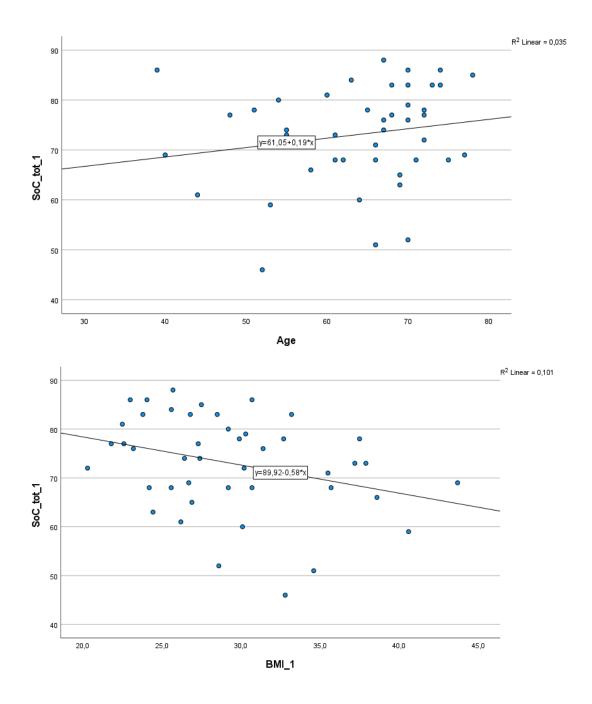
The next assumption that was checked was the homogeneity of variances, to see if the variances are homogeneous amongst the two groups. This is checked with the Levene's test. For both variables, there were no significant results found thus this assumption was met.

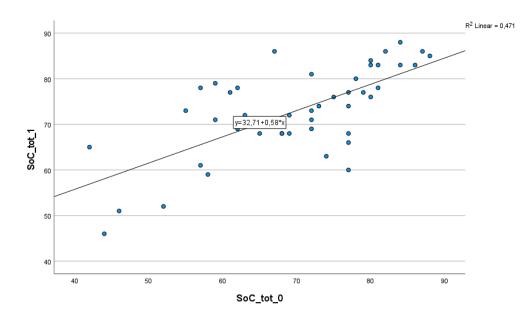
		Levene Statistic	df1	df2	Sig.
SoC_tot_0	Based on Mean	,003	1	43	,958
	Based on Median	,060	1	43	,808,
	Based on Median and with adjusted df	,060	1	40,718	,808,
	Based on trimmed mean	,011	1	43	,916
SoC_tot_1	Based on Mean	1,614	1	41	,211
	Based on Median	1,118	1	41	,296
	Based on Median and with adjusted df	1,118	1	40,686	,296
	Based on trimmed mean	1,418	1	41	,241

#### Tests of Homogeneity of Variances

#### Covariates are linearly related to the dependent variables

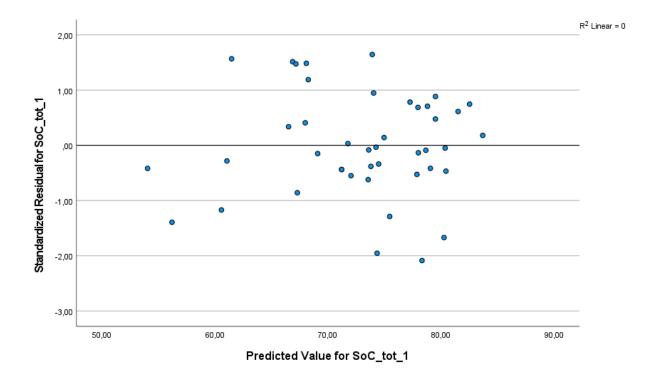
The next assumption that was checked, was if the covariates were linearly related to the dependent variable, in each group. This was done visually, through scatter plots. The results were acceptable (consulted a statistic expert of the WUR) thus this assumption was met. This was only checked for continuous variables.





#### Test for homoscedasticity

Homoscedasticity is checked visually through a scatter plot. To test for homoscedasticity, the standardized residuals are plotted against the predicted values for the dependent variable. We see that the deviation from the line in the middle, is not changing therefor this assumption is met.



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# **Appendix 8: Building the model**

Table 10: Steps in building the model, including the corresponding P-values per variable and the R-squared of the total model

Model	Variables included	<b>R-squared</b>	Р-
			value
Crude	Group	0.004	0,691
2	Group +	0.493	0,175
	SoC_tot_0		0,000*
3	Group +	0.510	0,202
	SoC_tot_0 +		0,000*
	age +		0,994
	sex +		0,410
	BMI_1		0,642
Final model	Group +	0.417	0,334
	SoC_tot_0 +		0,000*
	age +		0,961
	sex +		0,363
	BMI_1 +		0,716
	smokinginthepast +		0,954
	medication		0,602

\*= statistically significant with an alfa of 0.05

# Appendix 9: Full table of characteristics per subgroup

Table 11: Characteristics of the participants in each of the three subgroups

	Monday group (n=7)	Tuesday group (n=7)	Wednesday group (n=7)
	% (N) $or$ mean $\pm$ SD	% (N) $or \text{ mean} \pm SD$	% (N) $or$ mean $\pm$ SD
Women (%)	29% (2)	57% (4)	43% (3)
Age (y)	$49,86 \pm 6,04$	$67,57 \pm 5,03$	$62,86 \pm 12,21$
BMI (kg/m <sup>2</sup> )	$28.52 \pm 5,61$	$26,92 \pm 4,54$	33,00 ± 6,68
Nationality (%Dutch)	71% (5)	86% (6)	100% (7)
Education (%)			
Low	0% (0)	0% (0)	0% (0)
Middle	43% (3)	29% (2)	29% (2)
High	57% (4)	71% (5)	71% (5)
Work situation (%)			
Paid job	86% (6)	29% (2)	14% (1)
Retired	0% (0)	57% (4)	71%(5)
Other	14% (1)	14% (1)	14% (1)
Living situation (%)			
Alone	14% (1)	43% (3)	29% (2)
With partner	43% (3)	57% (4)	57% (4)
With partner and kids	14% (1)	0% (0)	14% (1)
With kids	29% (2)	0% (0)	0% (0)
Smoking (%)			
Never	86% (6)	43% (3)	57% (4)
Current	14% (1)	14% (1)	14% (1)
Past	0% (0)	43% (3)	29% (2)
Quit smoking (y) <sup>+</sup>	n.a.	$29,50 \pm 22,75$	$17,67 \pm 19,14$
Duration T2DM (y)	$6,55 \pm 4,42$	11,57 ± 7,21	$9,\!14\pm7,\!88$
Medication (%yes)	71% (5)	57% (4)	57% (4)

+: Excluding those who still smoke

#: Including the two-drop outs, who have not been taken into account in the other groups

## **Appendix 10: Overview of participant's objects**

Table 12: Overview of the objects participants brought to the focus group, and the meaning and reasoning behind that meaning

Participant	Object	Meaning	Reasoning behind object
Group 1			
Participant 1	Fitbit	Working on goals	Although the participant has had this Fitbit for 1,5 years, they only started to use it since the start of the study. It symbolizes that the participant was able to work on their goals, as a result from the program.
Participant 2	Sugar stick	Social support	Symbolizes the connection between the participants. It is what brought them together and allowed them to connect, also on an emotional level, and find support in people that are going through the same.
Participant 3	Clothing brush	Confrontation, reflection/awareness	Symbolizes the fact that the longer you wait to deal with something, the harder it becomes to fix it (e.g. the longer you wait to remove the hairs from you clothing/furniture, the more hairs will collect).
Participant 4	Bottle opener	Working on goals	Symbolizes the fact that the participant was able to work and achieve his goals during the program. One of these goals was consuming less alcohol, hence the bottle opener.
Participant	Stick behind the door	Motivation, social support	Symbolizes the fact that when you are in a group and (frequently) meet, you experience a bit of social pressure to work on your goals in order not to make a fool of yourself. This works motivating.
5	Walnut	Fun, confrontation and reflection	On one side it symbolizes the "happy nut", because the meetings with the group were fun. on the other hand it symbolizes the "hard nut", because you are stimulated to think about what you want and what is good for you, which can be confronting but in a good way.
Participant 6	Dopper	Working on goals, social support, reflecting	Symbolizes the fact that the participant was able to work on his goal (consuming more water), while at the same time being reminded to the group because of the word 'mindfulness' printed on the bottle. The bottle also symbolizes support from his family, as they use the phrase "Dopper Time" to collectively drink water and thereby stimulate the participant in reaching his goals.
Participant 7	Glucose meter and prickpen	Working on goals	Symbolizes what the participants wants to leave behind him: frequently measuring his blood glucose levels and diabetes. He has used this tool to get to know his body, and now that the is where he wants to be, he wants to leave this object behind.

#### Table 7: Continue

Group 2			
Participant 8	Smartwatch	Motivation, reflection, working on goals	The smart watch measures everything (stress, sleep, steps, heart rate) and the participant finds it interesting to monitor this. This also allows him to reflect on his goals. Furthermore, symbolizes motivation because the watch gives a notification if you have not moved in a while to remind you.
Participant 9	Chalk/crayons	Motivation, group feeling	During the session, this participant used her time to draw and be creative to avoid getting bored/dropping out. It symbolizes her adapting to the situation and finding a way to make the intervention work for her personally, without interrupting it for others which shows her motivation to follow the intervention. As the intervention went on, she started to like the group more and more and she was happy that she stayed in the program.
Participant 10	Leefstijlroer (lifestyle wheel)	Control, motivation	The wheel symbolizes everything that is also in the program (nutrition, movement, connection, relaxation, sleep) and it symbolizes that you are in control of what happens during your life through your lifestyle and that you are the boss in a way.
Participant 11	Cookbook (500 salads)	Working on goals, anticipating	The participants finds a lot of inspiration in the cookbook to make healthy salads. Since preparing other vegetables can be challenging for him, this is an easier way to incorporate more greens in his diet. It symbolizes anticipation, since he is finding ways to work on his goals in his daily life, even if that takes some adjusting.
Participant 12	Smart watch to counts your steps	Reflection, working on goals	Symbolizes that the participant is being more aware of his goals and how much exercise he gets in a day. The watch allows you to reflect on your steps of the whole week.
Participant 13	Diabetes cookbook	Working on goals, future anticipation	Usually the participant cooks recipes by heart, but from now on she wants to utilize this cookbook more. It symbolizes motivation for the future to keep working on her goals.
Participant 14	Nutrition labels	Reflection, awareness	During the program the participant learned (how) to read nutrition labels on food products and this has helped her a lot. Now she is more aware of what is in different food products, and whenever she sees a nutrition label she is reminded of the group.
	Wheel (imaginary)	Control	Participant feels as if she is more in control of her life now.

#### Table 7: Continue

Group 3			
Participant 15	One hiking shoe	Working on goals, future	Symbolizes the fact that the participant knows he is not yet where he wants to be (only 1 shoe instead of a pair), but he is on the right track. It also symbolizes that he has found something that allows him to be physically active every day, thereby working on his goals.
Participant 16	Mobile	Working on goals	The mobile also functions as an alarm clock for this participant. One of her goals was improving her sleep, and during the program she was able to work on that goal.
Participant 17	Notebook (revalue balance)	Reflection, balance	During the sessions the participant made notes in this book. On the cover is says revalue balance, which symbolizes her finding her balance again during this program and being aware of her lifestyle and trying to find the right balance.
Participant 18	Notebook	Motivation, reflection	During the program, the participant made all her notes in this book which now symbolizes everything she learned and will be a tool for her in the future to keep on track.
Participant 19	Mobile radio	Peace, Awareness	It symbolizes relaxation, because whenever this participant listens to music from this radio he feels calmer and more at ease.
Participant 20	Golf ball	Control, working on goals	Golf is an individual sport, and if something goals wrong you can only blame yourself. The same can be said about your sugar levels. It symbolizes that if you forget some things, it can have large consequences. Also, golf is a physical sport so it allows the participant to get his exercise in and work on his goals.
Participant 21	Kitchen scale	Reflection, confrontation	Symbolizes the fact that the participant was gaining weight and his insulin levels were rising, which is not a good thing. However, being aware of this is the first step in the right direction as if shows that the participant is able to reflect on his values when confronted with them.

# **Appendix 11: Specific overview valuable features**

Group / topic	General approach	Online format	Mindfulness	Blood glucose measurements
Monday	Overview of the program 'the red thread' (2,5) Earlier involvement of the partners (partner 5)	4, 5, 6		7
Tuesday	Nutrition labels (9, 12, 13, 14) More break out rooms (9, 14) Introduce the dietary advisor earlier, and then let her return (9, 14) Follow-up meeting in the coming months (10, 12, 13, 14)	8, 13		
Wednesday	Follow-up program (16) Some basic information at the start (20) Uniform BGM (20) More information on stress (17) Nutrition labels (15, 16, 17, 18, 19)	15, 18, 20	Not an online session, but in real life (15, 17, 18)	15, 17

Table 13: Specific overview of areas for improvement, per group