Flourish and Nourish

Development and Evaluation of a Salutogenic Healthy Eating Programme for People with Type 2 Diabetes Mellitus

Kristel (C.M.M.) Polhuis

Propositions

1. For people with diabetes type 2, intervening on *why* they eat is more important than on *what* they eat in order to attain a sustainable and healthy dietary change.
   (this thesis)
2. The essential ingredients of dietary care for people with type 2 diabetes are providing space for them to self-reflect and facilitating peer support.
   (this thesis)
3. Put the Ph back in PhD by means of a mandatory philosophy of science course.
4. Competitive university systems hamper effective multidisciplinary collaborations.
5. Both university students and teachers benefit from a strict binding study advice in the first year of the BSc-programme.
6. Short lunch breaks at Dutch schools contribute to lifelong unhealthy eating practices.
7. The only way to achieve the public health goals of the Dutch National Prevention Agreement is to enshrine the goals in law.

Propositions belonging to the thesis, entitled

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Kristel (C.M.M.) Polhuis

Wageningen, 20 September 2023

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This research is conducted under the auspices of the Wageningen School of Social Sciences (WASS).

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Thesis
submitted in fulfilment of the requirements for the degree of doctor
at Wageningen University
by the authority of the Rector Magnificus
Prof. Dr A.P.J. Mol,
in the presence of the
Thesis Committee appointed by the Academic Board
to be defended in public
on Wednesday 20 September 2023
at 4 p.m. in the Omnia Auditorium.

Kristel (C.M.M.) Polhuis
Flourish and nourish: development and evaluation of a salutogenic healthy eating programme for people with type 2 diabetes mellitus.
324 pages

PhD thesis, Wageningen University, Wageningen, the Netherlands (2023)
With references, with summaries in English and Dutch

ISBN 978-94-6447-725-2
DOI https://doi.org/10.18174/631882

Voor mijn ouders, Peter en Leonie,
en mijn dochters, Isabel en Rosalie.

"Do not try to become a person of success, but try to become a person of value."
Albert Einstein

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Voor- en dankwoord

(preface and acknowledgements)

Jaren van onzichtbaar werk eindelijk tastbaar gemaakt in dit boek: mijn meesterproef. Ik denk terug aan de zomervakantie voor de start van de brugklas op het Stedelijk Gymnasium in Leeuwarden. Ik was twaalf jaar en wilde weten wat de hoogste schooldiploma was. Mijn vader legde uit dat dat een doctoraat was. Wat dat precies inhield, wist ik toen niet, maar ergens ontstond mijn wens om zo'n doctoraat te behalen. In feite werd ik op die dag promovenda – wat in het Latijn betekent 'zij die *moet* promoveren' (gerundivum). Ik moest promoveren simpelweg omdat ik het mij had voorgenomen (een familietrekje).

Er waren ook jaren waarin ik me flink tegen de wetenschap hebt verzet. Ik weet dat ik tijdens mijn Masteropleiding riep ik dat ik in ieder geval géén PhD ging doen. Deels kwam dat omdat ik de universiteit misschien wat had geromantiseerd, deels omdat ik mijn opleidingen uitdagender had voorgesteld, deels door de horrorverhalen van promovendi. Aanvankelijk ben ik ook wat anders gaan doen. Ik had afstand van de universiteit nodig om te beseffen dat ik terug wilde, terug móest. Toen ik mijn vader vertelde dat ik wilde solliciteren op dit promotietraject was hij niet verbaasd. Hij vertelde dat toen ik nog op de basisschool zat hij al tegen mijn moeder zei: 'Kris, die gaat de wetenschap in'.

Het officiële promotietraject begon zes jaar geleden. Ik had me voorbereid op een pittige traject met pieken en dalen. Er waren in die tijd veel nieuwsberichten over ernstige mentale klachten bij promovendi. Gelukkig is mijn ervaring anders. Het was een (lange) klim de berg op: langzaam en vastberaden elke dag een stukje verder, *one day at the time*. Ik heb zoveel mogelijk genoten van alle mooie uitzichten onderweg omhoog: buitenlandse congressen, colleges geven, contact met deelnemers, contact met studenten, artikelen schrijven en publiceren. Het was een ontdekkingsreis in (en over) de wetenschap, die mij tegelijkertijd meer inzicht gaf in mijn eigen kunde en onkunde. De grootste les is misschien nog wel dat ik nog meer inzie wat ik allemaal niet weet. Ik voel me kleiner, meer bescheiden na deze klim over de berg der wetenschap.

Ik heb dus vooral genoten van de afgelopen jaren. Dat is voor een belangrijk deel toe te schrijven aan mijn begeleidingsteam: co-promotores **Lenneke Vaandrager** en **Sabita Soedamah-Muthu** en mijn promotores **Maria Koelen** en **Marianne Geleijnse**. Ontzettend inspirerend om begeleid te worden door vier sterke vrouwelijke mentoren. Zij gaven mij in vol vertrouwen de vrijheid om zelf een pad uit te stippelen. Enorm dankbaar ben ik voor de altijd positieve en constructieve feedback, de aanmoedigingen, de complimenten, het kritisch meedenken en aanscherpen en de levendige discussies. Bovenal dank voor de ruimte om zo nu en dan de vermoeide moeder te mogen zijn die even niet alle ballen in de lucht kon houden, voor het begrip als ik weer eens met een ziek kind thuis zat. Dit soort kleine dingen hebben voor mij een enorm verschil gemaakt.

Een andere reden waarom ik van de afgelopen jaren heb kunnen genieten is omdat het in mijn privéleven ook goed ging. In deze periode zijn Erik en ik (per ongeluk) getrouwd, kochten wij samen ons eerste huis en is ons gezin verrijkt met de komst van twee prachtige dochters. Gebeurtenissen waaruit ik veel blijdschap en energie putte. Dank lieve **Erik**, voor het delen van deze mooie gebeurtenissen, het altijd meer in mij geloven dan dat ik zelf doe, jouw steun, rust en geduld. In de (geparafeerde) woorden van dichter Loïs Kruidenier: 'je houdt me niet vast en je laat me niet gaan; je houdt me los'.

Twee keer moeder worden tijdens een promotieonderzoek in een competitieve wereld is op het eerste oog wellicht een onverstandige keuze. Ik grapte vaak dat ik *juist* door het krijgen van kinderen in staat was deze missie te volbrengen. Het moederschap was voor mij een welkome relativering: een promotieonderzoek werd opeens *maar* een promotieonderzoek; dat ervoer ik als bevrijding. Als ik in staat was nieuw leven op deze aarde te brengen, dan moest een proefschrift schrijven ook wel lukken. Tegelijkertijd heeft het moederschap mijn promotieonderzoek belangrijker gemaakt: de tijd die ik eraan besteedde, besteedde ik niet aan mijn kinderen, dus verplichtte ik mezelf om ook zoveel mogelijk uit die werktijd te halen. Maximale efficiëntie en daarna was ik weer volledig beschikbaar voor de meisjes; geen 'gepromoveer' na werktijd (althans, zo min mogelijk). Mijn dochters hielpen mij ont-stressen en met verwondering naar de wereld te kijken: ook dat kwam mijn proefschrift alleen maar ten goede. Het zwangerschaps- en ouderschapsverlof gaf een illusie van extra tijd en was een fijne manier om afstand tot het onderzoek te nemen om daarna weer met frisse ogen de draad op te pakken. Dus dank aan mijn ongelooflijke wijze, stoere en inspirerende dochters **Isabel** en **Rosalie**. Zonder jullie was er niks van terecht gekomen. Niets maakt me gelukkiger en trotser dan jullie moeder zijn.

Natuurlijk waren er ook tegenslagen de afgelopen jaren. Om er een paar te noemen: het per ongeluk verwijderen van een groot deel van een kwalitatieve analyse (lees: meer dan een maand werk in de prullenbak), een medisch-ethische commissie waar ik het niet altijd mee eens was, kinderen die om de haverklap ziek waren, eindeloos veel slapeloze nachten en niet te vergeten een pandemie die zowel het onderzoek als de zorg voor de kinderen bemoeilijkte. Toch gaf de pandemie ergens ook relativering en een (geforceerde) pas op de plek. Het was een unieke ervaring om zowel twee jaar in het pre-corona tijdperk als twee jaar tijdens het coronatijdperk èn twee jaar in het post-coronatijdperk onderzoek te doen.

Toch ben ik blij dat de coronatijd achter ons ligt, want ik merk dat buitenshuis werken, omringd door leuke collega's, mij goed doet. Dank aan al mijn gezellige **HSO collega's** voor de hulp, support en gezelligheid de afgelopen jaren. Het is een fijne, gemoedelijke en inspirerende afdeling om te werken. Ik ben blij dat ik hier voorlopig nog een deel van mag uitmaken. In het speciaal dank aan mijn lieve (oud) kamergenote **Yvette Beulen** voor het delen van lief en leed. Ook aan **Laura Bouwman** voor het creatief meedenken en schrijven aan dit project. Ik kijk er naar uit om weer opnieuw met je samen te gaan werken. Verder dank aan alle studenten die ik heb mogen

begeleiden de afgelopen jaren (in chronologische volgorde): **Stella Weiland, Rick Moorman, Caro-Lynn Verbaan, Marieke Mill, Mathilde Companger, Esther Speth, Anne van Remortel, Femke Muller (zowel BSc als MSc scriptie), Sophie Vliet, Eline van Bennekom, Dana van der Kraan** en **Annemone Siffels**. Ook veel dank aan **Nora Lokradi**, de student-assistent op mijn project. Het begeleiden van jullie heeft ook mij veel geleerd.

Dit promotieproject was mogelijk door een aantal belangrijke mensen buiten de universiteit. Ten eerste **alle deelnemers**: dank voor het tijd vrijmaken, de gastvrijheid, de mooie en soms kwetsbare verhalen. Deze hebben op mij een blijvende indruk gemaakt. Dit onderzoek was een onmogelijke taak geweest zonder de zorgverleners die het belang van onderzoek inzien, in het speciaal dank aan **Remy Bemelmans, Pieter Jansen, Astrid van Laar, Suzanne Oomen, Jag Muthu, Judith Moesker, Melody Kwint** en **Kim van Leeuwen.** Een extra groot dankjewel aan **Reina Buursen** De deelnemers droegen je op handen en dat is precies waar ik op hoopte. Jouw enthousiasme werkte aanstekelijk, wat tevens onze samenwerking erg plezierig maakte. Hopelijk kunnen we in de toekomst de draad weer oppakken!

Dan nog veel dank aan de mensen die mij de afgelopen jaren in mij geloofden, mij aanmoedigden, steunden en deden lachen wanneer nodig. Mijn lieve schoonouders **Cor** en **Leny**, die altijd voor ons klaar staan, mijn broer **Pieter** en (schoon)zus **Kirstin**, mijn lieve Fryske Vriendintsjes: **Arieke, Julia, Lisa, Neeke, Marrit** en **Sonja**; mijn sportschool meiden **Zoë** en **Charmain**, mijn 'aangetrouwde vrienden' **Rianne** en **Paul**, **Annet** en **Yuri,** en **Nathalja** en **Arthur**; en gezellige buren, in het speciaal **Joyce** en **Gerard**.

Een speciaal woord van dank voor twee vriendinnen die mij hebben bijgestaan in de aanloop naar de verdediging en op de dag: mijn paranimfen **Mara** en **Lisanne**. Lieve **Mara**, jij was de eerste persoon die ik in Wageningen ontmoette en we buffelden ons samen door een Bachelor, Master en VLAG Research traject. Nu zijn we opeens 12 jaar verder, beiden gepromoveerd en moeder (hoe dan?!). Dank voor deze mooie vriendschap. Lieve **Lisanne,** onze vriendschap kwam volledig tot bloei toen we collega's werden bij HSO en werd officieel verzegeld in Alicante. Veel dank voor het sparren tijdens lunchwandelingen, je peptalks, en gezelligheid de afgelopen jaren.

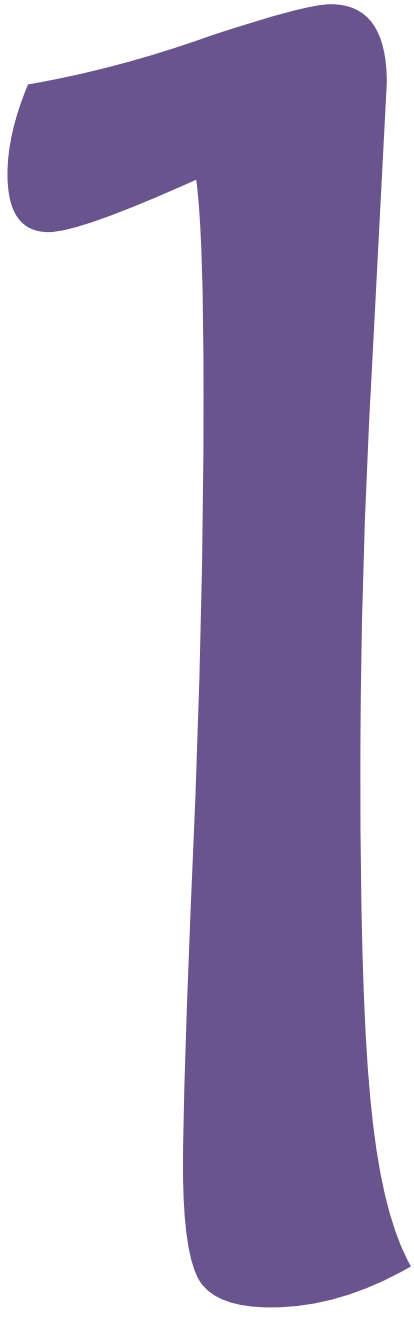
Tenslotte de mensen die ik de meeste dank verschuldigd ben, mijn ouders **Peter** en **Leonie**. Zonder jullie onvoorwaardelijke liefde en betrokkenheid was ik nooit gekomen waar ik nu ben. Het is onmogelijk mijn dank voor jullie goed onder woorden te brengen: het is te veel, te groot. Lieve **mama**, jij maakte mijn jeugd tot een fantasievol paradijs maakte waar altijd alles mogelijk was en (bijna alles) mocht. Nu ik zelf mama ben zie ik ook de andere (zware) kant daarvan. Ik hoop Isa en Roos zo'n zelfde jeugd te geven, want het gaf mij oneindig veel mogelijkheden om mijn nieuwsgierigheid te volgen en creativiteit te ontplooien. Als ik maar half zo'n goede moeder kan zijn, dan zou ik al erg trots op mezelf zijn. Lieve **papa**, de slimste mens op aarde, mijn belangrijkste leraar, onmogelijk om te evenaren. Nergens heb ik zoveel van geleerd als van

jouw secure feedback: van mijn allereerste basisschoolwerkstukjes en spreekbeurten tot aan dit proefschrift. Jij maakte filosofie toegankelijk en leuk tijdens wandelingetjes over de Groene Ster: Plato, Descartes, Kant, Thomas Kuhn, Martin Heidegger en (jouw favoriet) Bruno Latour. Uiteraard hebben deze grote denkers mijn denken en ontwikkeling sterk beïnvloed, maar geen van hen zo veel als jij. Pap en mam, dank voor alles, ik hou van jullie.

Dan nu, 18 jaar na die zomer voor de brugklas, is de metamorfose van promovenda tot doctor voltooid. Ik voel me behoorlijk op mijn gemak in de wetenschappelijke wereld en zie mijzelf hier voorlopig nog wel rondfladderen. Tegelijkertijd is deze wereld niet altijd zo mooi als ik aanvankelijk dacht: vaders lijken te worden verkozen boven moeders en meer dan je best doen is vaak niet goed genoeg. Hoe dan ook, met een open blik en vol vertrouwen kijk ik uit naar wat de toekomst verder voor mij in petto heeft. En wie weet kan ik de wetenschapspraktijk nog een stukje mooier maken.

Abbreviations

A:C = albumin:creatine ratio
ANCOVA = analysis of covariance
BMI = body mass index
BW = body weight
CHW = community health worker
CI = confidence interval
COVID-19 = corona virus disease-2019
DBP = diastolic blood pressure
Diabetes MILES-NL = diabetes miles the Netherlands study
DIRECT = the diabetes remission clinical trial
DHD-2015 = Dutch healthy diet index 2015
DHD-index = Dutch healthy diet index 2006
DGSES = Dutch general self-efficacy scale
FBG = fasting blood glucose
GP = general practitioner
GRD = general resistance deficits
GRR = general resistance resource
HbA_{1c} = glycated haemoglobin A1c
HDL = high-density lipoprotein cholesterol
HP = healthcare provider
IPA = interpretative phenomenological analysis
IPAQ = international physical activity questionnaire short form
LDL = low-density lipoprotein cholesterol
LMM = linear mixed models
Look AHEAD = action for health in diabetes trial
MET = Metabolic equivalent of task
METC = medical ethical committee
MHC-SF = mental health continuum - short form
OR = odds ratio
QoL = quality of life
RCT = randomised controlled trial
SALUD = salutogenic intervention for type 2 diabetes
SBP = systolic blood pressure
SD = standard deviation
SE = self-efficacy
SEM = standard error of the mean
SEP = socioeconomic position
SMH = salutogenic model of health
SoC = sense of coherence
SoC-13 = 13 items of the orientation to life (soc) questionnaire
SMBG = self-monitoring blood glucose
SPFLS = self-perceived food literacy scale
SRR = specific resistance resource
SS = symptoms severity
T1DM = type 1 diabetes mellitus
T2DM = type 2 diabetes mellitus
TC = total cholesterol
TG = triglycerides
TS = total symptoms
UC = urinary cortisol
VIF = variance inflation factors
WC = waist circumference
WHO = world health organisation
WHR = waist-hip ratio
WHOQOL-100 = world health organisation quality of life-100



Chapter 1

General introduction

1.1 Setting the scene: contrasting research paradigms

This doctoral dissertation describes an interdisciplinary research project that combines natural (nutritional) and social (health promotion) sciences in order to develop and evaluate an intervention programme that enables healthy eating among people with type 2 diabetes mellitus (T2DM) (see **Box 1.1** based on reference: [1]). Both the nutritional and health promotion sciences aim to support people to achieve optimal health. Yet both fields have developed in distinct ways, resulting in different paradigms with their own favoured and acceptable research practice. These resulting differences imply differences in research priorities, opinions on how research should be conducted and what types of explanations are acceptable [2].

In this first paragraph, the two paradigms and their main differences are discussed by describing the historical development of the fields of nutrition and health promotion sciences. This description is followed by the ontological, epistemological and methodological positioning of the dissertation. The second paragraph describes the background and the context underlying the research project. This chapter ends with the overall research aim, research objectives and outline of the dissertation.

Box 1.1 The founding mother: Johanna Edema, MSc.

This research project is fully funded by the Edema-Steernberg Foundation. The Edema-Steernberg Foundation is an initiative established by Wageningen-based scientist and teacher Johanna Edema (1923-2015). Edema was a strong personality with a clear opinion about the direction research and education should take. Nutrition scientists at that time worked predominantly from a natural sciences perspective, focusing on dietary assessment and the health effects of nutrients. Edema, however, kept saying that investigating the mechanisms behind eating behaviour was just as important in order to improve people's health. She was ahead of her time: over the last twenty years, prevention of lifestyle diseases has become a key focus.

The reason for why we eat what we eat; intrigued Edema throughout her career. In mid-2015, Edema realised a longstanding wish; she established a foundation to enhance 'research and knowledge exchange in the field of household sociology with special attention to nutrition patterns'. The foundation was named after her parents. In January 2016, the foundation became operational. Ultimately, 4 MSc scholarships (for female students originating from low-income countries), six PhD projects and one post-doc project were funded by the foundation. I am forever grateful to be one of the six 'Edema' PhD candidates. With this research project, I hope to honour Edema's ideas and keep her intellectual legacy alive.

1.1.1 A short history of modern science: positivism and interpretivism

In the seventeenth century, philosopher Rene Descartes introduced a dualistic word view [3]. Descartes proposed that there is a 'natural' world to be understood by physics and mathematics, and a 'divine' world that is difficult to grasp. Introducing logical reasoning as a source of knowledge was a radical move, as religion was considered the only route to knowledge about reality [3]. Descartes' dualism also changed the common conception of how the human body was viewed: he proposed that the body and the mind consist of two different and unlike substances, whereas until then, human beings were viewed as spiritual beings in which the mind and body were unified [3]. Because of his dualistic worldview, Descartes is seen as the founder of rationalism (i.e. knowledge can be obtained via intellectual reasoning). Rationalism and empiricism (i.e. knowledge comes from our senses, observation and experimentation) ultimately paved the way for a positivist science-based paradigm to understand reality [3,4].

A positivist paradigm argues that knowledge can be only obtained by empirical sciences following the 'hypothetico-deductive model': a scientific model based on forming a testable hypothesis and developing an empirical study to confirm or reject the hypothesis [5]. The hypothetico-deductive model is a circular process (i.e.: theory from literature → hypothesis → operationalising variables → experimentation → inform theory and contribute to literature). Within positivism, knowledge can and must be developed objectively, without the values of the researchers or participants influencing its development [5]. Positivism gave rise to a scientific paradigm that has the central aim to discover universal laws of reality to facilitate explanation and prediction of (natural and social) phenomena, guided by the principles of objectivity and deductive logic [4,5]. The positivistic movement led to the scientific revolution which caused enormous progression in the natural sciences (= the study of the physical/material world) [3,5].

Descartes' dualist world view can be considered as the first split between natural and social sciences (= the study of society and the manner in which people and the world around them interact). The progress and success of the natural sciences after the scientific revolution caused a further split [3]. Social sciences initially 'borrowed' positivism from the natural sciences in order to discover universal scientific laws of human conduct and society (e.g. Auguste Comte; Emile Durkheim) [6]. However, over the course of the nineteenth and twentieth centuries, a new philosophical tendency developed that questioned the axiom that social reality works in ways similar to those of natural reality. Philosophers such as Wilhem Dilthey, John Dewey and Edmund Husserl stated that humans should be studied differently than lifeless objects [7]. They put a spotlight on the subjective nature of social reality.

Consequently, an interpretivist paradigm was developed that argues that knowledge is constructed through the individuals' interaction with the environment in the course of experience. Contrary to (logical) positivism, interpretivism rejects the idea of the existence of universal social laws. Interpretivism rejects the view that empirical science is the basis for achieving an understanding

of the world, stressing instead the importance of the 'life world' or lived experience [6]. Instead, truth and knowledge are subjective, as well as culturally and historically determined, based on people's experiences and their understanding of those experiences [4]. Studying the lived experiences of people while acknowledging the researcher's personal beliefs and standpoints is needed in order to reveal and understand social phenomena [8]. Hence, the role of the researcher is also different: the researcher is the primary analytical instrument for understanding and making sense of reality [8]. The historical and sociocultural context, past experiences, and used concepts and language shape the researcher's understanding of the world which (s)he is investigating, studying and defining [4,8].

It is essential to note that positivism is not superior to interpretivism, nor vice versa. Both paradigms exist in parallel with each other and both have their own applications, strengths and limitations. Yet positivist views are still predominant in both the natural and social sciences (although interpretivist views are more common in the social sciences[1] compared to the natural sciences). In fact, positivism is still so predominant that it is often considered (implicitly) as 'the' philosophy of science in general [5].

Table 1.1 Summary of main differences in positivist and interpretivist paradigms.

	Positivism	Interpretivism
Reality	Singular, neutral, objective and measurable.	Subjective, multiple and socially constructed.
Scientific knowledge	Accumulation of data obtained theory-free and value-free from observation.	Studying someone's lived experiences to uncover the (social) reality.
Research methods	Quantitative methods to discover universal laws that facilitate explanation and prediction of phenomena.	Qualitative methods that aim to explore and understand the meaning of phenomena and context.

1.1.2 Positivism and interpretivism in nutrition and health promotion science

To a great extent, positivism and mind-body dualism determine how health and nutrition research is approached in the present. Positivism led to a biomedical approach to health in which human beings were viewed as biological organisms to be understood by examining their constituent (anatomical and physiological) parts [3]. Health was defined as the physical state in which disease was absent; medicine became synonymous with health [3]. The biomedical approach has been predominant in health-care and medicine science in the last 300 years [3]. It is a powerful field in which a lot of money, energy and dedication have been invested, which yielded significant returns in terms of technological success [3].

Nutrition sciences: positivist paradigm

Modern nutrition science is young: it has been less than one century since the first vitamin was isolated in 1926 [9]. Modern nutrition science is dedicated to find understandings of nutritional processes, components of our food, health issues surrounding food, eating and medicine.

1 The social sciences are characterised by the plethora of disciplines and research methodologies; an example of an interpretivist research tradition is the phenomenological tradition [4].

It is a multi-faceted field that is rooted in chemistry, biology and the social sciences. It is interesting that nutritional sciences are now often considered distinct from social sciences as nutrition science emerged originally as a social issue (i.e. could optimal nutrition increase industry productivity?) rather than a genuine concern for addressing nutrition as a discipline in itself [10]. However, from the beginning of the twentieth century, a significant and intentional effort was made to dissociate the nutrition sciences from social issues and reconfigure them as biomedical [10]. The fields of nutritional sciences adopted the positivist science framework with a biomedical orientation, a traditional realist epistemology and a reductionist approach to eating [10]. Although more social-oriented nutritional sciences have always co-existed with positivist-oriented ones, the dominant paradigm became biomedical, pathogenic-oriented, and quantitative. Biomedical models merely focus on the causes of a breakdown (pathogenesis) in order to prevent or reverse states of illness. Modern nutrition science is characterised by a strong focus on nutrients and the nutri-biochemical level interactions of food and physical health [11]. It encourages scientists to think about foods in terms of their nutrient composition, to make the connection between particular nutrients and physical health, and to construct nutritionally-balanced diets on this basis [11]. Hence, between 1910-1950, most nutritional research was focussed on isolating and chemically defining vitamins and single-nutrient deficiencies (e.g., Rickets = a vitamin D deficiency; anaemia = iron deficiency) [9]. This nutrient-focussed view hampered research focussed on socially engaging with food and contextualising the relationship between food and the body [10,11].

Health promotion sciences: interpretivist paradigm

Health promotion science is even younger than nutrition science. Health promotion appeared in the health lexicon in the latter part of the twentieth century [12]. This appearance is because people at that time were living longer than previously, and, therefore, researchers became interested in the exploration of life *enhancement*. Health promotion research is mainly rooted in social and behavioural sciences [13]. The conventional research setting used to favour positivist approaches over other methods [14,15], until the Ottawa Charter for Health Promotion. The Ottawa Charter is an international agreement focussed on 'action to achieve Health for All by the year 2000 and beyond' that was signed at the First International Conference on Health Promotion, organised by the World Health Organization and held in Ottawa, Canada, in November 1986 [16]. With the Ottawa Charter, the argument grew that (post)positivist approaches were insufficient to make sense of what health promotion science is, and the field shifted to an interpretivist perspective. The Ottawa Charter can be seen as the birth of modern health promotion sciences, as it defined health in a positive way as 'a resource for everyday life' rather than as the absence of diseases. This perspective on health was fundamentally different and consequently led to a totally different view on the research field of health promotion [16]:

> '.... the process of enabling people to increase control over, and to improve, their health. To reach a state of complete physical, mental and social wellbeing, an individual or group must be able to identify and to realize aspirations, to satisfy needs, and to change or cope with the environment. Health is, therefore, seen as a resource for everyday life,

> not the objective of living. Health is a positive concept emphasizing social and personal resources, as well as physical capacities. Therefore, health promotion is not just the responsibility of the health sector, but goes beyond healthy lifestyles to wellbeing' [16].

Contrary to the health view enacted by Descartes' mind-body dualism, the Ottawa Charter revived a dynamic and holistic concept of health. Whereas nutritional sciences focus on the individual (body), health promotion sciences are particularly focussed on the individual contexts. Health promotion is less concerned with specific diseases and more concerned with empowering people to gain control of their health and enabling resources in the settings of everyday life [13]. There is a strong research focus on social and behavioural interventions. Most researchers in health promotion agree that qualitative methods are useful and appropriate in health promotion research [13,15], particularly because mixed-methods study design (i.e. triangulate research findings by combining quantitative and qualitative methods) has become increasingly popular in health promotion to assess the validity and reliability of health interventions [13]. Another important distinguishing consideration in health promotion sciences is the extent to which objects of the research or evaluation should be involved in the undertaking of research [13,15]. In health promotion, there is a priority to provide meaningful opportunities for all of those with a direct interest in health promotion initiatives to participate in all the processes, including planning, priority setting, implementation and evaluation [13,15].

1.1.3 Ontological, epistemological and methodological positioning

Ontology refers to what sort of things exist in the world and assumptions about the form and nature of reality. It is concerned with whether or not social reality exists independent of human understanding and interpretation. Epistemology is concerned with the nature of knowledge and ways of knowing and learning about reality. Two main perspectives are positivism and interpretivism.

I share a realist ontological positioning regarding the physical/material world, meaning there is an external physical/material reality independent of what people may think or understand. Despite a 'real' physical reality, human beings mostly live in a shared, socially-constructed reality. Concerning that social reality, I come from a position of relativism, i.e. that reality is subjective and differs from person to person.

Concerning epistemological positioning: I think a positivist and interpretivist perspective can (and should) exist in parallel with each other. There is no need to choose between the two paradigms. Depending on the problem definition, a choice should be made on which paradigm is best suited to answer the knowledge gap. Hence, in this dissertation, knowledge is gathered in different ways. Positivist quantitative research methods had a central role in the development (Chapter 2 and 4) and empirical evaluation of the intervention programme presented in this dissertation (Chapter 6 and 7). In line with an interpretivist perspective, qualitative research

methods were used to gain a further, complementary understanding of what people need to be able to change eating behaviour in order to develop the intervention programme (Chapter 3 and 5). Qualitative research was also used to explore how, why and under which circumstances the intervention does (not) work (Chapter 8).

Throughout the dissertation, I have attempted to find a middle ground between objectivity and subjectivity, between context-specific and generalisability. The challenge of this dissertation is to combine these contrasting knowledge-gathering approaches in a meaningful and fair way (Chapter 9).

1.2 Background

1.2.1 Healthy eating

There are several aspects which comprise healthy eating: 1) a right energy balance between kilocalories and energy expenditure to maintain a healthy weight; 2) an overall eating pattern to prevent chronic diseases; 3) the right balance of micronutrients for a healthy nutritional status to promote wellbeing, growth and development; and 4) food safety regarding food production, food poisoning, food allergies and tolerances. Recently, a sustainability aspect is also increasingly emphasised in relation to healthy eating (i.e. plant-based diets are recommended over animal-based diets) [17]. Initially, the national dietary guidelines focussed on essential micronutrients and their role in deficiency diseases [9]. Beginning in the 1970, national dietary guidelines in Western industrialised countries shifted in focus to non-communicable diseases due to the rise of cardiovascular disease, obesity, and several cancers [9].

In the Netherlands, the Dutch Health Council (*Gezondheidsraad*) composes and updates the dietary guidelines based on systematic evaluation of the highest quality research available [17]. The first Dutch national dietary guidelines were published in 1986. These guidelines were *nutrient*-based and concerned the intake of fat, saturated fat, cholesterol, sugar, starch, fibre and sodium. Twenty years later, in 2006, a new set of guidelines replaced the old ones. These guidelines were a *mix* of nutrient and food-based guidelines. In 2015, less than ten years later, the guidelines were again revised, which resulted in the most recent set of Dutch dietary guidelines. These guidelines are *food*-based and recommend a dietary pattern that is high in vegetables, fruits, whole-grain products, nuts and legumes, and is relatively low in animal products (dairy and meat) [17]. National dietary guidelines are developed for the general population. In 2021, it was concluded that there was no reason to modify one or more of these dietary guidelines specifically for people with type 2 diabetes mellitus (T2DM) [18,19].

The Dutch Nutrition Centre (*Voedingscentrum*; 100% subsidised by the Dutch government) communicates the guidelines to the public. Nevertheless, the majority of Dutch people do not follow dietary recommendations; in particular, recommendations for fruit, vegetables, fish and

fibre are insufficient [20]. National food consumption surveys of other (Western) countries show similar findings [21–23]. In addition, overweight is common in adults and children [20]. In the Netherlands as of 2022, 50.2% of adults and 12.9% of children are overweight [24]. Globally, unhealthy dietary habits are responsible for more deaths than any other risk factor, including smoking [25]. A suboptimal diet, a lack of physical activity, and being overweight have contributed to the epidemic proportions of T2DM.

1.2.2 Type 2 diabetes mellitus

There are three main types of diabetes: 1) type 1 diabetes mellitus (T1DM): formerly called insulin-dependent diabetes, this auto-immune disease usually develops in children, teenagers or young adults; 2) type 2 diabetes mellitus (T2DM): formerly called non-insulin-dependent diabetes, this disease is characterised by insulin-resistant diabetes and life-style related diabetes and usually develops in adults; 3) gestational diabetes: this pregnancy-related diabetes is a risk factor for developing T2DM later in life. Diabetes has grown to epidemic proportions, affecting more than 415 million people worldwide [26,27]. T2DM accounts for more than 90% of these diabetes cases [26]. T2DM is a non-communicable disease characterised by increased hyperinsulinemia, insulin resistance and pancreatic β-cell failure [26]. T2DM is caused by genetic and environmental factors: genetic factors exert their effect when exposed to an obesogenic environment. Such an environment is characterised by two factors: 1) an abundance of ultra-processed products that are high in sugar and fat and 2) the encouragement of inactive, sedentary behaviours [26]. Considering the enormous increase in T2DM incidence compared to the previous century, environmental factors contribute disproportionately to the T2DM epidemic. Current projects suggest that T2DM prevalence will reach 700 million people by 2045 [28,29]. In the Netherlands, almost 1.2 million adults suffered from diabetes in 2022, and it is expected that this number will rise to 1.5 million adults in 2040 [30]. T2DM incidence is particularly high in people with low socioeconomic positions [30–32].

The organs involved in T2DM development include the pancreas (β-cells and α-cells), liver, skeletal muscle, kidneys, brain, small intestine, and adipose tissue [26]. T2DM increases the risk of developing microvascular complications (e.g. retinopathy, nephropathy, and neuropathy) and macrovascular complications (e.g. coronary heart disease and ischaemic stroke) [26]. T2DM increases the risk of all-cause mortality with 15% compared to people without T2DM [26,33]. Recent research shows that years of life lost due to T2DM varied from 2.5 years to 12.9 years in high-income settings [34].

Once diagnosed, treatment of T2DM consists often of a combination of medications and lifestyle advice. There are many different pharmacological options available to regulate the glycaemic control. An unhealthy diet is a major risk factor for developing T2DM; however, a healthy diet has the potential to prevent and reverse the disease [35–37]. Evidence shows that healthy nutrition can cause similar and sometimes even greater reductions in haemoglobin (HbA_{1c}) as

medical treatments for T2DM [38,39]. In some cases, fasting blood glucose levels normalise to <7 mmol/L, implying that medical treatment can be stopped [40–44].

Although health care providers increasingly emphasize the importance of adopting a healthy diet during T2DM consultations [45], 45% of the people with T2DM still does not achieve adequate glycaemic values (HbA_{1c} <7%) [46]. A main reason for this is that individuals with T2DM indicate that committing to a healthier diet in everyday life is the most complex aspect of T2DM self-management [47–49].

1.2.3 Healthy eating in everyday life

Healthy eating is notoriously difficult. Some dietary intervention studies indicate that non-adherence to healthy eating is caused by unwillingness to change, a lack of motivation and willpower, low self-control and a lack of nutrition knowledge [50–53]. This dissertation is rooted in another notion, namely that non-adherence to healthy eating results from the limited attention of dietary interventions towards the everyday-life contexts in which people with T2DM have to organise dietary change. Most previous dietary interventions that have been able to reverse T2DM are biomedically-oriented, based on strict diets (e.g. very low-caloric intake-diets) and performed in highly controlled research settings [37,42,43]. People may experience difficulties when they return from these clinical and controlled research settings to their everyday lives as sustaining a healthy diet/gained health benefits in the long term remains difficult for most [49,54–56].

In everyday life, healthy eating goes beyond the understanding of a good balance of macro- and micronutrients; it is also about structure and regularity (e.g. eating a fixed number of meals at fixed times, or weekly routines), how foods are produced (e.g. home-made, organic), and (psycho)social wellbeing (e.g. enjoying eating together) [57–60]. Eating is highly contextual, and personal interpretations of healthy eating are complex and diverse, as they reflect personal, social, and cultural experiences, as well as local (food) environments [59]. In everyday life, healthy eating requires a scale of personal and social skills and resources, ranging from practical cooking skills to personal agency [57–59]. Healthy eating is not a distinguishable action; rather, it is a chain of activities embedded in other social practices [61]. Consequently, dietary change means changing the social system in which one lives, a shared lifestyle or dominant values and existing norms [61]. This may explain why the Mediterranean diet is considered one of the healthiest diets with (long-term) healthy benefits, because it is not a restrictive diet and involves more than 'the act of eating'. The Mediterranean diet encompasses everyday life values on food production, processing, sharing, communication, cultural tradition and knowledge. It is a way of life that includes seasonal cooking, freshly cooked meals, and socialising with others [62]. Hence, people with T2DM do not necessarily need more guidance on *what* to (not) eat, but on *how* to navigate their eating behaviours in everyday life in a more healthier way.

1.2.4 Salutogenesis: a theory for healthy eating in everyday life

A theoretical framework that is especially centred in promoting health in everyday life, is the salutogenic model of health (SMH). 'Salutogenesis' loosely translates as 'the origin of health' (from the Latin word *salus* = health and the ancient Greek word *genesis* = the origin, the source). Salutogenesis is the opposite of pathogenesis, which refers to the origin of disease (*pathos* = ancient Greek word for disease). The founding father of the SMH is scholar of medical-sociology Aaron Antonovsky (1923-1994), born in New York, the United States of America, as the son of Russian-Jewish immigrants [63]. The SMH is developed from Antonovsky's study of Israeli women who survived the Holocaust. Antonovsky was fascinated by the observation that many of the Holocaust survivors stayed *well* and were even able to *improve* their health, despite the excruciating experiences in the concentration camps and the poor life conditions after immigration to Israel [64]. This led Antonovsky to the central question of his work: what are the origins of health? Antonovsky introduces the SMH for the first time in 1979 in his book *Health, Stress and Coping* [65], and discusses it further in his second book *Unravelling the mystery of health: How people manage stress and stay well* (1987) [66].

Until his sudden death in 1994, Antonovsky was considered the leader of a new innovative direction in public health research [63]. His fundamental and revolutionary contribution to the public health field was to raise the philosophical 'salutogenic' question of what creates health rather than to look for the causes of disease in the pathogenic direction [63]. He wanted to provoke a paradigm adjustment in health promotion: from a pathogenic paradigm to a paradigm that includes *both* pathogenesis and salutogenesis. A few years after the publication of Antonovsky's first book in 1979, the Ottawa Charter (1987) introduced a new paradigm in the field of health promotion, that partly adopting the SMH in its thinking to meet the health challenges of the post-modern world [13,63]. To date, the SMH is still thriving in health promotion research and theory building [67,68]: the first edition of *The Handbook of Salutogenesis* (2016) is listed as the fourth most accessed book in the Springer catalogue of open-access books [68]. A second edition of the *The Handbook of Salutogenesis* was published in 2022 [68].

Health as a continuum

The SMH seeks to understand what creates health and how health can be developed in society. Within the SMH, health assumed to be a complex concept incorporating multiple aspects of wellbeing that relate to the whole person [32,33]. According to Antonovsky, researchers should focus on human beings behind a disease, instead of focussing solely on the disease and one's physical health status. Health is not regarded as a dichotomy of 'healthy' or 'unhealthy', but as a dynamic continuum between pathogenesis (the origin of disease) and salutogenesis (the origin of health). In this dynamic health process, people may succumb to internal or external stressors, leading to a breakdown (towards 'dis-ease') or overcome the tension caused by stressors and move towards the health-end of the continuum ('ease'). Where one is situated on the continuum depends on the stressors one has to face and one's ability to use available resources to deal with

the tension created by the stressors in a health-promoting way (**Figure 1.1**).

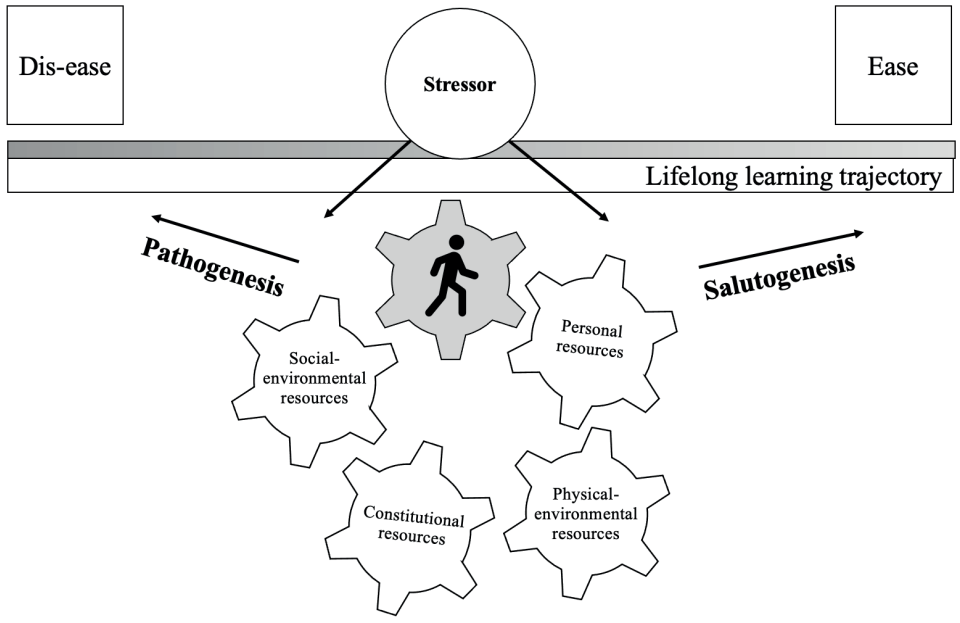


Figure 1.1 The health continuum according to the SMH. Source: based on the work of Bouwman [73].

Sense of Coherence

The sense of coherence (SoC) is the driving mechanism in the SMH that determines one's movement on the health 'ease'/'dis-ease' continuum (symbolised in **Figure 1.1** as the human figure). The SoC is a global life-orientation that expresses a dynamic feeling of confidence that things will work out as well as can be reasonably expected [65]. Originally, Antonovsky defined the SoC as follows:

> 'a global orientation that expresses the extent to which one has a pervasive, enduring though dynamic feeling of confidence that (1) the stimuli from one's internal and external environments in the course of living are structured, predictable, and explicable; (2) the resources are available to one to meet the demands posed by these stimuli; and (3) these demands are challenges, worthy of investment and engagement.' ([66]; p. 19)

The SoC captures one's way of thinking, the ability to comprehend the whole situation and the capacity to use the resources available in everyday life. The SoC has three sub-components: comprehensibility, manageability and meaningfulness. Confronted with a stressor, a person with a strong SoC is able to understand the stressor (= comprehensibility), is able to select an appropriate strategy to deal with the stressor (= manageability) and has a strong feeling that investing

in coping with the stressor is a meaningful process (= meaningfulness) [70]. As Antonovsky pointed out, these sub-components of SoC are comparable to other coping concepts, such as self-efficacy, locus of control, will to live, gratitude, hardiness etc. [70]. However, the particular combination of a cognitive (comprehensibility), behavioural (manageability) and motivational (meaningfulness) dimension is what makes SoC unique [70]. In addition, contrary to most cognitive-behavioural health theories, the motivational dimension (meaningfulness) refers to the *quality* of the motivation rather than the quantity of motivation one experiences in order to engage with the stressor at hand.

Originally, it was thought that SoC was a stable entity that developed mostly during the life experiences in the first decades of life and stabilised thereafter [37]. However, recent empirical evidence shows that SoC is indeed a solid and stable concept, but it can be affected by influential life experiences [46] and even interventions [47–51] throughout the life course.

(Re)sources for health

The other key concept in the SMH is Generalized Resistance Resource (GRR; symbolised as the gears in **Figure 1.1**). GRRs refer to the resources of a person, a group or a community that facilitates the individual's abilities in order to cope effectively with stressors and contribute to the development of the individual's level of SoC [71]. **Figure 1.2** provides the official definition of a GRR as defined by Antonovsky [65].

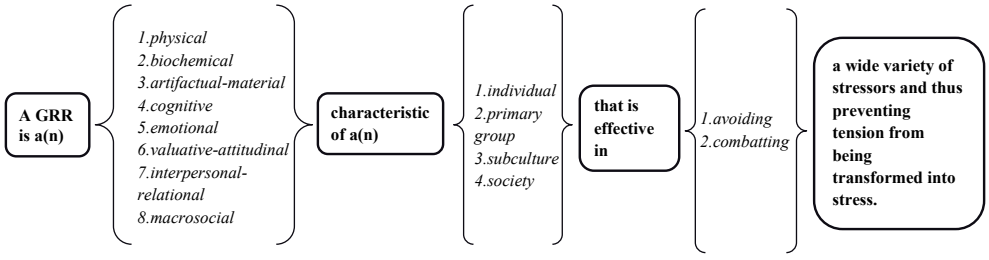


Figure 1.2 Official definition of a general resistance resource (GRR) [69].

As can been seen in **Figure 1.2**, a GRR can be anything – a characteristic, a phenomenon, a social relationship, a subgroup, etc. The defining factor that makes a resource a GRR is that it provides 'an experience in making sense of the countless stimuli with one is constantly bombarded' [65] (p. 121). Antonovsky mentioned that GRR may include the following factors: (1) material resources (e.g., money), (2) knowledge and intelligence (e.g., knowing the real world and acquiring skills), (3) ego-identity (e.g., integrated but flexible self), (4) coping strategies, (5) social support, (6) commitment and cohesion with one's cultural roots, (7) cultural stability, (8) ritualistic activities, (9) religion and philosophy (e.g., stable set of answers to life's perplexities), (10) preventive health orientation, (11) genetic and constitutional GRRs and (12) individuals'

state of mind [65,71]. In addition to GRRs, the SMH also distinguishes Specific Resistance Resources (SRRs). The difference between GRRs and SRRs is that GRRs can be applied to cope with a variety of stressors, whereas SRRs are only useful in coping in specific situations.

The relationship between individual SoC and GRRs is bidirectional, reinforcing and dynamic [66]: one develops strong SoC by successfully applying GRRs across a lifespan, but a strong SoC also enables the use of a variety of GRRs in tension management. The bidirectional relationship between individual SoC and GRR displays an important premise in the SMH: individual health is the result of dynamic *interactions* between the individual and one's environment over time (i.e. lifelong learning trajectory). There are four important source experiences along the life course that contribute to developing strong SoC [72]:

1. *Consistent experiences* are experiences in which people experience continuity between past, present and future [72]. These experiences relate to the human need for stability: without continuity, people feel lost [72]. Life is everchanging and chaotic, as people are it continuously bombarded with conflicting information from different sources. Within this chaos, it is difficult to make sense of how to relate to the world. Consistent experiences enable people to discover resources, (social) rules, guidelines, patterns and criteria that help to navigate through their everyday life environment in a healthy way. Consistent experiences contribute specifically to the comprehensibility component of SoC [72].
2. *Load experiences* are experiences that make demands upon people to act and mobilise resources for task performance [72]. People can experience an overload or underload in the balance between the demands made upon them and their resources. An overload implies that there is no access to all resources needed to cope with the demands of the stressor. An underload implies that the demands are too low: one's potential, skills, and capacities are not fully used. An underload may cause one's potential, skills and capacities to atrophy and vanish, similar to what happens to muscles when they are not stimulated. Load experiences contribute specifically to the manageability component of SoC [72].
3. *Experiences of participation in shaping outcomes* are experiences in which people feel they had a significant part in deciding their fate and feeling in control of actions/behaviour [71,72]. It refers to the 'why' of the action. The activity should be considered worthy to invest, and for most people it is also crucial that the activity is socially approved. Participation in shaping the outcome experiences contribute specifically to the meaningfulness component of SoC [72].
4. *Emotional closeness* refers to experiences in which people feel consistent emotional bonds and a sense of belonging in social groups of which they are a member [71]. Originally, emotional closeness was not viewed as a source experience to develop or strengthen strong SoC [65,72]: it was added later to the SMH by Antonovsky and Sagy [71]. Research supports the argument that the quality of close social relationships contributed to developing strong SoC in individuals across the life course [71]. Emotional closeness experiences contribute to

the meaningfulness component of SoC [71].

5. An individual who has access to a variety of GRRs tends to experience more consistency, a balanced load, participation in shaping outcomes and emotional closeness; thus, this individual has more opportunities to develop strong SoC [71,72] (**Figure 1.3**). On the other hand, an individual who has limited access to GRRs tends to experience inconsistency, an unbalanced load, low participation in shaping outcomes and a lack of emotional closeness is thus deprived of the opportunity to develop strong SoC [71,72]. The lack of GRRs is referred as general resistance deficits (GRDs) in the SMH [71].

As a summary, **Figure 1.3** provides a simplified schematic overview of the entire SMH. Together with chance and idiosyncratic factors, the sociocultural context determines the exposure to the sources of GRRs. GRRs influence the types of life experiences one has. These life experiences influence the level of individual SoC. Together with the available GRR, SoC determines one's ability to cope with a potential stressor. Successful tension management moves one to the 'ease' end of the health continuum, and unsuccessful tension management leads to stress, thereby moving one towards the 'dis-ease' end of the health continuum.

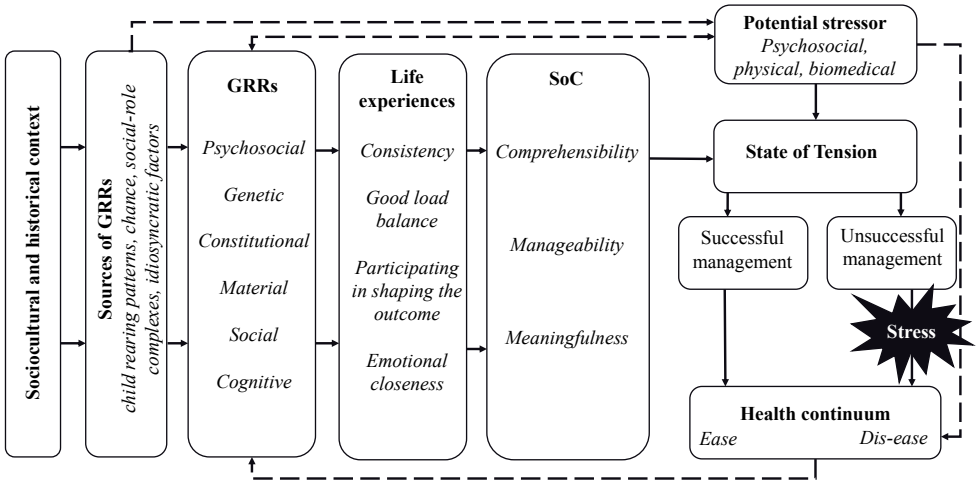


Figure 1.3 Simplified schematic overview of the Salutogenic Model of Health (adopted from [77]). How people cope with tension created by a stressor, determines whether a person moves to the ease or dis-ease end of the health-continuum.

1.2.5 What does the salutogenic perspective add to T2DM nutrition research?

The current Dutch T2DM care policy prioritises personalised patient-centred care [74,75]. This implies individualised HbA_{1c} targets (based on needs, preferences and individual risk profiles) and shared decision-making regarding the T2DM treatment plan [74]. In current patient-centred care models, it is assumed that, in order to 'activate' a patient, attention must be given

to perceptions about T2DM, knowledge about T2DM, self-management skills, self-efficacy, preferences regarding to T2DM management and motivation to self-management [75]. A recent 'real-world' evaluation of a person-centred approach in the Dutch T2DM care showed that people with T2DM have significantly higher patient engagement in self-management activities (patient activation) and lower distress levels after two annual reviews; however, absolute changes were small [75]. This evaluation shows there is room for improving patient engagement within the health care sector and a need for alternative approaches to improve personalised patient-centred care. The salutogenic perspective may *complement* biomedical, pathogenic-oriented approaches for enabling healthy eating among people with T2DM because of three main reasons:

1. SMH distinguishes from more traditional biomedical approaches by adopting a systems approach to healthy eating in which the interactions between an individual and that individual (physical and social) environment are central (**Figure 1.3**). The biomedical approach seems particularly appropriate for pathogenic-oriented questions, meaning investigating and treating the single-cause diseases. However, healthy eating is not a distinguishable action, but rather a chain of activities embedded in other social practices that requires a scale of personal and social skills and resources [57–59]. The SMH acknowledges that people are always connected with each other, and that knowledge about the world is contextual and constructed collectively. Applying the SMH to nutritional research requires accepting a holistic viewpoint on health and real-world complexity as starting points for conducting and evaluating nutritional interventions. Consequently, healthy eating is not regarded as a central goal in life, but rather as a resource for greater enjoyment of life [76]. Whereas biomedical approaches aim to eliminate contextual, everyday life factors and experiences, a salutogenic approach for T2DM centralises the everyday life context to support people with T2DM in navigating their everyday lives in a health-promoting manner. Focussing on (instead of eliminating) the contextual factors for healthy eating may aid in finding health-promoting strategies for healthy eating that can be easily embedded in people's everyday lives. The holistic viewpoint on health of the SMH is in line with the current Dutch guidelines for T2DM primary care, which emphasise the importance of tailoring dietary patterns to individual needs, capabilities and habits [77].
2. Salutary factors that promote healthy eating seem to be of a completely different nature than risk factors for unhealthy eating. A previous PhD study indicated that 'reversing' frequently identified risk factors for unhealthy eating – e.g. low nutrition knowledge, low social support and exposure to the 'obesogenic' food contexts – does not necessarily lead to healthy eating. For example, low nutritional knowledge is a risk factor for unhealthy eating, but adequate nutritional knowledge does not predict healthy eating. Factors that were linked to healthy eating behaviour were not the opposite of risk factors, but they seem to be of a completely different nature, for example, balance and stability, a sense of agency and a sensitivity to the dynamics of everyday life for healthy eating [78]. This distinction is in line with the central premises of the SMH: what creates health is fundamentally different

from what causes disease. Hence, applying the SMH to nutrition research implies a shift to investigating salutary factors that contribute to healthy eating.

3. There is a rapidly increasing amount of research that underscores SoC as important for health and lifestyle among people with T2DM. Systematic empirical evidence already demonstrated that strong SoC is associated with good physical health, wellbeing, lower morbidity and mortality [79–81], healthier dietary patterns and healthier lifestyles [82–84] in general populations. Regarding T2DM, chronic stress and low SoC are associated with higher risk of T2DM [85]. Furthermore, people without T2DM are more likely to have a high SoC compared to people with T2DM [86]. A recent systematic review concluded that the SoC has a strong correlation with T2DM in the different phases of the disease: strong SoC is associated with a reduced risk for T2DM; in addition, when having T2DM, strong SoC is associated with better HbA_{1c} values and less T2DM-related complications [87]. A higher SoC is associated with better metabolic control and glycaemic parameters (i.e. fasted blood glucose and HbA_{1c}) [85,88,89]. In addition, strong SoC was associated with an increased likelihood of successful lifestyle change after a lifestyle programme for people at risk of T2DM [84], implying that SoC can be an important starting point in guiding people to behavioural change. Empowerment and reflection processes are important suggested processes to strengthen SoC [90]. The current Dutch guidelines lines for T2DM in primary care accentuate personalised and empowering health care to guide people with T2DM to lifestyle changes. Hence, applying the SMH to nutrition research results in a shift from the traditional education-centred approaches to more reflective and empowering approaches to healthy eating.

Altogether, exploring the use of the SMH for dietary interventions for people with T2DM may result in new insights that can guide further optimisation of the T2DM care. Despite strong SoC being linked with numerous positive health outcomes, there is a scientific knowledge gap regarding evaluating salutogenic interventions [91]. An important reason for this gap is that Antonovsky did not provide direct guidance on how to operationalize the SMH for developing and evaluating salutogenic interventions [92].

1.3 Aim and outline of the dissertation

The aim of this dissertation is to contribute to the optimisation of health-promoting strategies for people with T2DM by developing and evaluating a salutogenic intervention to enable healthy eating. The salutogenic perspective may broaden the research lens by focussing on the individual context of and the salutary factors that contribute to healthy eating. The salutogenic intervention that has been developed and evaluated in this dissertation is named the Salutogenic Intervention for Type 2 Diabetes (SALUD) programme. The SMH acted as the theoretical underpinning of the SALUD programme's development and evaluation.

The work described in this dissertation is centred around three research objectives:

1. Establish what a salutogenic intervention entails (Chapters 2, 3, 4 and 9).
2. Determine how to develop a salutogenic intervention for healthy eating among people with T2DM (Chapters 5 and 6).
3. Assess the use of a salutogenic intervention for healthy eating among people with T2DM (Chapters 7 and 8).

This dissertation employs a mixed-methods research design, using both quantitative and qualitative research methods. Chapters 2-6 describe the development of the salutogenic intervention presented in this dissertation: the SALUD program. Three different types of explanatory research are used in the development of the SALUD programme: 1) systematic literature review (Chapter 2), 2) qualitative study (Chapter 3) and 3) cross-sectional study (Chapter 4). Chapter 5 describes how the results of Chapter 2-4 have been integrated in a coherent intervention programme via a (qualitative) participatory process. Chapter 6 outlines the study protocol of both the quantitative and qualitative effect evaluation of the SALUD programme.

Chapters 7 and 8 describe the effect evaluation of the SALUD programme on eating practices, health and wellbeing. In Chapter 7, the causal quantitative effects are examined via a randomised controlled trial (RCT) in which the SALUD programme is compared to standard Dutch T2DM care. In Chapter 8, the experiences of and the meaning to the participants of the SALUD programme are examined via a qualitative investigation. Finally, Chapter 9 summarises, discusses and integrates the outcomes of the Chapter 2-8 and reflects upon the implications of science and practice.

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Chapter 2

Developing SALUD: A systematic review of salutogenic-oriented lifestyle programmes

This chapter is published as:

Polhuis CMM, Bouwman LI, Vaandrager L, Soedamah-Muthu SS, Koelen MA. Systematic review of salutogenic-oriented lifestyle randomised controlled trials for adults with type 2 diabetes mellitus (2020). Patient Educ Couns. 2020 Apr;103(4):764-776. doi: 10.1016/j.pec.2019.10.017. Epub 2019 Oct 25.

Abstract

Objective: Describe the characteristics (development, intensity, deliverers, setting, strategies) and assess the effect of salutogenic-oriented lifestyle interventions on physical and psychosocial health outcomes in adults with type 2 diabetes mellitus (T2DM).

Methods: PubMed, Scopus and PsycINFO were systematically searched for randomised controlled trials (RCTs) published up to August 2019 that complied with predefined salutogenic criteria: the participant as a whole, the participant's active involvement and the participant's individual learning process. Characteristics of the salutogenic-oriented interventions with and without significant results were compared and qualitatively summarised.

Results: Twenty-eight RCTs were identified. Salutogenic oriented interventions that significantly improved both physical and psychosocial health were characterized by being based on formative research, culturally targeted, and delivered in 10–20 sessions in group settings, whereas salutogenic oriented interventions that neither improved physical or psychosocial health significantly were characterized by being individually tailored and delivered in less than 10 group sessions in individual settings.

Conclusions: This systematic review suggests that salutogenic-oriented lifestyle interventions are effective for physical and psychosocial health in the short term. More research is needed to determine how intervention characteristics moderate (long-term) effectiveness. The results provide a basis for purposefully developing effective salutogenic interventions for adults with T2DM.

2.1 Introduction

Lifestyle interventions can improve insulin sensitivity and glycaemic control in adults with type 2 diabetes mellitus (T2DM) [1–4]. In some cases, medication can even be stopped if fasting glucose levels normalise to <7 mmol/L [1,3,4]. Yet, sustaining these health effects in everyday life appears to be difficult to achieve employing current lifestyle interventions [5–8]. Standard lifestyle interventions are biomedically oriented and therefore driven by a risk-oriented approach focused on the examination and elimination of general risk factors leading to T2DM, achieved using medication to regulate blood glucose levels and control cardiovascular disease risk control [9]. Most lifestyle interventions are still narrowly focused on glycosylated haemoglobin (HbA_{1c}) and other biomedical health parameters [7,10]. Avoiding physical disease is the central goal, while the mental, social and spiritual dimensions of health are often ignored. Such de-contextualizing interventions ignore the fact that human beings are complicated creatures with complex inner and outer worlds that largely influence why, what, and how we do things in life [11,12]. Consequently, de-contextualisation makes it difficult to adhere to T2DM lifestyle guidelines in everyday life. The fact that increasing numbers of people with T2DM follow (unproven) complementary and/or alternative medicine can be seen as a negative side effect of de-contextualisation [13].

Increasingly, researchers advocate a holistic, patient-centred approach that is respectful of and responsive to the individual preferences, needs, and values of adults with T2DM [14–20]; however, confusion exists about what patient-centredness entails, how it should be accomplished, and how it should be measured [21]. Patient-centredness is still a rather abstract concept, and clear guidance for translating this concept into effective interventions is lacking, making it difficult to develop and implement innovative, patient-centred interventions.

It has been suggested that salutogenesis, a theoretical framework devised by Antonovsky [22], may be useful for guiding patient-centred lifestyle interventions for adults with T2DM [23–28]. Salutogenesis complements current biomedical approaches by adding three principles that may be important for successfully implementing and sustaining healthy behaviours in daily life; the participant as a whole, active involvement and learning.

The participant as a whole

It is often assumed that health is the absence of (physical) disease [29–31]; however, in salutogenesis, health is a complex concept incorporating multiple aspects of wellbeing that relate to the whole person [32,33]. According to Antonovsky, researchers should focus on human beings with T2DM, instead of focusing solely on the disease and its physical health consequences [33]. This necessitates the suggestion of T2DM lifestyle interventions that aim to improve multiple aspects of health and wellbeing, including the physical, mental, social, and spiritual dimensions. For example, depression is common among people with T2DM [34], which can obstruct the

improvement of health using lifestyle interventions [35]. Alternative interventions targeting multiple dimensions of health may therefore be more effective for these people.

The participant's active involvement

Understanding the unique life story and current life situation of adults with T2DM is important for providing meaningful care; however, these are often not taken into account in current interventions [36]. Langeland and Vinje [37] explain the importance of these factors as follows: 'Only in awareness of one's life situation can the resources that contribute to recovery be found, understood and fostered' (p. 300). Indeed, adults with T2DM express a need for more tailored support to self-manage T2DM, which should be meaningful to their everyday life [38,39]. Adjusting lifestyle intervention strategies to the individual's priorities, motivations and capabilities increases the chance of accomplishing meaningful and active participation in the interventions [40] and the successful implementation of newly adopted behaviours in everyday life. This can only be done successfully and respectfully when adults with T2DM are actively involved in the development and determination of their intervention strategies; for example, focus groups involving adults with T2DM can be used to determine the preferred intervention content.

The participant's individual learning process

Salutogenesis complements traditional information-providing approaches by supporting individuals in a learning process to develop self-identity. Antonovsky regarded self-identity as a crucial resource for coping as the image one has of oneself influences one's relationship with the world ([22]; 109–110). A learning process focussed on self-identify may lead to the discovery of individual internal and external resources that can be used to facilitate coping with T2DM-specific challenges, including the physiological defects, psychological consequences and implementation of structural changes in daily routines. Incorporating sessions dedicated to self-examination and coping in T2DM lifestyle interventions, such as through the use of narrative therapy (i.e., listening to the participant's experience and narrative identity in an open, accepting manner), may strengthen self-identity [41].

The aim of this review is to describe the characteristics and assess the effectiveness of randomised controlled trials (RCTs) comparing salutogenic-oriented lifestyle interventions (SOIs) with the usual care of adults with T2DM. The systematic literature search is based on inclusion criteria derived from the described salutogenic principles. The literature was not searched for RCTs based directly on salutogenesis because only one such study could be identified [42]. The results are used to more clearly define the (moderators of) effective patient-centred T2DM lifestyle interventions that could be used to develop salutogenic T2DM lifestyle interventions. To our knowledge, this is the first review translating salutogenic principles into selection criteria and applying them systematically to the current T2DM evidence base.

2.2 Methods

Search strategy

The systematic review was performed in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses [43]. The search strategies were based on the following key concepts and their corresponding synonyms: 1) type 2 diabetes mellitus, 2) lifestyle, 3) randomised controlled trial, 4) psychosocial health and 5) physiological health. As an example, the exact PubMed search strategy is provided in the supplementary materials (**Table A.1**). The literature search was continuously updated until 16th August 2019. Reference lists from relevant articles and reviews were manually searched for potentially relevant citations not detected by the electronic searches. All authors were involved in the development of the salutogenic criteria and search strategy, and were continuously consulted throughout the selection and analysis process. The execution of the search, selection and quality assessment processes were completed by CMMP.

Study selection

From salutogenic principles to inclusion criteria

Only RCTs that incorporated the three salutogenic principles (to a certain extent) were included. **Table 2.1** provides an overview of how the theoretical salutogenic principles were translated into inclusion criteria. These specific salutogenic inclusion criteria were determined based on the consultation of several literature sources (including [32,33,44,45]) and several discussions between the authors.

Table 2.1 The translation of salutogenic principles into inclusion criteria.

Salutogenic principle	Explanation	Inclusion criteria
The participant as a whole	Physical, mental, social and spiritual health are equally important, and all domains interact with one another	RCTs are included if they evaluated at least one physical and one psychosocial health outcome
The participant's active involvement	Adults with T2DM are involved in determining individual intervention strategies	RCTs are included if they explicitly described how the adults with T2DM were involved in the development of the intervention and/or the determination of individual intervention strategies
The participant's individual learning process	An individual's learning process leads to the discovery of resources and self-examination that facilitate their coping with the everyday challenges of living with T2DM	RCTs are included if they included sessions dedicated to self-examination and coping

Inclusion and exclusion criteria

Besides the three salutogenic criteria, studies were also selected based on criteria regarding the publication type, study design, population, control, development, strategy and outcomes (**Table 2.2**).

Table 2.2 Overview of all the inclusion and exclusion criteria for selecting articles.

Criteria	Included	Excluded
Publication type	1) Articles in English 2) Full-text available 3) Original study	1) Articles not in English 2) Full text not available 3) Book chapters, editorials, conference papers, opinion papers, letters
Study design	1) RCTs	1) Observational studies 2) Qualitative studies 3) Reviews 4) Meta-analyses 5) Non-randomized interventions 6) Non-controlled interventions
Population	1) Adults (>18 years) officially diagnosed with T2DM without severe (physical or mental) health complications	1) Adults with other types of diabetes (e.g. type 1, gestational) 2) Adults at risk of diabetes (e.g. prediabetes, metabolic syndrome) 3) Children/adolescents (<18 years) 4) Adults with T2DM with severe physical health complications (e.g. CVD, renal diseases, cancer) 5) Adults with severe mental diseases (e.g. schizophrenia, bipolar-disease, severe/clinical depression) 6) Pregnant women 7) Cognitively impaired adults
Control	1) RCTs that compared the intervention with a control receiving usual care[1]	1) RCTs that compared the intervention with other types of interventions/treatments 2) RCTs that compared the intervention with enhanced usual care[2] 3) RCTs that did not describe the control condition
Intervention development	1) RCTs that explicitly described how adults with T2DM were involved in development of the intervention and/or determination of intervention strategies	1) RCTs adopting a top-down approach (e.g. interventionists/deliverers determine intervention strategies) 2) RCTs that did not describe development of the intervention strategy
Intervention strategy	1) RCTs that included sessions dedicated to self-examination and coping	1) Pharmacological or surgical interventions 2) Lifestyle interventions using behavioural-oriented and/or traditional didactic strategies 3) RCTs evaluating cost-effectiveness of intervention 4) Interventions aiming to improve non-lifestyle-related matters (e.g. to treat alcohol abuse, to improve sleep quality)
Outcomes	1) RCTs that measured at least one physical and one psychosocial health outcome	1) RCTs that measured health outcomes in only one health dimension 2) RCTs with only behavioural outcomes (e.g. self-management behaviours) and/or cognitive outcomes (e.g. knowledge level)

[1] Usual care = care representative for standard medical treatment for T2DM in the concerning county/area.
[2] Enhanced usual care = care representative for standard medical treatment for T2DM in the concerning county/area combined with extra diet, education or mental guidance

Quality assessment

Quality was assessed using a quality assessment tool for quantitative studies (EPHPP) [46]. Nine studies were assessed as "strong", 11 as "moderate", and eight as "weak" (supplementary materials, **Table B.1**). Studies were not excluded based on quality, but the quality of the evidence was taken into account in the data synthesis.

Data extraction

Information extracted on the study characteristics described in **Table 2.3**

Table 2.3 Explanation of the information extracted from the RCTs.

Characteristic	Data extracted
Study population	Mean age, country, sample size, N% female and specific recruitment conditions.
Intervention development	Theoretical framework(s) and methods of involving participants during the intervention development process.
Intervention strategies	Description of overall intervention content and self-examination strategies, delivery setting, deliverer(s), delivery fidelity, intervention intensity and follow-up period.
Outcomes	The physical and psychosocial health outcomes measured closest to the end of the intervention were extracted, as well as the outcomes measured in a follow-up period, where available (mean±SD or mean±SE or mean±95% CI, and corresponding significance levels). To provide a clear overview the psychosocial health outcomes, the 90 different concepts were clustered into 15 categories (supplementary materials, **Table C.1**). For example, the QoL category covers general and diabetes-specific QoL measurements. Cognitive measures (e.g., knowledge level) and behavioural measures (e.g., performing self-management behaviours) were not extracted.

Note 1. Physical health outcomes were defined as measures indicating body composition (e.g., body mass index (BMI)), metabolic health (e.g., blood pressure), or T2DM severity (e.g., HbA_{1c}).
Note 2. Psychosocial health outcomes were defined as measures indicating (positive or negative) wellbeing (e.g., quality of life (QoL)), perceived control over life and/or disease (e.g., self-efficacy), and social health (e.g., social support).

Data synthesis

The research aim, search string and selection criteria were decided upon a priori. The initial plan to perform a meta-analysis was not possible due to the substantial differences observed in the definitions of variables, measurement methods, time of outcome assessment, intervention contents and contexts; therefore, the present data synthesis was decided upon a posteriori. The data synthesis used was inspired by R.E. Slavin's ideas on Best-Evidence Synthesis [47]. First, the study population, general intervention characteristics, and realisation of the three salutogenic principles among the SOIs were described. Second, physical and psychosocial health outcomes were displayed (significant when $p < 0.05$) and the effectiveness of the SOIs with a moderate to strong quality ($n = 20$) was assessed by calculating the effect sizes for each physical and psychosocial health outcome. An overall effect-assessment was given to each RCT based on the following criteria [48]:

- Small effect: >50% of the outcomes had an effect size of 0.50.
- Medium effect: >50% of the outcomes had an effect size of 0.50–0.80.
- Large effect: >50% of the outcomes had an effect size of >0.80. Finally, the characteristics of the SOIs with significant results for both physical and psychosocial health and those with no significant results for either physical or psychosocial health were compared and qualitatively summarised.

2.3 Results

Description of the search

Figure 2.1 provides an overview of the article selection procedure and the reasons for exclusion. The search resulted in the identification of 3591 articles. After the removal of duplicates, title, abstract and full-text screening, and the checking of reviews for relevant references, 28 RCTs were included in the final analysis. Most studies were excluded based on study design. All of the included RCTs were published between 2004 and 2018.

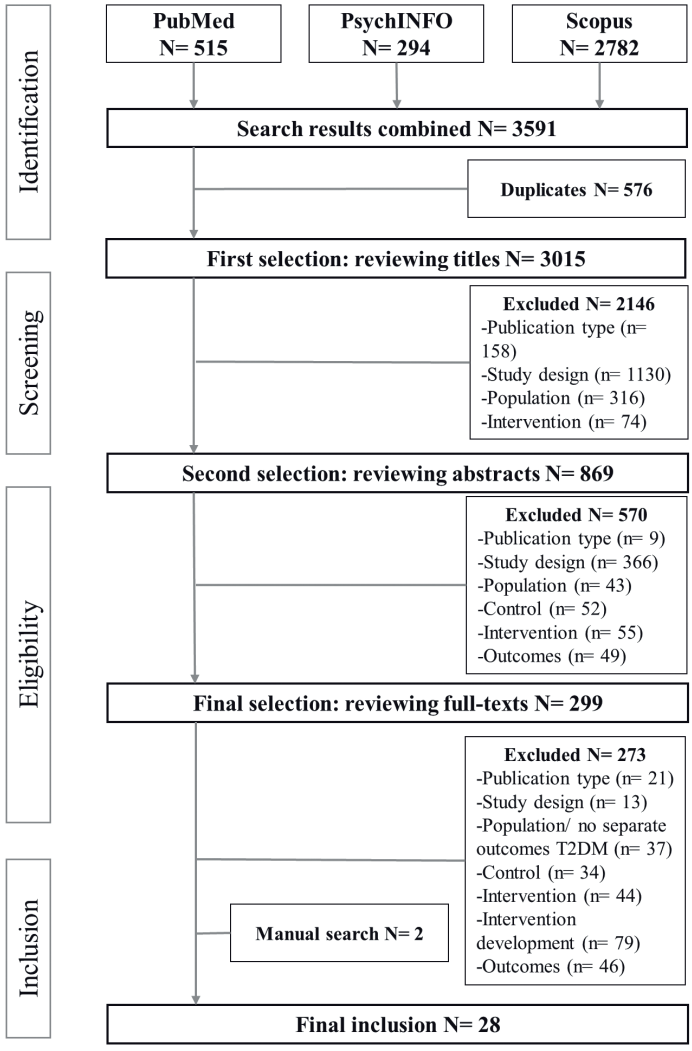

Figure. 2.1 Preferred reporting items for systematic reviews and the meta-analysis flowchart. See **Table 2.2** for a detailed explanation of the reasons for exclusion based on publication type, study design, population, control, intervention development, intervention strategy and outcomes.

General characteristics

Study population

Sample size used in the RCTs varied from 25 to 668 participants, with an average of 174 (SD = 147). Most SOIs were conducted in the USA [49,50,59–61,51–58], followed by Europe [62–68], Asia [69–75] and Australia [76]. The mean age of the study population was >50 for all studies except one [53]. RCTs recruited participants for the SOIs on the basis of age (>40 years) [56,62,70,73], poor glycaemic control (>7.5% HbA_{1c}) [50,51,54,56,61,63,65,66,69,73], low SES [50–53,55–57,59,63], and/or specific ethnicity or culture [51,51,52,53,55,56,59]. The average N% female was 59 (SD = 21), although in two RCTs, the gender distribution was unknown [56,74].

Intervention characteristics

Intervention intensity. The average number of sessions was 12.84 (SD= 19.08). Most SOIs involved between five and 10 sessions [52,56,76,58,61,62,66,68,70–72]. The average duration was 30.21 (SD= 25.51) weeks, with most SOIs lasting for >20 weeks [49,50,63–65,67,70,71,75,51,53,55–57,60–62]. The average contact time (i.e., number of sessions x session duration) was 19.40 (SD= 27.73) hours, with most having >10 h contact time [51,52,74,75,54,55,58,59,67–69,72].

Theoretical framework. 19 SOIs were based on a theoretical framework [49,51,66–69,71–75,52,54,56,57,59,61,62,65]. Most used a theoretical framework that focused on the process of people gaining empowerment (empowerment theory [57,62,66,67,73,74]) and on expectations of confidence in one's ability to take action (social cognitive theory [54,59,68,72], self-efficacy theory [69,71]).

Single vs. multicomponent. Six SOIs were single-component interventions, meaning that collaborative goal-setting was the only intervention strategy used [50,57,63,65,70,73]. The rest were multicomponent, meaning that collaborative goal-setting was combined with at least one other strategy, including education [51,52,66–69,71,72,74–76,53,54,56,58–62], self-monitoring blood glucose (SMBG) [49,51,53,59,62,64,74], nutritional therapy [49,52,55,58–60,74], stress management [52,55,58–61] and/or exercise therapy [49,55].

Delivery setting. The SOIs were delivered in a group setting [49,52,54,55,58,67–69,72,74], an individual setting [50,53,69,70,73,56,57,60,61,63–66], or in a combination of both [51,55,59,62,71]. Individual SOIs mostly combined in-person sessions with phone calls, except for two delivered solely over the phone [60,69] and one delivered solely in-person [64]. In two SOIs, the setting was determined by the participant's preference [62,76].

Deliverers. SOIs were delivered by medical health professionals [49,53,69,56,57,61,62,64,66–68], a multidisciplinary team [51,55,59,63,70,72,75], community health workers (CHWs) [50,52,71,74], peers [54,58], researchers [73,76] and mental health professionals [60,65]. The

multidisciplinary teams consisted of either medical professionals and CHWs/peers [51,55,59,75], medical and mental health professionals [70,72], or CHWs and peers [63].

Delivery fidelity. Fidelity was guaranteed by **1)** the training of the deliverers by the research team, (medical) experts, or special skill training [49,50,63–65,67,68,70,71,73–75,52,76,54,56–60,62]; **2)** the assessment of the deliverers' competence via video or audiotaped sessions [50,51 ,53,54,56,58,64,65,67,74]; 3) the supervision of the deliverers by the research team during the intervention [50–52,56,58,67,76]; and/or 4) an intervention manual [52,54,58,59,68,70,75]. Seven SOIs used only training [49,57,60,62,63,71,73], while the other three methods were always combined with at least one other method. In five SOIs, it was unknown whether and how delivery fidelity was ensured [55,61,66,69,72].

Follow-up period. Less than half of the RCTs included an intervention-free follow-up period [52,58,59,62,66–68,72,73,76]. The follow-up periods ranged from 12 to 96 weeks. The outcomes that were reassessed varied; some reassessed all outcomes [59,62,66,76], whereas others reassessed only HbA_{1c} [52,68,72,73]. One RCT reassessed the health outcomes of the intervention group only [58].

Realisation of the salutogenic principles

The participant as a whole

Health assessment. Physical health outcomes were the primary outcomes in most SOIs [49 ,50,74,51,53,54,62,66,67,70,73], with HbA_{1c} being the most commonly measured physical health outcome (n = 27; supplementary materials, **Table D.1**). Psychosocial health outcomes were the primary outcomes in ([71,75]), with self-efficacy being the most commonly measured psychosocial health outcome (n = 16; supplementary materials, **Table E.1**). Both physical and psychosocial health outcomes were the primary outcomes in ([52,55,56,61,63–65,68,76].) In ([69]), physical and psychosocial health measures were both secondary outcomes. In ([58–60,72]), it was unclear whether the health outcomes were primary or secondary outcomes.

The participant's active involvement

Three strategies to actively involve participants in the development of interventions strategies were identified:

1. Formative research (both quantitative and qualitative) was used for intervention development in 13 SOIs [49,51,74,75,53–55, 58,59,68,71,72], either to align interventions with the patient priorities, preferred topics and opinions on how they want to work on their health [49,53,55,59,68,72,75]; to align them with specific cultures [49,51,53–55,59,72,74]; or to align them with learning styles [59]. Formative research was also used to provide inputs on

intervention feasibility, format, and delivery [54,55,59,75], as well as educational content [59,71,74].

2. Pre-testing the intervention and adjusting it according to participant feedback featured in seven SOIs [51,52,55,61,64,68,69]. This led to modifications of the exercises, communication strategies, teaching methods [51,52,55,68], and/or tools and measurement instruments [52,69]. Pre-testing identified both important aspects to make the intervention more culturally sensitive [52] and processes that influence the implementation of lifestyle changes in daily life [61].
3. In a few SOIs [56,58,64], an exact explanation of the usage of the formative research, pilot-testing, and/or tailoring was either not given or was rather vague.

The participant's individual learning process

Three strategies that potentially facilitated self-examination and self-reflection were identified:

1. Collaborative goal-setting was used in all SOIs. Goal-setting can be seen as a direct strategy for enhancing self-examination. In general, the interventionists guided the participants in setting their own personal realistic goals and strategies or action plans for reaching these goals. In the majority of the SOIs, individual goal-setting was limited to self-management goals (i.e., goal-setting for healthy nutrition, exercise, SMBG, medication adherence and foot care). A total of 11 SOIs used individualised self-management plans as a tool for goal-setting, which were revised if necessary at every subsequent session [50,57,75,58,61–65,69,73]. In some SOIs, goal-setting was further delimited to only one facet of T2DM self-management (e.g., body weight [49]). Few SOIs allowed for goal-setting in other domains, such as goals for managing stress and depression [60,76] and reframing life's adversities within a more positive perspective [51]. Group sharing of experiences, feelings, and progress towards goals was part of the intervention in 12 SOIs [49,51,74,75,54,58,59,65,68,69,71,72]. In three of these, family members were involved [49,65,69]. Motivational counselling was used for goal-setting in 11 SOIs [50,51,73,56,60,64,65 ,69–72]. Fewer than half of the SOIs clearly explained that the reflection upon and revision of goals was part of goal-setting [50,52,75,76,54,60,64,66–69,71]; however, in most of these, reflection again related only to self-management, with few offering participants room for reflection on their feelings about life with T2DM and distress [60,66,76].
2. SMBG enables examination of the interactions between the body, behaviour and mental state. Participants were encouraged to SMBG at home on a regular basis in seven SOIs [49,51,53,59,62,64,74]. Some provided SMBG devices at the beginning of the intervention. SMBG values were commonly used as the starting point for evaluating personal goals.
3. Stress management therapy has the potential to stimulate self-examination. It was part of the SOI in six RCTs [52,55,58–61]. These exercises included: mindfulness, guided meditation, breathing exercises, body-scan exercises, thermal biofeedback, yoga, progressive deep relaxation and receptive imagery [52,55]. Two SOIs offered professional psychosocial support for stress management therapy [60,61].

Three strategies for enhancing T2DM-specific coping resources were identified:

1. Education on T2DM and self-management can be a valuable resource for coping with the practical and emotional aspects of T2DM. Education was part of the SOI in 19 RCTs [51,52,66–69, 71,72,74–76,53,54,56,58–62]. Most SOIs stressed that education was delivered interactively (e.g. [71],) and was based on the priorities of the group/individual (e.g. [61,72],).
2. Nutritional therapy can strengthen food and cooking resources, making it easier to cope with T2DM nutritional guidelines. Various nutritional therapies were used as part of the SOI in seven RCTs [49,52,55,58–60,74], including the provision of a certain diet, offering personalised dietary advice, cooking classes, and help with reading food labels and buying healthy foods.
3. Exercise therapy includes guiding, monitoring, and motivating exercise behaviour, which may develop/strengthen resources important for implementing and maintaining exercise in everyday life. Two SOIs included exercise therapy [49,55]. One ([55]) recommended 30 min of moderate aerobic activity most days per week and the performance of 10 strength-training exercises twice a week, while the other ([49]) encouraged exercise by providing incentives that could be redeemed for items.

Data synthesis

Effect sizes

In **Table 2.4**, the physical and psychosocial health outcomes of each SOI are displayed with the corresponding effect sizes. Twelve SOIs had a small effect, two a small-medium effect, two a small-large effect, and two a large effect. There was a large variation in how many and which types of outcomes were measured.

Table 2.4 Effect sizes of the physical and psychosocial outcomes used in each SOI.

SOI		Significant physical health outcome(s) with effect size(s)	Non-significant physical health outcome(s) with effect size(s)	Significant psychosocial health outcome(s) with effect size(s)	Non-significant psychosocial health outcome(s) with effect size(s)	Overall effect
Nelson et al. 2017	[50]		HbA_{1c} 0.08% BMI 0.18 kg/m^2 SBP 0.05 mmHg DBP 0.08 mmHg TC:HDL 0.12	Social burden 0.19	Phys. QoL 0.14 Psych. Qol 0.05 Diabetes-specific QoL 0.14	Small effect
Samuel-Hodge et al. 2017	[49]	HbA_{1c} 0.82% BMI 1.53 kg/m^2 BW 1.45 kg	SBP 0.16 mmHg DBP 0.49 mmHg	Depressive symptoms 1.11 Perceived diabetes control 0.76 Family support for diet 0.76 Family support for physical activity 1.01 Family cohesion 0.9	Phys. QoL 0.28 Psych. QoL 0.07 Family problem-solving communication 0.58 Unresolved family diabetes conflict 0.77	Large effect
Wichit et al. 2017	[69]		HbA_{1c} 0.23%	Diabetes-specific SE 1.35 Perceived therapeutic efficacy 1.06	Phys. QoL 0.08 Psych. QoL 0.55	Small-large effect*
Browning et al. 2016	[70]		HbA_{1c} 0.07% FBG 0.07 mmol/dL BMI 0.09 kg/m^2 BW 0.08 kg WC_{men} 0.47 cm WC_{women} 0.09 cm HC_{men} 0.2 cm HC_{women} 0.06 cm SBP 0.29 mmHg DBP 0.1 mmHg LDL 0.1 mmol/L HDL_{men} 0.13 mmol/L HDL_{women} 0.15 mmol/L TC 0.13 mmol/L TG 0.04 mmol/L	Psychological distress 0.19	Phys. QoL 0.03 Psych. QoL 0.08 Social-relationship QoL 0.08 Environment QoL 0.01 Diabetes-specific SE 0.01	Small effect
Kim et al. 2015	[51]	HbA_{1c} 0.59% FBG 0.47% LDL 0.02 mg/dL TC 0.07 mg/dL	SBP 0.11 mg/dL DBP 0.24 mg/dL HDL 0.11 mg/dL TG 0.04 mg/dL	Diabetes-specific QoL0.94 Depression 0.17 Diabetes-specific SE 0.61	Attitude toward diabetes 0.51	Small effect

SOI		Significant physical health outcome(s) with effect size(s)	Non-significant physical health outcome(s) with effect size(s)	Significant psychosocial health outcome(s) with effect size(s)	Non-significant psychosocial health outcome(s) with effect size(s)	Overall effect
Protheroe et al. 2016	[63]		HbA_{1c} 0.41		QoL 0.26 Diabetes-specific QoL 0.00 Health status *Physical 0.05* *Mental 0.32* Wellbeing 0.18 Illness perceptions 0.07	-
Shakibazadeh et al. 2016	[72]	HbA_{1c} 0.42%		Diabetes-specific SE 1.25 Health beliefs 0.89 Attitude *Positive 0.91* *Negative 0.3* Patient-satisfaction 0.87 Stigma 0.41	Depression 0.08	Small-large effect
Wagner et al. 2016	[52]		HbA_{1c} 0.02% UC 0.01	Depressive symptoms 0.09 Anxiety symptoms 0.08	Diabetes distress 0.00 Self-reported health 0.05	Small effect
Chen et al. 2015	[73]		HbA_{1c} 0.4%	Diabetes-specific QoL1.07 Diabetes-specific SE 1.0		Large effect
Garcia et al. 2015	[53]	TC 0.69 mg/dL Total symptoms 0.46 number	HbA_{1c} 0.00% SBP 0.11 mmHg DBP 0.16 mmHg LDL 0.53 mg/dL HDL 0.05 mg/dL TG 0.38 mg/dL	Diabetes-specific SE 0.67	Diabetes-specific QoL 0.26	Small effect
Karhula et al. 2015	[64]	WC 0.46 cm	HbA_{1c} 0.17% BW 0.15 kg SBP 0.02 mmHg DBP –0.8 mmHg LDL –0.06 mg/dL HDL –0.03 mg/dL TC –0.11 mg/dL TG 2.11 mg/dL		QoL *Phys. 0.12* *Psych. –4.2* *Phys. functioning 0.06* *Mental health 0.08* *Role-physical 0.00* *Bodily pain 0.14* *Soc. functioning 0.17* *General health 0.2* *Vitality 0.22* *Role-emotional 0.34*	Small effect

SOI		Significant physical health outcome(s) with effect size(s)	Non-significant physical health outcome(s) with effect size(s)	Significant psychosocial health outcome(s) with effect size(s)	Non-significant psychosocial health outcome(s) with effect size(s)	Overall effect
Sinclair et al. 2013	[54]	HbA_{1c} 0.13%			Diabetes distress 0.02	Small effect
Keogh et al. 2011	[65]	HbA_{1c} 0.33%	BMI 0.45 kg/m^2 SBP 0.21 mmHg DBP 0.16 mmHg	Wellbeing *Negative 0.47* *Positive 0.88* *Energy 1.16* *General 1.02* Diabetes-specific SE 1.07 Illness perception *Personal control 0.81* *Treatment control 0.59* *Symptoms 0.55* *Concern 0.67* *Understanding 0.89* *Emotional rep. 0.62* *Family support 0.54* *Non-support 0.44*	Illness perceptions *Consequences 0.52* *Timeline 0.28*	Small-medium effect**
Toobert et al. 2011	[55]	HbA_{1c} 0.33% BMI 0.4 kg/m^2		Problem-solving ability 0.75	SE 0.00 Social support 0.75	Small-medium effect**
Wolever et al. 2011	[60]		HbA_{1c} 0.27%	SE 0.72 Social support 0.2 Benefit finding 0.5	QoL 0.24 Perceived stress 0.34 Appraisal of diabetes 0.74	Small effect
Anderson et al. 2009	[57]	HbA_{1c} 0.15%		Diabetes-specific QoL 0.15 Diabetes-specific SE 0.08 Satisfaction with care 0.2	Depressive symptoms 0.12 Instrumental diabetes self-management SE 0.05	Small effect
Lorig et al. 2009	[58]		HbA_{1c} 0.07% BW 0.02 kg	Depression 0.47 Diabetes-specific SE 0.38 Patient activation 0.18	Fatigue 0.15 Self-rated health 0.13	Small effect
Sigurdardottir et al. 2009	[66]		HbA_{1c} 0.26% BMI 0.14 kg/m^2 BW 0.44 kg WC 0.5 cm		Wellbeing 0.00 Diabetes distress 0.01 Empowerment 0.58	-
Adolfsson et al. 2007	[67]		HbA_{1c} 0.08% BMI 0.27 kg/m^2	Confidence in diabetes knowledge***	Diabetes-specific SE*** Satisfaction with daily life***	Small effect

SOI		Significant physical health outcome(s) with effect size(s)	Non-significant physical health outcome(s) with effect size(s)	Significant psychosocial health outcome(s) with effect size(s)	Non-significant psychosocial health outcome(s) with effect size(s)	Overall effect
Whittemore et al. 2004	[61]		HbA_{1c} 0.00% BMI 0.27 kg/m^2	Distress 0.19 Integration 0.42 Treatment satisfaction 2.1		Small effect

Note 1. Only SOIs with a moderate-to-strong quality were included in this table. Note 2. Categorisation based on reported statistical significance level of 0.05. Note 3. Effect sizes were calculated based on the achieved means after intervention as provided in the studies. Calculations of the effect sizes were based on previous literature ([77]). Only studies with statistical significant outcomes were given an overall effect assessment. Overall effect assessments include: small effect (>50% of the outcomes have an effect sizes ≤0.50); medium effect (>50% of the outcomes have an effect size between 0.50-0.80); and large effect (>50% of the outcomes have an effect size >0.80). Note 4. HbA_{1c} = glycated haemoglobin; FBG = fasting blood glucose; BMI = body mass index; BW = body weight; WC = waist circumference; SBP = systolic blood pressure; DBP = diastolic blood pressure; LDL = low-density lipoprotein cholesterol; HDL = high-density lipoprotein cholesterol; TC = total cholesterol; TG = triglycerides; UC = urinary cortisol; A:C = albumin to creatine ratio; TS = total symptoms; SS = symptoms severity; QoL = quality of life; SE = self-efficacy. Note 5. Effect sizes of psychosocial outcomes are expressed in the scores of the measurement instruments. Measurement instruments for each psychosocial outcome can be found in Table C.1 in the supplementary materials.
*Small-large effect: of the total of five outcomes, two outcomes had a large effect, and two had a small effect.
**Small-medium effect: equal number of outcomes with a small and medium effect.
***Effect sizes for these outcomes could not be calculated.

Table 2.5 shows that seven SOIs reported significant results in both physical and psychosocial health (hereafter referred to as effective SOIs), two reported significant results in physical health, nine reported significant results in psychosocial health, and two reported no significant results (hereafter referred to as non-effective SOIs). The effect sizes of the effective SOIs varied from small to large, while the effects of the non-effective SOIs were small.

Table 2.5 Categorisation of SOIs based on the significant results in physical and psychosocial health.

	Significant result(s) in psychosocial health	**No significant result(s) in psychosocial health**
Significant result(s) in physical health	Garcia et al. 2015 [53] Anderson et al. 2009 [57] Kim et al. 2015 [51] Shakibazadeh et al. 2016 [72] Keogh et al. 2011 [65] Toobert et al. 2011 [55] Samuel-Hodge et al. 2017 [49]	Karhula et al. 2015 [64] Sinclair et al. 2013 [54]
No significant result(s) in physical health	Nelson et al. 2017 [50] Browning et al. 2016 [70] Wagner et al. 2016 [52] Wolever et al. 2011 [60] Lorig et al. 2009 [58] Adolfsson et al. 2007 [67] Whittemore et al. 2004 [61] Wichit et al. 2017 [69] Chen et al. 2015 [73]	Protheroe et al. 2016 [63] Sigurdardottir et al. 2009 [66]

Note. Only SOIs with a moderate-to-strong quality were included in this table.

Comparison of effective and non-effective SOIs

In **Table 2.6**, the seven effective and two non-effective SOIs are compared in terms of the study population, intervention characteristics, and the salutogenic criteria. Although there were fewer non-effective than effective SOIs, six differences were notable:

1. Most effective SOIs were performed in North America [47,52,54,56,58] and were culturally targeted [47,52,54,56,70], whereas the non-effective SOIs were mostly performed in Europe and were not culturally targeted [61,64].
2. Effective SOIs typically had 2:10 sessions [47,52,54,56,58,70] and >20 h of contact time [47,52,56,70], whereas all non-effective SOIs had <10 sessions and <10 h of contact time [61,64].
3. Most effective SOIs were group-based [47,52,56,70], whereas the non-effective SOIs were individually delivered [61,64]. Accordingly, the group sharing of experiences was a common part of goal-setting in the effective SOIs, whereas the non-effective SOIs were focused mostly on individualised self-management plans.
4. The effective SOIs measured self-efficacy [52,54,56,58,63,70], whereas none of the non-effective SOIs measured self-efficacy.
5. Most of the effective SOIs used formative research to involve patients in intervention development [47,52,54,56,70], whereas non-effective SOIs tailored the intervention

strategy to individual priorities at the baseline [61,64].

6. Many effective SOIs implemented SMBG [47,52,54], whereas the non-effective SOIs did not.

Table 2.6 Comparison of effective and non-effective SOIs.

Characteristics			**Effective SOIs (n = 7)**	**Non-effective SOIs (n = 2)**
General characteristics	Study population	*Sample size (mean*±SD)	203 ± 85.5	67 ± 9.00
		Country	USA (n = 5/7)	European (n = 2/2)
		Sex	> 50% female (n = 4/7)	> 50% male (n = 2/2)
		Health condition	Poor control (2/7) Overweight (1/7)	Poor control (n = 2/2)
		Low SES	Yes (4/7)	Yes (n = 1/ 2)
		Ethnicity/culture	Latino-Americans (n = 2/7) African-Americans (n = 1/7) Korean-Americans (n = 1/7)	- (n = 0/2)
	Intervention characteristics	*Sessions (number)*	10–20 (n = 5/7)	0–10 (n = 2/2)
		Contact time (h)	> 20 (n = 4/7)	< 10 (n = 2/2)
		Duration (week)	> 24 (n = 4/7)	< 24 (n = 2/2)
		Follow-up period	No (n = 6/7)	No (n = 1/1)
		Multi/single component	Multicomponent (goal-setting, education, SMBG) (n = 5/7)	Multicomponent (goal-setting, education) (n = 1/2)
		Delivery setting	Group (n = 5/7)	Individual (n = 2/2)
		Deliverers	One type of deliverer (n = 3/4)	One type of deliverer (n = 1/2)
		Delivery fidelity	> 1 delivery fidelity method (n = 2/7)	> 1 delivery fidelity method (n =1/2)
Salutogenic principles	The participant as a whole	*Use of theory*	Yes (n = 5/7)	Yes (n = 1/2)
		Physical health outcome	HbA_{1c} (n = 7/7)	HbA_{1c} (n = 2/2)
		Psychosocial health outcome	Self-efficacy (n = 6/7)	Wellbeing (n = 2/2)
	The participant's active involvement	*Participant involvement*	Formative research (n = 5/7) Pre-testing (n = 2/7) Tailoring (n = 2/7)	Tailoring n = 2/2)
		Culturally sensitive	Yes (n = 4/7)	No (n = 2/2)
	The participant's individual learning process	*Self-examination strategies*	Collaborative goal-setting (n = 7/7) SMBG (n= 3/7) Stress-management (n =1/7)	Collaborative goal-setting (n = 2/2)
		Enhancing coping resources	Education (n = 4/7) Nutritional therapy (n = 2/7) Exercise therapy (n = 2/7)	Education (n = 1/2)

2.4 Discussion and conclusion

Discussion

In this systematic review, 28 RCTs were identified that complied with predefined salutogenic principles. The characteristics of the effective SOIs included: 1) development based on formative research, 2) culturally targeted, and 3) delivered in 10–20 sessions 4) in group settings (**Table 2.6**). The magnitude of the effective SOIs varied from small to large effects (**Table 2.4**). To decide whether salutogenesis is useful for T2DM lifestyle interventions, it is important to reflect on the use of the salutogenic criteria and consider the extent to which the SOIs were developed, executed, and evaluated in line with true salutogenic thought. The realisation of the salutogenic principles and differences between effective and non-effective SOIs are discussed below.

The participant as a whole

It was assumed that, when both physical and psychosocial health outcomes were measured, these outcomes were also taken into consideration in the development of the interventions. Indeed, this assumption could have led to the inclusion of interventions that were not necessarily designed to improve multiple health dimensions; however, limited and poor descriptions made it difficult to assess whether and to what extent an intervention was specifically targeted to certain outcomes. HbA_{1c} was the primary outcome in most RCTs, suggesting a stronger focus on physical than psychosocial health, whereas true salutogenic interventions would be specifically designed to improve multiple health dimensions. Future (salutogenic) interventions should include a detailed content description and argumentation for the chosen outcomes.

Furthermore, there was large variation in how many and which types of outcomes were measured, especially regarding psychosocial health, making a fair comparison difficult. HbA_{1c} is a valid marker for physical health [78], but valid markers for psychosocial health in T2DM are less straightforward. In addition, there was great heterogeneity in the definitions and instruments used for psychosocial health, making the comparison of intervention effects even more problematic. For example, diabetes-specific QoL and diabetes distress were both measured with the Problem Areas in Diabetes scale, and five different instruments were used to measure diabetes-specific QoL (supplementary materials, **Table C.1**). Similar methodological issues regarding incoherent definitions of psychosocial health concepts and ways to measure these were also observed in two recent systematic reviews on obesity [79,80]. Evidently, there is a need for standardised and validated instruments to lower heterogeneity; however, given that psychosocial health is complex, quantitative measures alone may not be sufficient for its evaluation. A combination of quantitative and qualitative measures may aid the interpretation of psychosocial health in the context of everyday life.

The participant's active involvement

Different strategies to actively involve participants in the intervention development process were

observed, including formative research, pre-testing, and tailoring to individual priorities. Most of the effective SOIs used formative research, whereas all non-effective SOIs tailored the intervention (**Table 2.6**). Formative research in the effective SOIs involved focus groups and/or interviews with people with T2DM. All allowed adults with T2DM to co-create the intervention to some extent: from deciding which issues should be addressed [49], to deciding on the contents, frequency and format [55]. Co-created interventions may be more effective than tailored interventions because they force academics to work alongside adults with T2DM. This foregrounds the localized, lived experiences of T2DM making interventions meaningful to everyday life. Although research is limited, some recent studies using the PRECEDE-PROCEED model[2] in T2DM showed promising results for psychosocial health [81] and self-management [82–84][3] . Unlike the SOIs included in this review, the formative research in these studies consisted of questionnaires measuring predisposing, enabling and reinforcing factors [82–84]. Formative research has the potential for high societal impact [85]; however, more research is needed to determine which formative research strategies – quantitative, qualitative, or combined – are optimal.

The non-effective SOIs tailored the intervention to each patient at baseline. Tailoring has been found to be only marginally successful for improving physical health and self-management behaviours in individuals with chronic diseases [8,86]; however, successful tailoring is complex because numerous factors may moderate the health effects [87]. For example, tailoring on multiple levels (theoretical concepts, behaviour and demographics) seems to be more successful than single-level tailoring [87]. It was sometimes difficult to determine the exact amount of tailoring that had been used. Generally, the studies were tailored in response to patient behaviours, which might have been more effective if it was combined with tailoring based on theoretical concepts, including attitudes, self-efficacy, stage/process of change and social support [87,88]. In addition, only one of the SOIs described tailoring as being based on an individual's personal history with T2DM [61], whereas an understanding of someone's life history and lived experiences with T2DM are considered to be important starting points for health promotion using salutogenic interventions [42,89]. The future tailoring of interventions should involve all these aspects.

The participant's individual learning process

Collaborative goal-setting is widely recommended and used in T2DM interventions [90,91] and it seems to be more effective when delivered in multi-component interventions [5,10]. Despite this knowledge, research is still inconclusive about the effectiveness of any particular intervention strategy for managing T2DM [8,10,92]. Both effective and non-effective SOIs applied goal-setting and were mostly multicomponent (**Table 2.6**); therefore, what may have caused the differences in their effectiveness?

2 A model in which participants are involved in each stage of the development, implementation and evaluation of an intervention [103].

3 These studies were not included as they did not fulfil all our inclusion criteria.

First, goal-setting was focused on individualised self-management plans in all non-effective SOIs, whereas most effective SOIs combined this more generally with the group sharing of experiences. This might be a crucial difference, because social support is a vital coping resource according to salutogenesis [22]. Receiving and providing high-quality social support leads to experiences of emotional closeness that enhance self-identity and strengthen meaningfulness in everyday life [22,93–95]. On the other hand, a recent meta-analysis showed that both individual and group delivery are beneficial for improving HbA_{1c} [10]; however, social peer support seems particularly beneficial for adults with T2DM in socially disadvantaged situations [10,96,97].

Second, SMBG was implemented more commonly in effective than non-effective SOIs. Several meta-analyses have shown that SMBG is an effective stand-alone intervention strategy for improving HbA_{1c} in the short term (e.g., [98,99]). Indeed, a recent meta-analysis [88] suggested that feedback and monitoring strategies such as SMBG are essential for successful goal-setting. SMBG provides direct feedback to individuals on how daily events, choices and behaviours influence blood glucose levels, helping them to better understand and manage their T2DM. In salutogenic terms, SMBG is a resource in a self-regulating learning process towards establishing self-identity [41,100].

Finally, an alternative explanation is that intervention intensity affected effectiveness: effective SOIs generally involved more sessions (>10) and more contact time (>20 h) than non-effective SOIs. The evidence seems to suggest that more intensive interventions (minimum 10 h contact time) are most effective, especially for HbA_{1c} and weight loss [10,97,101].

Concerning the realisation of this salutogenic principle, it was assumed that goal-setting would enhance self-identity by initiating self-examination and reflective thinking; however, enabling self-examination is a complex process that requires substantial training, supervision, specific skills and experience [102]. It was often difficult to establish whether and to what extent the deliverers were properly and sufficiently trained to do this. Furthermore, in most SOIs, there was delimited freedom for participants to set goals, and aspects of self-examination were rarely mentioned. To realise the optimal outcomes from a salutogenic perspective, interventions should allow more freedom to decide what issues should be addressed, and individuals should be stimulated to reflect not only on the goal-setting process, but also on illness perceptions and wellbeing in relation to everyday life [42,89].

Limitations

This review has a number of strengths, including the inclusion of a large number of RCTs, limited confounding variables, and sufficient follow-up to assess cause and effect. For the first time, the salutogenic principles were compiled and applied as selection criteria to provide an innovative perspective on moderators for success in patient-centred T2DM lifestyle interventions. This review also has a number of limitations. As discussed above, the salutogenic principles were not

always integrated in the true meaning of salutogenesis. Our selection criteria could have omitted relevant RCTs (non-English, no description of intervention, development, or outcomes); however, using fewer or less strict selection criteria would make comparisons very complicated by increasing the already large variation in the realisation of the salutogenic principles. The results of this review should be carefully interpreted because the present data synthesis lacks robustness and generalisability of statistical testing. The inclusion of a low number of non-effective SOIs relative to the effective SOIs complicated the comparison of their study characteristics. In addition, methodological issues were observed in some of the underlying studies, such as not blinding the outcome assessors to the treatment conditions (n = 18/28).

Conclusion

This review contributes to the understanding of patient-centred interventions for adults with T2DM and the use of salutogenesis in this area. Most interventions that can, to a certain extent, be considered salutogenic were found to improve physical health, psychosocial health, or both; however, the heterogeneity of these studies made it impossible to link and/or analyse specific characteristics in relation to (specific) health outcomes. Although limited, interventions based directly on salutogenesis have already shown good results for people with mental disorders [89] and T2DM [42]. Future research should explore how to purposefully design salutogenic interventions and study their effectiveness before we can conclude whether these approaches are more effective than traditional interventions.

Practical implications

Culturally targeted SOIs based on formative research and delivered in 10–20 (group) sessions seem to improve both physical and psychosocial health outcomes in adults with T2DM. These are important elements to further research and to take into account when developing T2DM lifestyle interventions based directly on salutogenesis.

Funding: The authors of this review received a grant from the Edema-Steernberg Foundation, Wageningen, The Netherlands a non-profit foundation that supports and initiates multidisciplinary research related to nutrition and eating behaviours.

Authors' contributions: All authors were involved in the conceptualization and methodology of the study. CMMP performed the systematic search, analysed the results and wrote the initial draft. The other authors commented on the analysis and edited the initial draft during all research and publication stages.

Competing interest: The authors declare that there are no conflicts of interest.

Supplementary materials

Table A.1 Search strategy PubMed.

Nr.	Search term
1	"Diabetes Mellitus, Type 2"[Mesh]
2	Randomized Controlled Trials as Topic[Mesh]
3	Control Groups[Mesh]
4	"intervention"[tiab]
5	"trial"[tiab]
6	"RCT"[tiab]
7	"randomized controlled trial"[tiab]
8	2 OR 3 OR 4 OR 5 OR 6 OR 7
9	1 AND 8
10	"cognitive therapy"[Mesh]
11	Mind-Body Therapies[Mesh]
12	"Counseling"[Mesh]
13	Cognitive Remediation[Mesh]
14	Nutrition Therapy[Mesh]
15	"Self-Management"[Mesh]
16	"Patient Education as Topic"[Mesh]
17	"coping"[tiab]
18	"lifestyle" [tiab]
19	"life style"[tiab]
20	"self-care"[tiab]
21	10 OR 11 OR 12 OR 13 OR 14 OR 15 OR 16 OR 17 OR 18 OR 19 OR 20
22	9 AND 21
23	"Social Support"[Mesh]
24	"Sense of coherence"[Mesh]
25	"Quality of Life"[Mesh]
26	"self-efficacy"[Mesh]
27	"Internal-External Control"[Mesh]
28	"Holistic Health"[Mesh]
29	Depression[Mesh]
30	"mental health"[Mesh]
31	"SOC" [tiab]
32	"perceived quality of life"[tiab]
33	"perceived health"[tiab]
34	"active involvement"[tiab]
35	"food literacy"[tiab]
36	"diabetes distress"[tiab]
37	empowerment[tiab]
38	"well being'[tiab]
39	"wellbeing"[tiab]
40	"health literacy"[tiab]
41	23 OR 24 OR 25 OR 26 OR 27 OR 28 OR 29 OR 30 OR 31 OR 32 OR 33 OR 34 OR 35 OR 36 OR 37 OR 38 OR 39 OR 40
42	22 AND 41
43	"Glycated Hemoglobin A"[Mesh]
44	"Blood Glucose"[Mesh]
45	Body Weight Changes[Mesh]
46	"Body Weight Maintenance"[Mesh]
47	"Waist Circumference"[Mesh]
48	"Waist-Height Ratio"[Mesh]
49	"Body Composition"[Mesh]
50	"Triglycerides"[Mesh]
51	"Skinfold Thickness" [Mesh]
52	"Body Mass Index"[Mesh]
53	"Lipoproteins, HDL"[Mesh]
54	"Lipoproteins, LDL"[Mesh]
55	"Blood Pressure"[Mesh]
56	"Insulin Resistance"[Mesh]
57	43 OR 44 OR 45 OR 46 OR 47 OR 48 OR 49 OR 50 OR 51 OR 52 OR 53 OR 54 OR 55 OR 56
58	42 AND 57

Table B.1 EPHPP (quality assessment tool for quantitative studies) quality assessment of the included papers.

Study	Selection bias	Study design	Confounders	Blinding	Data collection methods	Withdraws and drop-out	Intervention integrity	Analysis*	Global rating**
[59]	MODERATE	STRONG	MODERATE	MODERATE	STRONG	WEAK	MODERATE	WEAK	**WEAK**
[47]	MODEATE	STRONG	MODERATE	WEAK	STRONG	STRONG	MODERATE	STRONG	**MODERATE**
[73]	WEAK	STRONG	STRONG	MODERATE	STRONG	STRONG	MODERATE	WEAK	**WEAK**
[46]	MODERATE	STRONG	STRONG	MODERATE	STRONG	STRONG	MODERATE	STRONG	**STRONG**
[66]	STRONG	STRONG	STRONG	STRONG	STRONG	STRONG	MODERATE	STRONG	**STRONG**
[67]	STRONG	STRONG	STRONG	STRONG	STRONG	STRONG	MODERATE	WEAK	**MODERATE**
[51]	MODERATE	STRONG	STRONG	MODERATE	STRONG	MODERATE	MODERATE	WEAK	**MODERATE**
[68]	WEAK	STRONG	STRONG	MODERATE	STRONG	STRONG	MODERATE	WEAK	**WEAK**
[60]	MODERATE	STRONG	STRONG	STRONG	STRONG	MODERATE	MODERATE	STRONG	**STRONG**
[69]	STRONG	STRONG	STRONG	MODERATE	STRONG	MODERATE	MODERATE	WEAK	**MODERATE**
[52]	MODERATE	STRONG	STRONG	MODERATE	STRONG	WEAK	MODERATE	STRONG	**MODERATE**
[70]	MODERATE	STRONG	STRONG	STRONG	STRONG	STRONG	MODERATE	WEAK	**MODERATE**
[53]	STRONG	STRONG	STRONG	MODERATE	STRONG	WEAK	MODERATE	STRONG	**STRONG**
[61]	WEAK	STRONG	STRONG	MODERATE	STRONG	STRONG	MODERATE	STRONG	**MODERATE**
[71]	WEAK	STRONG	WEAK	MODERATE	STRONG	WEAK	MODERATE	STRONG	**WEAK**
[54]	STRONG	STRONG	STRONG	MODERATE	STRONG	MODERATE	MODERATE	STRONG	**STRONG**
[72]	WEAK	STRONG	STRONG	MODERATE	STRONG	STRONG	MODERATE	WEAK	**WEAK**
[62]	MODERATE	STRONG	STRONG	STRONG	STRONG	MODERATE	MODERATE	STRONG	**STRONG**
[55]	MODERATE	STRONG	STRONG	MODERATE	STRONG	MODERATE	MODERATE	STRONG	**STRONG**
[49]	STRONG	STRONG	STRONG	MODERATE	STRONG	STRONG	MODERATE	WEAK	**MODERATE**
[56]	WEAK	STRONG	STRONG	MODERATE	STRONG	WEAK	MODERATE	WEAK	**WEAK**
[57]	MODERATE	STRONG	STRONG	MODERATE	STRONG	STRONG	MODERATE	WEAK	**MODERATE**
[58]	MODERATE	STRONG	STRONG	MODERATE	STRONG	STRONG	MODERATE	STRONG	**STRONG**
[63]	STRONG	STRONG	STRONG	MODERATE	STRONG	STRONG	MODERATE	STRONG	**STRONG**
[64]	WEAK	STRONG	STRONG	MODERATE	STRONG	STRONG	MODERATE	STRONG	**MODERATE**
[48]	WEAK	STRONG	WEAK	STRONG	STRONG	STRONG	MODERATE	WEAK	**WEAK**
[65]	WEAK	STRONG	STRONG	MODERATE	STRONG	WEAK	MODERATE	STRONG	**WEAK**
[50]	MODERATE	STRONG	MODERATE	MODERATE	STRONG	STRONG	MODERATE	WEAK	**MODERATE**

*Analysis was rated as STRONG when intention-to-treat analyses were performed, and as WEAK when no intention-to-treat analyses were performed

**Strong = no WEAK ratings; MODERATE = one WEAK rating; WEAK = two or more WEAK ratings.

Table C.1 Psychosocial concept clustering and measurement instruments.

Psychological outcomes		Measurement instrument		Studies
Category	***Concept***	***Abbreviation***	***Explanation***	
QoL	QoL *(general)*	EQ5D	Total score	[60]
		SF-12	12-item health survey; mental composite score and physical composite score	[46,47,49,66]
		WHO QoL-BREF	World Health Organization's Quality of Life instrument; four dimensions of QoL measures	[67,68]
		SF-36	36-item health survey; eight domains HRQL and two summary component measures	[61]
	QoL *(diabetes specific)*	ADDQoL	Audit of Diabetes Dependent Quality of Life	[48,59,65]
		Diabetes-39	Diabetes-39 instrument	[47,53]
		DQOL-BCI	The Diabetes Quality of Life Brief Clinical Inventory	[60]
		DQOL-15	Diabetes Quality of Life Measure; 15 items	[51]
			Chinese version of the Diabetes Quality of Life Scale	[70]
		PAID	Problem areas in Diabetes Scale	[57]
Wellbeing	Wellbeing *(general)*	W-BQ12	Total score of 12-item Well-Being Questionnaire	[63]
	Wellbeing *(mental)*	W-BQ12	12-item Well-Being Questionnaire, scores for Negative, Energy, Positive, General subdomains	[62]
		WEMW	Warwick-Edinburgh Mental Well-being instrument	[60]
	Wellbeing *(physical and mental)*	SF-12	12-item health survey; mental composite score and physical composite Score	[59]
	Health status	SF-12	12-item health survey; mental composite score and physical composite score	[60]
	Energy	???	Unknown	[72]
Distress	Diabetes distress *(general)*	PAID	The Problem Areas in Diabetes Scale	[50,56,63]
			Spanish version of the 5-item U.S. Problem Areas in Diabetes scale	[52]
		DDS	Chinese version of the diabetes distress scale	[68]
	Diabetes distress *(specific)*	DDS	DDS, Diabetes Distress Scale (including guilt, anger, depressed mood, worry, and fear)	[73]
		PAID	Problem Areas in Diabetes Scale	[54]
	Psychological distress	K10	Psychological distress scale	[67]
	Perceived stress	PSS-4	4-item Perceived Stress Scale	[49]
	Health distress	???	Unknown	[72]
	Fatigue	???	Unknown	[72]
		???	A visual numeric scale	[58]
Depression/ Anxiety	Depression	PRQ-9(K)	PRQ-9(K)	[51,58]
		HANDS	National Depression Screening Day Scale	[69]
		????	Unknown	[72]
		CES-D	Center for Epidemiological Studies–Depression Scale	[48]
	Depressive Symptoms	PHQ8/9	8-item Patient Health Questionnaire	[46,52]
			9-item Patient Health Questionnaire	[73]
			PRIME-MD version of 9-item Patient Health Questionnaire	[57]
	Anxiety symptoms	PROMIS	Spanish version of the PROMIS Emotional distress/anxiety scale	[52]

Psychological outcomes		Measurement instrument		Studies
Category	***Concept***	***Abbreviation***	***Explanation***	
Self-reported health	Self-reported health	National Health Survey	1 item from the National Health Interview Survey	[52]
			1 item from the National Health Survey	[58]
	Self-rated health	????	Unknown	[72]
Illness perception	Illness perception *(general)*	BIP	Brief Illness Perception Score; total score	[60]
		BFS	Benefit-Finding Scale	[49]
	Illness perceptions *(specific)*	BIP	Brief Illness Perception Questionnaire; per subdomain	[62]
		ADS	Appraisal of Diabetes Scale	[49]
	Illness intrusiveness	???	Unknown	[72]
	Perceived diabetes negative control	???	Unknown	[46]
	Confidence in diabetes knowledge	-	Items about knowledge of the disease, treatment, blood glucose monitoring, diet, physical activity, foot care, and complications	[64]
	Integration in daily life	TDQ	The Diabetes Questionnaire	[50]
Self-efficacy	Self-efficacy *(general)*	GSES	General self-efficacy scale	[68]
		COCSC	Confidence in Overcoming Challenges to Self-Care instrument	[55]
	Self-efficacy *(diabetes specific)*	DES	Diabetes Empowerment Scale	[56,57,68,69]
			8-item Chinese version of the Diabetes Empowerment Scale	[70]
			Sum score of: Perceived Diabetes Self-Management Scale (PDSMS) and The Diabetes Empowerment Scale (DES)	[53]
		DMSES	Diabetes Management Self-Efficacy Scale	[66]
			Chinese Diabetes Management Self-Efficacy Scale	[67]
			Chinese version of the 8-item Diabetes Management Self-Efficacy Scale	[72]
			UK version of the Diabetes Management Self-Efficacy Scale	[62]
			Diabetes Management Self-Efficacy Scale	[58]
		-	10 items on how the patients managed their diabetes	[64]
		-	Insulin Management Self-Efficacy Scale; subdomains of Insulin use, Oral glycaemic agents use, Self-monitoring, Exercise, and Diet	[48]
		-	Instrumental diabetes self-management self-efficacy	[57]
		SCDSE	Adapted Chronic Disease Self-Efficacy scale	[51]
		MDS	Subscale from the Multidimensional Diabetes Scale	[65]
	Perceived therapeutic efficacy	PTES	Perceived Therapeutic Efficacy Scale	[66]
Empowerment	Empowerment	DES	The Diabetes Empowerment Scale	[63]
Problem-solving ability		-	Diabetes Problem-Solving Interview	[55]
Attitude	Attitudes towards diabetes	-	Attitude appraisal questions assessing attitude towards T2DM, lifestyle issues, diet, controlling T2DM and having confidence in declaring having T2DM	[71]
		-	Attitudes towards diabetes (range: 10–50)	[51]
		DCP	Diabetes Care Profile's positive and negative attitudes sub-scale	[69]

Psychological outcomes		Measurement instrument		Studies
Category	***Concept***	***Abbreviation***	***Explanation***	
Beliefs	Health beliefs *(general)*	-	Brown's health beliefs instrument	[69]
	Beliefs *(specific)*	-	Beliefs about Diabetes Scale; three dimensions of T2DM cognitions	[65]
Activation	Patient activation	PAM	9-item short form of the Patient Activation Measure	[49,58]
	Patient involvement in the decision-making process	PDM	Patient involvement in the decision-making process	[59]
	Patient healthcare orientation	-	Patient healthcare orientation	[59]
	Medical resource use	-	Self-reported service use of family doctor and hospital care	[60]
Satisfaction	Satisfaction *(with care)*	NCQA/ADA	Patient satisfaction	[69]
		MDRTC	Diabetes history questionnaire	[57]
		ABIM-14	American Board of Internal Medicine satisfaction Questionnaire	[59]
		DTSQc	Treatment Satisfaction Questionnaire	[50]
	Satisfaction *(with daily life)*	-	10 items concerning present treatment, eating habits, physical activity, ability to perform daily activities, diabetes self-management, support from relatives, support from friends, sleeping habits, sex life, and self-satisfaction	[64]
Social burden	Social burden	Diabetes-39	Social burden subscale of Diabetes-39 score	[47]
	Stigma	IPQ	Five questions from the Illness Perception Questionnaire	[69]
	Unresolved family diabetes conflict	????	????	[46]
Social support	Social support	UCLA	Social Support Inventory	[55]
		ISEL-12	Interpersonal Support Evaluation list	[49]
	Family support *(general)*	DFBC	Diabetes Family Behaviour Checklist	[62])
	Family support *(specific)*	????	Unknown; support for diet and physical activity	[46]
	Family cohesion	????	Unknown	[46]
	Family problem-solving communication	???	Unknown	[46]

Note. Concept clustering is based on the definitions used by the authors of the RCTs.

Table D.1 Physical health outcomes and significance levels among the studies.

RCT	HbA_{1c}	FBG	BMI	BW	WC	SBP	DBP	LDL	HDL	TC	TC:HDL	TG	UC	A:C	TS	SS
[59]	NS		NS	NS	NS	NS	NS	NS	NS	NS		NS				
[47]	NS		NS			NS	NS				NS					
[73]	NS															
[46]	*		*	*		NS	NS									
[66]	NS															
[67]	NS	NS	NS	NS	NS	*	NS	NS	NS	NS		NS				
[51]	*	*				NS	NS	*	NS	*		NS				
[68]	NS[a]															
[60]	NS															
[69]	*[b]															
[52]	NS												NS			
[70]	NS[c]															
[53]	NS					NS	NS	NS	NS	*		NS			NS	*
[61]	NS			NS	*	NS	NS	NS	NS	NS		NS				
[71]	*	*	*			NS	NS	NS	NS	NS		NS		*		
[54]	*															
[72]			NS			*	NS									
[62]	*		NS			NS	NS									
[55]	*		*													
[49]	NS															
[56]	NS															
[57]	*															
[58]	NS			NS												
[63]	NS		NS	NS	NS											
[64]	NS		NS													
[48]	*		NS		NS	NS	NS	NS	NS	NS		NS				
[65]	NS[d]															
[50]	NS		NS													
Total (n)	27	3	12	6	5	11	11	7	7	7	1	7	1	1	1	1

Note. HbA_{1c} = Glycated haemoglobin; FBG= fasting blood glucose; BMI= Body Mass Index; BW= Body Weight; WC =waist circumference; SBP= systolic blood pressure; DBP= diastolic blood pressure; LDL= Low-density lipoprotein cholesterol; HDL= High-density lipoprotein cholesterol; TC= total cholesterol; TG= triglycerides; UC= urinary cortisol; A:C= Albumin to creatine ratio; TS= Total symptoms; SS= symptoms severity.

[a] HbA_{1c} was not measured directly after the intervention (at 28 wk), but only at 12 wk (significantly improved compared to control) and at 40 wk (not significantly improved compared to control)

[b] HbA_{1c} was not measured directly after intervention (at 8 wk), but only at 72–84 wk

[c] HbA_{1c} was not measured directly after the intervention (at 12 wk), but only at follow-up (at 24 wk)

[d] HbA_{1c} was not measured directly after the intervention (i.e. 5 wk), but only at 12 wk post-intervention

Table E.1 Psychosocial outcomes and significance levels among the studies.

RCT	Quality of life	Wellbeing	Distress	Depression/ Anxiety	Self-reported health	Illness perception	Self-efficacy	Empower-ment	Problem-solving ability	Attitude	Beliefs	Activation	Satisfaction	Social burden	Social support
[59]	NS	NS[a]										NS	NS		
[47]	NS													*	
[73]			NS	NS											
[46]	NS			*		*								NS	*
[66]	NS						*								
[67]	NS		*				NS								
[51]	*			*			*			NS					
[68]	NS		*				*[b]								
[60]	NS	NS				NS						NS			
[69]				NS			*			*	*		*	*	
[52]			NS	*	NS										
[70]	*						*								
[53]	NS						*								
[61]	NS														
[71]										*					
[54]			NS												
[72]		NS	NS	NS	NS	*	*								
[62]		*				*[c]	*								*
[55]							NS		*						NS
[49]	NS		NS			NS[d]						*			*
[56]			NS				*								
[57]	*			*			NS[e]						*		
[58]			NS	*	NS		*					*			
[63]		NS	NS					NS							
[64]						*	NS						NS		
[48]	NS			*			NS[f]								
[65]	*						NS				NS[g]				
[50]			*			*							*		
Total (n)	15	5	11	9	3	7	16	1	1	3	2	4	5	3	4

[a] This study measured psychosocial wellbeing and physical wellbeing. Psychosocial wellbeing was significantly improved compared to control, physical wellbeing was not.
[b] This study measured diabetes specific and general self-efficacy. Diabetes-specific self-efficacy was significantly improved compared to control, general self-efficacy was not.
[c] This study measured eight illness perceptions. Six of these (personal control, treatment control, symptoms, concern, understanding, emotional rep.) were significantly improved compared to control, the other two (consequences and timeline) were not.
[d] This study measured illness perception via BFS and ADS questionnaire. BFS was significantly improved compared to control, ADS was not.
[e] This study measured diabetes psychosocial self-efficacy and instrumental diabetes self-management self-efficacy. Psychosocial self-efficacy was significantly improved compared to control, instrumental self-efficacy was not.
[f] This study measured self-efficacy for five different self-management components. Self-efficacy for diet was significantly improved compared to the control, the other four (self-efficacy for exercise, self-monitoring, oral glycaemic agents, and insulin use) were not.
[g] This study measured three beliefs. Beliefs about effectiveness were significantly improved compared to the control, the other two about personal control and seriousness were not

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3

Chapter 3

Developing SALUD: Life-course interviews to identify turning points, resources and coping styles for healthy eating

This chapter is published as:

Polhuis CMM, Vaandrager L, Soedamah-Muthu SS, Koelen MA.
Salutogenic model of health to identify turning points and coping styles for eating practices in type 2 diabetes mellitus. Int J Equity Health.
2020 Jun 1;19(1):80. doi: 10.1186/s12939-020-01194-4.

Abstract

Background: It is important for people with Type 2 Diabetes Mellitus (T2DM) to eat healthily. However, implementing dietary advice in everyday life is difficult, because eating is not a distinguishable action, but a chain of activities, embedded in social practices and influenced by previous life experiences. This research aims to understand why and how eating practices are developed over the life-course by investigating influential life experiences - turning points - and coping strategies for eating practices of people with T2DM.

Methods: The Salutogenic Model of Health guided the study's objective, study design and analysis. Seventeen interviews were performed and analysed based on the principles of interpretative phenomenological analysis. Narrative inquiry and the creation of timelines and food boxes were used as tools to facilitate reflection on turning points and eating practices.

Results: Turning points for unhealthier eating were experiences that strongly disturbed the participants' emotional stability. These experiences included psychosocial trauma, physical health disorders, job loss, and smoking cessation. Turning points for healthier eating were experiences that significantly changed participants views on life and made participants reflective about the effects of current eating practices on future health and life goals. These turning points included confrontation with ill-health, becoming a parent, psychosocial therapy, and getting married. Notably, turning points for healthier eating seemed only to happen when life was relatively stress-free. All participants experienced turning points for healthier eating, yet, not all participants succeeded in improving their diets. Two coping styles were distinguished: active and passive coping. Active coping individuals were able to act in line with their personal intentions, whereas passive coping individuals could not. Differences between active and passive coping styles seemed to be explained by differences in available resources important for adapting and maintaining a healthy diet.

Conclusions: Disadvantaged childhood and later life adversities together with the inability to manage the mental stress explained the development unhealthier eating practices. All participants experienced turning points for healthier eating that caused eating to become a priority in their life. Yet, the fact that not all were able to eat as they intended, advocates for nutritional guidance for people with T2DM, with a greater emphasis on reflexivity, psychosocial well-being and social support.

3.1 Introduction

Poor dietary habits are responsible for more deaths than any other risk factor globally, including smoking [1]. National nutrition surveys show that the majority of people do not follow dietary recommendations [2–5], which is one of the reasons why the prevalence of Type 2 Diabetes Mellitus (T2DM) has reached epidemic proportions globally. Current projects suggest that T2DM prevalence will reach 700 million people by 2045 [6]. In the Netherlands, 1,186,400 adults had diabetes in 2018, and it is expected that this number will rise to 1,320,000 adults in 2045 [7, 8]. Incidence is particularly high in people with low socioeconomic position [9, 10]. Once diagnosed, there is a strong emphasis on adopting a healthy diet [11]. Healthy eating can drastically improve glycaemic control, and in some cases, reverse the disease [12–16]. However, individuals with T2DM have indicated that committing to a healthier diet in everyday life is the most complex aspect of self-management [17–20]. Reasons for the complexity experienced may be in regard to gaps in knowledge of biomedical understandings of healthy eating and daily practices. Indeed, research has suggested that lay individuals and health professionals often speak different languages when discussing health and diet [21–24]. Healthcare professionals commonly work within a biomedical paradigm in which taking care of one's diet is seen as an individual's responsibility. One should eat according to national dietary guidelines: no alcohol, lower intake of foods containing saturated fats, sugars and salt, and higher intake of foods containing unsaturated fat and fibre (fruits, vegetables, legumes) [11]. However, in everyday life, healthy eating goes beyond the understanding of a good balance of macro- and micro-nutrients; it is also about structure and regularity in eating (e.g. eating a fixed number of meals at fixed times, or weekly routines), how foods are produced (e.g. home-made or organic), and psychosocial well-being (enjoying foods together) [21–24]. Eating is highly contextual, and personal interpretations of healthy eating are complex and diverse, as they reflect personal-, social-, and cultural experiences, as well as local (food) environments [23]. Besides the social context, eating practices are also embedded in a temporal context. Past experiences direct how people make food choices in the future [23, 25, 26]. Evidence shows that meanings of and attitudes towards healthy eating can change over time and are specific to life stages [23]. For example, being married and having a young child has been associated positively with fruit and vegetable consumption [27].

In addition, eating practices can also drastically and suddenly change after experiencing a turning point [25, 28]. Turning points are generally defined as powerful emotional or existential experiences that lead to relative drastic changes (in eating practices) that involve self-redefinition and changes in ego-identities, from which people do not turn back [25, 28–30]. The transition to motherhood has been indicated as a turning point for instance [31, 32]. Some recent research has observed that existential experiences influenced self-management behaviours among people with T2DM [29, 30, 33, 34]. For example, distressing evidence about one's health led to small behavioural change action steps [29, 30, 33] as well as experiencing an 'a-ha' moment – a realisation that a particular self-management strategy actually worked – at critical points [34].

Nevertheless, the understanding of turning points for eating behaviour is still limited [25].

As indicated, the everyday life understanding of healthy eating overlaps but is not synonymous, with the biomedical understanding [35]. Furthermore, the fields of public health and medicine have been gradually shifting from a sole focus on the individual level models to a greater focus on socioecological models [36]. A theoretical model that is both closer to the everyday life understanding of healthy eating and has incorporated a socioecological approach is the Salutogenic Model of Health (**Figure 3.1**). The Salutogenic Model is centred around the idea that health results of continuous everyday life interactions between the individual and inevitable social-, economic-, cultural-, physical-, mental- and biochemical stressors [38]. The availability of resources that promote health and the capabilities in identifying and using these resources for overcoming tensions determines if health deteriorates, is sustained or is gained [37]. The individual capability to identify and mobilise resources is called the Sense of Coherence (SoC) and resources that promote health and facilitate coping with stressors are called Generalized Resistance Resources (GRRs). The SoC can be quantitatively measured and a stronger SoC is associated with better (mental- and physical-) health [39, 40] and healthier eating [41– 43]. Regarding T2DM, a higher SoC is associated with better metabolic control [44, 45]. Originally, it was thought that SoC was a stable entity that developed mostly during the first decades of life and stabilised thereafter [37], however, more recent evidence shows that influential life experiences [46] – turning points – and even interventions [47–51] can alter SoC later in life. GRRs can be genetic-, material-, constitutional- and/or psychosocial resources. GRRs determine the extent to which Specific Resistance Resources (SRRs) are available [52]. SRRs are useful in specific situations of tension [37]. The idea is that if SoC and GRRs are well-developed, it facilitates identification of SRRs and development of coping strategies for specific challenges, in this case, for healthier eating. Cues from the situational context may cause that individuals are suddenly able to recognize and mobilize resources important for healthful eating. This idea is widely accepted in other conceptual health psychology and coping models as well (e.g. social learning theory [53], coping theories [54], health belief model [55], teachable moment framework [56]).

In this research, life-course interviews are used to explore how and why the eating practices of adults with T2DM (and low socioeconomic position in particular) are developed over time by investigating the everyday life experiences that led to key turning points for eating practices and coping strategies for healthier eating. By adopting a constructivist view, a turning point was considered as turning point when the participant considered and mentioned it to be a turning point. The results extended the knowledge on turning points for eating practices, and on learning experiences significant for developing the SoC. This is relevant for realising more effective personalised nutritional therapy for people with T2DM.

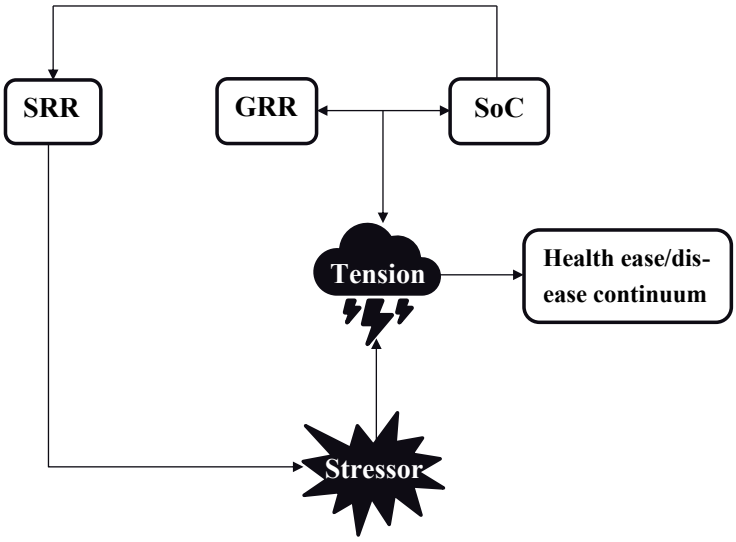

Figure 3.1 Simplified visual representation of the Salutogenic Model of Health (adapted from (35); p. 184-185). How an individual copes with the tension created by a stressor is the result of the strength of SoC (i.e. capability to identify and mobilise and the availability of GRRs. Via the SoC, GRRs determine the extent to which SRRs are available. A SRR is a resource that is activated specifically to cope with a specific stressor. The strength of SoC and availability of GRRs and SRRs leads to successful or to unsuccessful tension management, which eventually determines someone's position on the ease-disease continuum.

3.2 Methods

Participants

General Practitioners (GPs), practice nurses, and dieticians recruited people with T2DM in the province of Gelderland in the Netherlands between April and September 2018. Individuals that met the following criteria could participate: 1) low socioeconomic position; 2) native Dutch; 3) officially diagnosed with T2DM for at least 6 months; and 4) aged > 18 years. Adults with T2DM and low socioeconomic position were of interest, because T2DM is most prevalent among people with low socioeconomic position in the Netherlands [57], but at the same time, people with low socioeconomic position are underrepresented in research [58]. It was decided to focus on native Dutch people, as they generally share the same cultural- and historical backgrounds, are accustomed to similar products and food traditions, and have the same accessibility to food and healthcare. People had to be diagnosed for at least 6 months to ensure having sufficient experiences with dealing with T2DM in everyday life. People with cognitive disorders (e.g. dementia, or intellectual impairment) could not participate. Socioeconomic position was assessed by a researcher during the introductory meeting, as the recruiters were not comfortable asking about this. Twenty individuals were approached, 17 provided informed consent and participated in this study. Reasons for non- participation were not showing up in the introductory meeting

(n = 1) and issues with scheduling the interviews (n = 2)[4]. Data saturation was reached after 13 interviews. Four additional interviews were conducted because these interviews were already scheduled at that point. The study was approved by the Social Ethical Committee of the Social Sciences Department of Wageningen University.

Methods and materials

Timeline and food box

The study is based on principles of Interpretative Phenomenological Analysis (IPA). IPA was chosen because the ontological and epistemological positioning is similar to the Salutogenic Model of Health. Both view reality and people as inseparable; individuals are not viewers of the world, but are embedded in it [59]. Both also consider everyday life experiences as valuable sources for expressing the complexity and depth of human existence. IPA is a qualitative framework that is specifically suitable for analysing the meaning of everyday life experiences [60, 61]. In IPA, time and space are conceptualised that time is experienced as temporal and space is situated [59]. Temporality refers to how our past experiences direct how we are in the present. Situatedness does not refer to the geographical features of someone's world, but to the experiences (situations) that are brought into the foreground by someone because they are the most meaningful to that person [59].

Inspired by the study of Swan et al. [62], narrative inquiry, systematic listening to people's life stories, was used to facilitate a deep conversation on life-course experiences that influenced eating practices and to gain inside perspective of the personal life-worlds of participants. For this, the participants were asked in advance of the interview to create a timeline (from birth to present), in which they had to indicate turning points that changed their diet drastically, and construct a food box by collecting meaningful items (foods, but also non-edible objects, such as photos or utensils, were allowed) in a box that represented current eating practices. Timeline and food box are established research tools for sharing and reflecting upon experiences [62, 63]. In contrast to more structured interview methods, timelines and food boxes allow participants to tell their story in their own way, and steer the conversation to topics that are most important to them (situatedness), which facilitates the process of opening up on loaded/personal subjects, such as eating and weight. While the timeline was used to construct a temporal narrative on how eating practices had evolved, the food box was used to start the conversation on current eating practices. Hence, the timeline and food box were used as tools to facilitate reflection.

4 These participants indicated to be willing to participate, but after the initial phone call, it became clear that their life situations at that time would make it severely complicated to schedule the interviews. Hence, after mutual agreement, these two individuals were put on a reserve list instead. Once data saturation was reached, they were informed that participation was no longer necessary.

Protocol and measures

The researcher (CMMP) organised an introductory meeting with each participant individually to explain the research interests and procedure and to hand out the materials for the timeline and the food box. After signing the informed consent, questions related to demographics (age, living situation), socioeconomic position (income, educational level, occupation status), T2DM (T2DM duration, latest glycated haemoglobin (HbA_{1c}) level and/or fasted glucose level), and self-care management (physical activity, self-monitoring blood glucose, and smoking [64]) were asked. Individual SoC was also quantitatively assessed with the SoC-13 [65]. The SoC-13 is a validated questionnaire with a scale of 0 to 52. Some participants needed assistance with filling in the questionnaires due to difficulties with reading and/or writing (n = 4). The introductory meeting was also set to establish a relationship with the participant in advance of the interview.

One week after the introductory meeting, the in-depth interview took place. All interviews were conducted in Dutch. The interview began by asking the participant to explain his/her timeline from birth to present and how the turning points influenced eating practices. Secondly, the participant was asked to explain why (s)he had chosen the specific objects in the food box. The researchers probed with questions when they wanted the participant to describe events or coping strategies in more detail. The participant was stimulated to take the lead during the interview. Exemplar questions that were asked frequently are summarised in **Table 3.1**.

Interviews lasted on average 76 min, ranging from 55 to 104 min. Participants were rewarded a ten euro gift-voucher after the interview. Both the introductory meeting and the interview took place at convenient locations for the participant (participant's home or the university). One week after the interview, the researcher called the participant and asked him or her to reflect on the interview. The participant's GP would have been contacted if the researcher suspected emotional/psychosocial harm caused by the interview that required additional medical/psychosocial support (in none of the cases necessary). The interviews and follow-up calls were recorded on a handheld digital voice recorder and were described ad verbatim by two research assistants.

Table 3.1 Key interview questions and examples of follow-up questions

	Timeline	Food-box
Key questions	Could you talk me through your timeline? In what way did this specific moment change eating practices/behaviour/diet? What were the things you were eating during this specific period?	Could you explain why you have chosen these specific objects?
Sample follow-up questions	How was your childhood? Could you describe how things used to be at the dinner table when you were a child? What kind of foods did you eat as a child? How did you learn how to cook? When did you leave your parental house? What kind of foods are liked by your partner? When did you become a parent? What is it like being a parent? How did you experienced breakfast/lunch/dinner when your children lived at home? What foods did/do your children like? How did T2DM diagnosis affect you? How has T2DM diagnosis influenced your eating behaviour?	When did you start eating this specific product? Do you eat/use this at specific occasions or with specific persons? Are you satisfied with your current eating practices? And why (not)? What things make it easier for you to eat healthily? Why? What things make it difficult for you to eat healthily? Why? How do you deal with these? What would be your ideal eating pattern? What would help you to reach this ideal eating pattern? If you compare your eating practices in the past to now, what has changed?

Analysis

The IPA approach concentrates on properly exploring, understanding and communicating the individual- and unique meaning of specific events within personal contexts [60]. The researcher has an active role in this. The researcher tries to get an 'insider's perspective' of the participants world, but cannot do this directly nor completely. The access depends (and is complicated by) the researcher's own interpretations. The researcher's interpretation is necessary for the sense-making of the participant's world [59, 66]. Even though IPA is more of a philosophical 'stance', from which qualitative analyse is approached rather than a distinct method, the following steps (based on [60, 66, 67]) were followed to unravel the evolvement of eating practices over the life-course.

Firstly, a transcript was read and reread to engage with the data. The data consisted of the transcripts of the interviews. The timelines and food boxes were not used in the data analysis. The reason for this is that the conversations, not the timelines nor food boxes, provided insights in answers to our research question. Elaborating on the timeline and food box would distract from the main results. With the use of Atlas.ti (Version 8), the transcript was open-coded with notes about observations, comments and reflections. In IPA, notes are made about interesting or significant statements of participants [60]. There are no rules for what is commented upon (i.e. notes can be on a descriptive, conceptual, and linguistic level) [60]. In this study, coding was mostly on a descriptive (to let things speak for themselves) and interpretative level (to decode the underlying meaning of experiences). More specifically, notes included:

- Explanations of why this specific participant identified these specific events as turning points, and of how the social-, historical- and/or physical context influenced eating behaviour in turning points.

- Individual challenges to, coping strategies with, and resources for healthy eating
- The researcher's impression of the participant's character, and if (s)he seemed to be in charge of eating behaviour (i.e. eating in line with intentions, not necessarily with dietary guidelines) and life in general (i.e. is this person living his/her ideal life? Is (s)he happy with his/her life?).

Subsequently, the notes were clustered in preliminary themes. Each interview was independently analysed to completion before moving on with the next interview [67]. In the next stage, the preliminary themes were compared across the data set, identifiable themes were connected, and idiosyncratic differences were noted. In the final stage, the theory of salutogenesis was used to further elicit why turning points facilitated or challenged healthy eating by discussing how previous experiences, outlooks on life, and internal and external resources led to developing coping styles and strategies [65]. Data collection continued until data saturation was reached (i.e. no new information was observed in the data). All interviews were analysed independently by CMMP and (at least) one of the other authors, and were subsequently discussed until consensus was reached. The overarching themes were the result of various discussions between all authors. The themes are displayed with pertinent participant quotes and detailed interpretative commentary. The quotes were translated to English by a professional editor.

3.3 Results

The first part of the results describes the participants characteristics. The second part describes the key findings regarding the turning points for unhealthy and healthy eating. Temporal and situatedness-related aspects of the turning points are discussed as well. The final part describes how and why people react differently to similar experiences. The distinctive coping styles for healthy eating are described as active and passive coping.

Participants' characteristics

Eight men and nine women participated in the study (**Table 3.2**). Each was given a pseudonym for the purposes of tabulating the results. The average age was 67.7 (SD = 7.1) years old, ranging from 49 to 77 years old. All, except one, had children. Most lived with a partner and/or children, four participants lived alone. The average T2DM duration was 12 (SD = 6.5) years and ranged between 0.5 to 23 years. Six participants were able to keep HbA_{1c} and/or fasted glucose values below the recommend target values of 53 mmol/L and 6.9 mmol/L, respectively [68]. Four participants managed to be physically active for 30 min each day of the week. Six participants indicated that they regularly self-monitor blood glucose. One of the participants was a smoker; four participant have smoked in the past. The SoC was relatively high: more than half of the participants had a high SoC (n = 11). The average SoC score was 35 (SD = 9.1) and ranged from 21 to 49.

Table 3.2 Overview of the participants' personal, SEP, T2DM, self-management and SOC characteristics.

	Personal characteristics						T2DM			Self-management			SoC
Pseudonym	*Age (years)*	*Living situation*	*Children (n)*	*Education*[1]	*Income*[2]	*Occupation status*[3]	*Disease duration (years)*	*HbA_{1c}*[4] *(mmol/L)*	*FGL*[5] *(mmol/L)*	*Physical activity*[6] *(days/week)*	*SMBG*[7] *(days/week)*	*Smoking*	*SoC*[8] *(0-52)*
Diane ♀	49	Children	2	Medium	Low	Low[c]	5	69	6.4	0	0	No[h]	21
Ria ♀	75	Partner	2	Medium	Medium[a]	Low[d,e]	10	-	7.0	7	0	No	30.5
Annie ♀	60	Alone	0	Medium	Low	Low[c]	11	52	6.8	3.5	0	No[h]	42
Mieke ♀	56	Partner + children	2	Medium	Medium	Medium	16	-	7.0	7	0	No	35.5
Saskia ♀	67	Alone	2	Low	Low	Low[d,e]	20	92	11.1	1.5	1-2	No	24
Karin ♀	65	Alone	2	Medium	Low	Low[d,e]	0.5	69	11.0	1.5	0	No	35
Jan ♂	73	Partner	1	Low	Medium	Low[d]	0.5	-	-	0.5	0	No	41
Carla ♀	71	Partner	1	Medium	Medium[b]	Low[d]	10	-	9.4[g]	1.5	1	Yes	49
Freek ♂	72	Partner + children	3	Medium	Low	Low[d]	19	62	-	3.5	0	No[5]	41
Marja ♀	69	Partner	1	Medium	-	Low[d]	10	43	8.5	3.5	0	No	21.5
Henk ♂	66	Partner	3	Medium	Low	Low[f]	10	60	-	7	0	No	26.5
Mark ♂	66	Partner + children	3	Medium	Low	Medium[d]	21	66	-	7	7	No	43
Dennis ♂	69	Partner + children	3	Medium	Medium	Low[d]	10	-	5.5	3.5	0-1	No	36
Claudia ♀	77	Alone	2	Low	Low	Low[d]	15	-	6.4	1	0-1	No	22
Tygo ♂	71	Partner	2	Low	Low	Low[d]	10	-	-	5	0	No[h]	44
Theo ♂	62	Partner + children	4	High	High	Low[f]	10-12	-	7.2	0	0	No	43
Robert ♂	64	Partner	2	Medium	Low	Low[f]	23	61	-	3.5	1	No	40

[1] Based on the highest completed education. **High education:** Higher professional education or academic higher education (university) (Known as HBO or WO in Dutch) **Medium education:** Basis secondary education (Junior secondary pre-vocational education, junior secondary general education, secondary general education, pre-university education, senior secondary vocational education (Known as VMBO, VBO, MAVO, HAVO, VWO, MBO in Dutch); **Low education:** Primary education.

[2] Based on self-reported current net monthly income. Categorisation of incomes is based on the average net income in the Netherlands (i.e. net income of 2,120 euro/month (CBP 2019)). **Low income**: <2,120 euro/month; **Medium income**: 2,000-2,500 euro/month; **High income**: >2,500 euro/month.

[3] Based on current occupation status. When retired, the classification was based on the latest occupation. **High occupation status:** Occupations that require high education; **Medium occupation status:** Occupations that require medium education; **Low occupation status:** Unemployed, medically declared unfit for work, or occupations that do not require secondary education

[4] HbA_{1c} are self-reported. Cut-off values are based on Diabetes Fonds (60): **Low HbA_{1c}:** <53 mmol/L; **Slightly alleviated HbA_{1c}:** 54-63 mmol/; **Alleviated HbA_{1c}:** 64-85 mmol/L; **High HbA_{1c}:** >86 mmol/L.

[5] **FGL =** Fasting glucose levels; self-reported. Cut-off values are based on Diabetes Fonds (60): **Low FGL:** <6.1 mmol/L; **Medium FGL:** 6.1-6.9 mmol/L; **High FGL:** >6.9 mmol/L.

[6] Physically active for at least 30 min.

[7] **SMBG** = self-monitoring blood glucose.

[8] SoC-13 total score= 52. **Low SoC:** <17; **Medium SoC**: 18-35; **High SoC**: >35. Cut-off values are based on 52/3= 17.

[a] Husband's pension [b] Combined pensions (husband's and wife's) [c] Unemployed [d] Currently retired [e] No professional career; housewife [f] Medically declared unfit for work [g] Measured in non-fasting state

[h] Past smoker.

Turning points

A total of 15 different type of turning points were identified (**Table 3.3**). Turning points that led to unhealthy eating are identified with a fast-food icon ( ) and turning points that led to healthy eating with an apple icon ( ). The participants that experienced turning points for healthy as well as unhealthy eating, encountered generally more turning points for unhealthy eating than for healthy eating (**Table 3.3**). Some participants only identified turning points for healthy eating (Ria, Mieke, Jan, and Mark). For them, unhealthy eating was a matter of a gradual worsening of eating practices caused by specific life phases (i.e. work, marriage, having children, etc.) and lack of resources (i.e. disadvantaged childhood, lack of nutritional knowledge), rather than sudden changes caused by isolated events.

Turning points for unhealthy eating

Turning points that induced unhealthy eating were experiences that disturbed the participants' emotional stability through strong feelings of grief, loneliness, being out of control, and/or mental stress. The turning points ranged from traumatic experiences (childhood neglect; loss or sickness of loved ones; sexual abuse; domestic abuse), physical health problems (complicated pregnancy; pain; onset of chronic illnesses), mentally draining conditions (depression/burn-out), job loss, and smoking cessation. This stress was so overwhelming at the time that it required the full capacity of the participants' consciousness and coping abilities to carry on with 'normal' everyday life (i.e. work, taking care of family). Diet and the impact of food choices on (long-term) health became simply secondary to these overwhelming events.

> **Saskia:** It's just that worries about my daughter [*who was receiving care from a psychiatric institute*] were a priority [*above healthy eatin*g]. And those worries just dominated my life- the anxiety and everything […] Stress had a big influence on me at that time. […] If I am tense.. well, if I am tense and realise that, I really don't have to check my glucose, then I know that I am on a level of 13, 14 and sometimes 15 [blood glucose level]. When I am more rested, I can think more clearly, and when I can accept my situation, then I know that just go back again to a level of 8.

Participants found it difficult to regain stability over their emotional states in the context of everyday life. This manifested itself, in some instances through the participant not paying attention to what was eaten, sometimes by the participant eating very little (e.g. Carla), but mostly by participants eating excessively (e.g. Tygo). In case of the latter, excessive eating was used to progress and regain command of their (negative) emotions (i.e. emotional eating).

> **Carla:** [*Who talks about her partner leaving her and cheating her financially*] With that experience, I had such an emotional knock, I was like this [*pointing her index fingers together*]. I lost so much weight then. And I really couldn't eat or drink. Nothing. [...] My boys went to my mother [...], because I didn't cook. I didn't feel like it at all.

Table 3.3 Overview of all identified turning points.

	Child neglect	Domestic abuse	Sexual abuse	Children leaving the house	Losing job	Depres-sion	Pain/ complicated health	Still-born baby	Losing Partner	Death of parents	Preg-nancy	Smoking Cessation	Confrontation with ill-health	Psychological therapy	Becoming a parent	Getting married
Diane	🍔	🍔				🍔						🍔	🍎	🍎	🍎	
Ria													🍎			
Annie					🍔	🍔			🍔	🍔		🍔	🍎	🍎		
Mieke	🍔												🍎			
Saskia	🍔		🍔				🍔		🍔	🍔	🍔		🍎		🍎	🍎
Karin				🍔					🍔				🍎			
Carla	🍔								🍔		🍔				🍎	
Marja			🍔				🍔						🍎			
Claudia	🍔								🍔				🍎			
Jan													🍎			
Freek												🍔	🍎			
Henk						🍔							🍎			
Mark													🍎			
Dennis				🍔									🍎			
Tygo					🍔							🍔	🍎			
Theo							🍔	🍔					🍎			
Robert							🍔						🍎			

Note. Turning points for unhealthy eating are indicated with a fast-food icon: 🍔; turning points for healthy eating are indicated with an apple icon: 🍎.

Tygo: I am an emotional eater, if I feel bad, I eat everything I can get my hands on.

For example, losing a loved one, especially when it involved a spouse, caused loneliness, which led to less interest in cooking, and sadness, which led to emotional eating (e.g. Karin, Saskia).

Karin: I actually think that after my husband died, I started eating a lot due to grief. I would describe this as, responding through snacking. Then the weight piled on. Now that I think about it. Before that, it was different. When you have a partner, you don't sneakily snack. At least, I didn't.. but when you are alone [...] and you experience grief, you don't know what you have to do to cope with it. He always came home at 3 o'clock [in the afternoon; a typical time for tea/coffee in the Netherlands] [...] Well, now, I do have a cookie or something with may tea, but I used to have a nice chat with him. Now I have to drink my tea or coffee alone, you know. It is actually that I started to eat to cope with the grief.

Saskia: That's when I started injections, after he [*husband*] died. The anxiety, the stress, are cooped up inside me.

The onset of certain physical health problems caused stress, which led to unhealthy eating, because it confounded daily life through feelings of social isolation (i.e. in the instance that a participant was declared medically unfit for work), impediment of living an active healthy lifestyle, and chronic suffering from pain (e.g. Parkinson's disease, hernia, fibromyalgia). Excessive eating was also used to cope with the stress caused by smoking cessation. Commonly, the participants experienced a lack of social support while dealing with the emotional aftermath of turning points for unhealthy eating.

Turning points for healthy eating

Turning points that induced healthy eating were experiences that significantly changed participants views on life and made participants reflective about the effects of current unhealthy eating practices on future health and goals. These turning points included confrontation with ill-health, becoming a parent, psychosocial therapy, and getting married. It is important to emphasise that these turning points generally happened in late-adulthood when most participants were in comparatively 'calmer waters' in terms of life circumstances (e.g. retirement; financial stability) and mental wellbeing (e.g. a current stress-free state-of-mind, being loved/supported by family/friends).

Diane: Yes. I have recouped after hitting 'rock bottom'. I do notice that I manage my life more than before. That being healthy, and that quitting smoking also came up as an issue. I just succeeded with that in one go.

Secondly, it is important to note that turning points for healthy eating did not always have an infinite effect on eating practices. For example, Robert and Saskia managed to achieve significant weight loss (30–45 kg), but unfortunately regained much of it later due to other health complications (Parkinson's complicated Robert's strict lifestyle regimen; stomach operations and infections led to the need to remove Saskia's gastric band).

A confrontation with ill-health was the most frequently identified turning point, which also caused the most drastic and long-lasting dietary improvements. In some cases, the reason was external, because it came from health professionals (e.g. T2DM diagnosis, warning about high blood glucose values), or from family/friends (e.g. pressure from Robert's son to follow a lifestyle program; the advice of Tygo's fitness trainer to consult a dietician). In other cases, the reason was internal, because participants themselves noticed alarming cues: Claudia decided to start cooking more frequently after just feeling unwell, Henk started dieting after being shocked at his high weight, Theo decided to limit his alcohol intake after realising it was getting out of control, and Mieke took better care of herself after being shocked by the death of her mother. Participants improved their diets either on their own, or with help of a dietician, by following a lifestyle program, or by undergoing bariatric surgery.

> **Henk:** Not being entirely in control. Your body always craved food. And then it ended and now, I have it reasonably under control.
> **Interviewer:** Yes, and how did you succeed?
> **Henk:** Through shock. At 83 k, I realised that it was going wrong. And then other things came to light.

Secondly, becoming a parent was identified as turning point by Diane, Saskia and Carla. Although most participants had children and generally they indicated that this only changed eating practices slightly, Diane, Saskia and Carla stressed that parenting has improved their eating practices drastically. Unlike the other participants with children, Diane, Saskia and Carla experienced parental abandonment and child neglect in their own childhoods. Their parents were emotionally unavailable, and due to either financial or health reasons, were unable to provide food and enjoy foods together with their children. Being parents themselves gave their life a new sense of purpose that strongly motivated them to do things better. This included providing healthy meals, and enjoying meals together with their kids, but also taking better care of their own diets and weight, because they wished to stay as healthy as possible for as long as possible.

> **Diane:** That first year, before I had children [*I didn't cook*]. That time I associate with really living for fun. I was drunk almost every day [*laughing*]. Yes, that was quite something.. yes, wild! [...] I also sometimes used to say that she [*my daughter*] saved my life.
> **Interviewer:** How did you go about [*eating more healthily*]?
> **Diane:** Oh I just did. I knew clearly how it shouldn't be, but I didn't know exactly how

> it should be. And yes. Making the most of it […], but that is with everything. Also, with raising the children. I was not raised properly. That's way I needed assistance with raising them.. that's also how it is with cooking. However, I enjoyed having breakfast together in the morning [...] I thought that was always very important.

Thirdly, psychosocial group therapy was identified as a turning point by Diane and Annie. After suffering from depression, psychosocial therapy changed their outlook on life and equipped them with tools to take better care of their mental well-being. They emphasised that the most helpful aspect of their therapy was sharing their stories with others and feeling understood. Once their mental health was improved, there was more room to take better care of their diets as well.

> **Annie:** I have experienced it as a very wonderful experience. Due to the fact that you are sitting with a group of people, around 10, 12 people, who actually know very well what you are going through, because you are almost all going through the same thing, and that makes it easier to live with. You don't have to explain anything. [...] I still have contact with a few people from there. [...] You are, of course, receiving therapy at that time, and at some point, you start to see things differently. And then you have slowly elevated your perspective [...] this comes from how they support you in looking at things differently. You realise that the outlook is simply different. [...] And I have to say, I have benefitted a lot from it.

Finally, Saskia identified the prospect of getting married as a 'small' turning point. Her wedding motivated her to lose weight as quickly as possible. Looking thin was important for her, because she had felt always ashamed of her weight and appearance, as she had been overweight as a child.

> **Saskia**: Before getting married [...] I had also lost a lot of weight. [...] I wanted to fit into my wedding dress [...], but that motivation maybe lasted a week after that. After getting married, it was gone again [...] That now seems simply unwise: [...] to make sure you were slim as possible just to fit into your wedding dress.

Personal meaning of turning points

Although parallels and commonalities are described among the different types of turning points, it should be stressed that consideration of the personal connotations to the individual of the turning point, together with contextual- and the temporal aspects is needed to fully understand why a specific experience had such impact on a specific individual's eating practices at that specific time. The personal connotations explain why turning points varied in terms of impact and duration of the effect on eating practices. For example, from the nine turning points that Saskia mentioned, getting married improved her diet only for a short period of time, while the traumatic experience of being raped as a child still has a permanent impact on her eating behaviour. She identified this as the cause for developing emotional eating habits. In addition,

the personal meaning (or situatedness) explains why similar experiences can have different effects on eating practices. For example, the reason why losing a job was such a significant turning point for Annie, but did not affect eating practices of some others, is that Annie perceived losing her job as the main cause for the termination of her relationship.

> **Annie:** I was born in 1957 and until 1995 everything went smoothly. I never actually once thought that there was anything that could have an influence my eating. Well in 1995, I lost my job after 20 years and my relationship with my partner also fell apart. In response, I started to eat a lot [...] My partner and I also worked together. We used to see each other every day at work. And when that stopped, there were a lot of things that we didn't talk about anymore. Most of it was connected with work and then at some point.. [...] I stopped seeing him every day, you know? Then it just becomes very different, yes.

Furthermore, turning points are highly contextual, and, therefore, should be interpreted in the light of the everyday life circumstances at that time. For example, Mark identified the health warning from his GP as a turning point. Yet, coincidentally, watching a TV show on reversing T2DM with lifestyle reinforced the effect of this turning point, and being retired facilitated the implementation of the dietary advice into practice.

Finally, the strong temporal influence of past experiences on present eating practices is needed for a meaningful interpretation as this serves as an overall 'background' for the turning points. Particularly, the undeniable influence of the childhood experiences on later food norms, cooking skills and eating practices. Both food-related and more general growing-up experiences influenced eating practices in later life. Typically, the participants grew up in large families under relatively financially deprived circumstances. A few had a happy childhood, but most had a disadvantaged childhood, in which they had to work hard and felt invisible to their parents. Some even experienced severe child neglect or abuse. Living in large families implicated that all food always had to be shared. Seemingly, being in charge of what, when, and how much to eat became important for making food choices in their later lives, and may explain why participants indulged themselves with snacks once they started to live on their own. Not being in charge of food choices and feeling unacknowledged may explain for some experienced resistance towards dieting: the 'rules from the dietician' limited (again) their freedom of choice.

> **Freek:** A dietitian could tell me how much weight I would need to lose and this and that, but kind of authoritarian pressure doesn't work for me.

> **Dennis:** They [*health professionals*] don't think along with you, but more in the line of: "Let me tell you what's going to happen", and that does not work for me; I'd just tell them to piss off.

Furthermore, most participants were accustomed to eating fresh and self-produced foods during their childhoods (processed foods were relatively scarce and expensive at that time in the Netherlands). They learned and were taught food-related skills by helping their parents with harvesting, preparing, and persevering foods. Eating fresh products and cooking similar dishes to what their parents cooked was considered 'proper' and healthy food.

> **Freek:** [*My mother made*] all the old-fashioned traditional Dutch dishes; stamppot, kale with sausage, carrots, sauces, etc. We also slaughtered our own pigs and cattle ourselves, so there was plenty of everything. We had the potatoes ourselves, you had the fruit ourselves; all year round. [...] We only had to buy butter, a pack of sugar, and some flour. [...] In winter, apples were picked and peeled, and they were sent to the stone factory. There, they were dried and you could eat them on a winter's day. [...] Everything was used. [...] And then you also knew what you ate. Do you remember what you eat now? It's all stuff from abroad. People now don't know anything about half the food they eat.

Coping styles

Almost all participants experienced an ill-health confrontation turning point that led to reflectiveness on eating practices. However, how this affected actual eating practices in the present varied strongly among the participants: not all were able to eat in line with their new intentions. Broadly, two coping styles for healthy eating were distinguished: active and passive coping. In active coping, two subtypes are described: healthy coping and happy coping. The nuances within, and reasons for these coping styles are discussed in the next two paragraphs. Notably, of the participants with high SoC (> 35), most (n = 8/11) had an active coping style.

Active coping

Active coping is defined as cognitive and behavioural attempts to deal directly with stressors and their effects [69]. Two types of active coping were found that are referred to as 'healthy' coping and 'happy' coping. Healthy and happy coping have in common that the actual coping strategies are in line with deliberate decisions (intentions), however, the priority given to healthy eating in these decisions differed.

Healthy coping. Participants with a healthy coping style were able to realise their intentions to eat more healthily in everyday life. For some (Diane, Henk, Mark, Dennis, Tygo, Theo) this already led to weight loss and/or lower T2DM medication use, whereas others (Annie, Saskia and Jan) started with healthier eating only recently. All demonstrated an accurate assessment of the extent to which an unhealthy diet is indeed a threat by accepting their T2DM, and acknowledging their own influence on their health. They also internalised being a healthy eater as a part of their identity.

> **Annie:** [*While describing the items of her food box; pictures of all sorts of healthy foods*] That is what I eat. And people who really know me will recognize me in this because I eat healthy nowadays.

Secondly, their coping strategies for challenges for healthy eating were more flexible and creative than the other participants. Firstly, they generally focused on what they should and could eat instead of what they could not eat. Their new eating strategies were characterised by eating more instead of less (e.g. either eating more frequently, more of protein-rich foods, more vegetables, or more high-quality foods) and by being creative with foods (e.g. replacing snacks with healthy alternatives; experimenting with new recipes).

> **Dennis:** The thing with food is, as I have already mentioned, that if you have good food, you don't need any sauce, so there won't be any excess sugars.

In addition, they did not want to become obsessed about dieting and weight loss, and, therefore, lost weight rather slowly by changing diets gradually. Thirdly, they were actively involved in a trial-and-error process to understand their bodies better with the help of self-monitoring blood glucose.

> **Dennis:** For now, my values are okay, my weight is going down, so I am satisfied. Then I will not continue to hurt myself with the thought of having to do this or that, or worry about what's allowed or not. [...] If I do that, it becomes an obsession and I don't want that.

> **Saskia:** I want something that is entirely tailored to my needs – identify what makes me fat, like meat, so I can leave that out. I figured that out a bit and implemented it myself.

Lastly, almost all reached out for professional dietary help; either from a practice nurse/general practitioner or dietician. Notably, these participants reported pleasant and more positive experiences with their healthcare professional. Compared to the other participants, they felt trusted and supported by their healthcare professionals. They appreciated their healthcare professional's clear communication and ability to connect to their personal lives.

> **Tygo:** Well, I've been to a dietitian before [...], but they switched jobs a lot.. I have had three or four different ones there. And then the next one left and so on... That didn't work. And then I started exercising here, and there was Fleur [*dietician*]. Then Adam [*fitness trainer*] said: "Do you want to go to a dietician?" I wanted to, so then I went two or three times and then she [*Fleur*] quit, then she went to Loenen [*another city*]! I said: [...] "I would like to continue working with you!". And then we went to Loenen [...] That click that was there. If I have a good feeling with someone...

> **Dennis:** Josien, [*practice nurse*] she talked about it and then she said she could also send me to a dietician. "Would you like that?" she asked. It wasn't that I had to, but she really asked for my consent. "If you want, she can call you to make an appointment." Well, I thought it wouldn't hurt to try. And that whole conversation with the dietitian then also

came back to Josien [...] You are not rushed along or anything. Because you get that a lot, those professionals who just become snappy if you don't do as they ask.

However, there were individual differences in the level of satisfaction with, and attitudes towards current eating strategies. For Mark, Jan and Dennis, adhering to new eating strategies was easier than for Diane, Annie, Saskia, Henk and Tygo. The two extremes in this type of coping were Mark and Diane; while Mark seemed to be 'effortlessly healthy', Diane seemed more 'miserably healthy'.

Mark: We eat a lot of vegetables, lots of fresh vegetables if possible. And in the evening I do eat eggs or nuts for 2 or 3 days a week instead of a sandwich. So, no bread on those days, that's how I started this diet. And I feel very comfortable with that [...] She [*practice nurse*] always pushed for those medicines. But then those shows about diabetes were on television [*shows on national TV in which people improved their T2DM by making dietary changes*]. Then I thought: if it works that way with food, why wouldn't it work me? I will just go for it and see what the results will be.

Diane: And then I stopped smoking last year and then I was at 109–110 [*kilos*]. And now I am a year further and I am around 105 [*whispering*]. So, I lost five kilograms in a year's time .. even though my life [*style*] [...] this is very small, don't you think? Five kilos in 1 year [...], I really don't understand how that is possible. And if I were to have a bad week, I'd easily gain 3–4 k again.

Two clear differences between Mark and Diane were that Diane's diet tactics were more restricted and less flexible, and that Diane changed her diet without the help of a professional due to prior negative experiences. Together, this could lead to a situation in which Diane's frustration about healthy eating per se becomes a stressor.

Happy coping. Ria and Freek did not necessarily have the most optimal, healthy diets, and were also aware of this, but, nonetheless, were satisfied with their diets as they were and did not have a wish to improve their diets. It is important to emphasise that they were not careless about their diets: both were eating healthier compared to how they used to eat before. Yet, they were simply not willing to restrict themselves any further. Feeling good and being able to do the things that they wanted to were more important to them than improving dietary habits and losing weight. They were focused on the 'here and now', rather than worrying about their future health.

Ria: It is not important to me, eating. I mean, let me put it this way: I care very little at all for food.

Freek: Just do what you have to do and what makes you feel best. And that's it in a nutshell [...] It's the little things, but if you do it that way every day, you can do a lot.

Compared to the 'healthy' coping, the willingness of these participants for developing and considering new eating strategies seemed to be lower. They were more focused on preventing health complications by remaining on the same weight rather than actively losing weight. Their eating strategies were overall less drastic, more restricted (not buying snacks; limiting overall food intake) and less creative (e.g. using an air fryer and drinking diet drinks, but not developing new cooking skills) compared to 'healthy' coping.

> **Ria:** No, I thought that I was [*eating healthily*], I'm satisfied with it [...] I will keep it up, if nothing else comes into my body. And that I get the answers of 'yes you are doing good' when I go to the GP check-ups.

Passive coping

Passive coping is defined as cognitive attempts to avoid actively confronting problems and/or behaviours to indirectly reduce emotional tension through such behaviours [69]. These participants (Mieke, Karin, Carla, Marja, Claudia and Robert) experienced worries about their health and the incongruency between their intentions and actual eating behaviours after experiencing a confrontational turning point caused by ill-health, yet, they struggled to realise their intentions to eat more healthily into everyday life. Multiple reasons attributed to this. Firstly, they had more difficulties in accepting T2DM and facing the reality of the disease. Self-monitoring blood glucose was, therefore, perceived as very stressful and was often avoided.

> **Interviewer:** Has anything changed [in how you view the disease] compared to 10 years ago?
> **Mieke:** No, no. I still think 'oh, that one is sick' [*points to empty seat on couch*]. Not me, you know.

Secondly, they expressed to a greater extent that healthy eating in combination with T2DM is complex, particularly adjusting medications to sudden dietary changes. In addition, they were more confused by conflicting information from healthcare professionals and family members and/or friends (e.g. are diet or low calorie products healthy or not?). They also did not know how to eat healthily without starving themselves and/or comprising their enjoyment of eating (i.e. lacking knowledge/cooking skills). Instead of thinking of new ways to handle difficult situations better (i.e. active coping), these participants eating strategies were characterised by being more restricted (e.g. sticking to a strict routine; eating the same things) and more avoiding (e.g. eating at home as much as possible).

> **Marja:** In terms of food and drink, we just ate the same things as always, nothing special. You can cook nasi once, but then you bear in mind what you put into it. And that you would eat that once. We also never eat at a Chinese restaurant or anything.

Mieke: but it is often his job, [...], which always causes problems. So, now I've told him [*her husband*] if you have some event again, then I'll stay home. [...] especially when it involves food, you know? If I have to hand over control to someone else. That I no longer have control of it myself. Yes, that, that's difficult for me [...] Regularity is actually best for me. Just go to bed on time, eat on time, and get up on time.

Finally, they felt less supported by healthcare professionals and have disappointing experiences with dieting in the past (i.e. regaining weight after periods of dieting; unsupportive healthcare providers) which made them reluctant towards dieting.

Claudia: I lost a lot of weight years ago, at that time, I went to the dietitian and everything. [...] But when I stopped, it immediately came back again, so I said to myself that I wouldn't do that anymore.

Instead, they try now to accept themselves as they are. This can be seen as a 'last resort': instead of changing diets, they changed their attitudes towards diet and health.

Karin: So ... yes. That's why I just do it. I also have no idea if my sugar gets too high, what I have to do then.. how I can notice it or something. I don't know that either [...] So.. I do actually find it a bit tricky. [...] And why you do it or not; I don't think that my doctor would be concerned.

Mieke: I'm really getting sick of it. [...] And then I also said to Marijke [*practice nurse*] "I'll just give up". I'd say, take me as I am, even if that means I'm overweight. I don't care anymore. [...] Do you understand? I mean, ... then you have peace with yourself. And maybe that's when you will lose weight.

There was individual variation in the attitude towards this type of coping: some (e.g. Karin) were overwhelmed by worries, stress and emotions at the time of the study, however, most seemed to have been moved past this initial 'crisis' stage.

Interviewer: And what are things that make it easier for you to eat healthily?
Karin: Well.. I don't really know that. I don't find it easy at all. But it just has to happen. I have to be careful. If my sugar is too high then you will also have problems and I also think about being a mother where the father is no longer there for the children. I then think, yes, this mother should of course continue to live a little longer. Yes, it sounds a bit strange but that is of course how it is. That can make me a little bit emotional [*crying*].

3.4 Discussion and conclusion

Impactful, and unfortunately often bitter, life stories, rather than a lack of motivation or nutritional knowledge, explained the development unhealthy eating practices in people with T2DM and of low socioeconomic position. Adverse childhood experiences followed by an unequal share of hardship in later life deprived participants from developing strong psychosocial resources important for both managing emotional stress and healthy eating, paving the way to developing unhealthy eating practices. Indeed, a meta-analysis showed that adverse childhood experiences – especially neglect – increased the risk of T2DM by 32% [70]. The findings are also in line with a large body of evidence that demonstrates that suboptimal coping with stressful life events and negative emotions are associated with lower individual resilience [71], unhealthy eating [72, 73], weight regain [74–76], the onset of cardiovascular diseases [77] and T2DM [70], and suboptimal self-management behaviours [78–80].

The study identified moments when people are potentially more open for dietary change (confrontation with ill-health; becoming a parent, particularly when experienced child neglect; psychological therapy for treating depression), but also under which circumstances dietary change is more difficult or even impossible (losing a loved one, depression, suffering from pain, etc.). A confrontational health turning point was the most powerful turning point for healthy eating. The powerful impact for T2DM self-management of such an experience has also been observed in previous research [29, 30, 33, 34]. An important distinction between the present study and previous ones is that the present one adopted a life-course perspective, whereas the previous studies focused on a more defined period (i.e. T2DM diagnosis and onwards) [29, 30, 33, 34]. For example, one study identified experiencing coherence between newly adopted health behaviours and illness-related results as an important turning point for T2DM self-management [34]. Interestingly, in the present study, such illness-coherence experiences were not identified as turning points, but as consequences of the turning points for healthy eating. This does not mean that illness-coherence is irrelevant, in fact, insights of this nature were mentioned as useful for self-management by the 'healthy' copers. The present study complemented these insights by showing how someone's relationship with food develops over time, and, importantly, that also non-disease and non-food related life experiences, as well as the availability or resources play a role in people's attitude towards and coping strategies for self-management behaviours.

The period after a confrontational ill-health turning point is an opportune time for changing eating practices. However, it should be stressed explicitly that confrontational health turning points cannot be forced externally; they come from within the individual. A meta-analysis showed that confrontational health warnings are only effective if the receiver's self-efficacy is already high, but, otherwise, have minimal and even negative effects for health behaviour [81]. Therefore, confrontational ill-health turning points are windows of opportunity for dietary change if health professionals recognise them at the right time and provide appropriate guidance

for a self-reflective process. In addition, this study emphasised the importance of the timing of life-events: turning points for healthy eating only occurred when someone was not facing (too many) stressors at the same time.

Finally, the results show that people can turn back from turning points due to the fact that life – maybe particularly in socioeconomically disadvantaged conditions – is everchanging in terms of (stressful) circumstances, physical (ill)health, and/or significant resources. For example, Robert regained weight due to Parkinson's disease as it complicated his healthy lifestyle. Positively, an initial negative event for healthy eating such as childhood neglect can have a positive effect under different life circumstances (becoming a parent). In addition, participants were even at later age still motivated to change lifestyle behaviours, given the right conditions.

Theoretical interpretations

Applying a salutogenic lens, turning points for unhealthy eating lead to overload of the SoC-GRR-SRR pathway whereas turning points for healthy eating were 'SoC-strengthening' experiences. The detrimental effect of turning points for unhealthy eating can be explained by the incapability to manage stress in combination with an unequal share of life adversities; healthy eating was no priority under such circumstances. There was so much tension that the pathway's full capacity was required to handle the emotional aftermath of the turning points for unhealthy eating (**Figure 3.2**). This necessitated appraising diet as a comparatively small stressor or non-stressor. Even more troublesome, some individuals used eating to cope with the tension resulting from the turning point, which can lead eventually to a situation in which diet becomes an additional stressor on top of the already unmanageable tension. Turning points for unhealthy eating seemed also to affect psychosocial GRRs negatively (e.g. damaged ego identity due to losing a job; feeling unsupported during times of grief). This complicated dealing with stressors further.

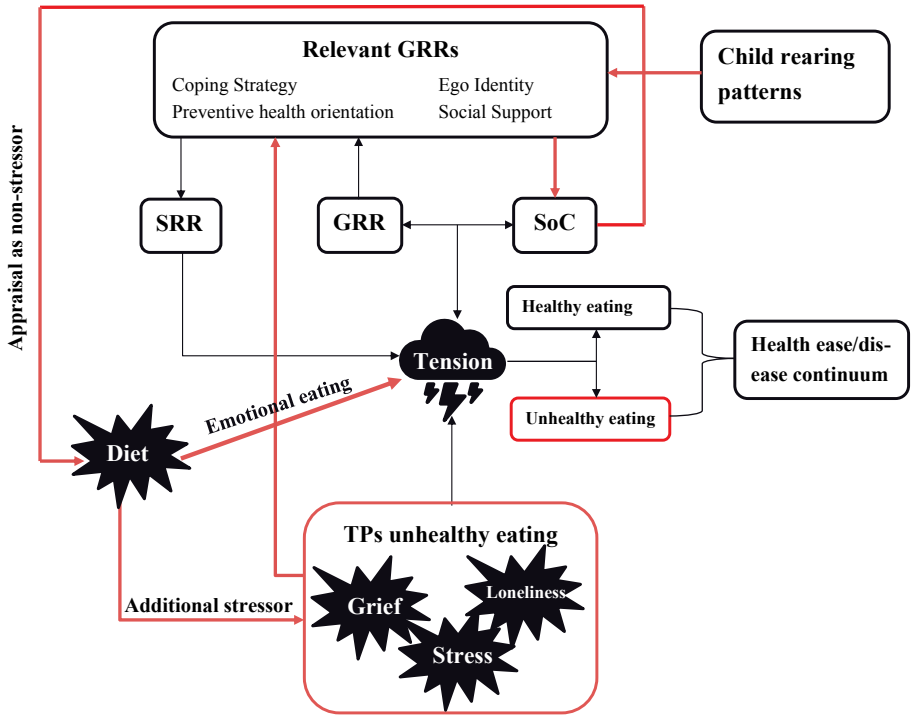

Figure 3.2 Proposed salutogenic explanation of the turning points (TPs) for unhealthy eating. Turning points for unhealthy eating caused an overload of stress(ors) that disturbed the emotional stability strongly. The SoC-GRR-SRR pathway's full capacity was needed to handle the tension created, which necessitated appraising diet as non-stressor. In some, (unhealthy) eating was used for dealing with the tensions (i.e. emotional eating). Often this caused rapid weight gain which complicated the situation further because diet became then a stressors on top of the tension-overload. Child-rearing patterns are important for developing GRRs. Growing up in poverty, experiencing childhood neglect/abuse, not feeling acknowledged by parents for the unique human being they are, were early life conditions/experiences that hindered an adequate development of psychosocial GRRs. In addition, turning points for unhealthy eating affected psychosocial GRRs negatively (e.g. damaged ego identity; feeling unsupported), which weakened the SoC-GRR-SRR pathway, and complicated dealing with stressors further.

Turning points for healthy eating strengthened the SoC-GRR-SRR pathway as they involved reflexivity and self-redefinition, an observation in line with previous research [25, 28–30, 82, 83]. It changed participants' outlooks on life and induced reflexivity on how current eating practices may comprise future goals. By this, diet became more of a priority to participants (i.e. healthy eating as a resource for health/life; meaningfulness) and it gave them insights into what needed to be changed (i.e. old habits, emotional eating behaviours; understandability) and what is needed to realise this (i.e. seeking help form a professional; manageability). Turning points for healthy eating also seemed to affect psychosocial GRR positively and directly (ego identity, social support), which strengthened the overall SoC-GRR-SRR pathway (**Figure 3.3**). Previous research also suggested that self-examination (introspection and reflection) is fundamental for enhancing SoC [84] and adopting active coping [85]. Remarkably, most participants with high

SoC score had indeed an active coping style.

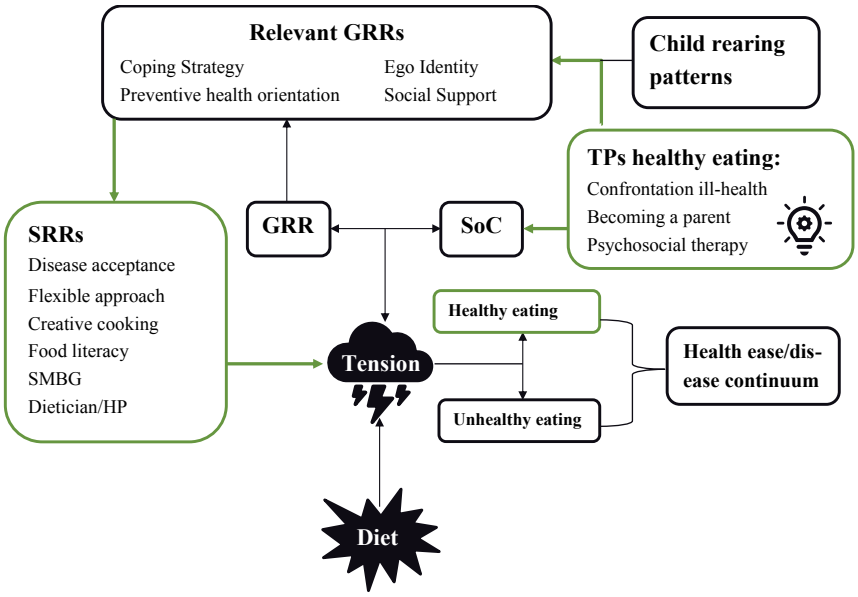

Figure 3.3 Proposed salutogenic explanation of turning points for healthy eating. Turning points for healthy eating only happened when someone was not facing other significant stressor(s) at that time. The effect of turning points for healthy eating can be interpreted as 'SoC-strengthening' as these experiences changed outlooks on life and induced reflexivity on how current eating practices may comprise future goals. By this, diet became more of a priority (meaningfulness), which led to insights on what needs to be changed (understandability) and what was needed to realise this (manageability). Turning points for healthy eating also affect psychosocial GRR positively, which strengthened the overall SoC-GRR-SRR pathway. A psychosocial GRR that seemed particular relevant for realising diet changes is coping strategy. If this GRR is well-developed, it facilitates developing coping strategies for specific situations/challenges, which requires in this case, understanding the importance of healthy eating and personal challenges within in this, making plans to overcome the challenges, anticipating challenging situations, and being flexible with this. Logically, this facilitates identification and use of SRRs relevant for realising dietary intentions.

However, even though almost all participants experienced a turning point for healthy eating, only a part of the participants seemed to be acting in line with dietary intentions (i.e. active coping) and a smaller group seemed to adhere to dietary guidelines (i.e. 'healthy' copers). This argues that self-examination alone may be a start for health behaviour change, but actual change requires also the presence of (other) well-developed internal and external GRRs/SRRs. Difference between passive- and active coping can be largely explained by difference in the extent that GRRs and SRRs were developed. Important GRRs were coping strategy, preventive health orientation, ego identity and social support. Important SRRs were disease acceptance, a flexible approach to eating, creative cooking, food literacy, self-monitoring blood glucose, and a supportive dietician/healthcare professional (with the ability to connect on a personal level). In active coping, these GRRs and SRRs were used to deal with the tensions created by the turning points. This enhanced their capability to eat in line with their intentions and develop effective and flexible diet strategies.

Participants with passive coping on the other hand had difficulties in successfully overcoming the initial emotional consequences of turning points and incorporating active coping strategies. Passive coping seemed not so much the result of deliberate decisions, but of frustration caused by the incapability to implement nutritional advice successfully into new eating strategies. Among participants with passive coping, feelings of anxiety, confusion and being a failure were more profound compared to participants with active coping. SoC and psychosocial GRRs might be developed to a lesser extent, which may explain the less frequent (use of) SRRs for healthier eating (manageability) and the perceived complexity of healthy nutrition (comprehensibility). They also felt less supported by healthcare professionals, so in a way, participants with passive coping were lacking this important and highly valued SRR of participants with active coping. Lacking well-developed GRRs and SRRs necessitated suppressing fears/worries and avoiding confrontation with T2DM in order to cope with the tensions caused by confrontational turning points.

Happy coping can be easily misinterpreted as having less developed SoC and/or GRRs as well, however, this type of coping seems not so much the results of incapability to implement nutritional advice, but rather of not prioritising (physical) health to the same level as in 'healthy' coping. Other aspects of life (work/hobbies, family) were simply more meaningful to these participants. Prioritising diet more than they already do, would possibly interfere with their quality of life.
A particularly important SRR for the individuals with 'healthy' coping was a flexible approach to eating. Adopting a positive and flexible attitude also has been identified previously as an important resource for individual resilience for coping with T2DM self-management [71], diet [62], and academic barriers [86]. In addition, a flexible approach has been associated with successful weight loss and maintenance [42, 73, 76, 87–92]. The participants with passive coping showed an approach to eating was rigid and restrictive rather than flexible. Adopting a flexible approach to eating is challenging, especially for individuals with T2DM who have an eating history that includes repeated unsuccessful weight loss attempts, emotional eating and eating beyond physical satisfaction [93].

Strengths and limitations

An important strength is the use of timelines and food-boxes, because these are easy, informal and accessible tools that facilitate a quick establishment of a trust relationship between the participant and the researcher. Participants easily opened up and enjoyed being part of the research. They felt someone was listening sincerely, and the interview gave them new personal insights. One participant even explained in the final phone call that the interview in itself was a turning point in a way. In our experiences, the current methodology led to richer data compared to structured interview methods that addressed eating practices and health behaviours more directly. Another related strength of the methodology is that participants themselves identified what they considered to be a turning point by preparing the timeline in advance, therefore, the study was closely connected to the participant's lived experiences. In previous research, the definition of which experiences were turning points and which were not seemed more part of the

analysis, and thus, more dependent on the researchers' interpretation [25, 82, 83].

Yet, an important practical limitation of the present methodology is that it is more time-consuming regarding both execution and analysis. Secondly, this study did not include measurements on actual food intake and HbA_{1c} (glycated haemoglobin) and blood glucose levels were self-reported, therefore, no firm statements could be made as to what extent the participants were truly eating in line with dietary recommendations. Some of the 'healthy' copers managed their glycaemic measurements in line with recommended targets, others did not. However, this should not be interpreted necessary as social desirability, because multiple factors (including genetics, age) influence glycaemic control [94, 95]. Instead, how people talked about their current eating practices was key for the categorisation of coping styles. Regarding externally validity, it can be argued that the participants were of medium-low rather than of low-socioeconomic position. SoC values were also relatively high. In addition, the present study focused on native-Dutch. The onset of T2DM is generally at an earlier age in migrant-Dutch [96, 97], and socioeconomic position plays a markedly different role in explaining diet quality among migrant-Dutch people [98]. Hence, future research on turning points for eating practices in cultural minorities is needed. Furthermore, the focus of this study was on eating practices, therefore, no statements can be made as to whether these findings apply to other T2DM self-management behaviours or not. Future research that is focused on multiple aspects of T2DM self-management is desirable. Finally, it was difficult to recruit sufficient participants. The participants in this study may have had different viewpoints to those who could not be reached by the recruiters or refused to participate. Nevertheless, this exposes another important point requiring scientific attention: effective ways to reach and engage individuals of (the) low(est) socioeconomic position in research [99].

Conclusion

This study demonstrates the consequences of the social environment for healthy eating over the life-course. The findings imply that individual differences in coping strategies for healthy eating are not the result of specific experiences or personal factors, but of a reflective, positive attitude towards life, and the presence of psychosocial (general and specific) resources. Healthy eating has the potential to improve long-term health, but the exploitation of that potential requires self-examination and supportive psychosocial resources. A stress-free state-of-mind, a flexible approach to eating, and feeling supported seem crucial in this. Overall, the findings are in line with previous research, stating that healthy eating is associated with an internal motivation, autonomy, self- efficacy, flexible dietary strategies, social support, effective stress management, and overall more psychological strength and stability [73, 100–104].

Therefore, especially individuals with T2DM with more passive coping might benefit from a healthcare system that is dedicated to empowerment of individuals by involving them actively in learning trajectories focused on reflexivity, self-examination, psychosocial well-being and social support. Crucial for this is that healthcare professionals are equipped with the right skills and

sufficient time to do so [102, 105]. While acknowledging the complexity of what such a learning trajectory should entail exactly and the many institutional- and practical obstacles in this, incorporating reflective tools, such as timelines and food-boxes, may be a relatively easy first step towards creating a more empowering healthcare system. In addition, dietary therapy should aim at making healthy eating and cooking uncomplicated and enjoyable. Indeed, a growing body of research suggest that positive emotions – independent of negative emotions/stress – are associated with lower cardiovascular morbidity and mortality via suggested indirect (i.e. improved health behaviours) and direct physiological mechanisms (i.e. including neuroendocrine-, inflammatory-, immunological- and cardiovascular systems) [106]. Finally, the research shows that targeting at the right moment in life may be important for the success of a dietary therapy. More research that adopts a life-course perspective to illuminate the interaction between turning points and eating practices (and other self-management behaviours) is recommended.

Ethical disclosure: This study was approved by the Social Ethical Committee of the Social Sciences Department of Wageningen University. Written informed consent was obtained from all participants.

Acknowledgements: We would like to thank the participants for sharing their personal life stories with us. We are also thankful to the healthcare professionals that made time for recruiting individuals. A special thanks to Marieke Mill and Mathilde Compagner for their efforts in organising the interviews. Finally, a sincere thank you to Marieke Mill and Babette Dingemans for their assistance during transcription of the interviews.

Funding: The research was funded by the Edema-Steernberg Foundation (Wageningen, The Netherlands). The Edema-Steernberg Foundation is a non-profit foundation that supports and initiates multidisciplinary research related to nutrition and eating behaviours.

Authors' contributions: All authors were involved in the conceptualisation of the study. CMMP set up the recruitment and conducted the interviews. All interviews were analysed independently by CMMP and (at least) one of the other authors, and were discussed until consensus was reached. The overarching themes are the result of various discussions among all authors. CMMP wrote the manuscript, and the other authors edited and commented on the manuscript. All authors have read and approved the final manuscript.

Data availability statement: The datasets generated and/or analysed during the current study are not publicly available in accordance with protection of confidentiality and privacy, but are available from the corresponding author on reasonable request.

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

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Chapter 4

Developing SALUD: Exploring the relationships between mental health and lifestyle

This chapter is published as:

Polhuis KCMM, van Bennekom E, Bot M, Nefs G, Vaandrager L, Habibovic M, Geleijnse JM, Pouwer F, Soedamah-Muthu SS.
Flourishing mental health and lifestyle behaviours in adults with Type 1 and Type 2 Diabetes Mellitus: results from the Diabetes MILES - The Netherlands Study.
J Psychosom Res. 2022 Sep;160:110950.
doi: 10.1016/j.jpsychores.2022.110950. Epub 2022 May 28.

Abstract

Background: To examine the associations between mental health and lifestyle in adults with type 1 and type 2 diabetes mellitus (T1DM and T2DM).

Methods: Online survey data from the cross-sectional Diabetes MILES - The Netherlands Study was analysed, including 270 adults with T1DM and 325 with T2DM. Mental health status (flourishing, moderate and languishing) in relation to diet, physical activity, alcohol consumption and smoking was analysed with ANCOVA and logistic regressions (adjusted for confounders).

Results: 47% of T1DM-, and 55% of T2DM participants reported flourishing mental health. Due to an insufficient number, participants with languishing mental health were excluded. In T2DM, participants with flourishing mental health had more optimal diet quality (mean ± SEM: 70 ± 1 vs 68 ± 1 diet quality score, $p = 0.015$), and physical activity levels (mean ± SEM: 3484 ± 269 vs 2404 ± 273 MET minutes/week, $p = 0.001$) than those with moderate mental health, but did not differ with respect to alcohol consumption and smoking. In T1DM, no significant associations were found.

Conclusions: Only in T2DM, people with flourishing mental health had more optimal lifestyle behaviours compared to people with moderate mental health. Further research is needed to determine if mental health is more important for specific lifestyle behaviours, and if the mental health effect differs across diabetes types.

4.1 Introduction

The global burden of diabetes mellitus is high: in 2019, the prevalence was approximately 463 million, and it is estimated that this will rise up to 700 million by 2045 [1,2]. Lifestyle behaviours, such as a balanced diet and regular physical activity, are important for both type 1 and type 2 diabetes mellitus (T1DM and T2DM), because they lower the risk of long-term vascular complications [3]. The success of current lifestyle improving approaches has been variable, and sustained long-term improvements remain difficult to achieve [4,5,6]. For sustainable lifestyle changes, it is inevitable to pay attention to contextual factors that influence lifestyle behaviours in everyday life [7,8]. An important factor in this is mental health.

Mental ill-health (e.g. anxiety, depressive and psychiatric disorders) is an important risk factor for developing diabetes [9,10]. There is a large body of research that has demonstrated that mental ill-health among people with diabetes increases changes of an unhealthy lifestyle [11], cardiovascular complications [12], and all-cause mortality [13]. Associations between mental ill-health and glycated haemoglobin (HbA_{1c}) seem bi-directional: depressive symptoms have been associated with developing suboptimal HbA_{1c}, and suboptimal HbA_{1c} has been associated with an increased risk of developing depression [14].

Most research on diabetes and lifestyle behaviours focussed on mental ill-health rather than mental health per se [15]. Mental health is not simply the absence of negative mental states. The WHO defines mental health as a multidimensional concept: 'a state of well-being in which an individual realizes his or her own abilities, can cope with the normal stresses of life, can work productively and is able to make a contribution to his or her community' [16]. This definition is in line with theoretical frameworks such as positive psychology and salutogenesis that focus on factors that improve and create health well-being [17,18].

Yet, there is an increasing interest in how positive mental health can contribute to lifestyle and vice versa [19,20,21]. Especially since positive mental health and lifestyle seem bi-directionally related as well: maintaining a healthy lifestyle improves mental well-being [22], and more optimal mental health increases changes towards a healthy lifestyle [23]. There are several concepts available that have been used to measure positive mental health (e.g. positive affect, well-being, self-efficacy, empowerment, optimism) [19]. Indeed, a meta-analysis of 26 studies found that well-being was associated with lower rates of mortality in populations with and without medical conditions, independent of traditional risk factors [24]. In T1DM and T2DM, mental health (measured by, among other concepts, positive affect, and well-being) was associated with reduced mortality, more self-care activities and more optimal HbA_{1c} [19,25]. Simultaneously, psychological interventions were able to improve mental wellbeing and HbA_{1c} [26,27]. However, these concepts for mental health are closely related to, but not synonymous with mental health. They merely related to one aspect of mental health: either the hedonic (feelings of happiness)

or the eudaimonic (individual functioning) aspect. Yet, the WHO definition of mental health comprises both hedonic and eudaimonic aspects. To the best of our knowledge, one study so far used a measure for mental health that included both hedonic and eudaimonic aspects among people with diabetes [28]. This study showed that a state of flourishing mental health (i.e. optimal positive mental health) was associated with more exercise, better self-rated health, fewer comorbidities, less functional- disability and lower likelihood of smoking [28]. However, this study neither investigated diet, nor adjusted analyses for potential confounders, nor investigated the results for T1DM and T2DM separately.

Since the relationships between mental health and lifestyle in diabetes has been insufficiently investigated so far, this study examines the relationships between mental health –ranging from languishing to moderate to flourishing mental health– and lifestyle behaviours (diet, physical activity, alcohol consumption and smoking) using the data from the Diabetes MILES-the Netherlands (Diabetes MILES-NL). The effect of mental health was investigated separately for T1DM and T2DM, because these are different conditions which potentially yield different conclusions. It was hypothesised that for both T1DM and T2DM, flourishing mental health would be associated with more optimal lifestyle behaviours compared to languishing and moderate mental health.

4.2 Methods

Study design and procedure

Data from the Diabetes MILES-NL study was used, which was a national cross-sectional study conducted in 2011 using an online survey to investigate psychosocial aspects in people with diabetes. The rationale and methods of the entire study were described elsewhere [29]. The Psychological Research Ethics Committee of Tilburg University approved both the Diabetes MILES-NL study (EC-2011 5), and the current secondary analysis (RP-2019).

The online survey consisted of a core questionnaire (questions on demographics, clinical variables, and lifestyle behaviours) and five modules with additional questionnaires, each with its own topic (self-care, depression, mindfulness and positive mental health, sleep, and relations to others). After finishing the core questionnaire, participants were randomly offered one of the five modules. The current study focussed on data from the core questionnaire and module 3: mindfulness and positive mental health.

Participants

Participants were recruited via Dutch health websites and media channels of national diabetes organisations. Inclusion criteria were 1) adults (>18 years old) and 2) any type of (self-reported) diabetes diagnosis. It was indicated that participation was voluntary, and data would be analysed anonymously. Participants signed a digital informed consent before participation. In total, 3301

participants finished the core questionnaire and one of the five modules, with 684 participants being allocated to module 3. The current study included the 595 participants who completed the both the core questionnaire and module 3 (**Fig. A.1**).

Variables

Mental health

Mental health was assessed with the Mental Health Continuum-Short Form (MHC-SF). The MHC-SF has been validated among Dutch adults, has high internal reliability, good test-retest reliability and good convergent validity [30]. The MHC-SF consists of two subscales: emotional and psychological well-being. The emotional subscale relates to the hedonic (feelings of happiness) aspect of well-being and consists of three items (happiness, interest and life satisfaction). The psychological subscale relates to eudaimonic (optimal functioning) aspect of well-being and consists of six items (self-acceptance, mastery, positive relations, personal growth, autonomy and purpose in life). Per item, the participants indicated how often they had experienced each feeling over the past month by using a 6-point Likert scale. The scores were divided into three categories based on existing guidelines for categorising mental health as measured by the MHC-SF: 1) languishing mental health, 2) moderate mental health and 3) flourishing mental health [31]. Please note that flourishing mental health is different from the term 'flourishing' as used in the positive psychology model of Seligman [18]. Participants were categorised as having languishing mental health when they indicated a score of zero or one on at least one of the items of emotional well-being, and at least four items of psychological well-being. Participants were categorised as having flourishing mental health when they indicated a score of four or five on at least one of the items of emotional well-being, and at least four items of psychological well-being. The participants who could not be categorised as either flourishing or languishing mental health were categorised as having moderate mental health. Previously, flourishing mental was associated with more physical activity, better sleep, less stress, lower likelihood of smoking, better self-rated health, fewer co-morbidities, and less functional disability [28,32].

Lifestyle behaviours

Diet. Diet was assessed using a 38-item food frequency questionnaire [29], in which participants indicated how many days per week they consumed certain foods with use of a four-point Likert-scale ('0 days per week', '1–3 days per week', '4–5 days per week' and '6–7 days per week'). Unfortunately, questions regarding portion sizes were not included. Therefore, we estimated the portion sizes for each item to calculate the consumed quantity of food products in grams per day. First, we linked a product code based on the Dutch National Food Composition Database (NEVO, online version 2019/6.0) to each item, followed by the average portion size based on the Dutch National Food Consumption Survey (DNFCS 2012–2014) [33] and the portion-size online tool (National Institute for Public Health and the Environment, version 2017/ 1.1). Total

consumed quantity (g/d) was calculated, by multiplying the frequency of consumption by the estimated portion sizes.

Diet quality and the intake of specific food components was calculated using the Dutch Healthy Diet index (DHD-index): an index that enables ranking participants based on the extent to which they follow the Dutch dietary guidelines of 2006 [34]. The DHD-index originally consisted of ten components, of which eight were included in the current study (the components physical activity and acidic drinks and foods were not included, because physical activity was measured separately, and there was insufficient information collected on acidic drinks and foods). Each component was scored on a scale ranging from 0 (not following of the dietary guidelines) to 10 (complete following of dietary guidelines), eventually providing a total score between 0 and 80. For the categorical analyses, the diet quality scores were categorised into tertiles, with higher scores indicating a more optimal diet quality (i.e. low: a score up to 64.76; intermediate: a score between 64.76 and 71.98; and high: a score above 71.08).

Because more research became available on dietary patterns and chronic diseases, the Dutch dietary guidelines have been updated in 2015, which led to an updated DHD-index: the Dutch Healthy Eating 2015 index (DHD15-index) [35]. The data was collected in 2011 and analysed in 2021. Hence, all analyses that focused on diet were performed twice: based on the guidelines of 2006 (i.e. DHD-index), and based on the guidelines of 2015 (i.e. DHD15-index). The main difference between the guidelines of 2006 and 2015 is that the guidelines of 2006 were based on nutrients, and the guidelines of 2015 are based on foods. Other differences are: the addition of three new guidelines (for legumes, nuts, and tea), the guideline for fish/polyunsaturated acids is less stringent, and the guidelines for fruits, vegetables, and alcohol consumption are more strict (see **Table A.1** for a comparison). The results based on the guidelines of 2006 are displayed in the main tables, because this was the advice the participants were receiving at time of inclusion in this study. The results based on the guidelines of 2015 are displayed in the appendices.

Physical activity. Physical activity was assessed with the validated International Physical Activity Questionnaire short form (IPAQ) [36], in which participants self-reported the frequency and the duration of vigorous and moderate activities, and of walking and sitting (additional items). The answers were used to calculate the Metabolic Equivalent of Task (MET) minutes over the previous week. For the continuous analyses, the total amount of vigorous, moderate and walking MET-minutes per week was used. For the categorical analyses, physical activity was separated into three categories based on existing IPAQ scoring criteria [37]: low, intermediate and high physical activity.

Alcohol consumption. Alcohol consumption was assessed by a singular item in which participants had to self-report the number of units of alcoholic drinks per week (0, 1–7, 8–14, 15–21, 22–28, 29–25 or 36 or more alcoholic drinks per week) [29]. We estimated the grams per day based

on the assumption that one alcoholic beverage contains 10 g of alcohol. Categorised measures of alcohol intake were also calculated, based on the Dutch dietary guidelines of both 2006 and 2015 [35,34]. Hence, alcohol consumption was categorised as 'low' if consumption was according to either the guidelines of 2006 or 2015, respectively, and as 'high' if consumption was not according to the guideline of either 2006 or 2015, respectively (**Table A.1**).

Smoking. Smoking was assessed with use of a self-reported singular item in which participants indicated the frequency of their smoking behaviour (daily, weekly, once in a while, never, or unknown) [29]. In the analyses, the answers were dichotomized (i.e. daily smoking or not).

Demographic and clinical characteristics

The following demographic variables were included: sex (male/female), age (years), marital status (having a partner yes/no), ethnicity (Dutch or ethnic minority), education (based on the highest completed education, subdivided in low/middle/high; based on the criteria of Statistics Netherlands [38]), current employment (paid employment yes/no). Clinical characteristics included were: diabetes type, diabetes duration (years), diabetes treatment regimen (insulin injections, insulin pump, GLP injections, oral medication, or lifestyle), most recent HbA_{1c} (mmol/mol, or ticking the box "I don't know"; HbA_{1c} % was calculated by the following formula: *% = 0.0915*mmol/mol + 2.15*), BMI (kg/m2), the number of comorbidities (the sum of indicated comorbidities), and the number of hospitalisations (the sum over the past 12 months).

Statistical analysis

The demographic and clinical characteristics of the total sample, and the sample stratified by diabetes type and mental health category were calculated and tabulated as mean and standard deviation (mean ± SD) or as percentage ((%)N). Differences in demographics and clinical factors between moderate and flourishing mental health were tested with chi-square tests (categorical variables), and Mann-Whitney U tests (continuous variables). Missing values for age (n = 9), current employment (n = 1), and BMI (n = 9) were imputed with use of multiple imputation. All main analyses were stratified by diabetes type. In all analyses, mental health was the independent variable, and the lifestyle behaviours (all continuous variables except smoking) were the main dependent variables. The group with languishing mental health was excluded from the final analyses due to a small number of participants (n = 33). It was decided not to collapse the languishing and moderate mental health group because it would impair the distinction between mental health and mental ill-health. Therefore, ANCOVA was used to test the differences between flourishing and moderate mental health. Three models were used to adjust for confounders step-by-step. The first model was unadjusted (i.e. the crude model), the second model was adjusted for age and sex, and the final model was additionally adjusted for having a partner (yes/no), BMI, diabetes duration (years), education (low, middle, high), and employment (paid employment yes/no). These confounders are often adjusted for in similar analyses, facilitating comparability of the results [39,40,41]. Outcomes were displayed as adjusted mean and the standard error of

the mean (SEM). Subsequently, multivariate binary and multinomial logistic regression analyses were performed, despite some loss of statistical power, based on categorical measures of the lifestyle behaviours due to three reasons: 1] smoking was a categorical outcome and cannot be analysed with ANCOVA, 2] the odds ratio's (OR) of lifestyle behaviours can be more easily compared to previous literature, and 3] it allows for ranking people in sequential groups from low-intermediate-high diet quality and physical activity. In more detail, the multinomial logistic regression analyses were performed to investigate the associations between the independent variable mental health and the ordinal dependent variables diet quality and physical activity with three categories ('low', 'intermediate' or 'high'). Because the proportional odds assumption was not met (i.e. the predictors did not have the same effect on the odds of moving to a higher-order category along the scale), multinominal logistic regression (instead of ordinal logistic regression) was performed. Binary logistic regression analyses were performed for the dichotomous dependent variables alcohol consumption and smoking. Moderate mental health and the lowest categories of the lifestyle behaviours were the reference categories. The same three models as in the ANCOVA analyses were used to adjust for confounders. Outcomes are tabulated as OR and 95% Confidence Interval (95%CI). Effect modification was tested with use of interaction terms. To test whether the associations differed between sex (male vs female), BMI categories (overweight (= BMI >25) yes/no), presence of comorbidities (yes/no), having a partner (yes/no), and educational level (low/middle/high), interaction terms were added to each final model separately to test for interaction. The models were also tested for multicollinearity by evaluating the Variance Inflation Factors (VIF). Data was analysed using IBM SPSS Statistics 25. p-values of 0.05 were considered statistically significant.

4.3 Results

Sample characteristics

Table 4.1 shows the demographic, clinical and behavioural characteristics for the total sample, and stratified by diabetes type and mental health category. Of the 595 participants, 45% had T1DM and 55% T2DM. Regarding T1DM, more female participants (51%) had flourishing mental health. Participants with T1DM and flourishing mental health had a higher intake of fruits and grains compared to moderate mental health (**Table A.2** and **A.3**). Regarding T2DM, more male participants had flourishing mental health (58%). Participants with T2DM with flourishing mental health were also more likely to have a partner (**Table 4.1**), and had a higher intake of nuts compared to moderate mental health (**Table A.3**).

Table 4.1 Characteristics of the total sample, and characteristics stratified by diabetes type and mental health category.

	T1- and T2DM (n= 595)	T1DM (n= 270)				T2DM (n= 325)			
		Mental health category				Mental health category			
		Languishing (n=15)	Moderate (n=128)	Flourishing (n=127)		Languishing (n=18)	Moderate (n=130)	Flourishing (n=177)	
	%(N) or mean±SD	%(N) or mean±SD	%(N) or mean±SD	%(N) or mean±SD	P-value	%(N) or mean±SD	%(N) or mean±SD	%(N) or mean±SD	P-value
Demographics									
Women	52(307)	27(4)	67(86)	51(65)	**0.009***	50(9)	53(69)	42(74)	**0.050***
Age (y)	55±14	51±12	46±15	49±15	0.104	54±11	61±10	62±9	0.114
Ethnic minority	2(12)	0(0)	1(1)	2(2)	0.557	0(0)	4(5)	2(4)	0.416
Education level					0.887				0.419
Low	22(129)	20(3)	17(22)	16(20)		33(6)	23(30)	27(48)	
Middle	34(201)	47(7)	28(36)	31(39)		39(7)	35(45)	38(67)	
High	45(265)	33(5)	55(70)	54(68)		28(5)	42(55)	35(62)	
Having a partner	82(488)	80(12)	81(103)	84(106)	0.534	67(12)	75(97)	89(158)	**0.001***
Paid employment	51(301)	40(6)	63(80)	72(91)	0.120	44(8)	36(47)	39(69)	0.613
Clinical characteristics									
Diabetes duration (y)	17±13	24±15	24±15	23±15	0.607	8±5	10±8	11±8	0.092
Diabetes treatment					0.091				0.853
Insulin pump	25(150)	33(5)	56(71)	45(57)		0(0)	7(9)	5(8)	
Insulin injections	47(278)	67(10)	45(57)	55(70)		56(10)	42(54)	44(77)	
GLP injections	1(5)	0(0)	0(0)	0(0)		6(1)	1(1)	2(3)	
Oral medication	25(148)	0(0)	0(0)	0(0)		39(7)	46(60)	46(81)	
Lifestyle only	2(14)	0(0)	0(0)	0(0)		0(0)	5(6)	5(8)	
HbA_{1c} (mmol/mol)	56±12	55±12	58±12	58±11	0.647	54±13	55±12	53±10	0.119
HbA_{1c} (%)	7.2±1.1	7.2±1.1	7.4±1.1	7.4±1.0		7.1±1.1	7.2±1.1	7.0±1.0	
BMI (kg/m^2)	28±6	26±12	25±5	26±5	0.791	33±7	30±6	29±5	0.216
BMI ≥*25*	62(366)	27(4)	42(54)	43(54)	0.957	89(16)	80(104)	76(134)	0.373
Co-morbidities ≥*1*	78(465)	93(14)	71(91)	71(90)	0.968	78(14)	84(109)	83(147)	0.853
Hospitalisations ≥*1*	18(104)	20(3)	18(23)	17(21)	0.740	17(3)	19(25)	16(29)	0.517

Note. Outcomes are displayed as percentage ((%)N) or as mean and standard deviation (mean±SD) (chi-square tests for categorical variables and Mann-Whitney U tests for continuous variables).
*Statistically significant ($p \leq 0.05$).

Associations between mental health and the lifestyle behaviours

Tables 4.2 and 4.**3** show the associations between mental health and the lifestyle behaviours based on ANCOVA and the logistic regression analyses, respectively. There were no significant interaction effects between mental health category and sex, BMI, presence of comorbidities, having a partner and education level on lifestyle behaviours. Evaluation of the VIF showed no multicollinearity between the variables in the models.

Table 4.2 Associations between flourishing and moderate mental health (independent variable) based on the continuous variables of the lifestyle behaviours (dependent variables) (ANCOVA).

	T1DM (n=255)			**T2DM (n=307)**		
	Mental health category			***Mental health category***		
	Moderate (n=128)	**Flourishing (n=127)**		**Moderate (n=130)**	**Flourishing (n=177)**	
	mean±SEM[a]	***mean±SEM[a]***	***P-value***	***mean±SEM[a]***	***mean±SEM[a]***	***P-value***
Diet quality *(score)*						
Model 1	66±1	68±1	**0.047***	67±1	69±1	**0.026***
Model 2	66±1	68±1	0.064	67±1	69±1	**0.041***
Model 3	66±1	68±1	0.053	68±1	70±1	**0.016***
Physical activity *(MET-minutes/week)*						
Model 1	3195±268	3483±269	0.449	2291±247	3451±211	**<0.001***
Model 2	3300±276	3496±270	0.611	2270±245	3442±212	**<0.001***
Model 3	3730±324	3880±335	0.695	2380±280	3472±272	**0.001***
Alcohol *(g/day)*						
Model 1	11±1	11±1	0.850	10±1	9±1	0.624
Model 2	12±1	11±1	0.605	10±1	9±1	0.370
Model 3	9±1	8±1	0.510	9±1	7±1	0.318

Note. Model 1: crude model; model 2: adjusted for age and sex; model 3: additionally adjusted for having a partner (yes/no), BMI, diabetes duration (years), education level (low, middle or high), and employment (paid employment yes/no).
*Statistically significant (p≤0.05).
[a]Outcomes are displayed as estimated marginal mean with standard error of the mean (SEM).

TYPE 1 DIABETES MELLITUS

Diet quality. The ANCOVA showed that flourishing mental health was significantly associated with a higher total diet quality score compared to moderate mental health in the crude model (mean ± SEM: 68 ± 1 vs 66 ± 1, p = 0.047), but this association was attenuated in model 2 (**Table 4.2**). When repeating the ANCOVA for diet quality with the 2015 dietary guidelines, flourishing mental health was not associated with higher diet quality compared to moderate mental health in any of the models (**Table A.4**). The logistic regression showed that people with flourishing mental health had a 1.6 times higher odds (95%CI: 0.9–3.1) to have high diet quality compared to people with moderate mental health in the final model, albeit this was not significant (**Table 4.3 and Table A.5**).

Physical activity. No significant associations were found in any of the analyses (**Table 4.2, Table 4.3**).

Alcohol consumption. No significant associations were found in any of the analyses (**Table 4.2, Table 4.3 and Table A.5**).

Smoking. No significant association was found (**Table 4.3**).

Table 4.3 The associations between flourishing and moderate mental health (independent variable) based on the categorical measures of the lifestyle behaviours (dependent variables) (binary and multinomial logistic regression analyses).

			T1DM (n=255)	T2DM (n=307)
			Flourishing vs. Moderate Mental Health	Flourishing vs. Moderate Mental Health
			OR(95%CI)[a]	*OR(95%CI)*[a]
Diet Quality *(score)*	Model 1	*Low*	1.0(reference)	1.0(reference)
		Intermediate	0.8(0.4-1.4)	1.4(0.8-2.4)
		High	1.6(0.9-2.8)	1.5(0.9-2.7)
	Model 2	*Low*	1.0(reference)	1.0(reference)
		Intermediate	0.8(0.4-1.4)	1.3(0.7-2.2)
		High	1.5(0.8-2.8)	1.5(0.8-2.7)
	Model 3	*Low*	1.0(reference)	1.0(reference)
		Intermediate	0.7(0.4-1.4)	1.3(0.7-2.3)
		High	1.6(0.9-3.1)	1.5(0.8-2.8)
Physical Activity *(MET-minutes/week)*	Model 1	*Low*	1.0(reference)	1.0(reference)
		Intermediate	0.9(0.4-2.0)	1.0(0.6-1.9)
		High	1.1(0.5-2.5)	1.9(0.998-3.7)[b]
	Model 2	*Low*	1.0(reference)	1.0(reference)
		Intermediate	0.9(0.4-2.1)	1.0(0.6-1.9)
		High	1.1(0.5-2.5)	1.9(0.995-3.7)[b]
	Model 3	*Low*	1.0(reference)	1.0(reference)
		Intermediate	1.0(0.5-1.9)	1.0(0.5-2.0)
		High	1.7(0.9-3.5)	1.8(0.9-3.6)
Alcohol consumption *(g/day)*	Model 1	*Low*	1.0(reference)	1.0(reference)
		High	1.1(0.5-2.1)	0.9(0.4-1.8)
	Model 2	*Low*	1.0(reference)	1.0(reference)
		High	1.1(0.6-2.3)	0.9(0.4-1.9)
	Model 3	*Low*	1.0(reference)	1.0(reference)
		High	1.2(0.6-2.5)	0.9(0.4-1.9)
Smoking *(smoking vs non- smoking)*	Model 1	*Low*	1.0(reference)	1.0(reference)
		High	0.7(0.3-1.9)	0.7(0.3-1.6)
	Model 2	*Low*	1.0(reference)	1.0(reference)
		High	0.6(0.2-1.7)	0.8(0.3-1.7)
	Model 3	*Low*	1.0(reference)	1.0(reference)
		High	0.6(0.2-1.9)	0.7(0.3-1.7)

Note. Model 1: crude model; model 2: Adjusted for age and sex; model 3: additionally adjusted for having a partner (yes/no), BMI, diabetes duration (years), education level (low, middle or high), and employment (paid employment yes/no). [a]Outcomes are displayed as odds ratio (OR) and 95% confidence interval (95%CI).

TYPE 2 DIABETES MELLITUS

Diet quality. The ANCOVA showed that flourishing mental health was significantly associated with a higher diet quality score (mean ± SEM: 70 ± 1 vs 68 ± 1, p = 0.016) compared to moderate mental health in the final model (**Table 4.2**). The logistic regression confirmed this relationship with ORs of 1.5 (95%CI: 0.8–2.8) for higher diet quality in the final model, albeit not statistically significant (**Table 4.3**). When repeating the ANCOVA for diet quality with the 2015 dietary guidelines, flourishing mental health was also significantly associated with higher

diet quality compared to moderate mental health in the final model (mean ± SEM: 87 ± 1 vs 83 ± 1, p = 0.006; **Table A.4**). When using the 2015 dietary guidelines, people with flourishing mental health had a 2.1 higher odds (95%CI: 1.1–3.9) to have high diet quality compared to moderate mental health in the final model (**Table A.5**).

Physical activity. The ANCOVA showed that flourishing mental health was significantly associated with higher physical activity (mean ± SEM: 3472 ± 272 vs 2380 ± 280, p = 0.001) compared to moderate mental health in the final model (**Table 4.2**). The logistic regression analyses confirmed this relationship with a 1.8 OR (95%CI: 0.9–3.6) for higher physical activity in the final model, albeit not statistically significant (**Table 4.3**).

Alcohol consumption. Based on the Dutch alcohol guideline of 2006, mental health was not associated with alcohol consumption (**Table 4.2, Table 4.3**). When using the 2015 alcohol guideline, flourishing mental health was associated with suboptimal following of the guideline in model 2 (OR(95%CI): 1.6(1.008–2.6)), but this association was attenuated in the final model (**Table A.5**).

Smoking. No significant association was found (**Table 4.3**).

4.4 Discussion and conclusion

This cross-sectional analysis of the Diabetes MILES-NL study showed that people with T2DM with flourishing mental health had a diet more in line with dietary guidelines, and were more physically active compared to those with T2DM and moderate mental health. Regarding physical activity, findings are in line with a recent Canadian cross-sectional study that found that flourishing mental health was positively associated with more physical activity in people with diabetes (T1DM and T2DM together) [28]. Furthermore, several other cross-sectional studies showed that positive mental state constructs (such as positive affect, self-esteem and empowerment) were significantly associated with physical activity in T2DM [42,19,43]. Although the relationship between flourishing mental health and diet has not been previously investigated, previous studies showed that high self-efficacy was significantly associated with a healthier diet in T2DM [42,19,43]. Particularly for diet, it is important to reflect on socioeconomic status (SES). A high-quality diet is generally easier for people with a higher SES [44], while incidence of diabetes is higher among people with a lower SES [45]. Indeed, a previous study demonstrated that flourishing mental health was significantly associated with a higher level of income in people with diabetes [28]. In the present study, the level of income was not measured, but the percentage of highly educated people (45%) was larger than the national average of 32% [46]. Although all analyses were adjusted for education level, this may limit the generalisability to the total Dutch population.

Interestingly, the associations of flourishing mental health with diet and physical activity were not significant in people with T1DM. This was rather unexpected as previous studies demonstrated significant positive associations between self-efficacy and diet, and between self-efficacy and physical activity in T1DM [19,47,48]. Although self-efficacy does not equal mental health, it has been described as an important positive psychological characteristic in diabetes [19]. Further research seems needed to examine if the effect of mental health on lifestyle behaviours differs across diabetes types.

Regarding alcohol consumption, no significant associations were found with mental health in both T1DM and T2DM, which is in line with a Canadian cross-sectional study on flourishing mental health in diabetes [28]. Yet, when applying the Dutch alcohol guideline of 2015, flourishing mental health was significantly associated with suboptimal adherence to the guideline among people with T2DM in the first two models. This is somewhat contradictory with previous research demonstrating that mental ill-health (i.e. depressive and anxiety symptoms) are associated with higher alcohol use among T1DM and the general population [49,50]. During the data-collection (2011), the national alcohol guideline was less restrictive compared to the current guideline, hence, this may explain the suboptimal adherence in people with flourishing mental health. Alternatively, research suggested that people with mental ill-health use alcohol as a coping mechanism for anxiety and depression [49]. Perhaps, people with flourishing mental health use alcohol for other reasons, such as relaxation, social company or celebration. This hypothesis seems supported by a cross-sectional study that demonstrated culture-specific effects of mental health and alcohol consumption: more frequent alcohol consumption predicted more optimal mental health in German, but more suboptimal mental health in Chinese students [51]. More research in different contexts seems needed for a better understanding of mental health in relation to alcohol consumption.

Regarding smoking, the current study did not find significant associations with mental health in both T1DM and T2DM as well. This is in contrast to a Canadian cross-sectional study that found that flourishing mental health was in fact associated with a lower likelihood of smoking among people with diabetes [28]. Other previous studies showed that smoking was a predictor of mental ill-health (e.g. depression, negative affect, anxiety and stressors) [52,53,51]. Possible reasons that the present study did not find an association might be the relatively small percentages of smokers in the sample (8%) compared to the general Dutch population (15%) [54], and that the sample consisted of people with relatively optimal mental health as the group with languishing mental health was excluded from the analyses.

Strengths and limitations

This study is one of the first that focused on mental health (rather than mental ill-health) and lifestyle in diabetes, and it is the first study that investigate the association between flourishing mental health and diet. A second strength is that mental health was determined based on two-

dimensions (e.g. emotional and psychological mental health), whereas other studies usually use a mental health measure that relates to one of these dimensions [19,21]. Hence, a more comprehensive measure of mental health was used compared to previous studies. A third strength is that the association between mental health and multiple lifestyle behaviours was investigated, rather than focussing on a single behaviour. A final strength is the robustness of results as demonstrated by multiple confounder models, and analyses based on the old and the most recent Dutch dietary guidelines.

A limitation of this study is the cross-sectional design, which means no conclusions on causality or temporality can be made. Hence, it is possible that optimal diet and physical activity levels precede mental health. Randomised controlled trials (RCTs) have shown indeed that a healthy lifestyle can improve mental health [55,56]. RCTs regarding the other direction of the association are relatively scarce [57], but it seems plausible that the relationship is bidirectional [19]. Secondly, the data collection was based on self-reported measures, which might have caused an information bias. However, since the additional categorical analyses yielded similar results as the main analyses, this problem was reduced, because these errors have a smaller effect in categorical analyses where participants are ranked. Thirdly, the measures for assessing SES were quite limited, which may have caused residual confounding. Future studies are highly recommended to included more thorough SES measures. Fourthly, the group of participants with languishing mental health was too small for meaningful analysis. Previous research has shown that mental ill-health was consistently associated with more suboptimal health behaviours [12,13,11]. Hence, it seems likely that languishing mental health would have been associated with more suboptimal lifestyle behaviours compared to moderate and flourishing mental health. A future study with a larger group of people with languishing mental health would be needed to test this hypothesis. To reach sufficient people with languishing mental health, future studies may consider other/additional recruitment strategies.

Conclusion

This is one of the first studies that investigated a composite measure of positive mental health in relationship to lifestyle behaviours among people with T1DM and T2DM. The present findings support the importance of flourishing mental health for two key cornerstones of diabetes self-management: diet and physical activity. Although no conclusions can be made about causality/temporality, this study, together with numerous previous studies, has shown that mental health (rather than mental ill-health) plays an important role in healthy lifestyle behaviours among people with diabetes [19,20]. Biologically, flourishing mental health might directly cause favourable physiological effects, such as lowering the cortisol and the inflammatory responses to psychological stressors [19,58,59]. Behaviourally, flourishing mental health may facilitate healthier lifestyle behaviours and treatment adherence, and, thereby, mediate optimal blood glucose levels [19]. As it is likely that flourishing mental health and lifestyle behaviours reinforce

each other, it is pivotal to design RCTs evaluating interventions aimed at promoting mental health to accomplish a healthy lifestyle. Especially since most of the (relatively limited available) interventions for improving mental health as a means to a healthier lifestyle are still focussed on coping with mental ill-health (e.g. decreasing perceived barriers, coping with diabetes-related distress and depression) [15,57]. Only a few interventions applied holistic strategies to enhance skills and behavioural processes important for psychological flexibility/mental health explicitly; the so-called third wave behaviour therapies (e.g. acceptance and commitment therapy, mindfulness and self-compassion training) [60]. The use of third wave behavioural therapies for T2DM seems promising so far [15]. Theoretical models such as positive psychology or salutogenesis are useful for designing mental health promoting interventions [15,20,61].

Finally, this study raises the question if positive mental health is more important for specific lifestyle behaviours (i.e. diet and physical activity) compared to others behaviours (i.e. alcohol and smoking), and if the effect of mental health on lifestyle behaviours differs across diabetes types. Although further research is needed, intervention developers may take this in consideration when designing mental health promoting strategies. For clinical practice, it is recommended to think of ways how to include mental health-promoting strategies, such as self-examination or mindfulness, in the primary care setting for T2DM.

Acknowledgements: We would like to thank all participants who participated in Diabetes MILES-NL study. We also thank Professor Jane Speight (affiliated with the Deakin University, and The Australian Centre for Behavioural Research in Diabetes) for her central role in the international Diabetes MILES collaborative, and her advice for setting up the Diabetes MILES study in the Netherlands. We thank the Dutch Association for Diabetes Research for the grant for the Diabetes MILES study. Finally, we thank the Dutch Diabetes Association and the Dutch Diabetes Research Foundation for their kind and very valuable assistance in the recruitment of participants.

Funding: The Diabetes MILES-NL study was supported by the Prof. dr. J. Terpstra Young Investigator Award 2010 from the Dutch Association for Diabetes Research (Nederlandse Vereniging voor Diabetes Onderzoek)/ Lilly Diabetes to GN. The funding source had no role in the design, data collection, analysis or interpretation of the study, or in the decision to submit the manuscript for publication.

Authors' contributions: Diabetes MILES-NL is an international collaborative, initiated and conceptualized by Professor FP in the Netherlands. FP, GN, and MB, set up the Diabetes MILES-NL study, acquired funding, and collected the data. The idea for this paper was generated by SSM. Data analysis was conducted by EvB. Interpretation of the data has been done by CMMP, SSM and EvB. The paper was written by CMMP. FP, MH, LV, MB, GN, JMG, and SSM revised the paper for important intellectual content. All authors have read and approved the final article.

Data availability statement: Data sets are available upon reasonable request via contacting the corresponding author.

Competing interest: The authors have no competing interests to report.

Supplementary materials

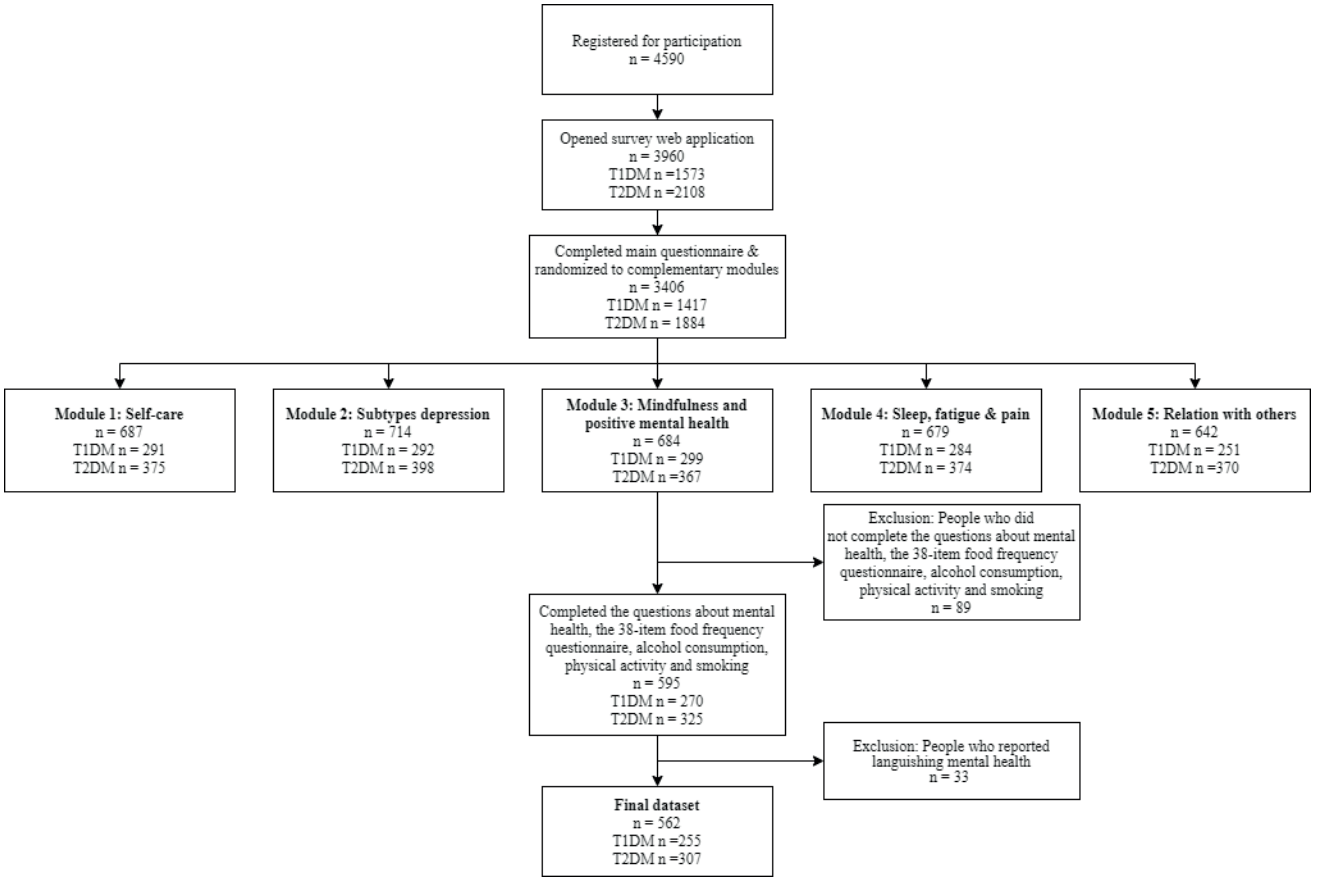

Figure A.2 Flowchart of the inclusion of participants.

Table A.1 Comparison of components of the DHD-index and the DHD15-index and their cut-off (maximum score) and threshold values (minimum score).

DHD-Index			DHD15-Index		
Components	***Minimum score (=0)***	***Maximum score (=10)***	**Components**	***Minimum score (=0)***	***Maximum score (=10)***
1. Physical activity[a]	0 activities	≥5 activities	1. Vegetables	0 g/day	≥200 g/day
2. Vegetables	0 g/day	≥200 g/day	2. Fruit	0 g/day	≥200 g/day
3. Fruit	0 g/day	≥200 g/day	3. Wholegrain products	0 g/day OR Ratio wholegrain/refined grains ≤0.7	≥90 g/day OR Ratio wholegrain/refined grains ≥11
4. Fiber	0 g/4.2 MJ	≥14 g/4.2 MJ	4. Nuts	0 g/day	≥15 g/day
5. Fish	EPA+DHA: 0 mg/day	EPA+DHA: ≥450 mg/day	5. Dairy	0 g/day OR ≥750 g/day	300-450 g/day
6. SFA	≥ 16.6 en%	< 10 en%	6. Fish	0 g/day	≥15 g/day
7. TFA	≥ 1.6 en%	< 1 en%	7. Fats and oils[a]	No consumption of soft margarines, liquid cooking fats and vegetable oils OR Ratio liquid cooking fats/solid cooking fats ≤0.6	No consumption of butter, hard margarines and cooking fats OR Ratio liquid cooking fats/solid cooking fats ≥13
8. Acidic drinks and foods[a]	> 7 occasions	≤ 7 occasions	8. Red meat	≥100 g/day	≤45 g/day
9. Sodium	≥ 2.45 g/day	< 1.68 g/day	9. Processed meat	≥50 g/day	0 g/day
10. Alcohol	Male: ≥60 g Female: ≥40 g	Male: ≤20 g Female: ≤10 g	10. Sweetened beverages and fruit juices	≥250 g/day	0 g/day
			11. Alcohol	Male: ≥30 g Female: ≥20 g	Male: ≤10 g Female: ≤10 g
			12. Sodium	≥3.8 g/day	≤1.9 g/day

[a]Not included in the present analyses due to insufficient information.

Table A.2 Consumption of food components and total energy intake (Dutch dietary guidelines 2006) in flourishing mental health compared moderate mental health, stratified by diabetes type and mental health category (Mann-Whitney U tests).

	Total (n=562)	**T1DM (n=255)**			**T2DM (n=307)**		
		Mental health category			*Mental health category*		
		Moderate (n=128)	Flourishing (n=127)		Moderate (n=130)	Flourishing (n=177)	
	mean±SEM[a]	*mean±SEM*[a]	*mean±SEM*[a]	P-value	*mean±SEM*[a]	*mean±SEM*[a]	P-value
Vegetables (g/day)	167±2	167±5	175±5	0.169	158±5	167±4	0.149
Fruit (g/day)	156±4	137±7	164±8	**0.008***	156±7	163±6	0.361
Fiber	20±0	20±0	20±0	0.306	19±0	20±0	0.159
Fish (g/day)	24±1	21±1	21±1	0.790	26±1	27±1	0.330
SFA (g/day)	19±0	20±1	19±0	0.571	19±1	19±0	0.690
TFA (mg/day)	379±6	392±14	377±13	0.675	386±14	366±10	0.372
Sodium (mg/day)	1641±18	1620±40	1623±39	0.795	1668±37	1649±31	0.798
Alcohol	10±1	11±1	11±1	0.627	10±1	9±1	0.074

[a]Outcomes are displayed as estimated marginal mean with standard error of the mean (SEM).
*Statistically significant (p≤0.05).

Table A.3 Consumption of food components and total energy intake (Dutch dietary guidelines 2015) in flourishing mental health compared moderate mental health, stratified by diabetes type and mental health category (Mann-Whitney U tests).

	Total (n=562)	**T1DM (n=255)**			**T2DM (n=307)**		
		Mental health category			***Mental health category***		
		Moderate (n=128)	**Flourishing (n=127)**		**Moderate (n=130)**	**Flourishing (n=177)**	
	mean±SEM[a]	*mean±SEM*[a]	*mean±SEM*[a]	P-value	*mean±SEM*[a]	*mean±SEM*[a]	**P-value**
Vegetables (g/day)	167±2.0	167±5.0	175±5.0	0.169	158±5.0	167±4.0	0.149
Fruit (g/day)	156±4.0	137±7.0	164±8.0	**0.008***	156±7.0	163±6.0	0.361
Wholegrains (g/day)	76±1.0	77±2.0	76±3.0	0.759	73±3.0	77±2.0	0.565
Grains ratio[b]	1.8±0.1	1.7±0.1	1.8±0.1	**0.045***	1.8±0.1	1.9±0.0	0.054
Nuts (g/day)	10±1.0	9±1.0	10±1.0	0.580	9±1.0	11±1.0	**0.040***
Dairy (g/day)	204±4.0	201±7.0	214±8.0	0.234	199±7.0	202±7.0	0.820
Fish (g/day)	24±1.0	21±1.0	21±1.0	0.790	26±1.0	27±1.0	0.330
Red meat (g/day)	24±1.0	25±2.0	23±2.0	0.469	23±2.0	23±1.0	0.652
Processed meat (g/day)	34±1.0	30±2.0	32±2.0	0.443	37±2.0	36±1.0	0.872
Sugary drinks (g/day)	116±6.0	104±13.0	120±13.0	0.158	112±12.0	125±13.0	0.911
Sodium (mg/day)[c]	1641±18.0	1620±40.0	1623±39.0	0.795	1668±37.0	1649±31.0	0.798
Energy intake (kcal/day)	1550±14.0	1549±29.0	1570±29.0	0.593	1529±31.0	1551±22.0	0.553[d]

[a]Outcomes are displayed as estimated marginal mean with standard error of the mean (SEM).
[b]Wholegrains to refined grains ratio.
[c]Only from foods
[d]Based on t-test.
*Statistically significant (p≤0.05).

Table A.4 Differences between moderate and flourishing mental health in diet quality based on the Dutch nutritional guidelines of 2015 (ANCOVA).

	T1DM (n=255)			**T2DM (n=307)**		
	Mental health category			*Mental health category*		
	Moderate (n=128)	Flourishing (n=127)		Moderate (n=130)	Flourishing (n=177)	
	mean±SEM	*mean±SEM*	P-value	*mean±SEM*	*mean±SEM*	P-value
Diet quality (score)						
Model 1	83±1	85±1	0.253	83±1	86±1	**0.018***
Model 2	83±1	85±1	0.217	83±1	86±1	**0.019***
Model 3	82±1	84±2	0.231	83±1	87±1	**0.006***

Note. Model 1: crude model; model 2: adjusted for age and sex; model 3: additionally adjusted for having a partner (yes/no), BMI, diabetes duration (years), education level (low, middle or high), and employment (paid employment yes/no).
*Statistically significant (p≤0.05).

Table A.5 The associations between mental health (flourishing versus moderate mental health, independent variable) and diet quality and alcohol consumption (dependent variables) based on the Dutch dietary guidelines 2015 (binary and multinomial logistic regression analyses).

			T1DM (n=255)	**T2DM (n=307)**
			Flourishing vs. Moderate Mental Health	Flourishing vs. Moderate Mental Health
			OR(95%CI)[b]	*OR(95%CI)*[b]
	Model 1	*Low*	1.0(reference)	1.0(reference)
Diet Quality		*Intermediate*	1.4(0.8-2.6)	**2.5(1.4-4.4)***
(score)[a]		*High*	1.4(0.8-2.5)	**2.0(1.1-3.5)***
	Model 2	*Low*	1.0(reference)	1.0(reference)
		Intermediate	1.4(0.8-2.7)	**2.4(1.3-4.2)***
		High	1.4(0.8-2.7)	**2.0(1.1-3.6)***
	Model 3	*Low*	1.0(reference)	1.0(reference)
		Intermediate	1.4(0.7-2.6)	**2.4(1.3-4.3)***
		High	1.4(0.7-2.6)	**2.1(1.1-3.9)***
	Model 1	*Low*	1.0(reference)	1.0(reference)
Alcohol consumption		*High*	1.3(0.8-2.1)	**1.7(1.1-2.7)***
(g/day)	Model 2	*Low*	1.0(reference)	1.0(reference)
		High	1.0(0.6-1.8)	**1.6(1.008-2.6)*[c]**
	Model 3	*Low*	1.0(reference)	1.0(reference)
		High	1.0(0.5-1.7)	1.6(0.962-2.5)[c]

Note. Model 1: crude model; model 2: adjusted for age and sex; model 3: additionally adjusted for additionally adjusted for having a partner (yes/no), BMI, diabetes duration (years), education level (low, middle or high), and employment (paid employment yes/no).
[a]Diet quality categorisation is based on tertiles of the total DHD15 score: low (tertile 1) indicates a score ranging from 0 to 78.93, intermediate (tertile 2) indicates a score between 79.02 and 90.89 and high (tertile 3) indicates a score ranging from 90.91 to 130.
[b]Outcomes are displayed as odds ratio (OR) and 95% confidence interval (95%CI).
[c]A larger amount of decimals is displayed to prevent wrong interpretation of results.
*Statistically significant

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5

Chapter 5

Integrating the findings in a coherent programme via a participatory developmental process

This chapter is published as:

Polhuis KCMM, Vaandrager L, Soedamah-Muthu SS, Koelen MA.
Development of a salutogenic intervention for healthy eating among Dutch type 2 diabetes mellitus patients.
Health Promot Int. 2021 Dec 23;36(6):1694-1704.
doi: 10.1093/heapro/daab020.

Abstract

Background: Healthy eating can be challenging for type 2 diabetes mellitus (T2DM) patients. The theory of salutogenesis, which focuses on the resources required to organize behavioural changes in everyday life, was used to develop an intervention for healthy eating. The aim was to describe the development, structure and content of this salutogenic intervention.

Methods: The development consisted of two phases that were based on the operationalization of important key principles of salutogenesis. In Phase 1 (Exploration and synthesis), a systematic review and three qualitative studies were performed to explore important characteristics to enable healthy eating in everyday life. The results were used to develop the draft intervention. In Phase 2 (Validation and adjustment), interviews and workshops were conducted with T2DM patients, healthcare providers and scientists. Based on this, the draft intervention was modified into its final form.

Results: The developmental process resulted in a 12-week, group-based intervention that aimed to enable important resources for healthy eating via self-examination, reflection, setting goals and sharing experiences. Attention was also paid to disease information, disease acceptance, food literacy, stress management, self-identity and social support. The group sessions began following an individual intake session, with a booster session held 3 months after the intervention.

Conclusions The researcher's translation of the stakeholders' priorities into an intervention was corrected for and approved by the stakeholders concerned. This comprehensive salutogenic intervention was developed based on practical and scientific evidence. Providing transparency in developmental processes and content is important because it determines the scientific integrity and credibility of an intervention.

5.1 Introduction

Nutritional therapy [nutritional therapy = to promote and support healthy eating patterns, emphasizing a variety of nutrient dense foods in appropriate portion sizes, in order to improve overall health [1] is effective for improving glycaemic control and other metabolic biomarkers in type 2 diabetes mellitus (T2DM) patients [2–4]. Studies have shown that the total energy intake, rather than the macro-nutrient composition of diets, has the most impact on glycaemic control, weight loss and cardiovascular risk factors [5–7]. Nutritional therapy has impressive effects in controlled research settings, but in everyday-life things are more complex; previous T2DM interventions using diet only resulted in small declines in weight and glycaemic blood markers [8–11], and sustaining health effects appears to be even more difficult [9,10,12,13].

Current interventions for encouraging healthy eating in T2DM patients are therefore not yet optimal. Non-adherence to nutritional therapy has been attributed to a lack of motivation, self-control or nutritional knowledge (e.g. [14,15]); however, from the patient's perspective, non-adherence may be due to the assumptions underlying the interventions. Most interventions are based on the cognitive–psychological assumption that an individual has to be moved in a more healthy direction by influencing internal mental processes, such as increasing problem awareness and addressing behaviour [16]. Within the cognitive–psychological tradition, the social world is seen from within the individual [16]; however, many challenging situations for healthy eating appear when people interact. In everyday life, eating is more than an understanding of macro- and micro-nutrients; it is also about sharing, celebrating, caring and connecting together [17–19]. Eating is a chain of activities, embedded in a social context that influence why, when and what we eat [20]. Influencing internal mental processes is important, but will only lead to sustainable behavioural change if people are guided and supported in the process of implementing and executing a healthy diet in their unique everyday-life contexts [16]. Without considering contextual influences on eating behaviour, the relevance of interventions to everyday life as well as their long-term effectiveness are limited [21].

This inspired us to use another scientific perspective for the development of an intervention to address healthy eating among T2DM patients: the theory of salutogenesis [22,23]. Salutogenesis is centred around the idea that health results of continuous everyday-life interactions between the individual and inevitable social-, economic, cultural-, physical-, mental- and biochemical stressors. Its aim is to understand the resources that facilitate coping with these stressors in a health-promoting way. Salutogenesis acknowledges that people are always connected, and that knowledge about the world is constructed collectively. Similar to systems theory, salutogenesis assumes that changing one part of a social system (e.g. dietary practices) affects other parts of the system (e.g. social relationships); hence, it is inherently contextual. The central concept in salutogenesis is the sense of coherence (SoC): the individual capability to identify and mobilize health-promoting resources. Resources that promote health and facilitate coping with stressors

are referred to as general and specific resistance resources (GRRs and SRRs). The difference between GRRs and SRRs is that GRRs can be applied to cope with a variety of stressors (i.e. social support), whereas SRRs are only useful in specific situations (i.e. a glucose meter).

In this article, main principles of salutogenesis were operationalized to guide the development of the Salutogenic intervention for Diabetes Type 2 (SALUD intervention). The SALUD intervention aims to enable healthy eating among people with T2DM in everyday life via enhancing/mobilizing important GRRs/SRRs for healthy eating. The aim of this article is to describe the developmental process, structure and content of the SALUD intervention. In the present developmental process, a wide range of relevant literature from four previously published studies has been used. Providing transparency in these aspects is important for the evaluation and replication of interventions consisting of multiple components [24].

5.2 Methods

The developmental process of the SALUD intervention consisted of two phases. These two phases were based on operationalization of three important principles of salutogenesis:

1. **The participant as a whole.** In salutogenesis, health is a complex and dynamic concept incorporating multiple aspects of wellbeing that relate to the whole person [23]. This requires interventions that aim to improve multiple aspects of health.
2. **The participant's active involvement.** To facilitate the mobilization of health resources, intervention strategies should be adjusted to real-life to increase the chance of successful implementation of newly adopted behaviours in everyday life. This can only be done successfully and respectfully when T2DM patients and healthcare providers (HPs) are actively involved in the development of interventions.
3. **The participant's individual learning process.** Salutogenesis complements traditional information-providing approaches by supporting individuals in a learning process to mobilize personal and environmental health-promoting resources to cope with stressors.

Phase 1, Exploration and synthesis, compromised four studies (Studies I–IV) that were the basis for the analysis that led to the development of the initial version of the intervention reported in this manuscript. Study I [25] was a systematic review to indicate and assess effective characteristics of salutogenic-oriented lifestyle interventions for T2DM patients. In Study II [26], open and unstructured interviews were held with 17 T2DM patients to investigate the meaning of turning point experiences to uncover GRRs and SRRs for healthy eating. Following the operationalization of salutogenic principle 2, Studies III and IV researched the opinions of 14 T2DM patients and 13 practice nurses regarding intervention setting and content via semi-structured interviews. Detailed information on the Studies I and II is provided in the full publications [25,26]. Detailed information on Studies III and IV is provided in MSc theses that

can be requested by contacting the corresponding author.

The results of Studies I–IV were extracted and compared regarding intervention structure (i.e. intensity, setting, instructor, study outcomes and development) (**Supplementary Table A**), and regarding the intervention content (i.e. input for intervention sessions and tailoring) (**Supplementary Table B**). The salutogenic principles as well as various discussions among all authors about the data extractions led to the draft SALUD intervention.

In phase 2, Validation and adjustment, the draft SALUD intervention was validated and adjusted based on feedback from the following stakeholders:

- Five T2DM patients [mean age of 62 (range 58–73) years, diagnosed on average 16 years ago (range 10–21), all had previous experiences of lifestyle interventions)].
- Six HPs [one dietician, three practice nurses, one general practitioner (GP) and one internist)].
- Thirty nine scientists (10 health promotion scientists, 21 psychology scientists and 8 education scientists).

All stakeholders were approached via the local network of the authors, the Nutrition & Healthcare Alliance, and the Dutch Diabetes Foundation. Individual meetings were organized with the patients and the HPs. Three workshops were organized for the scientists. The draft SALUD intervention was sent to the T2DM patients and the HPs one week in advance. The patients and the HPs were asked to share their general impression of the intervention, explain what aspects appealed to them and what they did not like. Each session of the draft SALUD intervention was discussed separately. The scientists were asked to develop concrete intervention strategies based on the presented findings of Phase 1. The scientists wrote their ideas down in small subgroups, and these strategies were explored in a plenary discussion. Consent for participation in the study was obtained verbally, and conversations were audio-recorded. Reports were written of all the meetings/workshops, which were used to finalize the draft SALUD intervention.

5.3 Results

PHASE 1: EXPLORATION AND SYNTHESIS

Intervention structure

Intensity. Study I showed that effective studies last at least 10 weeks and have at least 10 sessions. Study IV highlighted the importance of continuous guidance and spending face-to-face time with participants; however, Study III showed that patients found it important that the intervention is not too invasive in their daily lives in terms of time constraints. Hence, the draft SALUD intervention was a 12-week programme with weekly sessions with a maximum duration of 2 h.

Setting. Study I demonstrated that the most effective interventions were group-based. Studies II and III indicated that meeting peers and sharing experiences are extremely helpful for coping with healthy eating and feeling supported; therefore, the draft SALUD programme was a group-based intervention.

Instructor. The four studies were inconclusive in terms of the ideal instructor for the intervention. Study III showed that patients preferred their regular health provider, whereas Study IV showed that practice nurses opted for a mental health coach instead. Lifestyle coaches are educated in managing lifestyle-related matters and have (psychosocial) coaching skills [27]; therefore, it was decided that a lifestyle coach should deliver the draft SALUD intervention. The lifestyle coach will be supported by a practice nurse for taking measurements, and by a dietician for the food literacy sessions.

Study outcomes. Study I showed that the most commonly used physical and psychosocial outcomes for assessing intervention effectiveness in previous randomized controlled trials (RCTs) were HbA_{1c} and self-efficacy. Study IV indicated that HPs preferred a more human-based, holistic health evaluation, in which psychosocial- and behavioural change process-oriented outcomes are important as well. The draft SALUD intervention was therefore developed to primarily improve nutritional intake, HbA_{1c} and self-efficacy, and secondarily to improve body mass index (BMI), and SoC. HbA_{1c} and BMI are important biomarkers for evaluating disease remission. Self-efficacy and SoC are important indicative measures for determining people's ability to navigate everyday challenges.

Development. Study I showed that studies based on formative research seemed more effective in terms of improving health, therefore, it was decided to submit the draft SALUD intervention to patients, HPs and scientists for feedback (i.e. Phase 2).

Intervention content

Studies I–IV revealed that the following GRRs were important for healthy eating: self-identity, social support and stress management. Important identified SRRs were: goal setting, disease acceptance, a flexible approach to eating (a sensible balance between healthy and unhealthy foods), creative cooking, practical nutritional knowledge and self-monitoring blood glucose. Particularly the GRRs self-identity (i.e. knowing who you are and how a healthy diet relates to this) and social support seemed essential for T2DM patients. These GRRs seemed to contribute to healthy eating via a process of empowerment and therefore are considered to be crucial mediators for healthy eating (see **Supplementary Figure C** for a schematic overview of the assumed relationships between the GRRs and healthy eating). Besides the GRRs and SRRs, Studies I–IV showed that paying authentic attention to someone's past and present and tailoring the intervention on a holistic, personal and cultural level is important.

Therefore, the draft SALUD intervention was developed to enhance the GRRs self-identity and social support via weekly self-reflection, goal setting and sharing experiences with peers to enable healthy eating (i.e. 'learning by doing'). In addition, the topics of self-identity and social support are also addressed more explicitly by providing participants information/theory on how self-identity and social support relates to behaviour and motivation. The other sessions have a specific theme inspired by the GRRs/SRRs (i.e. disease acceptance, goal setting, food literacy, stress management and progress evaluation). One open session is included to tailor the intervention to the group's specific needs, priorities and interests. Where possible, intervention themes are approached via learning by experience to equip participants with practical tools and skills (i.e. a cooking workshop, relaxation/mindfulness exercises and a nature walk). The draft SALUD is summarized in **Supplementary Table D**.

PHASE 2: VALIDATION AND ADJUSTMENT

Intervention structure

Intensity, duration and follow-up. Even though not all stakeholders agreed, it was decided that the intensity of the intervention should not be altered because patients had no objections to the proposed intensity. The changes included the addition of an individual intake session prior to the group sessions to build trust, to perform baseline measurements and to make an inventory of relevant issues. In addition, a booster session was included 12 weeks after the intervention for performing long-term measurements and encouraging commitment to long-term goals, as well as to strengthen the social support between participants.

Recruitment. Based on the recommendations of the HPs, GPs will be responsible for participant recruitment. The HPs believed that GPs are perceived as health authorities to a greater extent than other HPs. Furthermore, the SALUD research team will provide the recruiters with clear instructions and supportive information for both recruiters and participants.

Setting. Based on the feedback, it was decided to keep the groups small (6–8 individuals). All stakeholders agreed that some diversity regarding the participants may be beneficial, but also emphasized that the participants should not be too different from each other to facilitate social bonding. It was decided that the groups should be varied in terms of disease duration, but kept similar in terms of age, culture and socioeconomic status. Following the recommendations, the SALUD intervention will take place at a pleasant, comfortable and easily accessible location.

Instructor(s). All stakeholders indicated that the success of the intervention is likely highly dependent on the personal qualities and coaching skills of the instructor. All agreed that a (lifestyle) coach would be an appropriate person to guide the intervention. Following the recommendations, the instructor should be experienced in motivational interviewing as well as

mindfulness. All stakeholders liked that the regular practice nurse and dietician are also involved.

Delivery. All stakeholders were positive about the way the intervention stimulates learning by experiencing. Following the recommendations, each session will start with a quick assessment of the group's knowledge level and attitude towards the session's topic, which will be used to tailor the session. Finally, celebrating successes and giving compliments will be emphasized in the training of the intervention instructors.

Intervention content

Session 1: building trust and disease acceptance. Based on the recommendations, this session will be kept informal. The main emphasis will be on getting to know each other and creating a safe environment. This will be done by sharing experiences related to managing T2DM, diet and overall wellbeing. A break will be included to give the participants the chance to explore each other on their own terms. An informative presentation on the disease process, long-term medical consequences and the role of nutrition was added to the session as the stakeholders found this was lacking. Furthermore, social issues related to T2DM (e.g. how to deal with shame, and social pressure) will be discussed during this presentation. The stakeholders indicated that discovering that others face similar challenges to you is beneficial for social bonding and disease acceptance.

Session 2: goal setting. All stakeholders considered it a good idea that people would have to come up with their own goals. Following the feedback, participants will be helped to formulate their goals specifically, and to split up goals into smaller and more concrete steps. In addition, the intervention instructor will help participants to connect their goals to a personal intrinsic motivation. Every session will start with an evaluation of and reflection on the goals and the process. The skill of reflection (i.e. when and how to reflect?) will therefore be explained, as well as exploring how to use self-monitoring of blood glucose for self-reflection and goal evaluation.

Sessions 3 and 4: food literacy. Following the recommendations, both sessions will be used to explore how to enjoy eating while watching your diet, including socially challenging situations (e.g. dining out, holidays and birthdays). The intervention instructions will be personalized nutritional advice to the individual's daily routine, family situation, culture, income and preferences. In Session 3, participants will learn how to read nutritional labels and use other useful resources, as well as receiving practical tips for healthy grocery shopping. In Session 4, participants will follow a cooking workshop for healthy meals; learn where to find trustworthy resources for easy and healthy recipes; receive tips for convenient, affordable and healthy snacks; and get advice on dealing with 'cheat' days. In addition, a method of sharing recipes/tips between participants will be established. Finally, small blind tastings sessions (e.g. low- and full-fat cheese) will be incorporated during the cooking workshop to make it more fun.

Sessions 5 and 6: stress management. The stress management sessions were regarded as being

very important. Following the recommendations, stress levels will be assessed during the individual intake before the group sessions begin. Furthermore, T2DM-related stressors, such as challenging social situations, sleep deprivation, emotional eating and the impact of a variety of emotions (e.g. anxiety, shame, loneliness, etc.), will be discussed during Session 5. The fact that stress management has two sides, making external changes (e.g. changes in a weekly routine) and internal changes (attitude towards external factors), will also be discussed. Besides mindfulness exercises to teach people how to turn inwards, other possible methods of stress management will also be addressed (such as exercise). In Session 6 (nature walk), breaks will be included to give people the chance to share things they noticed within their surroundings and within themselves.

Sessions 7 and 11: progress evaluation. Biomedical measurements and quantitative psychosocial measurements (i.e. questionnaires) will be only performed at the intake session and during Session 11, because disappointing outcomes may be demotivating. Measurements will be taken by each participant's regular practice nurse at their regular health centre for privacy and practical reasons. Short questionnaires will be used for evaluating psychosocial health quantitatively. In Session 7, the psychosocial health progress will be evaluated qualitatively via discussions about any experienced changes in health, energy, vitality, stress or wellbeing. Furthermore, participants will be empowered to come up with their own ideas regarding how they will maintain motivation and stay on track with their health progress after the intervention. Finally, local sport consultants will be invited to Sessions 7 and 11 to create awareness of local sports initiatives.

Session 8: social support. The social support was identified as a fundamental part of the SALUD intervention. Following the recommendations, more strategies to establish and maintain social support were included throughout the intervention. During Session 2, the benefits of teaming up with a buddy for goal commitment/motivation and social support will be explained. In Session 8, the participants will be asked whether they want to establish a social platform (via Whatsapp or Facebook) for sharing problems or requesting advice. The booster session after the intervention was also added to increase the chance of participants establishing strong social support. Although some stakeholders thought that the partner/friend should also be invited to participate at the start of the intervention, it was decided that partners would only be invited to attend Sessions 8 and 12, because we believe that inviting partners in the beginning may hinder social bonding between participants.

Session 9: self-identity. The self-identity session was identified as a fundamental part of the SALUD intervention. The main strategy to enhance self-identity is by weekly reflection and sharing experiences at the start of every session ('learning by doing'). However, also a specific session on self-identity is included to discuss the topic more directly. Following the recommendations, this session includes an explanation of how the mind works and how the environment often directs behavioural patterns, because this was considered essential for disease acceptance and stimulating introspection. This will be done in a down-to-earth manner by letting participants interview each

other about their long-term life and health goals, and the underlying reasons for their eating behaviours. In addition, a positive role model will be invited to share their experience with changing eating behaviour. Finally, the participants will list their own personal strengths and this list will be extended by the other participants.

Session 10: open session. Based on the feedback, some examples for topics will be given if a group has difficulties coming up with a topic on its own.

Session 12: festive closure. All stakeholders liked the idea of a celebration at the end of the intervention. Participants will be asked to bring an object that symbolizes their experience with the intervention. The group will be stimulated to think of ways to continue working towards their goals and supporting each other. Finally, a date will be set for the booster session.
The final SALUD intervention is summarized in **Supplementary Table E**.

5.4 Discussion and conclusion

The process reported here enabled the development of a comprehensive salutogenic intervention that takes into account the preferences, needs and priorities of all stakeholders. The developmental process revealed that healthy eating is a complex social phenomenon that requires a multicomponent intervention, more specifically, an intervention that includes strategies to develop self-identity, social support, food literacy, disease acceptance and stress management. Based on Studies I–IV, self-identity and social support were the most important resources for healthy eating for this particular target group, hence, the main strategy of the intervention was to enhance these two resources. Self-identity has been proposed to be a steering mechanism that guides whether an individual changes their life towards greater health and wellbeing [28]. From this perspective, self-identity may provide a conceptual link between the skills and competencies that interventions often target and the outcomes these skills and competencies serve [28] . In salutogenesis, self-identity is regarded as a crucial resource for coping and possibly as even a necessary precondition for a strong SoC [22]. Our hypothesis is that strengthening/mobilizing self-identity has an indirectly effect on healthy eating via empowerment. Considering the strong interdependency between SoC and GRRs (particularly between self-identity and SoC), mobilizing/strengthening self-identity may also enhance SoC. In addition, empowerment has been suggested to be a direct mechanism to improve SoC [29]. In the SALUD intervention, it was decided to approach healthy eating via mobilizing GRRs/SRRs rather than stimulating SoC directly, because the identified GRRs/SRRs led to concrete and practical intervention strategies/ topics that remained close to the input of the stakeholders.

Promoting self-identity is rarely used as a strategy for improving healthy eating. The focus of most nutritional research has been on targeting cognitions and feelings related to food and health instead [30,31]. The limited available evidence is mostly cross-sectional and/or focussed

on proximal indicators of healthy eating rather than healthy eating itself [32]. Some promising results do exist however; e.g. systematic reviews of qualitative research demonstrated the important role of self-identity for healthy eating and weight management [17,33]. In addition, a 'healthy-eater identity' has been shown to be a significant predictor of healthy eating behaviour, even after controlling for nutrition knowledge [32]. Moreover, an experimental study that encouraged participants to identify as a healthy eater led to more healthy food consumption [34]. Regarding T2DM, self-identity has been demonstrated to be an intervening variable for most self-management behaviours, including diet [35]. Furthermore, there is a growing body of research using psychological theories that incorporated aspects of self-identity for health behavioural change, such as social-learning theory [36]. Both observational [37] and experimental research [38] have shown that self-efficacy is an important determinant of healthy eating. Self-efficacy is also already frequently applied in the context healthy eating and T2DM [39]. Useful strategies to promote dietary self-efficacy include stress management, goal setting and goal evaluation [40]. Indeed, Studies I and II also confirmed that addressing stress management and goal setting/evaluation simultaneously is important for healthy eating.

Social support for healthy eating, especially sharing experiences with others, was considered useful for disease acceptance, motivation and goal evaluation. It is also a great way to facilitate self-examination and reflection and thus enhancing self-identity. Indeed, social support has been linked to better clinical outcomes, decreased mortality and increased mental stability [41,42]. Evidence showed that the effect of social support on glycaemic control may be mediated sequentially by self-efficacy and adherence to self-management [43]. Hence, it seems that it is important to enhance one's sense of self as well as social support to enable healthy eating.

Previous literature has suggested several times that the paradigm for evaluation currently used within clinical medicine and disease prevention is not ideal for evaluating multicomponent interventions [30,44]. The golden standards for intervention evaluation are RCTs; however, these generally do not require reporting with sufficient depth and detail to assess the validity, verifiability and reproducibility of multicomponent interventions [24,30,45]. The reporting guidelines for RCTs focus mainly on outcome evaluation and internal validity (e.g. research population, randomization, blinding, etc.) rather than external validity (e.g. developmental process, intervention content and context) [46,47]. This is perhaps sufficient for single-component interventions for which the active component(s) is/are known and relatively easy controllable (e.g. pharmacological trial), but not for multicomponent interventions in which the intervention is a process of change rather than a 'dose' or 'treatment' [30,48]. Intervention strategies that consist of multiple components may cause independently or interdependently (un)foreseeable health effects, which are usually the result of complex interactions between the intervention and the local context in which the intervention is embedded. This embeddedness makes it extremely difficult to specify and control for the 'active ingredient' of the intervention; however, separating the context from the intervention is not only impossible but also meaningless, because the contextual

factors make health-promoting interventions useful, appealing and relevant to healthcare practice [24,45]. The appropriate evaluation of multicomponent interventions therefore requires an accurate and thorough description of the content of the intervention and the context in which it took place. Transparency in the developmental process is also crucially important because it significantly determines the scientific integrity and credibility of an intervention. Furthermore, it is unethical (and a waste of money and time) to include participants in an intervention that has not been well thought through.

Strengths and limitations

Important advantages of the present developmental process are (i) the use of salutogenesis, (ii) the bottom-up approach and (iii) that the researcher's translation of the priorities into an intervention was corrected for and approved by the stakeholders concerned. Combining theory with participatory methods was extremely useful for developing concrete intervention strategies/exercises. Even though participatory methods are a common practice in health promotion [49], in certain research fields (e.g. nutritional sciences), these methods are rarely used are relatively unknown. This article may serve as an example for how to approach and report such process. A limitation is that during the participatory process some disagreements among the stakeholders were ultimately solved by the research team. Bringing all stakeholders together to discuss these disagreements one final time might have been a better way to solve the dispute. Nevertheless, we have provided transparency about which decisions were based on the opinions of the research team. Furthermore, different people were approached in Phase 2 due to practicalities. Although this also had benefits (e.g. provided new insights), it may have been preferable to validate our interpretations with help of the same people involved in Phase 1. Additionally, the number of patients/HPs that participated in Phase 2 may be relatively low to the number of scientists. However, in total (=Phase 1+2), 56 patients/HP participated compared to 39 scientists. Finally, not all stakeholders agreed on the intervention structure; some preferred a regular structure, others a more flexible design. Patients indicated that the intervention should be not too invasive on normal life; however, enhancing self-identity requires a significant time investment and a proactive attitude. Hence, the SALUD intervention might be specifically suited for more motivated patients. We plan to pilot the intervention via a RCT to gain more insight in this as well in its effectiveness, despite the significant challenges that multicomponent interventions pose for designing and evaluating RCTs.

Conclusion

The developmental process implemented here enabled the design of a comprehensive salutogenic intervention that takes into account the preferences, needs and priorities of all stakeholders. Here, we describe the developmental process, structure and content of the intervention clearly and openly. Such a detailed description of the intervention developmental process is incredibly rare. We are only aware of two other publications in which this was done [50,51], although neither involved T2DM patients. Possible reasons for this lack of developmental process descriptions may

include the absence of clear guidelines for reporting multicomponent interventions, as well as strict journal word limits. Due to the increasing prevalence of lifestyle-related diseases, policy makers are increasingly asked to judge multicomponent interventions; therefore, providing transparency in the developmental process as well as content of interventions is particularly important. We recommend that researchers describe their intervention developmental processes, structures and contents as precisely as possible. Clear reporting guidelines for multicomponent interventions are needed for this too. An extended CONSORT statement about RCTs of non-pharmacologic treatments is available, which provides some guidance for reporting multicomponent interventions[52]; however, this statement lacks items regarding the reporting of an intervention's developmental process. No ideal evaluation method exists for multicomponent interventions [53]. Nevertheless, RCTs can be helpful for evaluating the effectiveness of a multicomponent intervention, especially when close attention is paid to contextual factors. Qualitative process and content evaluations are useful for this; however, researchers and policy makers should also be more open to alternative evaluation methods (such as realist evaluation [53]). Finally, we strongly recommend the use of salutogenesis for nutritional intervention development (and evaluation) to minimize the science-practice gap.

Acknowledgements: We are grateful for the enthusiastic participation of all individuals with type 2 diabetes mellitus, health care professionals and fellow scientists involved in this study. We would also like to thank the Nutrition & Healthcare Alliance and the Dutch Diabetes Foundation for their assistance during the recruitment of participants. Finally, we would like to thank the Department of Medical and Clinical Psychology of Tilburg University, and the Health and Society group and Education and Learning Sciences group of Wageningen University and Research for participating in the workshops.

Funding: This work was supported by the Edema-Steernberg Foundation (Wageningen, The Netherlands), a non-profit foundation that supports and initiates multidisciplinary research related to nutrition and eating behaviours.

Authors' contributions: All authors were involved in the conceptualization of the study. K.C.M.M.P. set up the recruitment and conducted the interviews and workshops. All authors were involved in development of the draft and final versions of the D2SAL intervention. K.C.M.M.P. wrote the manuscript. The other authors edited and commented on the manuscript. All authors have read and approved the final manuscript.

Competing interest: The authors declare that they have no conflict of interests.

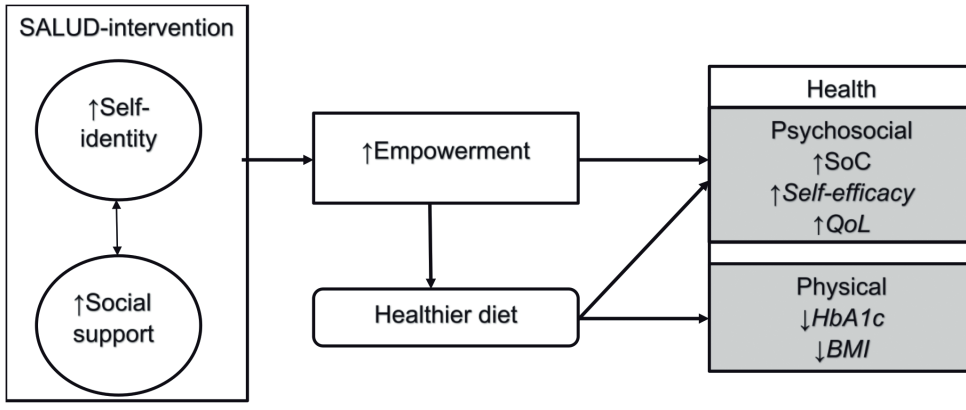
Supplementary tables

Supplementary Table A Data extraction and comparison based on studies I-IV for developing the intervention structure of the draft SALUD intervention.

	Duration (wk)	Sessions (n)	Setting	Instructor	Outcome	Development
Study I	>10	>10	Group	Inconclusive	HbA_{1c} Self-efficacy	Formative research
Study II			Group			
Study III			Group	Practice nurse/GP		
Study IV		Weekly		Psychologist/Coach	Human-based Holistic	

Supplementary Table B Data extraction and comparison based on studies I-IV for developing the intervention content of the draft SALUD intervention. GRRs = general resistance resources; SRRs = specific resistance resources.

	Intervention Content	
	GRRs/SRRs	**Tailoring**
Study I	Goal setting	Personal level
	Self-monitoring blood glucose	Cultural level
Study II	Self-examination/self-identity	Everyday-life
	Reflection	Life history
	Stress management	
	Disease acceptance	
	Social support	
	Flexible approach to eating	
	Creative cooking	
Study III	Disease acceptance	Not feeling like a patient
	Social support	Keeping normal life intact
	Flexible approach to eating	
	Practical nutritional advice	
	Self-monitoring blood glucose	
Study IV	Self-examination/self-identity	Holistic
	Reflection	



Supplementary Figure C Schematic overview of mechanism of action SALUD-intervention.

Supplementary Table D Draft version of the SALUD intervention (results of phase 1).

Session topic	Facilitator/ instructor	Time	Aim	Group discussion	In-session activity	Home activities
#1 Building trust	Coach with MI experience	20 min	General introduction and overview of the trajectory			**Finishing timeline**
	(Dietician	25 min	Developing trust	Who are you?		
	Practice nurse)			What is important to you/ what gives your life meaning?		
			Social bonding			
			Self-identity			
		45 min	Understanding and reflecting on eating behaviours:	What kind of eater are you? How do you feel about current eating practices? What is your eating history? What made healthy eating difficult?	Timeline exercise (instructions and start)	
#2 Goal setting	Coach with MI experience	20 min	Reflection	Sharing experiences (with eating, timeline or personal insights)		Working on goals
			Emotional support			
		50	Disease acceptance	How do you feel about T2DM? How did you manage T2DM to date?	Post-its of easy and difficult aspects on flip-over board	
			Emotional support	What did you learn about T2DM since diagnosis (what is easy, what is difficult) Is there something you want to work on?		
		50	Goal setting	What do you want to improve? How important is it for you? What do you need to do? What do you need? How confidence are you that you will start working towards your goal? How confident are you that you will achieve this? How does this make you feel?	Formulating SMART goal(s) Thinking along about mobilisation of SRRs *(referral dietician, arranging eating together, SMBG)*	
#3 Food literacy I	Coach with MI experiences	20 min	Reflection	Sharing experiences		Healthful grocery shopping
		90 min	Food literacy	Healthful eating for T2DM Flexible eating strategies/skills Healthful grocery shopping	**Healthful grocery shopping**	
	Dietician	10 min	Reminder of goals	What will you do to reach your goal?		

Session topic	Facilitator/ instructor	Time	Aim	Group discussion	In-session activity	Home activities
#4	Coach	20 min	Reflection	Sharing experiences		Cook a new
Food literacy	with MI	90 min	Food literacy	Healthful eating for T2DM	**Creative cooking class: preparing**	dish
II	experiences			Flexible eating strategies	**simple quick healthy dishes**	
		10 min	Reminder of goals	Can you use this new insights to reach you goal		
	Dietician					
#5	Coach	30/45	Reflect on goals	Sharing experiences		Body scan
Stress-	with MI	min		Did you work on your goal?		and breathing
management	experiences		Emotional support	How did it go?		exercises (when
				Easy or not?		necessary)
				Do you need to adjust?		
				Do you need more help?		
				New goal?		
		45 min	Stress-management	What do you do when you are stressed? How do you feel?	**Stress awareness**	
				What do you do to relief stress?	Locate where you feel stress in your body	
					Body scan Breathing exercise	
		10 min	Reminder of goals	How can you use this to reach your goal?		
#6	Coach	120 min	Reflect on goals	While walking: Sharing experiences	**Nature break/walk**	Paying mindful
Nature break	with MI			How did it go? New goals?	Enjoying walk/nature	attention to
	experiences		Stress-management	How do your surroundings affect your inner world?	Enjoying social interactions	automatic
					Enjoying little things	everyday life
			boosting positive emotions		Think of other activities that make you happy (physical activity, being together...)	behaviours (eating, washing hands, etc.)
						Enjoy nature!
#7	Coach with	45 min	Understandability/ manageability	Measuring biomedical and psychosocial progress	Measuring biomedical and psychosocial progress	Bring partner/
Measuring	MI experience					close friend or
progress		20 min	Reflect on goals	How does the outcomes make you feel?		family member
	Practice nurse			Self-compassion		to next session
				Celebrate		
				Need to adjust?		
				New goals?		
				What is progress for you?		
		20 min	Decide on topic	Group consensus on topic of session 10		
			Reminder of goals			

Session topic	Facilitator/ instructor	Time	Aim	Group discussion	In-session activity	Home activities
#8 Social support	Coach with MI experience	30 min	Reflection	Sharing experiences How do you feel? How does it feel to have you partner here? Introduce partner and the importance of this person for you		
		45 min	Social support	What does the partner think of goals? What does the partner think of T2DM? Express feelings about T2DM Explain why you goal is important to partner Express how partner can help you	Set a joint goal for more healthful eating	
		15 min	Reminder of goals			
#9 Self-identity	Coach with MI experience	20 min	Reflection	Sharing experiences on goals Feedback on trajectory		
		45 min	Self-identity	Who are you? What is important for you? What are your personal (health) resources?	List personal strengths and supportive resources	
				Where do you see yourself next year?	Action plan for mobilisation of resources	
		30 min	Stress management		Exercise guided meditation	
		15 min	Reminder of goals			
#10 OPEN	To be decided	120 min	To be decided	To be decided	To be decided	
#11 Measuring progress	Coach with MI experience	45 min	Understandability/ manageability	Measuring progress (biomedical/ psychosocial		Bring healthful food to share for pot-luck dinner
	Practice nurse Coach with MI experience	30 min	Reflection	Sharing experiences Support each other Celebrate / self-compassion How can you measure progress yourself?		
		15 min	Reminder of goals Discuss healthful potluck dinner		Invite partner!	

Session topic	Facilitator/ instructor	Time	Aim	Group discussion	In-session activity	Home activities
#12 Festive closure	Coach with MI experience		Social bonding	Organise the dinner tables Have fun Festive pot-luck dinner/ eat		
	Dietician		Reflection	Review progress to goal: biomedical and psychosocial level		
	Practice nurse			Encourage continuing working on goals: up-and-down process		
				Encourage to stay in touch		
			Personal message/ compliment to all individually			

Supplementary Table E Final version of the SALUD intervention (results of phase 2).
HIGHLIGHTED IN BLUE = added to the programme based on developmental phase 2 (i.e., feedback of patients, health care providers and scientists)
HIGHLIGHTED IN YELLLOW = altered because of developmental phase 2 (i.e., feedback of patients, health care providers and scientists)

Session topic	Instructor	Time	Goal(s)	In-session activity	Home activities
#0 Individual intake	Lifestyle coach + practice nurse	30 min	Getting to know the participants Authentic attention to participants' past and present Overview of the intervention	Baseline measurements of biomedical and psychosocial health	-
#1 Building trust	Lifestyle coach (Dietician + practice nurse also available)	10 min	General introduction	-	**What goal do you want to work on and why?**
			Explaining Reflection as a skill		
		45 min	Developing trust Social bonding Self-identity Safe space	**Why do you eat what you eat?** Everyone describes one experience/ memory that they consider important for the way they eat in the present	
		10 min	*Break*	-	

Session topic	Instructor	Time	Goal(s)	In-session activity	Home activities
		45 min	Disease acceptance Emotional support	**Physical and social aspects of T2DM** Information about the body, disease, nutrition and long-term T2DM consequences Discussing challenging social aspects of T2DM and nutrition and how to deal with them	
		10 min	Explaining SMART goals – what are they, why are they important and how to set them	-	
#2 **Goal setting**	Lifestyle coach	15 min	Reflection and sharing Emotional support	-	**Working on goal(s)**
		10 min	SMBG	Instruction on how and when to SMBG	
		45 min	Setting goals	**Goal setting** Setting individual goals and helping each other to clearly articulate their goals	
		10 min	Emotional support	Discuss the online platform for sharing/ support and explain the buddy system	
#3 **Food literacy I**	Lifestyle coach + dietician	20 min	Reflection and sharing	-	**Healthful grocery shopping and bring a healthy recipe to next meeting**
		90 min	Food literacy Practical tips/tools	**Diabetes-proof grocery shopping list** Setting up an individualised and healthful week of meal planning based on someone's preferences, weekly routine, cooking ability	
				Demonstrate how to use online sources to compare products Tips for social occasions	
		5 min	Reminder of goals	-	
#4 **Food literacy II**	Lifestyle coach + dietician	20 min	Reflection & sharing	-	**Cook a new dish**

Session topic	Instructor	Time	Goal(s)	In-session activity	Home activities
		90 min	Food literacy	**Creative cooking workshop** Everyone learns how to cook a new and simple healthy recipe Blind tasting low and full-fat cheese, milk Dietician to collect recipes and compose recipe book	
		10 min	Reminder of goals	-	
#5 **Stress management**	Lifestyle coach	20 min	Reflection and sharing Emotional support	-	**Body scan and breathing exercises** (when necessary)
		25 min	Disease acceptance	**What is stress?** How do you recognise and notice stress? Locate where you feel stress in your body **Discuss** T2DM as a stressor and consider sleep and eating in relation to stress	
		45 min	Stress management	**Mindfulness / Acceptance commitment therapy exercises** (body scan and breathing exercise)	
		10 min	Reminder of goals	-	
#6 **Nature break**	Lifestyle coach	120 min	Reflection on goal Stress management Boosting positive emotions Emotional support	**Walk through nature** Enjoying walk/nature/social interactions Reflect on other activities that make you happy Reflect on goals and how you feel *Break every 30 min*	**Paying mindful attention to automatic everyday life behaviours** (eating, washing hands, etc.) **Enjoy nature!**
#7 **Measuring progress I (psychosocial health)**	Lifestyle coach Practice nurse	45-60 min	Understandability and manageability of T2DM Reflection and sharing Compassion Emotional support Long-term health	**Reflecting on psychosocial progress so far** -What goes well? -What is difficult? -How can we support? Think of ways to maintain and monitor your health in the long term (e.g., local sport initiatives)	**Invite partner (*or other supportive individual*) to the next meeting** **Finish psychosocial questionnaires before next week**

Session topic	Instructor	Time	Goal(s)	In-session activity	Home activities
		20 min	Decide on topic for session 10	Decide on topic for session 10	
#8 **Social support**	Lifestyle coach	30 min	Introduce partner/friend Opportunity for partners/friends to ask questions	-	**Working on goals**
		45 min	Emotional support	**Support contract** Set a joint agreement with your partner/ friend about how they can help you with your personal goal(s)	
		15 min	Reminder goals	-	
#9 **Self-identity**	Lifestyle coach	20 min	Reflection and sharing	-	**Working on goals**
		45 min	Identity	**Interview each other about:** Long-term health goals Underlying reasons and self-image	
				List personal strengths and supportive resources List personal strengths and leave list on the table. Every other participant will add to your list what they consider to be one of your strengths	
		30 min	Disease acceptance Social support Identity	**Role model** Invite role model; share experiences and opportunity to ask questions	
		15 min	Reminder of goals	-	
#10 OPEN *Topic will be decided in session 7 based on the needs of the group*	To be decided	*120 min*	To be decided	To be decided	**Working on goals** **Medical appointment with practice nurse (measurements)**

Session topic	Instructor	Time	Goal(s)	In-session activity	Home activities
#11 Measuring progress II (biomedical and psychosocial health)	Lifestyle coach	45 min	Understandability and manageability of T2DM	Reflection on biomedical and psychosocial outcomes	**Prepare and bring a (healthy) dish to the next meeting**
	Practice nurse			-how does it make you feel? -what do you want to change?	
	Lifestyle coach	30 min	Reflection on progression and goals		**Invite partner/friend to the next session**
			Compassion		**Bring object that represents your personal journey**
			Emotional support		
		15 min	Reminder of goals Explaining pot-luck dinner	-	
#12 Festive closure	Lifestyle coach	120 min	Social bonding	**Pot-luck dinner** Eat	**Medical appointment with practice nurse (over 11 weeks)**
	Dietician		Reflection	Enjoy Explain your symbolising object	
	Practice nurse		Boosting positive emotions	Share experiences Share recipes Encouragement to continue working on goals/ health	
				Encourage to stay in contact	
			Self-identity	Personalised compliment to all	
#13 Booster session (12 weeks after session 12)	Lifestyle coach	120 min	Reflection and sharing on experiences over the past 12 weeks	**Reflection on biomedical and psychosocial outcomes**	
	Dietician		Social bonding		
	Practice nurse		Reflection		
			Long-term commitment		

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6

Chapter 6

The study protocol for the effect evaluation of SALUD

This chapter is published as:

Polhuis KCMM, Vaandrager L, Koelen MA, Geleijnse JM, Soedamah-Muthu SS. Effects of a Salutogenic Healthy Eating Program in Type 2 Diabetes (the SALUD Study): Protocol for a Randomized Controlled Trial. JMIR Res Protoc. 2023 Mar 21;12:e40490. doi: 10.2196/40490.

Abstract

Background: Healthy eating can improve the course of type 2 diabetes mellitus (T2DM) considerably. As changing eating behaviors in everyday is challenging, there is a need for a nutritional strategy with an eye for everyday life of people with T2DM. A theory centered around the everyday life context is salutogenesis. Salutogenic principles have been operationalized in a new nutritional program for T2DM on food literacy and well-being: the Salutogenic Intervention for Type 2 Diabetes (SALUD) program. This study aims to describe the protocol of the invention study that will examine the quantitative and qualitative effects of the SALUD program.

Methods: A semiblinded randomized controlled trial will be performed in the Netherlands. A sample size of 56 (including a 30% dropout rate) people with T2DM has been calculated, of whom half (n=28, 50%) will follow the SALUD program (intervention) and half (n=28, 50%) will receive usual care (control). Recruitment strategies consist of advertisement via local health care professionals, posters, social media, and local newspapers. The SALUD program consists of 12 weekly web-based group sessions under the supervision of a certified lifestyle coach. Fidelity of the delivery is guaranteed by selecting a salutogenic coach, use of an intervention manual, training of the coach, weekly evaluation forms, and recording several sessions. The theoretical salutogenic principle of the intervention is mobilizing 2 important psychosocial resources required for organizing healthy eating in everyday life: self-identity and social support. Measurements will be performed at 3 times: at baseline (T0), after 12 weeks (postintervention; T1), and after 24 weeks (follow-up; T2). The primary outcome is food literacy, measured with the self-perceived food literacy scale questionnaire (expected effect size=0.9). Secondary outcomes are self-efficacy, quality of life, sense of coherence, diet quality, body weight, BMI, and waist-hip ratio. All outcomes will be tested with linear mixed models, following an intention-to-treat approach and standard principles of randomized controlled trials. In addition, a qualitative analysis will be performed.

Results: The proposed study will provide useful information on the effects of a salutogenic program on healthy eating and well-being in people with T2DM in everyday life. Recruitment started on October 1, 2021. The intervention participants followed the SALUD program between January and August, 2022. The acquisition of the data was completed on August 1, 2022; publications are expected in 2023**.**

Conclusions: This study will be one of the first salutogenic interventions for T2DM, which will provide valuable information on what salutogenic intervention entail. The SALUD program may serve as a concrete, web-based tool. The combination of quantitative and qualitative measures allows a comprehensive evaluation of effects. These insights can be used for further optimalization of T2DM interventions.

6.1 Introduction

Healthy eating is important for the disease course and quality of life (QoL) of people with type 2 diabetes mellitus (T2DM) [1]. Healthy eating may lower hemoglobin A1c (HbA_{1c}) to a similar extent as medical treatments for T2DM [2,3]. In some cases, healthy eating can put the disease in remission [4-12]. However, people with T2DM indicated that implementing healthy eating recommendations in their everyday lives is challenging [5,7,8].

Several strategies are available to support people with T2DM with healthy eating. The strategies approach healthy eating in dissimilar manners that could be broadly categorized as dietary prescription, lifestyle counseling, and behavioral therapies [13]. Dietary prescription is characterized by a "top-down" and biomedical approach: the therapist actively provides the solution in the form of a strict calorie-restricted diet, and the main goal is to achieve weight loss or improved HbA_{1c} levels (eg, [12]). In lifestyle counseling, the participant has a more active role: the therapist provides lifestyle education, meal plan templates, and personalized advice to implement nutritional recommendations. The main goal is adherence to a healthy lifestyle (eg, the Look AHEAD [Action for Health in Diabetes] trial [14] and the Diabetes Remission Clinical Trial [DIRECT]; [15]). Behavioral counseling is characterized by a more "bottom-up" and holistic approach: the starting point is the participant's preferences; the goals and approaches are collaboratively planned. The therapist has an enabling role in the process: stimulating the participant's problem-solving abilities and self-efficacy by motivating and supporting the participant. The main goal is achieving a mindset that favors healthy lifestyle behaviors (eg, [16]).

All of these strategies have been successful in initiating health benefits such as weight loss and improved HbA_{1c} levels [12,16,17] but have struggled with maintaining the benefits in the long term [8,18-21]. Even after the most well-known T2DM interventions—the Look AHEAD [14] and the DIRECT trial [15]—health benefits gradually disappeared. The Look AHEAD trial (restricted caloric intake using portion-controlled meal plans, calorie-counting techniques, and meal replacements combined with moderate physical activity) demonstrated average weight loss of 8.6% (SD 6.9%) in the intervention participants, but half of the initial weight loss was regained after 5 years of follow-up [22,23]. The DIRECT trial (a very low–calorie diet, followed by stepwise food reintroduction) demonstrated that almost half of intervention participants achieved T2DM remission at 12 months, but this percentage declined to 36% at 24 months [24].

Most previous studies used dietary description or lifestyle counseling strategies. These strategies either included strict (ie, very low–calorie) diets or were performed in highly controlled research settings (intensive intervention regarding diet and physical activity combined with frequent contact with health care providers) [12,25,26]. However, people may experience difficulties when they return from these clinical and controlled research settings to their everyday lives. In everyday

life, healthy eating requires a scale of personal and social resources, ranging from practical cooking skills to personal agency [27-29]. It is not only about what people eat but also why and how they eat: the ability to prepare food, social economic resources, the food environments, social support, self-image, mental health, etc. This may explain why the Mediterranean diet is considered as one of the healthiest diets with (long-term) health benefits [30]; the Mediterranean diet is not a strict diet, rather a way of life that includes seasonal cooking, freshly cooked meals, and socializing with others [31].

Hence, there seems to be a need for a strategy with an eye for everyday life of people with T2DM to promote long-term healthy eating. A health theory centered around the everyday life context is salutogenesis. Applying salutogenesis to nutritional research leads to the assumption that healthy eating is not regarded as a central goal in life but as a resource for greater enjoyment of life [32]. It requires to accept a holistic viewpoint on health and real-life complexity as starting points for conducting and evaluating nutritional interventions. In salutogenesis, health results from the continuous everyday life interactions between the individual and the social, economic, cultural, physical, mental, and biochemical stressors [33]. The central concept in salutogenesis is the sense of coherence (SoC), which is the individual capability to mobilize and use health-promoting resources [33]. Understanding the resources that facilitate coping with these stressors in a health-promoting manner can help to unravel underlying principles of creating health [34]. Salutogenesis guided the development of the Salutogenic Intervention for Type 2 Diabetes (SALUD) program [35].

The aim of this study protocol is to outline the randomized controlled trial (RCT) in which the SALUD program is compared with the Dutch usual care for T2DM. The theoretical principle behind the program is mobilizing 2 important psychosocial resources required for organizing healthy eating and improved well-being in everyday life: self-identity and social support [35]. The present hypothesis is that mobilizing these resources will initiate a process of empowerment, leading to improved food literacy (direct effect) and improved health (indirect effects). Food literacy is the capability to navigate different food situations to make healthy eating choices [36], which is important for healthy eating and well-being in the long term. It is a measure that combines all relevant aspects for healthy eating in everyday life, that is, knowledge, skills, and behaviors. Hence, the primary objective is to determine the effect of the SALUD intervention on food literacy. Diet quality as well as several physical and psychosocial outcomes will be evaluated as secondary outcomes.

6.2 Methods

Study Design

A 2-arm, semiblinded RCT will be conducted with 56 people with T2DM in the Netherlands. The whole study duration will be 24 weeks, with measurements planned at baseline (T0), after

12 weeks (postintervention; T1), and 24 weeks (follow-up; T2). Participants will be randomly allocated to the intervention group (SALUD program) or to the control group (usual T2DM care [37]). The SALUD program will consist of 1 individual intake session (at the start), group sessions for 12 consecutive weeks, and 1 booster session (at 24 weeks). The study procedure is outlined in **Figure 6.1.**

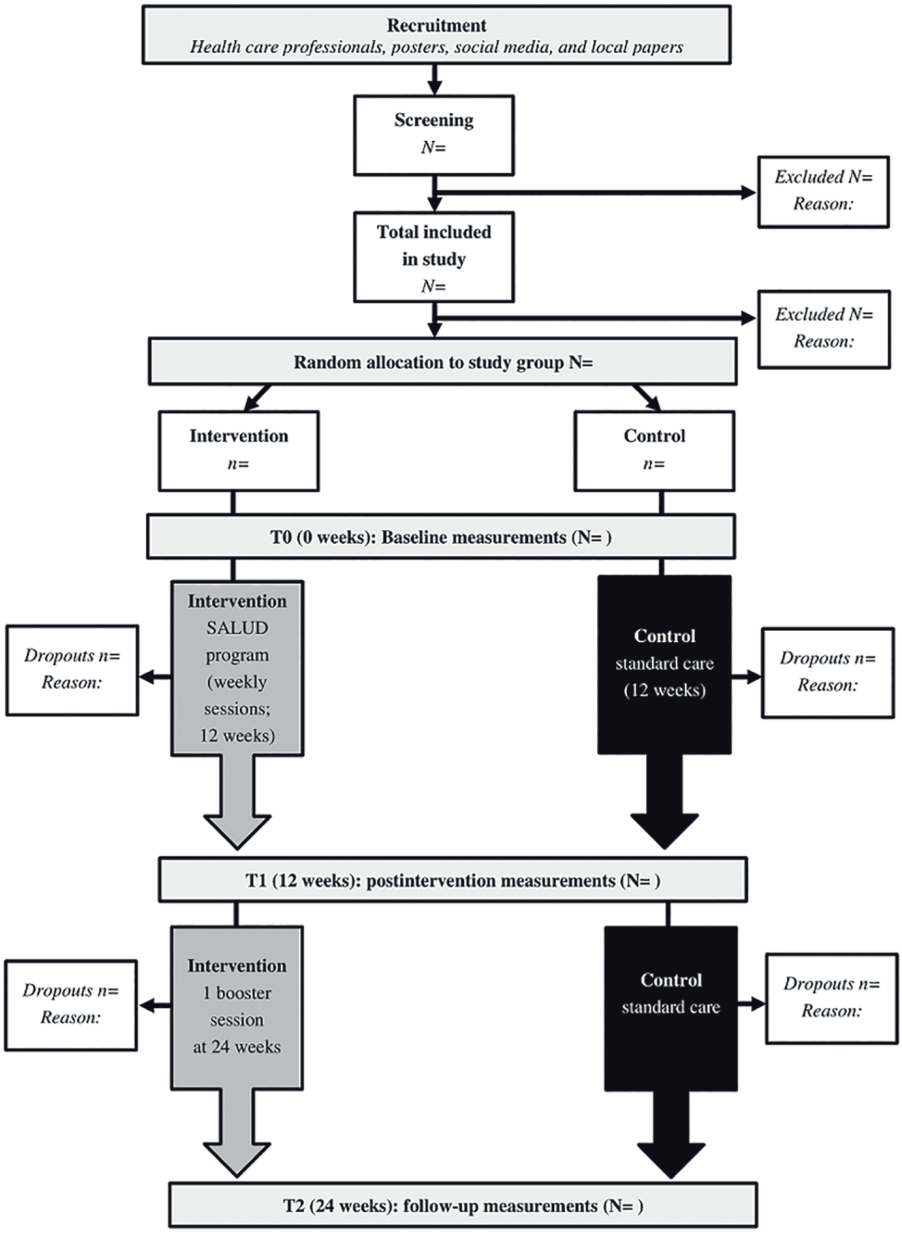

Figure 6.1 Salutogenic Intervention for Type 2 Diabetes (SALUD) study procedure.

Ethics Approval

Medical Ethical Committee Oost-Nederland has granted medical ethics approval for this study on August 8, 2021 (Medical Ethical Committee number 2021-12949).

Trial Registration

The study has been registered at Netherlands Trial Registry with registration number NL8963 [38] (registered on October 12, 2020).

Participants

The target population consists of Dutch-speaking men and women with T2DM. Inclusion criteria are as follows: officially diagnosed with T2DM by a general practitioner (GP); aged ≥18-75 years; fluent in Dutch, competent to make own decisions; and in possession of a computer device with internet connection. Exclusion criteria are as follows: pregnant, lactating, or intention to become pregnant in the upcoming 6 months; severe chronic illnesses or condition or comorbidities (other than T2DM, eg, kidney failure, severe form of chronic obstructive pulmonary disease [gold III or IV], heart failure [class 2-4], cancer, dementia, or severe depression); bariatric surgery in the past; and eating disorders (eg, anorexia or bulimia).

Recruitment

Participants are recruited via posters in GP practices, advertisements in local papers, social media, and websites of national diabetes organizations. In addition, several local GPs and practice nurses approach clients during regular health appointments or via phone or mail. Before commencement, all participants receive the information brochure that explains the study in detail and a phone call from the investigator for further explanation. At least 7 days after the phone call, participants sign an informed consent form and send it to the investigators before the start of the study. Participants are informed (written and verbally) that they will be randomly allocated to either the intervention or control group.

Randomization and Blinding

Randomization of participants will be performed by an independent researcher (not involved in the study) with use of a web-based randomization tool. The data analysis for the primary outcome will be run blinded by an independent researcher. Treatment codes will be broken after finalization of the data analyses. Participants and researchers are not blinded during the measurements owing to the nature of the intervention.

Intervention: SALUD Program

Theory Operationalization. For the development of the SALUD program, 3 main principles of salutogenesis were operationalized:

- The participant as a whole: in salutogenesis, health is a complex and dynamic concept

incorporating multiple aspects of well-being that relate to the whole person [39]. This requires interventions that aim to improve multiple aspects of health. Hence, in the SALUD program, physical and psychosocial health are valued equally.

- The participant's active involvement: to facilitate the mobilization of health resources, intervention strategies should be adjusted to real life to increase the chance of successful implementation of newly adopted behaviors in everyday life. This can only be done successfully and respectfully when people with T2DM and their health care providers are actively involved in the development of interventions. Hence, people with T2DM, health care professionals, and scientists of different disciplines provided their perspectives multiple times during intervention development (the participatory developmental process has been described by Polhuis et al [35]). The participatory developmental process revealed that self-identity, social support, food literacy, disease acceptance, and stress management were crucial resources to enable healthy eating in everyday life.
- The participant's individual learning process: salutogenesis complements traditional information-providing approaches by supporting individuals in a learning process to mobilize personal and environmental health-promoting resources to cope with stressors. Hence, the strategy of the intervention was to enhance the generalized resistance resources (GRRs) and specific resistance resources (SRRs) for enabling healthy eating through a reflective and empowering approach. The main strategy was based on mobilizing the GRRs self-identity and social support; session themes were based on the identified SRRs food literacy, disease acceptance, and stress management (**Table 6.1**).

Table 6.1 Summary of the Salutogenic Intervention for Type 2 Diabetes (SALUD) program sessions.

Session topic	Setting	Goals
0. Intake	Coach and participant (face to face)	• Getting to know the participant; personal history, motivations, and goals
1. Building trust	Coach and peer-group (web-based)	• Establishing a safe place • Social bonding
2. Goal setting	Coach and peer-group (web-based)	• Formulating at least one personal Specific, Measurable, Achievable, Relevant, and Time-Bound (SMART) health goal
3. Food literacy I	Coach and peer-group (web-based)	• Reflection • Question hour with a dietician • Setting up an individualized diabetes-proof week menu • Practical skills for meal planning, grocery shopping, and cooking
4. Food literacy II	Coach and peer-group (web-based)	• Reflection • Learning and sharing recipes (SALUD recipe book)
5. Stress management	Coach and peer-group (web-based)	• Reflection • Stress management • Diabetes-related stress • Mindfulness exercises (body scan and breathing exercises)
6. Nature break	Coach and peer-group (web-based)	• Reflection • Stress management • Boosting positive emotions • A mindful, individual walk outside (20 minutes)
7. Measuring progress	Coach and peer-group (web-based)	• In-depth reflection, evaluation, and adjustment of health goals • Social support
8. Social support	Coach and peer-group (web-based)	• Involve partner or friend in the health process • Opportunity for partners or friends to ask questions about program or health • Social support
9. Self-identity	Coach and peer-group (web-based)	• Reflection • Why do you eat what you eat? • Values and life goals • Disease acceptance • Social support: question hour with role model
10. Open session	Coach and peer-group (web-based)	• The participants choose the topic of this session during session 7
11. Measuring progress	Coach and peer-group (web-based)	• In-depth reflection, evaluation, and adjustment of health goals • Social support • Long-term health strategies
12. Festive closure	Coach and peer-group (web-based)	• Reflection on personal learning trajectory • Boosting positive emotions • Long-term health strategies
13. Booster session	Coach and peer-group (web-based)	• Reflection and sharing of experiences over the past 12 weeks • Social bonding • Long-term commitment to a healthy lifestyle

Setting. The SALUD program takes place in a web-based group setting (7-8 participants per group) under supervision of a certified and experienced lifestyle coach. The communication platform Microsoft Teams (Microsoft) is used for hosting the sessions. The job of lifestyle coach in the Netherlands entails coaching and motivating people to sustainable lifestyle changes regarding nutrition, physical activity, sleep, and stress. Certified lifestyle coaches are extensively trained in various communication and coaching techniques. They have basic knowledge of lifestyle-related diseases, physiology, and nutrition. The current coach has been externally hired for the study by the authors and is not part of the research team. The coach is specifically experienced in group coaching (>5 years), particularly people with T2DM. The participants will be divided

into separate groups on different days (based on their availability), all under supervision of the same coach.

Content. The SALUD program consists of 1 individual intake session (at the start), 12 weekly group sessions, and 1 booster session. Each weekly session has its own theme and goals (summary in **Table 6.1**). The sessions' themes are based on the GRRs and SRRs that were identified during the participatory intervention development: self-identity, social support, food literacy, disease acceptance, and stress management. A "learning by experience" approach will be used to equip participants with practical tools and skills. The coach uses several reflective (on- and off-screen) exercises related to diet, health, stress, and life during each session. The sessions are intended to be highly interactive and informal. Most sessions end with a practical home exercise (eg, "cook a new recipe this week"). A registered dietician will be invited to 1 of the sessions to answer specific nutrition-related questions. In 2 of the sessions, participants are encouraged to bring an important person (their best friend, partner, neighbor, or family member). Session 10 is deliberately left "open" to provide the participants with the opportunity to choose a topic based on their needs. More details about the intervention content can be found in the study by Polhuis et al [35].

Fidelity of Delivery. Fidelity of the intervention delivery is assured by the following: selecting a coach in line with salutogenic principles, that is, whole person view on health and a participatory and empowering way of coaching using a program manual in which the program's core (salutogenic) values, the sessions, the exercises, and goals are outlined thoroughly discussing with the coach about the (salutogenic) approach of the program before the start of the study weekly evaluating forms that will be filled in by the coach after each session to keep track of deviations from the manual and feedback of participants weekly checkups between the coach and the principal investigator (KP) to evaluate the previous session and to discuss the upcoming session recording a (small) number of sessions (with permission of the participants).

Control: Usual T2DM Care

The participants in the control group receive the usual Dutch T2DM care according to the Dutch General Practitioners Association (Nederlands Huisartsen Genootschap) protocols [37]. The usual care of T2DM is based on medical treatment, education, and lifestyle advice. Newly diagnosed persons and persons who require insulin administration are referred to a dietician by the GP. In some cases, the GP recommends a referral to a psychologist for help with dietary advice or to a physical therapist to help with physical activity. The GP refers to a specialist in case of complications (such as retinopathy and nephropathy). Generally, a person with T2DM has 4 quarterly checkups with the practice nurse and 1 yearly checkup with the GP. However, the exact frequency of the appointments depends on the specific agreements between the health care provider and the patient.

Quantitative Evaluation

The primary outcome is food literacy; secondary outcomes are self-efficacy, QoL, SoC, diet quality (Dutch Healthy Diet Index 2015 [DHD-15 index]), body weight, BMI, and waist-hip ratio (WHR). Self-efficacy and SoC are measured to evaluate the empowerment process of the SALUD program; diet quality to assess changes in nutritional intake; QoL to assess effects on psychosocial health; and body weight, BMI, and WHR to assess the effects on physical health (**Figure 6.2**). All measurements take place at the participants' homes.

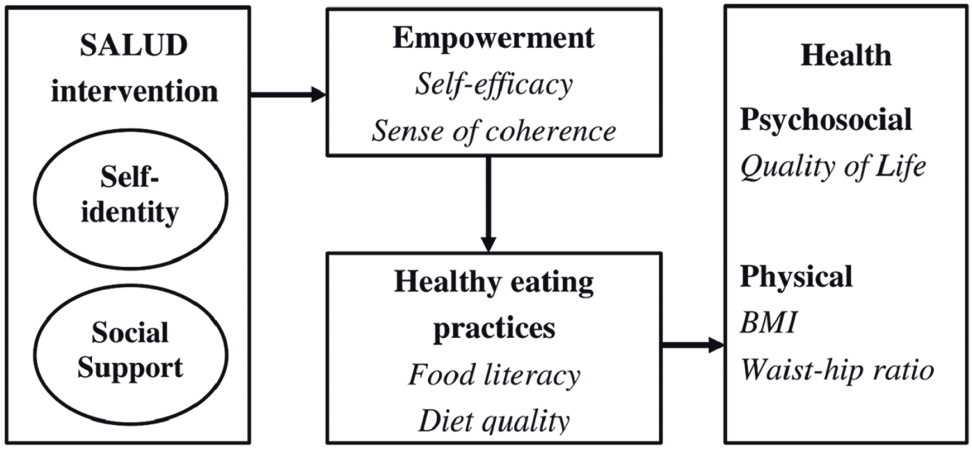

Figure 6.2 Proposed mechanism of action of the Salutogenic Intervention for Type 2 Diabetes (SALUD) program.

Food Literacy (Self-perceived Food Literacy Scale). The self-perceived food literacy scale (SPFLS) [36] is used to determine the capability to make healthy food choices in different contexts, settings, and situations. The SPFLS is a relatively new tool developed by Dutch researchers and validated among healthy Dutch adults (with a high internal reliability; Cronbach α=.80) [36] as well in people who underwent kidney transplant [36,40]. In the general population and in the patients who underwent kidney transplant, higher food literacy was associated with a healthier nutritional intake [36,40]. The SPFLS scale is proven to be capable of distinguishing between different populations [36,40]. The SPFLS contains 29 items related to 8 domains: food preparation skills, resilience and resistance, examining food labels, daily food planning, healthy budgeting, and healthy food stockpiling, healthy snack manners, and social and conscious eating. Response options include a 5-point Likert scale (1="not at all/never" to 5="yes/always"), eventually providing a score between 29 and 145. A higher score indicates higher food literacy. Domain scores and a total score are computed for each participant. Permission to use the SPFLS in this research has been formally granted by the developers of the SPFLS.

Self-efficacy (Dutch General Self-Efficacy Scale). The Dutch General Self-Efficacy Scale

(DGSES) [41] is a unidimensional free accessible questionnaire that measures the confidence someone has in their own abilities to cope with external challenges. The original DGSES was developed in German and is currently adapted to 32 languages [41]. Internal consistencies yielded typically Cronbach α between .76 and .90 [41]. Criterion validity is documented in numerous correlation [41]. The DGSES consists of 10 questions related to how people generally think and act. The response options include a 4-point Likert scale (1=completely false; 4=completely true), eventually providing a score between 10 and 40, with a higher score indicating higher self-efficacy. A total score will be computed for each participant.

QoL (World Health Organization Quality of Life Questionnaire). The Dutch and abbreviated version of the World Health Organization Quality of Life-100 (WHOQOL-100) questionnaire is used to determine how people perceived their QoL over the last 2 weeks [42]. The abbreviated WHOQOL-100 is known as WHOQOL-BREF. The WHOQOL-BREF has been validated by comparing it with the original WHOQOL-100 domain scores (domains scores correlate at around 0.9 with the original) [43]. Internal validity is high (Cronbach α>.70) [44]. The WHOQOL-BREF contains a total of 26 questions that assess 5 domains of health and well-being: general perceived QoL, physical health, psychological health, social relationships, and environment. Response option includes a 5-point Likert scale (1=not at all; 5=extremely true), eventually providing a score between 26 and 130. Higher scores denote better QoL. A score is computed for each QoL domain as well as a total QoL score. Permission to use the Dutch version has been granted by the World Health Organization.

SoC (13 Items of the Orientation to Life Questionnaire). The Dutch version of the 13 items of the Orientation to Life Questionnaire (SoC-13) is used to assess the participants' SoC [34]. The SoC measures to what extent participants perceive the world as comprehensible, meaningful, and manageable. The SoC-13 has been validated in multiple countries with a high internal validity (Cronbach α between .70 and .92 [45]). The Dutch version is validated among Dutch adults (Cronbach α=.86; based on the validation study of Swan, E, unpublished data, June 2013). Response options include a 7-point Likert scale (1=very often; 7=almost never), eventually proving a score between 13 and 91, with a higher score indicating a stronger SoC. Domain scores for manageability, comprehensibility, and meaningfulness as well as a total SoC score are computed for each participant. Permission to use the SoC-13 has been granted to the authors.

Diet Quality (DHD-15 Index). The DHD-15 index is used to assess the diet quality via a scoring system based on the Dutch food-based dietary guidelines [46]. The DHD-15 index is a relatively short food frequency questionnaire consisting of 40 questions. The DHD-15 index has been validated with 24-hour recalls and food frequency questionnaire data among Dutch adults with a Dutch dietary pattern [46]. The DHD-15 index calculates a score for 16 food components: vegetables, fruit, wholegrain products, legumes, nuts, dairy, fish, tea, fats and oils, coffee, red meat, processed meat, sweetened beverages and fruit juices, alcohol, salt, and

unhealthy food products (snacks and cookies). Each component is scored on a scale ranging from 0 (implies nonadherence) to 10 (optimal adherence), eventually providing a total score between 0 and 160. A higher score indicates a more optimal diet quality (ie, a diet in line with the Dutch dietary guidelines). For the calculation of the scores, specific cutoff and threshold values were used as suggested by Looman et al [46]. A separate score for each component as well as a total score will be calculated. Formal permission to use the DHD-15 index was granted by the developers to the authors.

Anthropometry. Body weight is measured at the participant's home with use of a scale (type: UC-411PBT-C) that measures to 2 decimals precisely. The scale will be calibrated before each measurement. The researcher makes sure the measurements are performed in similar circumstances (time of the day, placement of the scale, and layers of clothing). In addition to weight, height is measured once (during the first measurement). The scale calculates BMI (BMI [kg/m2]=body weight [kg]/height [m]2) and estimates fat percentage (%), muscle mass (kg), and basal metabolic rate (kcal).

Waist Circumference and WHR. Waist circumference and WHR are simple and useful measures of fat distribution. The measurements are performed according to the instructions of the World Health Organization [47]. In short, the participant must stand with arms at the sides, feet positioned close together, and weight evenly distributed across both feet. The measurement is performed at the end of a normal expiration. The researcher uses a measuring tape to measure the midpoint between the lower margin of the least palpable rib and the top of the iliac crest to determine waist circumference. Hip circumference is measured around the widest portion of the buttocks, with the tape parallel to the floor. All measurements are performed at the same time of the day (morning, afternoon, or evening). WHR is calculated using the following formula: WHR=waist circumference (cm)/hip circumference (cm). A healthy WHR is considered ≤0.90 for men and ≤0.85 for women [47].

Participant Characteristics. A questionnaire consisting of personal contact details (name, age, address, phone number, and email), living situation, ethnicity, educational level, and clinical details (disease duration, medication use, and smoking [past and present]) is filled out during screening.

Qualitative Evaluation

Consecutive to the 12th session, participants are invited to a focus group to provide feedback and share their personal experiences with the program. The participants' partners are also invited to the focus group. One week before the focus group, the coach instructs the participants to bring an object that symbolizes their experiences with the SALUD and to think about what they liked or disliked about the program. The focus groups will be video recorded and used for qualitative effect analysis of the program. In the video recording, all participants (and partners) are asked

to provide informed consent to record the session and to use the video recording for qualitative analysis. The following sample question will be used:

- If you were the program director of SALUD, what would you change? Why?
- Would you recommend SALUD to other people? Why? Why not?
- What did SALUD mean to you? Which parts were valuable/useful for you?
- Which elements of SALUD were not valuable/useful for you?
- Did you change things in your everyday life because of SALUD (eg, daily life, interactions with others, and the way you think)? Why?

The video recording will be transcribed ad verbatim and pseudonymized. Two researchers of the research team analyze the transcripts independently. First, the transcripts are read and reread to engage with the data. Then, the transcripts are open coded on a descriptive and interpretative level. More specifically, transcripts will be coded on active components of the intervention, the mechanism of action, health-promoting resources, and the influence on everyday life. Subsequently, the codes are clustered in preliminary themes. Then, the 2 researchers compare and discuss the preliminary themes until consensus is reached. The overarching themes are the result of various discussions between the researchers. The themes will be displayed with pertinent participant quotes and detailed interpretative commentary. The Dutch quotes will be translated into English by a professional translator.

Sample Size Calculation

Sample size calculation is based on the known mean value and SD of the SPFLS (food literacy measure) for the Dutch general population [36]. There are no RCTs with lifestyle interventions in the scientific literature that assessed food literacy (measured with SPFLS or another measure for food literacy) as a primary outcome. However, as RCTs evaluating lifestyle interventions that targeted psychosocial outcomes such as self-efficacy have demonstrated effect size of between 1.1 and 1.7 [48,49], it seemed reasonable to expect an effect size of 0.9. With use of the Cohen d calculation for effect size, an anticipated mean of 4.20 SPFLS score in the intervention group, and an anticipated mean of 3.83 (SD 0.41) in the control group is expected at T1 (based on references values [36]). With a standard power of 80% and a significance level of 5%, a total of 19 participants per group (38 participants in total) are needed. Adding a 30% dropout rate, the ideal sample size was set at 28 participants per group (56 in total).

Statistical Analyses

Statistical analyses are carried out using IBM SPSS Statistics for Windows, version 28 (released in 2021; IBM Corp). Two-sided P values <.05 are regarded as statistically significant. Analyses are performed with the intention-to-treat principle, meaning that all patients were analyzed in their original allocation group regardless of the extent to which they followed the intervention. Dropouts are counted, and reasons for dropping out are recorded. If missing is completely at

random, all available data at T0 (baseline), T1 (12 weeks), and T2 (24 weeks) are used to conduct the analyses. If missing is at random, multiple imputation techniques are used to impute the missing data.

Scores are calculated for multiple-item instruments (ie, DGSES, WHOQOL-BREF, SoC-13, DHD-15 index, and SPFLS). Randomization will be checked, and variables will be normalized if needed. Descriptive statistics are performed to tabulate mean (or median) values of all study characteristics and baseline values of the independent variables. Chi-square tests (for categorical variables) and 2-tailed t tests (for continuous variables) are used to compare the descriptive statistics between study groups and to identify potential covariates. Data are tabulated as mean (SD) or median (IQR) if skewed. Categorical data are presented as n (%) where appropriate.

According to a strict data analysis protocol, primary and secondary outcomes are tested with mixed models. Secondary outcomes are also tested if the primary outcome is not statistically significant. The analyses scripts will be written by the researchers; the analysis of the primary outcome will be run by an independent researcher who is blind to the intervention code. Assumptions for mixed models are checked. The mixed models will test the difference compared with baseline in the scores and values (ie, dependent variables) between intervention and control (ie, independent variable) at T1 and T2. Fixed effects are the treatment condition, time, and the covariates; random effects are the repeated measures per participant at T0, T1, and T2. Multiple models are tested; a crude model, and additional models that are adjusted for confounders commonly adjusted for in literature (eg, sex, age, education, and BMI). Variables that statistically significantly differed at baseline are also included in a model as covariates. The final results are presented in a table displaying the estimated marginal means, 95% CIs, and P values for the treatment effect for all primary and secondary outcomes.

Incentive

All participants receive a financial compensation of €150 (US $159.5) after completion of the study (ie, after finishing the last measurements at T2). The financial compensation is calculated based on the time commitment and invasiveness of the measurements.

Data Management

The handling of personal data complies with the European Union General Data Protection Regulation, the Dutch Act on Implementation of the General Data Protection Regulation (in Dutch: Uitvoeringswet Algemene Verordening Gegevensbescherming), and the Findability, Accessibility, Interoperability, and Reusability principles. Participants are assigned a unique participant identifier number (ie, a random 4 digits number) that does not change during the study to ensure that data cannot be tracked back to the participants. This number is linked with the name, address, and date of birth of the participant. The identifier number is used on raw and processed data files. The file that contains the link between the participant's information and

the participant's identifier number is stored on a password-secured location during the study. Participants indicate in the informed consent form whether their data may be used for other studies. If a participant indicates that they do not allow further use of their data, their data will be removed from the file that can be requested for future research. The file with the link between the participant identifier number and the personal data of the participant will be destroyed after finalizing the data files for future research.

6.3 Results

The project of which this study is part of received funding from the Edema-Steernberg Foundation in November 2016. Recruitment started on October 1, 2021. The intervention participants followed the SALUD program between January and August, 2022. The acquisition of the data was completed on August 1, 2022. The data analysis and publications are expected at the end of 2023.

6.4 Discussion and conclusion

This study will be one of the first salutogenic interventions for T2DM. Both the quantitative and the qualitative effect analyses are expected to provide valuable insights for further optimalization of interventions in people with T2DM.

Strengths and Limitations

A first strength of this study includes the RCT design, especially because previous Dutch "diabetes reversal" interventions have been evaluated via an observational pre- and posttest design [4,50]. Furthermore, there is also a shortage of evaluating salutogenic programs via RCTs [51]. Although RCTs are considered the gold standard for intervention evaluation, the RCT design has also some limitations for this particular study. The SALUD program is difficult to fit the experimental framework of an RCT, as it is a multicomponent intervention that cannot be strictly standardized [52-54]. Furthermore, RCTs are limited when the implementation context is a determinant of the result [52-54]. In the SALUD study, the success of the program will be dependent on the extent to which the program integrates with the everyday lives of the participants. Nevertheless, RCTs can be helpful for evaluating multicomponent interventions if close attention is paid to contextual factors via qualitative analysis [54]. Hence, a second strength is the proposed qualitative evaluation. This will increases the value of this RCT as it may help to understand the "black box" of the SALUD program (eg, the active components of the SALUD intervention, participant satisfaction, and points of improvement) [54]. In addition, the qualitative evaluation together with the quantitative evaluation may gather new insights regarding the theory of salutogenesis [51,54]. A third strength is that participants can follow the program on the web in the comfort of their own home: it saves the participants' time and travel efforts. Considering the recent COVID-19 pandemic, it is also a safe manner of group interactions, and the group sessions can continue during a possible lockdown. It also provides valuable information on how to perform a group-based coaching program in a web-

based setting. A third strength is the open and flexible nature of the SALUD program, which provides the lifestyle coach opportunities to tailor the program to situational factors and individual needs. A final strength is the inclusion of both physical and psychosocial health measurements that enable assessment of the program's effect on different dimensions of health. However, because of limited budget, the study does not include HbA_{1c} and blood measurements to assess T2DM management.

A limitation is the limited follow-up period. Ideally, measurements would be repeated over 1, 5, or even more years to determine whether the program led to sustainable change. However, the current Dutch university and funding structures make it difficult to execute such long-term research projects (eg, temporary research contracts). Challenges the study may face are the recruitment; owing to the COVID-19 pandemic, health care professionals are overflooded with work and are short staffed. Especially in the case of a new infection peak, health care professionals may be unable to assist in the recruitment of participants. Furthermore, the intervention might be specifically suited for more motivated people because of the time investment and because self-identity and self-reflection require a proactive attitude. This might cause dropouts in the intervention group.

Conclusions

The proposed study will provide useful information on the effects of a salutogenic program on healthy eating and well-being in people with T2DM in a daily life setting. The SALUD program—if effective—may serve as a concrete, web-based tool to empower people with T2DM and guide them toward a healthier dietary pattern for the long run. In addition, the study may provide valuable information on what salutogenic interventions entail as well as new insights regarding the theory of salutogenesis. The combination of quantitative and qualitative measures allows a comprehensive evaluation of the intervention's effects.

Funding: This study received funding from the Edema-Steernberg Foundation. The Edema-Steernberg Foundation is a Dutch non-profit organization that stimulates multidisciplinary nutrition research.

Data availability statement: All pseudonymized data will be stored for 10 years on a password-protected server of Wageningen University. If other researchers wish to use the data, they have to send a request to the principal investigator. If the request is approved, the principal investigator will grant a copy of the file.

Authors' contributions: KCMMP generated the idea for this paper, submitted the protocol to medical-ethical committee, and wrote the initial draft of the paper (therefore, I am first author). The other co-authors were continuously and equally involved in the decisions on methodological choices in this study as well as their contributions to the revisions of the initial draft of this the paper.

Competing interest: None declared.

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7

Chapter 7

The quantitative effect evaluation of SALUD

This chapter is submitted to: Public Health Nutrition

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Abstract

Background: Optimalisation of strategies to enable healthy eating among people with type 2 diabetes mellitus (T2DM) is desirable. The aim of this study is to evaluate the effects of the SALUD programme primarily on food literacy, and secondary on dietary intake, psychosocial and physical health.

Methods: A two-arm, randomised controlled trial (RCT) with measurements at baseline (T0), 12 weeks (post-intervention; T1), and 24 weeks (follow-up; T2) **in** 47 participants officially diagnosed with T2DM, aged between 18-75 years (Setting Europe, The Netherlands). Food literacy, self-efficacy, quality of life (QoL), Sense of Coherence (SoC), diet quality, body weight, BMI, and waist-hip ratio were measured. Following an intention-to-treat approach, linear mixed models were performed and effects sizes were calculated.

Results: Food literacy, diet quality, SoC, QoL, body weight, BMI, and waist circumference improved significant in both groups over time. There seems to be a trend towards a pattern where the intervention group consistently improves slightly more than the control. However, intervention effects were not significant. For SoC, a significant time*intervention interaction was found.

Conclusions: Statistically, the SALUD programme was only effective for enhancing SoC, indicating that introspection and social support are effective strategies to increase SoC. The results look promising for food literacy, diet quality, and body weight, yet, a larger replication study and additional qualitative analysis would be useful to get a clearer picture of the SALUD programme's effectiveness.

Trial registration: Netherlands Trial Registry, NL8963; https://trialsearch.who.int/Trial2.aspx?TrialID=NL8963. **International registered report identifier (irrid):** DERR1-10.2196/40490. **Medical ethical approval** has been granted by the Medical Ethical Committee Oost-Nederland (2021-12949).

7.1 Introduction

Type 2 Diabetes Mellitus (T2DM) is a public health crisis that tripled in global burden from 151 million adults in 2000 to 469 million people in 2019 [1,2]. Healthy eating can alter the disease course and the quality of life of people with T2DM substantially to a similar extent as medical treatment [3]. In some cases, healthy eating can put the disease in remission [3,4]. Healthy eating plays an integral role in overall T2DM self-management. However, incorporating healthy eating in everyday life is difficult for most people with T2DM [5–7]. Although current T2DM strategies have been successful in initiating health benefits, such as weight loss and improved HbA_{1c} [4,8], they struggled with maintaining the benefits on the long-term [8–10]. Hence, further optimalisation of strategies to enable healthy eating among people with T2DM seems justified.

Why is healthy eating difficult? For most people with T2DM – independent of socioeconomical status – a lack of nutritional knowledge is not the driving factor for unhealthy eating behaviors [5,6,11]. Instead, psychosocial factors, such as mental stress and social influences, have been pointed out as more important for explaining eating behavior [5–7]. Secondly, eating behavior is integrated in everyday life routines and habits, thus, changing eating behavior involves changing everyday life contexts in which the behavior is embedded [5,11]. Thirdly, someone's self-identity can be partly derived from eating behaviors. Evidently, changing someone's self-identity is complicated [11]. Fourthly, unhealthy behaviors that persist tend to be functional to people in some way: competing priorities complicate dietary changes [5,11]. Finally, eating behavior is simply not entirely under our rational control: eating choices are highly influenced by the environment and can be driven by automatic unconscious responses to environmental or social cues (e.g., nudges) [11]. It may be clear, enabling healthy eating is complex and requires more than providing nutritional knowledge [11]. People with T2DM do not necessary need more guidance on *what* to (not) eat, but on *how* to implement dietary changes in *their* everyday life.

In this study, the salutogenic model of health (SMH) was applied to develop the SALUD programme (Salutogenic intervention for Type 2 Diabetes Mellitus) that aimed to enable healthy eating among people with T2DM [12,13]. The main theoretical principle behind the SALUD programme is mobilising two important health-promoting resources required for organising healthy eating behaviour and improved wellbeing in everyday life: self-identity and social support [12]. Compared to previous (cognitive-behavioural) T2DM approaches, the SALUD programme stimulates behavioural change through an introspective learning process to mobilise a set of health enhancing resources necessary for coping with challenges for healthy eating. The individual's capability to use available resources in a health-promoting way is referred to as the Sense of Coherence (SoC) within the SMH [14]. SoC is the key concept in salutogenesis [14]. A salutogenic approach considers the person as a whole, by probing into the deeper motivations underlying a (health) behaviour and how this relates to what someone wants to get out of life

[15]. Compared to most previous T2DM programs [4,16,17], the SALUD programme was not performed in a (highly clinically) controlled-setting nor did it include strict dietary/lifestyle instructions. Instead, themes and topics were starting points for social support, conversation, reflection, and introspection, rather than traditional knowledge transfer or top-down rules. Consequently, the line of approach was to empower people by supporting them in (re)discovering and using health-promoting resources in their everyday life.

The aim of this study was to evaluate the effects of the SALUD programme primarily on food literacy, and secondary on dietary quality, psychosocial- and physical health. Food literacy is a broader and more complex concept than nutritional knowledge or dietary intake; it can be seen as one's skills to navigate between different food situations to make healthy choices [18]. The importance of food literacy for T2DM self-management has been recognised [19,20]. Investing in food literacy seems fundamental for developing healthy eating behaviour and effective T2DM self-management. Food literacy fits within the salutogenic perspective on health as it can be interpreted as a useful indicator of someone's ability to deal with challenges for healthy eating in everyday life.

7.2 Methods

SALUD programme

In the SALUD programme, three main principles of the SMH were operationalised (**Table 7.1**). The SALUD programme was a (peer) group-based program (7-8 participants per group), under supervision of a certified and experienced lifestyle coach, consisting of twelve weekly sessions and one booster session at 24 weeks [13]. The SALUD programme's approach can be described as reflective, empowering, open and flexible. This approach provided opportunities for the coach to tailor the program to situational factors and individual needs The sessions were intended to be highly interactive and informal. A detailed description of the themes, topics and exercises covered in each session and the ways to ensure fidelity of intervention delivery can be found here [13]. Initially, the SALUD programme was planned face-to-face, but due to the COVID-19 regulations in 2020-2022, it was decided to conduct the SALUD programme online.

Table 7.1 Operationalisation of the SMH in the SALUD-RCT study.

Principle	The participant as a whole	The participant's active involvement	The participant's individual learning process
Explanation	In salutogenesis, health is a complex and dynamic concept incorporating multiple aspects of wellbeing that relate to the whole person. This requires interventions that aim to improve multiple aspects of health.	To facilitate the mobilization of health resources, intervention strategies should be adjusted to real-life to increase the chance of successful implementation of newly adopted behaviours in everyday life. This can only be done successfully and respectfully when the people concerned are actively involved in the development of interventions.	Salutogenesis complements traditional information providing approaches by supporting individuals in a learning process to mobilize personal and environmental health-promoting resources to cope with stressors.
Operationalisation	In the SALUD programme, physical and psychosocial health are valued equally (both in the content of the program and in its evaluation).	People with T2DM and healthcare providers were actively involved in the development of the SALUD programme [13]. Additionally, the SALUD programme was highly interactive and one session was deliberately left 'open' to provide the participants the opportunity to choose a topic based on their needs.	The SALUD programme's main strategy was mobilizing the health-promoting resources self-identity and social support through a reflective, empowering approach. Flexible eating, disease acceptance and stress-management were also important focal points in the program.

Study design

A two-arm randomised controlled trial (RCT) was conducted in 47 people with T2DM in The Netherlands (September 2021- August 2022). The whole study duration was 24 weeks, with measurements at baseline (T_0), after 12 weeks (post-intervention; T_1), and after 24 weeks (follow-up; T_2). Participants were randomly allocated to the SALUD programme (intervention group) or to the usual T2DM care (control group) by a researcher that was not involved in the study with use of a randomisation tool. The SALUD programme consisted of one individual intake session (at the start), twelve weekly consecutive group sessions and one booster session at 24 weeks. Participants and researchers were not blinded during the measurements. The data-analysis for the primary outcome was run blindly. Medical Ethical Committee Oost-Nederland (METC Oost-Nederland) has granted medical-ethical approval for this study on 2021-08-18 (METC number 2021-12949). The study has been registered at Netherlands Trial Registry, NL8963; https://trialsearch.who.int/Trial2.aspx?TrialID=NL8963 (International registered report identifier (irrid): DERR1-10.2196/40490). The study protocol can be found here [13].

Participants

The target population consisted of Dutch-speaking men and women with T2DM. Inclusion criteria were: being officially diagnosed with T2DM by a GP; ≥18-75 years of age; fluent in Dutch, competent to make own decisions; and in possession of a computer device with internet connection. Exclusion criteria were: pregnant or lactating or intention to become pregnant in the upcoming 6 months, severe chronic illnesses/condition/comorbidities (other than T2DM, for example kidney failure, severe form of chronic obstructive pulmonary disease (gold III or IV), heart failure (class 2-4), cancer, dementia or severe depression); bariatric surgery in the past; eating

disorders (e.g. anorexia, bulimia). Participants were recruited via GP practices, advertisements in local papers, social media, and websites of national diabetes organisations (between September – December 2021).

With a power of 80%, and an alpha of 5%, 19 participants per group (= 38 participants in total) were needed at minimum. The total sample size was set on 56 participants (assuming a potential drop-out rate of 30%). In total, a smaller number of 47 participants (intervention= 23, control= 22) were eventually included, mainly due to the COVID-19 pandemic (still above the minimum of 38 participants). Two participants dropped out before randomisation, and two intervention participants dropped out during the study (actual drop-out rate: 4.5%) (**Figure 7.1**).

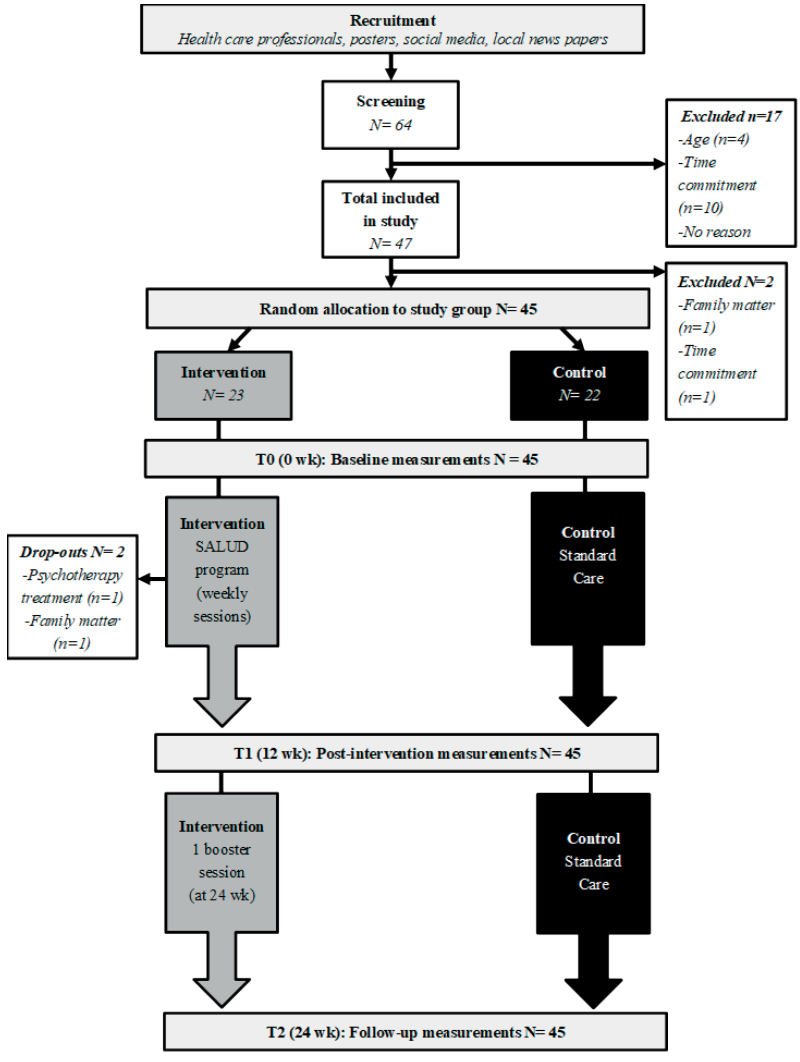

Figure 7.1 Flow-chart of participants in the SALUD-RCT study.

Measurements

Table 7.2 displays an overview of the measurements that were conducted at T_0, T_1, and T_2. At T_0, a questionnaire with participant details (education, ethnicity, living situation, work status, smoking, T2DM duration, T2DM medication use) was filled in as well. The primary outcome was food literacy; secondary outcomes were diet quality, self-efficacy, Sense of Coherence (SoC), quality of life (QoL), body weight, BMI, and waist-, and hip circumference and waist-hip ratio (WHR). All measurements were executed at the participants' homes.

Table 7.2 Overview of the repeated measurements of the SALUD-RCT study.

Healthy eating	Empowerment	Psychosocial health	Anthropometric measurements
Food literacy (*SPFLS*)	Self-efficacy (*DGSES*)	Quality of life (*WHOQOL-BREF*)	Body weight
Diet quality (*DHD15-index*)	Sense of Coherence (*SoC-13*)		BMI
			Waist- and hip circumference
			Waist-Hip Ratio (*WHR*)

Food literacy (SPFLS). The self-perceived food literacy scale (SPFLS) was used to determine the capability to make healthy food choices in different contexts, settings and situations. The SPFLS is validated among Dutch adults and has a high internal reliability (Cronbach's alpha of 0.80) [18]. The SPFLS contains 29 items related to eight domains regarding food planning, preparation and consumption. Response options include a 5-point Likert scale (1= 'not at all/never' to 5= 'yes/always') eventually providing a score between 29 and 145. A higher score indicates higher food literacy.

Self-efficacy (DGSES). The Dutch General Self-Efficacy Scale (DGSES) measures the confidence someone has in own abilities to cope with external challenges. Internal consistencies yielded typically Cronbach's alpha between 0.76 and 0.90 [21]. Criterion-validity is documented in numerous correlations [21]. The DGSES consists of ten questions related to how people generally think and act. Response options include a 4-point Likert scale (1= completely false; 4= completely true) eventually providing a score between 10 and 40. A higher score indicates higher self-efficacy.

Quality of life (WHOQOL-BREF). The Dutch version of the WHOQOL-BREF questionnaire of World Health Organisation was used to determine how people perceived their quality of life over the last two weeks. The WHOQOL-BREF has been validated by comparing it to the WHOQOL-100 domain scores (domains scores correlate at around 0.9 with the original) [22]. Internal validity is high (Cronbach alpha >0.70) [23]. The WHOQOL-BREF contains a total of 26 questions that assess five domains of health and wellbeing. Response options include a 5-point Likert scale (1= not at all; 5= extremely true) eventually providing a score between 26 and 130. Higher scores denote better quality of life.

Sense of Coherence (SoC). The Dutch version of the 13 items of the Orientation to Life Questionnaire (i.e. SoC-13) was used to assess the participants' SoC [24]. The SoC measured to what extent participants perceive the world as comprehensible, meaningful, and manageable. The SoC-13 has been validated in multiple countries with a high internal validity (Cronbach alpha between 0.70 to 0.92 [25]). Response options include a 7-point Likert scale (1= very often; 7= almost never), eventually providing a score between 13 and 91, with a higher score indicating a stronger SoC.

Diet Quality. The Dutch Healthy Diet Index 2015 (DHD15-index) was used to assess the diet quality via a scoring system based on the Dutch food-based dietary guidelines [26]. The DHD-15 index has been validated with 24h recalls and Food Frequency Questionnaire (FFQ) data among Dutch adults with a Dutch dietary pattern [26]. The DHD-15 index is a relatively short FFQ questionnaire consisting of 40 questions that calculates a score for sixteen different food components. Each component is scored on a scale ranging from 0 (implies non-adherence) to 10 (optimal adherence) eventually providing a total score between 0 and 160. A higher score indicates a higher diet quality (=diet more line with Dutch dietary guidelines). For the calculation of the scores, specific cut-off and threshold values were used (see [26]).

Body weight/BMI. Body weight was measured with use of a scale (type: UC-411PBT-C) that measures to two decimals precisely. The scale was calibrated before each measurement. The researcher made sure the measurements were performed in similar circumstances (time of the day, placement of the scale, layers of clothing). Height was measured once (during the first measurement). The scale calculated BMI, and estimated fat percentage (%) and muscle mass (kg) (based on the height, sex, age, and body weight of the participant).

Waist- and hip circumference and Waist-Hip Ratio (WHR). Waist- and hip circumference, and Waist-Hip ratio (WHR) were measured to determine a participant's fat distribution. The measurements were performed according to the instructions of the World Health Organisation [27]. A measuring tape (cm) was used to measure the midpoint between the lower margin of the least palpable rib and the top of the iliac crest to determine waist circumference. Hip circumference was measured around the widest portion of the buttocks, with the tape parallel to the floor. WHR is calculated by the formula: *WHR = waist circumference (cm) / hip circumference (cm)*. A healthy WHR is considered ≤0.90 for men, and ≤0.85 for women [27].

Statistical analyses

Statistical analyses were carried out using IBM SPSS Statistics version 28.0.11. Two-sided *p*-values <0.05 were considered statistically significant. The analyses were performed according to the intention-to-treat principle. Descriptive statistics were obtained for the sample as a whole, and separately for the intervention and control group. Normality and homogeneity of variance was assessed for all continuous variables (i.e. Shapiro-Wilk test, and Levene's test, respectively).

All variables met the assumptions of normality and homogeneity of variance. Independent t-tests (continuous variables) and independent Chi-square (categorical variables) were used to compare the descriptive characteristics between the study groups to check for randomisation. The descriptive data was tabulated as *mean±standard deviation (SD)*, or as *%*(*n*) where appropriate.

According to a strict data analysis protocol, effects of the intervention vs control on primary and secondary outcomes were tested with Linear Mixed Models (LMM; random coefficient models). LMM are the preferrable statistical model to evaluate the effectiveness of RCT studies with multiple groups and multiple time points [28]. LMM offers a straightforward interpretation of the effects of individual experimental groups, provides more statistical power compared to other methods (e.g. mixed ANOVA or ordinary least squares regression), and are more flexible compare other methods (e.g. LMM can missing values, and is less restrictive regarding the model assumptions) [28].

In the crude model, the dependent variable was the one of the study outcomes. The fixed main effects included the intervention-, time- (T_0, T_1 and T_2), and interaction effect (time*intervention). The random effects were the repeated measures (i.e. T_0, T_1, and T_2) per participant (i.e. the intercept, with variance components as covariance structure).

In addition, adjusted LMM models were performed (adding sex, age, education, BMI, medication use, nationality, employment status, and living situation as fixed main effects) to check if the additional factor(s) improved the explained variance of the model. When one of these additional factors was significant, the adjusted model was used instead of the crude model. If an additional factor was significant, interaction effects between the additional factor and intervention were tested as well to identify possible vulnerable subgroups (subgroups that were more responsive for the intervention). As an indication of the model fit, the (conditional) pseudo-R^2 is displayed for each individual model. Assumptions for LMM were checked; the assumptions of normally distributed residuals and of homogeneity of variances of the residuals were checked visually with normality- and scatter plots of the residuals/predicted values. All models met the assumptions.

Secondly, the effect sizes for mean differences were calculated in order to quantify the magnitude of the experimental effects (i.e. the point estimate). First, the relative changes (delta's; Δ) were calculated for the study outcomes at post-intervention and follow-up (T_1-T_0, and T_2-T_0, respectively). Consequently, the mean delta value and SD was calculated at T_1 and T_2. Based on the mean delta's and SDs (of the control group) effect sizes were calculated at T_1 and T_2 via Cohen's *d*:

$$d = \frac{\Delta Mean_{intervention} - \Delta Mean_{control}}{Standard\ Deviation_{control}}$$

Effect sizes were considered as large when d > 0.50, moderate when d > 0.20 and ≤ 0.50, and trivial when d ≤ 0.20 [29]. Accordingly, the 95% Confidence Interval (95%CI) of the effect size was calculated to determine the precision of the effect. In order to do so, first the SD(d) was calculated via [29]:

$$\sigma(d) = \sqrt{\frac{N_{intervention} + N_{control}}{N_{intervention} \times N_{control}} + \frac{d^2}{2(N_{intervention} + N_{control})}}$$

With the SD(d), the 95%CI of the effect size was calculated: 95%CI(d)= [d – 1.96 × σ(d), d + 1.96 × σ(d)] [29]. The final results were presented in tables displaying the estimated marginal means, standard errors (SE), the p-values (LMM), and the effect sizes with 95%CIs for all primary and secondary outcomes.

7.3 Results

Descriptive characteristics

Table 7.3 displays the distributions of the descriptive variables between the intervention and control group. The participants of the control group were on average 6 years older than the intervention group, although this was not statistically significant (mean±SD: 66.1±7.8 vs 60.8±10.8 years, p= 0.070). In the control group 90.9% reported to manage the T2DM with medication, whereas this percentage in the intervention group was 60.9 (p=0.0019). In both groups, metformin was the most commonly used T2DM medication among those who were using medications. Furthermore, the control group had a significantly higher SoC at baseline (mean±SD: 73.5±11.4 vs 66.6±11.2, p= 0.048). Randomisation was successful for all other characteristics.

Table 7.3 Descriptive characteristics the SALUD RCT-study participants at baseline.

	Total (n= 45) Mean ± SD or %(n)	Intervention (n= 23) Mean ± SD or %(n)	Control (n =22) Mean ± SD or %(n)	P-value
Age (y)	63.4 ± 9.7	60.8 ± 10.8	66.1 ± 7.8	0.070[a]
Sex (%female)	37.8 (17)	43.5 (10)	31.8 (7)	0.420[b]
Nationality (%non-Dutch)	11.1 (5)	12.9 (3)	9 (2)	0.561[b]
Living situation (%)				
Alone	24.4 (11)	30.4 (7)	18.2 (4)	0.686[b]
With partner	57.8 (26)	52.2 (12)	63.6 (14)	
With partner + child(ren)	11.1 (5)	8.7 (2)	13.6 (3)	
With child(ren)	6.7 (3)	8.7 (2)	4.5 (1)	
Education (%)				
Low[c]	15.6 (7)	8.7 (2)	22.7 (5)	0.298[b]
Medium[c]	33.3 (15)	30.4 (7)	36.4 (8)	
High[c]	51.1 (23)	60.9 (14)	40.9 (9)	
Employment status (%)				
Paid employment	40.0 (18)	39.1 (9)	40.9 (9)	0.732[b]
Retired	55.5 (25)	52.1 (12)	59.0 (13)	
Job seeking	2.2 (1)	4.3 (1)	0.0 (0)	
Incapacitated	2.2 (1)	4.3 (1)	0.0 (0)	
Smoking (%current smoker)	6.7 (3)	13.0 (3)	0.0 (0)	0.080[b]
T2DM duration (y)	9.2 ± 7.0	9.6 ± 7.7	8.8 ± 6.4	0.709[a]
T2DM medication (%yes)	75.6 (34)	60.9 (14)	90.9 (20)	**0.019**[b]
No medication (lifestyle)	24.4 (11)	39.1 (9)	9.1 (2)	0.059[b]
Metformin	46.7 (21)	34.8 (8)	59.1 (13)	
Metformin + Sulphonylurea derivative	20.0 (9)	13.0 (13)	27.3 (6)	
Insulin + (Metformin OR Sulphonylurea derivative)	8.9 (4)	13.0 (3)	4.5 (1)	
Body weight (kg)	89.9 ± 17.2	89.6 ± 15.2	90.1 ± 19.5	0.924[a]
BMI (kg/m²)	29.6 ± 5.5	29.7 ± 5.8	29.5 ± 5.2	0.907[a]
Fat (%)	34.5 ± 7.4	32.1 ± 6.8	36.3 ± 7.5	0.087[a]
Male (n= 28)	32.0 ± 6.5	30.0 ± 5.4	33.7 ± 7.1	0.136[a]
Female (n= 9)	42.3± 3.6	41.2 ± 4.2	42.8 ± 3.5	0.569[a]
Muscle mass (kg)	53.1 ± 10.6	54.0 ± 9.7	52.4 ± 11.4	0.636[a]
Male (n= 28)	57.6 ± 6.8	57.7 ± 6.2	57.6 ± 7.6	0.958[a]
Female (n= 9)	38.9 ± 7.1	38.2 ± 4.2	39.3 ± 8.5	0.840[a]
Waist (cm)	106.5 ± 14.4	106.5± 14.9	106.5 ± 14.3	0.642[a]
Male (n= 28)	106.5 ± 13.1	102.5 ± 13.7	109.9 ± 12.0	0.140[a]
Female (n= 17)	106.5± 16.7	111.7 ± 15.3	99.1 ± 16.8	0.098[a]
Hip (cm)	107.3 ±13.2	108.4 ± 12.2	106.2 ± 14.4	0.587[a]
Male (n= 28)	104.7 ± 9.1	102.1 ± 8.8	107.0 ± 9.0	0.159[a]
Female (n= 17)	111.5 ± 17.5	116.5 ± 11.2	104.4 ± 23.0	0.168[a]
Waist-Hip ratio	0.99 ± 0.08	0.98 ± 0.09	1.00 ± 0.08	0.642[a]
Male (n= 28)	1.02 ± 0.08	1.00 ± 0.10	1.03 ± 0.07	0.462[a]
Female (n= 17)	0.94 ± 0.06	0.96 ± 0.06	0.93 ± 0.06	0.312[a]
Food literacy *(range 29–145)*	103.1 ± 13.9	102.9 ± 13.0	103.4 ± 15.1	0.898[a]
Diet quality *(range 0–160)*	104.1 ± 19.2	102.6 ± 21.3	105.6 ± 17.3	0.610[a]
Self-efficacy *(range 10–40)*	33.0 ± 3.9	32.6 ± 4.0	33.4 ± 3.8	0.494[a]
Quality of Life *(range 26–130)*	100.9 ± 12.7	101.0 ± 13.5	100.8 ± 12.2	0.953[a]
Sense of Coherence *(range 13–91)*	70.0 ± 11.7	66.6 ± 11.2	73.5 ± 11.4	**0.048**[a]

[a] Independent t-test.
[b] Pearson Chi-square test of independence
[c] Low, medium, high education is based on the criteria of Statistics Netherlands [30].

The effects of the SALUD programme

The statistical probability of the intervention effects of the SALUD programme are tested with LMM and the results are displayed in **Table 7.4**. In both groups, a significant time effect for food literacy, diet quality, SoC, QoL, body weight, BMI and waist circumference was found. Both groups improved in these outcomes during the study, but no significant intervention effect was

found (**Table 7.4**).

A significant time*intervention interaction was found for SoC (**Table 7.4**). The intervention group had a relative larger increase in SoC between baseline and post-intervention (meanΔ±SE: 5.9±2.0) compared to the control (meanΔ±SE: 0.09±1.4) (**Table 7.5**). Yet, it should be noted that the control group had a significantly higher baseline SoC compared to the intervention group (**Table 7.3**).

The additional adjusted models indicated that sex was a significant factor for food literacy, diet quality, QoL, hip circumference and WHR. BMI was a significant factor for food literacy, diet quality, QoL and WHR (**Supplementary Table 1**). The interactions sex*intervention and/or BMI*intervention were not significant in neither of the models, indicating that sex nor BMI influenced responsiveness to the intervention.

Figure 7.2 displays the line graphs of a selection of the outcomes. There seems to be a trend towards a pattern where the intervention group consistently improves slightly more than the control (**Figure 7.2**). **Table 7.5** displays the relative changes and the magnitude of the intervention effect at post-intervention and at follow-up. At post-intervention (T1), large effects (d> 0.50) were found for SoC, self-efficacy, body weight and BMI (**Table 7.5**). Moderate effects (d between 0.20-0.50) were found for food literacy and diet quality. Trivial effects (d< 0.20) were found for QoL, waist- and hip circumference and WHR. Yet, all 95%CIs are wide (>0.5), indicating large uncertainty of the precision of the effect size estimates. At follow-up, the effects seem to become stronger for food literacy and diet quality (**Table 7.5; Figure 7.2**). The effects seem to vanish for self-efficacy and body weight/BMI (**Table 7.5; Figure 7.2**). Again, 95%CIs are wide.

Table 7.4 The intervention, time, and time*intervention interaction effects of the SALUD-RCT study on the study outcomes (linear mixed models).

Outcome	Time	Intervention	Control	P-value			Pseudo-R^2
		(mean ± SE)	(mean ± SE)	Intervention effect	Time effect	Time * Intervention	
Food literacy[1]	T_0	101.9 ± 2.4	103.0 ± 2.5	0.632	**<0.001**	0.187	0.783
	T_1	110.0 ± 2.4	108.0 ± 2.5				
	T_2	111.7 ± 2.4	107.9 ± 2.5				
Diet quality[1]	T_0	100.0 ± 3.5	105.7 ± 3.7	0.554	**0.039**	0.242	0.849
	T_1	105.8 ± 3.5	108.0 ± 3.7				
	T_2	105.7 ± 3.5	106.0 ± 3.7				
SoC	T_0	66.6 ± 2.2	73.5 ± 2.2	0.265	**0.008**	**0.024**	0.754
	T_1	72.5 ± 2.2	73.6 ± 2.2				
	T_2	72.4 ± 2.2	74.2 ± 2.2				
QoL[1]	T_0	99.8 ± 2.3	98.4 ± 2.4	0.619	**<0.001**	0.450	0.791
	T_1	104.4 ± 2.3	104.4 ± 2.4				
	T_2	106.0 ± 2.3	103.1 ± 2.4				
Self-efficacy	T_0	32.6 ± 0.8	33.4 ± 0.8	0.671	0.178	0.128	0.581
	T_1	34.1 ± 0.8	33.1 ± 0.8				
	T_2	34.4 ± 0.8	33.5 ± 0.8				
Body weight (kg)	T_0	89.6 ± 3.6	90.1 ± 3.7	0.864	**<0.001**	0.301	0.992
	T_1	88.4 ± 3.6	89.9 ± 3.7				
	T_2	87.8 ± 3.6	88.5 ± 3.7				
BMI (kg/m^2)	T_0	29.7 ± 1.1	29.5 ± 1.2	0.968	**<0.001**	0.968	0.990
	T_1	29.3 ± 1.1	29.4 ± 1.2				
	T_2	29.1 ± 1.1	29.0 ± 1.2				
Waist (cm)	T_0	106.5 ± 3.0	106.5 ± 3.1	0.945	**0.006**	0.945	0.935
	T_1	105.5 ± 3.0	105.3 ± 3.1				
	T_2	104.2 ± 3.0	103.6 ± 3.1				
Hip (cm)[2]	T_0	108.8 ± 2.5	108.0 ± 2.7	0.897	0.096	0.860	0.934
	T_1	108.0 ± 2.5	107.1 ± 2.7				
	T_2	107.0 ± 2.5	107.2 ± 2.7				
Waist-Hip Ratio[1]	T_0	0.98 ± 0.01	0.99 ± 0.02	0.862	0.394	0.904	0.658
	T_1	0.98 ± 0.01	0.98 ± 0.02				
	T_2	0.97 ± 0.01	0.97 ± 0.02				

Note. Means and SEs are displayed for intervention and control at baseline (T_0) post-intervention (T_1) and follow-up (T_2).[1] Model was additionally adjusted for sex and BMI as these were significantly associated with the outcome (**Supplementary Table 1**). Interactions sex*intervention, and BMI*intervention were not significant. [2] Model was additionally adjusted for sex as this was significantly associated with the outcome (**Supplementary Table 1**). The interaction sex*intervention was not significant.

Table 7.5 Relative changes (Δ) (compared to baseline; T_0) and corresponding effect sizes (d) of the of the outcomes of the SALUD-RCT at T_1 (postintervention) and T_2 (follow-up).

Outcome	Time point	Treatment	Mean (Δ) ± SE	Effect size (*d (95%CI)*)
Food Literacy	T_1	Intervention	8.0 ± 2.1	0.35 (-0.24, 0.93)
		Control	5.1 ± 1.8	
	T_2	Intervention	9.4 ± 1.6	0.44 (-0.16, 1.03)
		Control	4.6 ± 2.4	
Diet Quality	T_1	Intervention	6.3 ± 2.2	0.36 (-0.24, 0.96)
		Control	1.8 ± 2.7	
	T_2	Intervention	5.1 ± 2.9	0.60 (-0.01, 1.20)
		Control	-0.3 ± 1.9	
Sense of Coherence	T_1	Intervention	5.9 ± 2.0	0.86 (0.25, 1.48)
		Control	0.1 ± 1.4	
	T_2	Intervention	5.8 ± 1.9	0.73 (0.12, 1.33)
		Control	0.7 ± 1.5	
Quality of Life	T_1	Intervention	4.6 ± 1.9	-0.25 (-0.84, 0.33)
		Control	5.7 ± 0.9	
	T_2	Intervention	6.0 ± 1.6	0.18 (-0.41, 0.76)
		Control	4.5 ± 1.8	
Self-Efficacy	T_1	Intervention	1.5 ± 0.8	0.90 (0.29, 1.52)
		Control	-0.3 ± 0.4	
	T_2	Intervention	1.8 ± 0.8	0.52 (0.30, 1.12)
		Control	0.0 ± 0.7	
Body Weight (kg)	T_1	Intervention	-1.2 ± 0.3	-0.53 (-1.13, 0.06)
		Control	-0.2 ± 0.4	
	T_2	Intervention	-1.8 ± 0.6	-0.07 (-0.65, 0.52)
		Control	-1.6 ± 0.6	
BMI (kg/m^2)	T_1	Intervention	-0.4 ± 0.2	-0.62 (-1.22, -0.02)
		Control	-0.1 ± 0.1	
	T_2	Intervention	-0.6 ± 0.2	-0.09 (-0.68, 0.49)
		Control	-0.5 ± 0.2	
Waist (cm)	T_1	Intervention	-1.0 ± 1.6	0.07 (-0.52, 0.65)
		Control	-1.3 ± 0.7	
	T_2	Intervention	-2.3 ± 1.3	0.18 (-0.40, 0.77)
		Control	-2.9 ± 0.7	
Hip (cm)	T_1	Intervention	-0.8 ± 0.9	-0.06 (-0.65, 0.52)
		Control	-0.4 ± 1.5	
	T_2	Intervention	-1.6 ± 0.8	-0.14 (-0.73, 0.44)
		Control	-0.4 ± 1.8	
Waist-Hip Ratio	T_1	Intervention	0.0 ± 0.0	-0.03 (-0.61, 0.56)
		Control	0.0 ± 0.0	
	T_2	Intervention	0.0 ± 0.0	0.12 (-0.46, 0.71)
		Control	0.0 ± 0.0	

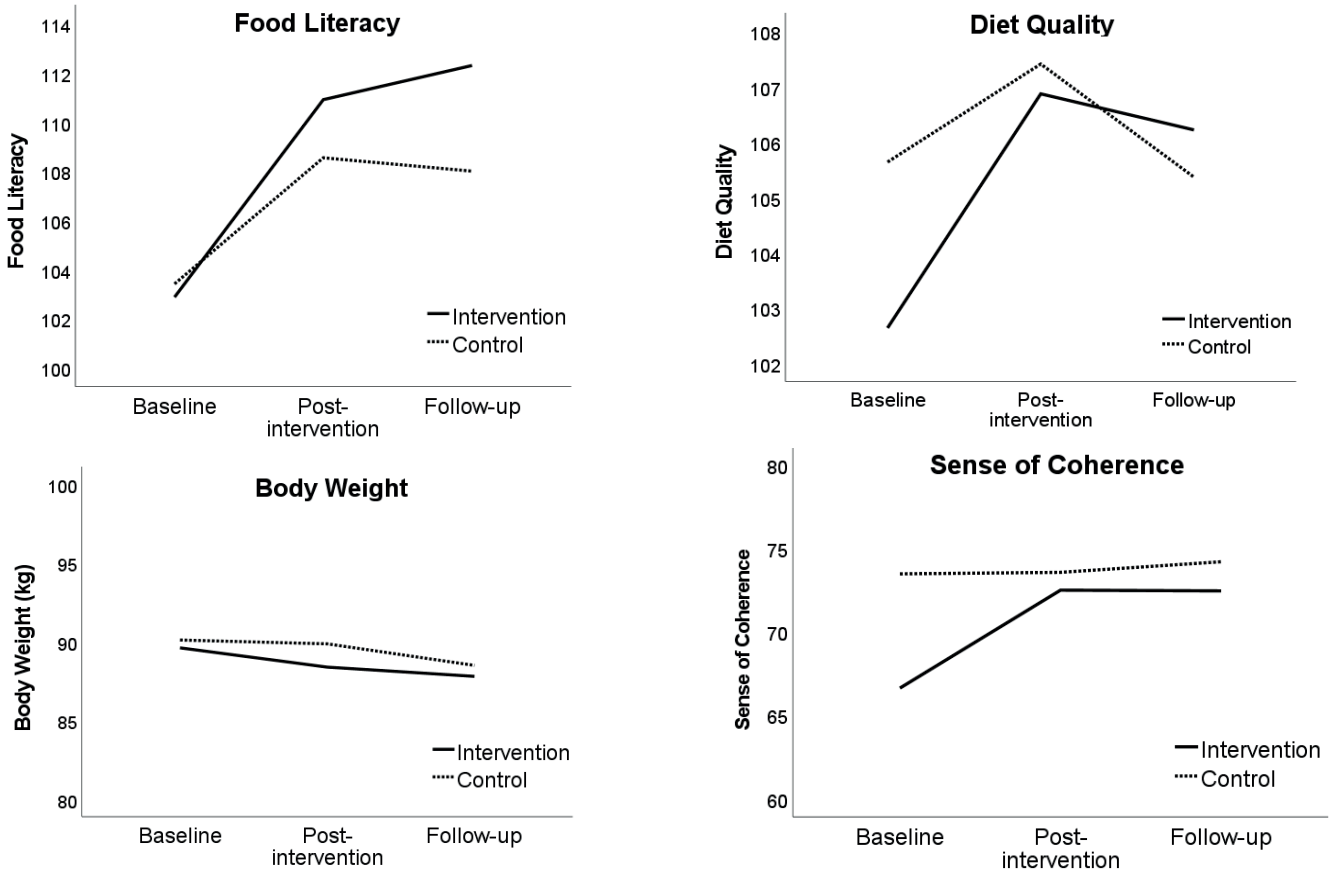

Figure 7.2. Line graphs for a selection of the outcomes. A significant time effect was found (food literacy: p <0.001, diet quality: p= 0.038, body weight: p <0.001 and SoC: p= 0.008). For SoC, a significant time*intervention interaction effect was found as well (p= 0.024).

7.4 Discussion and conclusion

In this RCT study of 45 Dutch people with T2DM, the SALUD programme resulted in an improved overall pattern of eating behaviour, personal autonomy and physical health. This is in line with previous lifestyle T2DM programs that showed significant improvements in physical measures [8,10,31,32] and personal autonomy measures [32,33]. Considering the magnitude of the intervention effects, large effects were found for SoC, self-efficacy and body weight/BMI, and moderate effects for food literacy and diet quality. However, current intervention effects were not statistically significant for most of the individual outcomes, except for a significant time*intervention effect for SoC.

The effect of the SALUD programme on primary outcome food literacy was modest compared to usual care. However, the food literacy of the intervention participants increased further at follow-up, whereas the (smaller) increase of the control group at T_1 was not sustained. Diet quality showed a similar trend. In addition, the weight loss was slightly larger in the intervention group (1.8 vs 1.6 kg). Changing dietary behaviours is a complex combination of knowledge, skills and strategies, which requires a trial-and-error strategy to acquire new skills and routines that takes time [5,34]. This may explain why the effects on food literacy and diet quality seem to become stronger at follow-up. Indeed, a previous study has also demonstrated that participants of a food literacy program continued practicing new knowledge and skills after completion of the program [35].

The significant interaction effect for SoC indicates that that time and the SALUD programme jointly improved SoC. This finding validates that the SALUD programme worked as an empowering, reflective learning process aimed at improving individual capacity to mobilize coping resources. This is in line with a previous salutogenic program (with comparable sample size) that showed significant improvements in SoC in the intervention group relative to the control (although the effect size (=0.26) was lower than in the current study) [33]. Unfortunately, the present control group had a significantly higher SoC at baseline (SoC=73.5), which was also higher than previously reported for (non-diabetic) adults of similar age (i.e. SoC= 69.1 in 324 German adults aged 50-83) [36]. The baseline SoC of the intervention group was slightly lower than this average (SoC= 66.6). This complicates the interpretation, because a ceiling effect may have appeared (i.e. control's SoC near the upper limit leaving little room for improvement). Yet, evidence has shown that SoC is surprisingly stable over time [37], but can be enhanced (even in adulthood) by salutogenic interventions [15]. SoC-enhancing strategies require active involvement in a reflective learning process [15] similarly to what was advocated in the SALUD programme. Therefore, from a theoretical standpoint, it seems plausible that the intervention group's improvement in SoC is triggered by the SALUD programme and it also makes sense that the control group's SoC remained stable.

Previous research demonstrated that the factors driving healthy eating are different from factors driving unhealthy eating [38]. A strong SoC has been demonstrated to be an important predictor of healthy eating [38]. Other research showed that proactive coping abilities and personal autonomy are indeed important for effective healthy eating strategies [39–42]. Perhaps, investing in SoC is a necessary first step to be able to eat more healthily, which may explain that the effects on dietary behaviour became more apparent at follow-up. Additional qualitative research with the intervention participants may assist further interpretation of the interplay between SoC and changing dietary behaviour (qualitative analysis is being prepared at the moment).

Furthermore, an intriguing finding of the SALUD study is that participation in the study, irrespective of treatment, resulted in significant improvements in most of outcomes over time. Previous studies showed that people with T2DM generally gradually lose weight after T2DM diagnosis; on average 2.5 kg six years after diagnosis [43]; the present weight loss in both groups is considerably higher than what is normally observed in T2DM. In addition, dietary intake is generally better in winter compared to summer [44], but in the current study food literacy and diet quality actually improved from winter (T_0) to summer (T_2). This suggest that Hawthorne- or reactivity of measurements effects may have occurred [45]. The Hawthorne effect (commonly known as placebo effect) implies that participants change their diet behaviours simply because they know they are participating in a study [45]. Reactivity of measurement is a broader concept that implies that collecting data on diet can be a health-promoting intervention by itself [45]. Furthermore, it could have been that the study attracted particularly people with T2DM with a longstanding desire to improve their lifestyle; participating in the study might have been the 'final push' to start implementing lifestyle changes (selection bias). These unavoidable interference of contextual factors, such as the Hawthorne/placebo effect, exposes the difficulties of applying a RCT for a lifestyle program in a real-life situation. Yet, contextual variables should not be considered as annoying nuisance. On the contrary, it shows how powerful human attention, context and communication are for health and wellbeing. Instead of questioning how to get rid of these effects, a more interesting/relevant question is: how can we optimize the use of these variables for health and wellbeing [46]?

A possible explanation why the intervention effects are not statistically significant may be that the current study is performed in a relative healthy T2DM population. Where most health-promoting T2DM interventions selected T2DM participants based on weight/BMI [8,31] or a relative short T2DM duration (<6 years) [16], the SALUD study was open to a wider T2DM population. In the current study, BMI is lower, T2DM duration longer and age higher compared to other studies [8,16,31]. In addition, almost 40% of the intervention participants did not use any T2DM medication, whereas in some studies medication use is a prerequisite for participation [31]. Hence, possible effects of the SALUD programme might have been harder to detect in the current sample than when applying stricter selection criteria. Conversely, using a fairly unselected sample better reflects the real-life situation.

Strengths and limitations

The SALUD programme is an intervention *without* intensive lifestyle restrictions, evaluated via a RCT in a real-life setting using a fairly unselected group of people with T2DM. This all contributes to high external validity of the study. The use of a control group is a strength since a number of previous Dutch lifestyle programs are evaluated in pre-post-test designs (6,41). Another strength is that the SALUD programme is based on a clear theoretical framework, which is important to understand why, and under which circumstances the intervention is effective (or not) [47]. Many previous (T2DM) lifestyle interventions do not explicitly explain if and how theory was used in the program development [16,17,31]. Furthermore, there was a low drop-out rate (4.5%) and a low amount of missing data.

The main limitation is the small sample size: large-to-moderate effect sizes that are statistical insignificant may suggest that the sample size was too small for the observed effects to reach significance. The actual effect size for primary outcome food literacy (0.35 post-intervention and 0.44 at follow-up) was considerably lower than expected beforehand (0.9). Recalculating the sample size using the actual effect size of 0.35 for food literacy results in a sample of 270 participants (135 per group, with power 0.80, and alpha 0.05). Yet, for complex interventions, it has been suggested that qualitative interpretation of the contextual factors might as well aid in overcoming the limitations regarding small samples as it provides insight in when, why and where interventions work [48,49]. A second limitation concerns the short follow-up period. A longer follow-up period is needed to determine the sustainability of the results. Thirdly, randomisation was successful, except for medication use and SoC. Yet, additional correcting the models for the unbalanced variables did not alter the current conclusions. Fourthly, a critical reflection is needed on the food literacy questionnaire (SPFLS). Flexible eating was indicated as a key resource for healthy eating and a central theme in the SALUD programme [12]. Flexible eating implies a sensible balance between healthy (nutritious) and unhealthy (pleasure) foods. Yet, the SPFLS includes only a limited number of questions regarding flexible eating strategies, and questions regarding social influences are limited too. Finally, a seasonality effect of physical activity might have occurred during the study. The weight loss of the intervention group occurred mostly during the SALUD programme, and the weight loss of the control group during the follow-up. People are generally more physically active during summer than winter [50], and the measurements were performed from winter to summer. Future studies are recommended to include physical activity measures.

Conclusion

This study is one of the first salutogenic interventions for T2DM that is evaluated in a RCT. Statistically, the SALUD programme was effective for enhancing SoC, which implies that introspection and social support are important strategies for strengthening SoC. The results are promising for food literacy, diet quality and body weight as both groups improved in these outcomes with consistently greater improvements in the intervention group. It seems plausible

that the SALUD programme contributed to these improvements. This may indicate clinically/practically relevance of the SALUD programme for eating behaviour and health despite the statistical insignificance of the results. A salutogenic intervention might be a necessary step for enabling healthy eating behaviour, but additional (replication and qualitative) research is needed to conclude this. The present findings are particularly interesting as the sample was unselected and the SALUD programme was non-invasive in terms of 'top-down' goals regarding weight loss goals or diet intake. Instead, the SALUD programme prioritised mobilising health enhancing resources and strengthening psychological flexibility over traditional nutritional knowledge-transfer. Altogether, the results are encouraging in the sense that if people are given the authentic attention, reflective guidance and social support, people seem independently able to find effective ways to improve their diet and health in everyday life.

Recommendations

Considering the methodology limitations, a replication study with a large sample and longer follow-up time seems useful to establish a clearer picture of the effects of the SALUD programme. At the same time, this study exposed the difficulties of applying a RCT for evaluating a complex lifestyle program: the unavoidable interference of contextual factors such as selection bias, seasonality effects and Hawthorne/placebo effects. The role of RCT as 'golden standard' has been questioned in evaluating complex interventions, because of their limited value to real-life settings and their inability to uncover why, how and under which circumstances an intervention program works [48]. Therefore, it has been stressed to use additional qualitative evaluation to interpret complex lifestyle programs [48,49]. Qualitative evaluation is especially important in programs such as SALUD were the success or failure involves an element of personal autonomy (SoC) [48]. The relationships between personal autonomy and dietary behaviour are subjective to context-specific interactions [48]. Furthermore, qualitative evaluation provides guidance for further optimalisation of the SALUD programme [48]. The current RCT should be seen as a 'first-cut' of the results for what warrants further (qualitative) consideration. A qualitative interpretation of the SALUD programme is advised before preceding to larger and more expensive replication RCT evaluations. For practice, the study showed that authentic reflective guidance and providing social (peer) support should be part of the T2DM cure-care agenda.

Ethical disclosure: This study was conducted according to the guidelines laid down in the Declaration of Helsinki and all procedures involving research study participants were approved by the Medical Ethical Committee Oost-Nederland (METC Oost-Nederland, number 2021-12949). The study has been registered at www.trialregister.nl (registration number NL8963; registered on 2020-10-12).Written informed consent was obtained from all subjects.

Acknowledgements: We are grateful for all health care professionals that helped with the recruitment of the participants, especially since the recruitment took place in a hectic COVID-19 peak. A sincere thank you for Annemone Siffels and Nora Lokradi for their assistance in the data

collection and processing. Most important, we are extremely grateful for all the participants: thank you for your interest, time commitment and active involvement in the study. Without your participation, this study would not have been possible.

Funding: The SALUD is funded by the Edema-Steernberg Foundation. The Edema-Steernberg Foundation is a Dutch non-profit organisation that stimulates multidisciplinary nutritional research. The Edema-Steernberg Foundation had no role in the design, analysis or writing of this article.

Authors' contributions: All authors were involved in the conceptualisation and preparation of the study. KCMMP set-up the recruitment, conducted the measurements, and analysed the data. Data analysis was discussed among all authors. KCMMP wrote the manuscript; the other authors edited and commented on the manuscript. All authors have read and approved the final manuscript.

Competing interest: The authors declare that there are no conflicts of interest.

Supplementary Table

Supplementary Table 1. All factors that are included in the final LMM models with corresponding *P*-values.

Outcome		Factor	*P*-value
Food Literacy	*Crude Model*	Intercept	**<.001**
		Time	**<.001**
		Intervention	0.572
		Interaction Time * Intervention	0.174
	Adjusted Model	Intercept	**<.001**
		Time	**<.001**
		Intervention	0.187
		Interaction Time * Intervention	0.174
		Sex	**0.004**
		BMI	**0.003**
Diet quality	*Crude Model*	Intercept	**<.001**
		Time	0.077
		Intervention	0.795
		Interaction Time * Intervention	0.245
	Adjusted Model	Intercept	**<.001**
		Time	**0.039**
		Intervention	0.554
		Interaction Time * Intervention	0.242
		Sex	**<.001**
		BMI	**<.001**
SoC	*Crude Model*	Intercept	**<.001**
		Time	**0.008**
		Intervention	0.265
		Interaction Time * Intervention	**0.024**
QoL	*Crude Model*	Intercept	**<.001**
		Time	**<.001**
		Intervention	0.913
		Interaction Time * Intervention	0.497

Outcome		Factor	*P*-value
	Adjusted Model	Intercept	**<.001**
		Time	**<.001**
		Intervention	0.619
		Interaction Time * Intervention	0.450
		Sex	**0.038**
		BMI	**0.043**
Self-Efficacy	*Crude Model*	Intercept	**<.001**
		Time	0.178
		Intervention	0.671
		Interaction Time * Intervention	0.128
Body weight	*Crude Model*	Intercept	**<.001**
		Time	**<.001**
		Intervention	0.864
		Interaction Time * Intervention	0.301
BMI	*Crude Model*	Intercept	**<.001**
		Time	**<.001**
		Intervention	0.968
		Interaction Time * Intervention	0.395
Waist (cm)	*Crude Model*	Intercept	**<.001**
		Time	**0.006**
		Intervention	0.945
		Interaction Time * Intervention	0.927
Hip (cm)	*Crude Model*	Intercept	**<.001**
		Time	0.096
		Intervention	0.717
		Interaction Time * Intervention	0.860
	Adjusted Model	Intercept	**<.001**
		Time	0.096
		Intervention	0.897
		Interaction Time * Intervention	0.860
		Sex	**0.047**
WHR	*Crude Model*	Intercept	**<.001**
		Time	0.496
		Intervention	0.653
		Interaction Time * Intervention	0.876
	Adjusted Model	Intercept	**<.001**
		Time	0.394
		Intervention	0.862
		Interaction Time * Intervention	0.904
		Sex	**<.001**
		BMI	**0.016**

Note. For food literacy, diet quality, QoL, hip circumference and WHR the additionally adjusted model was used in the final analysis (= Table 3), because adding the additional factor improved the model. Interactions between the additionally factor and intervention were tested as well, but none of these interactions were significant (not shown for the sake of clarity).

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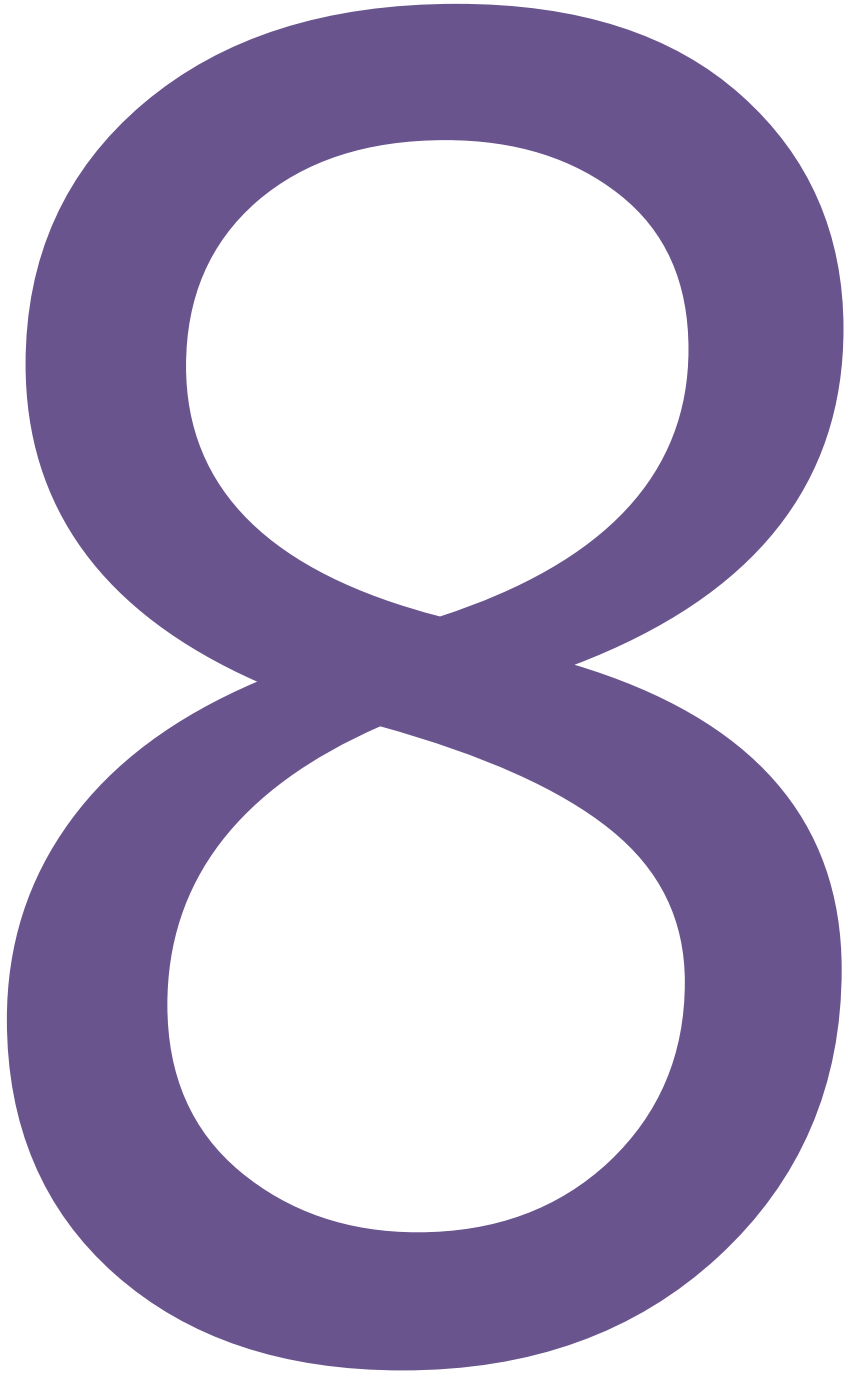

Chapter 8

The qualitative effect evaluation of SALUD

This chapter is submitted to: Health Promotion International

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Abstract

Background Healthy eating can be equally effective for treating type 2 diabetes mellitus (T2DM) as medical treatment, yet optimalisation of strategies to enable healthy eating is desirable. Hence, the salutogenic model of health was used to develop the SALUD-programme (Salutogenic intervention for Type 2 Diabetes Mellitus). The aim of this study is to gain insight in how participants with T2DM experienced the content and meaning of the SALUD-programme.

Methods Three focus groups with participants (6-8 participants/group) that finished the SALUD-programme were conducted. The focus groups were video-recorded, transcribed ad-verbatim and thematically analysed.

Results The SALUD-programme was perceived by the participants as a positive, meaningful learning experience. Key factors why the participants described the programme as positive were that they felt a sense of social belonging and (emotionally) safe (theme 1). The SALUD-programme's positive encouraging approach presented by the coach invited participants to join an active learning process (theme 2). Performing trial-and-error experiments and weekly reflecting on goals is what characterised the active learning. The meaningfulness of the learning process (theme 3) was derived from: 1) positive self-confrontation; 2) exploring mind-body connections and perceiving improved health, and 3) noticing positive changes in their social environment (theme 3).

Conclusions To conclude, the study uncovered that the SALUD-programme incited a positive, meaningful learning process for healthy eating and the contextual factors important in this. Potential leads to further improve the SALUD-programme are discussed in order to maximise the chance of inciting an inclusive, active learning process.

8.1 Introduction

Type 2 Diabetes Mellitus (T2DM) is a public health crisis that tripled in global burden in the last 20 years [1,2]. Healthy eating can be similarly effective for treating T2DM as medical treatment [3,4]. Several strategies to support people with T2DM with healthy eating are available and can be broadly categorised as cognitive-behavioural strategies that include either dietary prescription, lifestyle counselling, behavioural therapies or a mix of these [5]. These strategies have been successful in initiating health benefits such as weight loss and improved HbA_{1c}, but struggled with maintaining the benefits in the long term [6–8]. Further optimalisation of dietary strategies for people with T2DM is desirable.

Therefore, the SALUD-programme (Salutogenic intervention for Type 2 Diabetes Mellitus) was developed [9]. An important difference between the SALUD-programme and most previous T2DM programmes is that the SALUD-programme was inspired by the salutogenic model of health (SMH), rather than a cognitive-behavioural theoretical model. This led to a different way of approaching dietary behavioural change. In line with the SMH, the SALUD-programme considered healthy eating as a resource for living, rather than a central goal in life [10]. The SALUD-programme applied a holistic and reflective approach to enable coping with stressors in a health-promoting way. The key concept in the SMH is the Sense of Coherence (SoC): the individual capability to cope with stressors by mobilising (internal and external) resources in a health-promoting way [11,12]. A strong SoC is associated with good physical health, wellbeing and healthy eating [13,14].

The effects of the SALUD-programme on dietary behaviour, psychosocial and physical health have been quantitatively evaluated in a Randomised Controlled Trial (RCT) [9]. The first results of the SALUD-programme look promising for health, wellbeing and eating behaviour (Chapter 7). However, additional qualitative evaluation is strongly recommended to interpret RCTs testing complex lifestyle programmes, especially when the programme's success or failure involves an element of human-agency, such as SoC [15,16]. Relationships between human-agency and dietary behaviour are subject to context-specific interactions [15]. Qualitative evaluation can assist in uncovering these interactions, providing a clearer understanding of why, how and under which circumstances the SALUD-programme works [15]. Finally, qualitative evaluation provides guidance for further optimalisation of the SALUD-programme [17]. Therefore, the aim of this study is to gain insight in how participants experienced the content and meaning of the SALUD-programme.

8.2 Methods

Theory operationalization in the SALUD-programme

The SALUD-programme was the result of a theory-informed and participatory process. Three

main salutogenic principles operationalised in the SALUD-programme [18]:

1. *Consider the participant as a whole:* in the SALUD-programme, physical and psychosocial health are valued equally. A holistic perspective on health was applied in the programme's content and evaluation.
2. *Aim to incite participant's active involvement:* people with T2DM and healthcare providers were actively involved in the development of the SALUD-programme. The SALUD-programme was highly interactive, and one session was deliberately left 'open' to provide participants the opportunity to choose a topic based on individual needs.
3. *Aim to facilitate the participant's individual learning process*: the SALUD-programme's main strategy was a self-reflective approach to enable the mobilisation of the following previous identified health-promoting resources: self-identity, and social support. Flexible eating strategies, disease acceptance and stress-management were also important focal points [18].

The SALUD-programme is a peer group-based programme (7-8 participants per group) consisting of 12 weekly sessions and one booster-session at 24 weeks. All groups were guided by the same certified and experienced coach. Due the COVID-19 regulations in 2020-2022, the programme changed from an in-person to a web-based format. A detailed description of the themes, topics and exercises covered in each session can be found elsewhere [9,18].

Participants

The target population consisted of Dutch-speaking men and women with officially diagnosed T2DM, between ≥18-75 years, who were competent to make their own decisions. Participants could not participate if they were pregnant or lactating, had severe chronic conditions other than T2DM or had bariatric surgery or an eating disorder in the past. Participants were recruited directly via general practitioners (GP) or practice nurses and via posters, advertisements in newspapers, social media, and websites. In total, there were 47 participants, with 23 participants randomly allocated to the intervention-group and 22 participants allocated to the control-group. No qualitative data of the control participants has been obtained. Intervention participants could bring their partners to the focus group if they wanted to. Three focus group were conducted: group 1 (n= 7 intervention participants+4 partners), group 2 (n= 8), and group 3 (n= 6) (21 participants in total).

Procedure

The focus groups took place after completing the final session of the SALUD-programme. One week prior, the coach informed the participants about the upcoming voluntary focus groups, and asked who was willing to participate. The coach explained that the focus group would be video-recorded, transcribed, shared with the research team, and used for analysis to report the programme's effects. All participants agreed to participate. The formal verbal informed-consent of the participants and partners was recorded before the start of the focus group.

In advance of the focus group, the lifestyle coach asked the participants to bring an object that symbolised their experiences with the SALUD-programme. The object functioned as a preparatory exercise to encourage the participants to articulate their thoughts, allowing the participants to explain their experiences with the programme in a more undirected way. The SALUD-coach guided the focus group; the researchers did not partake. First, the participants explained the reason why they brought their object. Then the coach asked five questions (prepared by KCMMP). The coach was given freedom to add questions on the spot and to probe to allow participants to further. The questions were asked in an informal way. The coach ensured that each participant had the opportunity to express his/her views on each question. The focus groups' duration ranged between 102 to 111 minutes. The five main questions were:

- If you were the SALUD-programme director, what would you change? Why?
- Would you recommend SALUD to others? Why (not)?
- What did SALUD mean to you?
- Which parts were useful for you? Which parts were not useful for you?
- Did you change things in your everyday-life because of SALUD? Why?

Thematic analysis

The video-recordings were transcribed *ad verbatim*. The names and personal information were pseudonymised. The central analytical question of the data-analysis was: how do participants give content and meaning to the SALUD-programme? First, the transcripts were read and re-read. Then, the transcripts were open-coded on a descriptive and interpretative level. Initial codes were discussed with LIB and LV, and consequently KCMMP finalized the coding list. The final coding list consisted of normal codes and category codes (secondary themes) (**Supplementary Table 1**). These codes were applied to the transcripts using Atlas.ti version 22. Subsequently, KCMMP categorised the codes into three tertiary themes which were again discussed among LIB, LV, and MAK (**Supplementary Table 2**). This led to the three final themes and theme integration (**Supplementary Table 3**). The participants' objects were also coded and analysed (**Supplementary Table 4**). The themes are displayed with relevant participant quotes and detailed interpretative commentary. The Dutch quotes were translated into English and re-translated.

Ethical approval

Medical Ethical Committee Oost-Nederland (METC Oost-Nederland) has granted medical-ethical approval for the RCT-study (number 2021-12949). Additionally, the present qualitative analysis have been retrospectively inspected by the social-ethical committee (SEC) of Wageningen University and Research that decided that the requirements of fair and respectful treatment of participants were fulfilled and the burden of the study for the participants was acceptable.

8.3 Results

Participants' characteristics

Table 7.1 displays the descriptive characteristics of the three groups. All participants were highly educated. The average age of group 1 was lower than in group 2 and 3. Group 2 and 3 had relative more retired people than group 1. In group 1 and 3 the majority of the participants was male, in group 2 most participants were female.

Table 7.1 Descriptive characteristics of the SALUD participants per group.

	Group 1* **(n = 7)**	**Group 2** **(n = 8)**	**Group 3** **(n = 6)**
Age (years)	49.7 ± 6.0	68.1 ± 4.9	61.3 ± 12.6
Sex (%female)	28.6 (2)	62.5 (5)	33.3 (2)
Nationality (%non-Dutch)	28.6 (2)	12.5 (1)	-
Living situation (%)			
Alone	14.3 (1)	37.5 (3)	33.3 (2)
With partner	42.9 (3)	62.5 (5)	50.0 (3)
With partner + child(ren)	14.3 (1)	-	16.7 (1)
With child(ren)	28.6 (2)	-	-
Education (%)**			
Low	-	-	16.7 (1)
Medium	42.9 (3)	25.0 (2)	16.7 (1)
High	57.1 (4)	75.0 (6)	66.7 (4)
Employment status (%)			
Paid employment	85.7 (6)	25.0 (2)	16.7 (1)
Retired	0 (0)	75.0 (6)	66.7 (4)
Job seeking	14.3 (1)	-	-
Incapacitated	-	-	16.7 (1)
Smoking (%current smoker)	14.3 (1)	12.5 (1)	16.7 (1)
T2DM duration (years)	6.5 ± 4.4	12.6 ± 7.3	7.3 ± 6.9
T2DM medication (%yes)	71.4 (5)	62.5 (5)	50.0 (3)
No medication (lifestyle)	28.6 (2)	37.5 (3)	50.0 (3)
Metformin	42.9 (3)	37.5 (3)	33.3 (2)
Metformin + Sulphonylurea derivative	14.3 (1)	0.25 (2)	0 (0)
Insulin + other type of T2DM medication	14.3 (1)	0 (0)	16.7 (1)

Note. Mean ± SD or %(n)
* The partners of participant 4, 5, 6 and 7 also participated in focus group 1, but the partners are not included in this table.
** Low, medium, high education is based on the criteria of Statistics Netherlands.

Individual experiences with the SALUD-programme

The participants' experiences with the SALUD-programme are described in three themes:

1. **The SALUD-programme: a positive experience** which describes the general, positive evaluation of the SALUD-programme. Social-belonging, the positive approach and feeling emotionally safe were particularly emphasised by the participants (§3.2.1).
2. **The SALUD-programme: an active learning experience** which describes how participants talked about their learning as an active process to reach self-set health goals in everyday-life (§3.2.2).
3. **The meaningfulness of the SALUD-experience** which describes more in-depth the aspects of the learning process that the participants found meaningful (positive self-confrontation, body-mind connections and the positive effects on others). A deviant-case is discussed, as well (§3.2.3).

The theme integration describes how the themes are interlinked (§3.3).

Theme 1. The SALUD-programme: a positive experience

All groups experienced participation in the SALUD-programme as a positive, enjoyable experience. Most participants were a bit sad that the programme had ended and indicated they would miss the weekly group-sessions. All participants would recommend the programme to others.

> **Participant 2:** When I started I didn't know that I had diabetes for a very long time, so to speak, so for me it has been just a quite big learning process for a lot of things. Learned a lot of things from other people, yes, I'm really going to miss this enormously [...], that's just the way it is. I think it is just wonderful […] you can exchange thoughts […], you hear things from other people who have had diabetes a lot longer […],and, yeah, I've found it hugely enjoyable.
> *Group 1; line 329*

Social-belonging. The participants highly appreciated the group-format and peer-support. Peer-support was considered the most fun, motivating, and informative element of the SALUD-programme. The importance of the peer-support is also illustrated by five objects that participants brought, for example, participant 2's object (table sugar) symbolised that 'sugar disease' is what brought them together and allowed them to connect. These objects represented the feeling of social-belonging and experienced connectedness during the programme. Participants explained the peer-support made them feel less alone and less ashamed about their disease. For some, peer-support aided tremendously in disease acceptance.

> **Participant 16:** And, um, what I found nice is to experience that you are not the only

one with diabetes, […] And now you notice that you are not alone, and then it's kind of shared sorrow is sorrow halved, so to speak.
Participant 17: Yes, I do understand what [*participant 16*] means […] I was a bit ashamed your know. And, also, it felt it's your own fault, and, you know, that's it is known as… eh…[…] a welfare disease, you know, and then you think, yes, I was really a bit ashamed […] And now, now, yes, I actually don't have all that. Yes, it's just that, indeed, you have more people around you now that make you think it's not just your *[own*] fault.
Group 3; line 267-269

Furthermore, the group's social support functioned as a 'big stick' to keep up with the individual goals. All groups used a group chat to motivate each other between the sessions by sharing pictures, personal achievements and complimenting each other. Finally, the groups indicated they have learned a lot from each other by sharing stories, practical tips and recipes.

Participant 12: Yes, and you also get inspired by other people's stories […]. Also really nice to hear other things, or to get tips […].
Participant 14: Yes, I really like meeting like-minded people, also on the chat […]. Normally, I don't come across diabetic people, at least, I don't go there and say: 'hello I'm [*participant 14*] and I have diabetes'. You just don't do that. But this, I really liked this a lot.
Group 2; line 310–318

Safe-place. Furthermore, participants explained that the programme felt as a positive and safe-place, which was important for opening-up on sensitive issues and sharing personal experiences. The groups explained that the coach had a fundamental role in creating a positive safe-place and enabling the social connectedness among the participants. The coach was described as positive, encouraging, enthusiastic, driven, and experienced: 'the connecting factor' of the programme. For some, the web-based format played an important role because being in the comfort of their own home assisted in opening-up emotionally.

Participant 8: I found your coaching very accessible and welcoming, [*coach*], which I appreciated very much, and I still do [...] Your spontaneity and the positive energy you have, also on us, is just, yes, positive. Maybe it sounds a bit cliché, but I really mean it, and, so, you just did that well. In a very fun, playful, spontaneous way, and nobody felt hampered or inhibited or anything like that. I'm very pleased with it.
Participant 9: And coaching. Coaching, you do it with your heart, right? That's not just what you learned, but your 'being' is your tool, and you definitely have that.
Group 2; line 816-818

Participant 17: And that the approach was positive, that helped me a lot. What I just said to [*participant 15*]: when you sin once, that is how it feels, but actually 'sinning' is a very

wrong term, isn't it? You [= *coach*] always found other words like: 'yes, that can happen', you know […] Be kind to yourself in that respect, yes.
Participant 16: [*coach*] also used to say: 'to fall down is okay, but staying down is not'.
Group 3, line 416-420

Theme 2. The SALUD-programme: an active learning experience
Beside that the SALUD-programme was experienced as a positive and enjoyable experience, the participants talked about how the SALUD-programme incited active learning, which is also exemplified by the objects the participants brought to the focus groups. These objects symbolised the new tools or resources or newly developed health-promoting coping strategies (nine objects) as well as goal achievement during the programme (12 objects). Participants talked about how they learned to set realistic goals, develop health-promoting coping strategies, and mobilise new tools/resources. Most participants (except for one) explained they reached their goal(s) and were proud of that, as expressed in the following quote:

Participant 7: Yes, about myself, but I think it's kind of true for all of us -please shake no or nod yes- that it's actually doable, all our goals. Those were deliberately, realistically chosen but for everyone it was not heavy, not super heavy, to pursue them. And you also achieve results [*your goals*] and I got the insight: with small adjustments in your lifestyle you do achieve quite nice results. But also my social-environment becomes much more aware, and I become much more aware of how I live, and yes that has a direct impact on my [*blood*] glucose level. But, that is almost secondary at a certain point, because your life pattern changes, your food, your exercise, your stress, everything hobbles along. And as a bonus, your glucose level improves and it's not even that hard.
Group 1; line 463

Trial-and-error experiments. Participants talked about trial-and-error experiments they conducted in order to find new- healthier practices that fitted within their everyday-life. Participants that talked about trial-and-error experiments expressed an eagerness to learn and enjoyed the process (including the failures). One example of such an experiment was the stepwise re-introduction of more unhealthy foods after a few weeks of a relatively strict diet to find a sensible balance between healthy and unhealthy foods (participant 7, group 1). In particular self-monitoring glucose was considered useful for monitoring progress and providing direct feedback of undertaken experiments. The weekly sessions were considered 'a place for reflection' to evaluate the learning and goal-setting process/progress.

Participant 15: Um, I started thinking again about my sugar intake and how to prevent a relapse […]. I think that in previous attempts I sometimes set goals that were a bit too ambitious. I could persevere for a while, but then, then I failed again. Now I'm thinking that shouldn't happen again. So how, how do I manage to stay on track? And

> that's actually another [*important*] insight. So I think, yes, I just have to grind in these new healthy eating and exercise patterns And, I must fine-tune them. Finetuning for me is, for example that I replace the soy sauce I really love by something else that is as good [*without added sugar*].
> *Group 3, line 559-561*

Health-promoting coping. The trial-and-error experiments led to identification of existing and new resources and how to apply these in a health-promoting way. Examples of applying existing resources included using a smartwatch or (cooking) books. The most mentioned identified existing resource was social support from the direct social-environment, particularly from the participants' partners. Supportive partners who help with the participants' health goals were considered extremely motivating, as these partners made implementing behavioural changes not only easier, but also more enjoyable. A compliment of a partner regarding new healthy behaviours was perceived as particularly motivating, illustrated by the following quote:

> **Participant 5:** Well, if they [*the partners*] know your goal well, that's already an advantage of course, and I think they [*the partners*] can also be motivating, right? So if you a weak moment and [...] they support you again, by saying: 'you did well' or something like that, that also gives a bit of a positive feeling. […] So, you see, [*it is*] that positive approach. You can give yourself a compliment, but when someone else does it, it is often just a little bit more powerful. Perhaps, it also makes it a bit easier to do it yourself a next time.
> *Group 1; line 730*

Newly identified resources included peer support (i.e. social belonging, motivating and learning from each other), nutrition-apps (to compare the nutritional value of products), a self-made cookbook with self-selected healthy recipes and a reflection booklet to keep track of goal setting and achievements. Participants mentioned several concrete coping strategies that they started to implement in their everyday-life, such as searching for and preparing new recipes, reading nutritional labels, swapping unhealthy foods for more healthier alternatives, eating mindfully, eating more regularly, adding vegetables to recipes, homemade meals, drinking more water, limiting sugar intake and daily exercise.

Theme 3. Meaningfulness of the SALUD-experience

Participants declared participation in the SALUD-programme as meaningful because they experienced positive self-confrontation, explored body-mind connections and noticed a positive effect of their health progress on others. The programme was described as 'inward journey' and as 'self-exploration in a group' that led to a critical re-evaluation of health behaviours in everyday-life. However, there were notable differences in which phase of that journey the participants were. For most participants, the SALUD-programme was the start of an internal journey (i.e. starting to change behaviours, reaching goals, but it still takes effort); only a few reached their

intended destination during the SALUD-programme (i.e. lowering medications, automating new behaviours). Nevertheless, in both cases, the SALUD-programme was considered meaningful. Illustrations of being on an internal journey were:

> **Participant 7:** I brought these [*objects*]: a [*finger*] prick-pen and a [*glucose*] monitor. I was actually very faithfully measuring every day for the last 3 months. Mainly because I was on journey of self-discovery, especially […] in the context of this programme... and I do hope to use those [*pen and monitor*] a lot less now. Most of you brought a new object, a remainder of this [*programme*], and I actually [*brought objects that I*] just want to forget. I'm where I want to be actually so, so that's nice. […] The periodic check-up is in a fortnight time - I'll be there for the first time so, so I hope they *[= practice nurse and GP*] agree with me that the current blood levels are um, yes sufficient. So I'm now at 51 *[=HbA_{1c}*] without medication. I'm quite happy with that.
> *Group 1; line 283-295*

> **Participant 15:** And -eh- I brought one shoe, not two, just one [*shows one hiking shoe*]. Because I'm very aware that I'm not there where I want to be, but that I have to keep going, so I'm halfway, I think. That shoe represents exercise, but actually also, I think it's *[=the SALUD-programme*] a kind of an anchor for me. I think I did quite a lot of exercise, but not just daily. Sometimes very much, and sometimes nothing […] I actually do my exercises daily [*and*] I'm still working on my diet. It's [=*the SALUD-programme*] really a kind of an anchor. And that -eh- I hope I can improve and it will help me.
> *Group 3; line 243*

Positive self-confrontation. The SALUD-programme was considered a self-confronting experience but 'in a good way'. It incited introspective and reflective overthinking of what is truly important in life by reflecting on previous thoughts, feelings, values and memories related to (eating) behaviour/habits. Feeling confronted led to more awareness *why* one was making certain health choices, which helped the participants to change behaviours in line with health intentions. Five objects of the participants symbolised the self-confronting element of the programme, one example of these objects is a walnut:

> **Coach:** A walnut!
> **Participant 5**: Yes, so this is the happy nut and this one is the heavy nut that we had to crack occasionally, so to speak. [...] The session were fun, for sure; that is the happy nut [...]
> **Coach:** Yes, I liked it too, yes. So, that's your happy nut, and what was the heavy nut...?
> **Participant 5:** Well, yes, well, it makes you think about your goals: 'what do I actually want?' [...] We were forced to face the facts about what is really important for us, what exactly do you want and how to persevere, that kind of stuff, and that is very good for us.

Group 1; line 206-223
**In Dutch, the word for 'nut' and 'note' are the same, making the symbol more powerful in Dutch.*

Participant 1: Well, mainly that you talk about your health and physical exercise, what you don't, because of hectic work. I think it's just good to look into the mirror [...] it is a good reflection of how your life is, and what you don't dwell on normally. And, that's a good thing about these sessions, so to speak, that you now just really have an insight of 'I have to change' or 'I have to approach things differently'.
Group 1; line 511

Participants explained that the simultaneous combination of self-confrontation in a group and working individually on health goals led to gaining more control over health or life in general.

Participant 10: I have a steering wheel, this symbolizes the programme for me. And, I actually gave it a title: 'you are the master of your own steering wheel', because, yes, you have to do it yourself, don't you?
Participant 14: That's, that's funny [*participant 10*], because I was looking for a steering wheel, I thought: 'I give more direction to my life now'. And, I feel like I'm more in control now, and I couldn't find a steering wheel. Well, I find it very funny that you have brought a steering wheel!
Group 2, line 270-286

Partner participant 6: Yes, [*participant 6*] is really much more energetic. And, it comes from himself now, he often stands with the coat already on and says: come we're going for a walk! […] Whereas sometimes it was the other way around, […] he also had periods that he was really tired and just fell asleep on the sofa after dinner. Well, not anymore. […] I see from everything that he just feels better and that's what it's all about of course [...] And he's also much better in making those choices himself instead of me saying 'hey dear, shouldn't you this or that…'.
Group 1; line 375-389

Participant 15: Um, I have learnt especially in terms of my health, I, um, transfer the lead from the gut to the brain from now on.
Group 3, line 551

Furthermore, participants indicated that being more in control of health/life led to increased awareness of challenges (stressors) for healthy eating. Stressors that were discussed by the groups included seasonal challenges (e.g. the winter: less energy, being less outside; summer: enjoying life, too hot to exercise), corona/sickness (being taken out of your routine), disagreements with

partner about food, feeling disappointed in yourself after a set-back and tenacious habits (e.g. late night snacking). Most participants declared that they were now in a calm phase stress-wise, which made it relatively easy to actively work on health goals, but they acknowledged that sustaining healthy behaviours could be hard when stressful events occur:

> **Participant 6:** Well, I think, what I see as a kind of risk is a combination of a lot of things at once. For instance busy at work and still trying to exercise a lot. I mean I am used to my schedule that I have in mind right now, but summer time is coming up, which means that instead of doing my exercise, I will longer linger outside in the garden. So, a combination of different things makes me think: yes, these are quite busy weeks to maintain this lifestyle. […] Um, yes that, that, there is a kind of risk there, yes.
> *Group 1, line 694*

Body-mind connection. Participants appreciated the holistic and the reflective approach of the SALUD programme as well as the broad variety of discussed topics. They mentioned that the holistic approach to health and eating behaviour made them more aware of body-mind connections, such as the influence of emotional stress on their wellbeing, blood glucose and behaviours. Participants talked about an increased ability to identify, assess, understand and respond appropriately to internal signals, which helped in understanding their bodies better. Participants mentioned they were eating more mindfully and became more aware of different types of hunger, satiety signals and reasons for food cravings. Participants noticed beneficial physical effects that varied from lowered blood glucose medication or a considerable weight-loss to less tangible physical effects, such as simply feeling better (e.g. less bloated, or more energized). The mentioned psychosocial health effects included: feeling acknowledged, more confident, calmer, better able to deal with emotional stress, more self-compassionate and better able to accept their disease after the SALUD-programme. The partners in group 1 affirmed the noticeable improvement in the participants' overall health.

> **Participant 6:** And what I liked about the programme [...] that it's not some kind of glorified diet programme, like weight watchers and all that, but that it is much broader than just, just that. You know, a piece of mindfulness, a piece of stress management, a piece of food awareness - but not so much focused on losing 10-20 kilos for example. Yes, that's my point: that the overall programme also makes you think at multiple levels. It opens doors you didn't have before -eh- so it opens doors of, of things. I have already started measuring [*blood glucose*] for example during this programme, yes. Didn't do that before either. All this, in order to get to know your body and how it reacts.
> *Group 1; line 471-477*
> **Participant 8***:* Well, I found the [*process of*] mind-setting [*important*] - it has given me more insight. I am someone with a very emotional character, you can't always tell, but that's how I am, I know that about myself, and I know that if I have it all neatly lined up

in my head, I feel much better, both physically and mentally. So I did learn that it's good to relativize, also with regard to your glucose and so on. […] Allow yourself moments of rest in order to improve yourself from there. […] I think physically I'm doing pretty well, but with me, it's more in my head.
Group 2; line 500–504

Participant 17: I have discovered that […] stress has a huge impact. I had that glucose monitor in December, and, then, it [*blood glucose*] was always very high. And now, I have another job and […] everything is much calmer and my blood levels are better. So, I really think stress has a lot of influence, which I didn't expect before.
Group 3, line 347-349

Positive effect on others. The SALUD-programme was experienced as meaningful, because the participants noticed that their health process had a positive effect on their close social environment. Several participants noticed that their health progress inspired family members to do the same. In addition, for certain participants the SALUD-programme helped to talk openly about eating behaviour with their partners without frustrating each other.

Participant 8: I also like that my wife is also a bit contaminated by it.
Group 2; line 202
Partner participant 7: I am actually very happy that he was able to take part in the programme, because I have been saying certain things for years, but the penny never dropped. And he was always like: 'well, that food you eat, and the healthy meals with so many vegetables, I don't need that'. That's all nonsense of course. And: 'pizza is healthy', and I could say whatever I want, but I say, yes, of course pizza is not healthy…
Participant 7: …it has vegetables on it.
Partner participant 7: He always says: 'it has vegetables on it'. And 'the Italians eat it too, and pizza's healthy'- yes. And he kept saying that, and then I thought, yes, I eventually stopped, I think, there's no point in explaining it, he actually had to experience it himself, it didn't really come across. […]
Participant 7: But, besides that, I haven't changed at all! [*both laughing*]
Group 1; line 351-353

The deviant-case: externally-focused coping. One participant had a different experience with the SALUD-programme compared to the rest. Like the others, participant 21 enjoyed the SALUD-programme but the programme did not lead to any behavioural change. Participant 21 was the only participant that was not able to reach (any of) his goals, in fact, he gained weight and glucose levels worsened:

Participant 21: That object is a scale, a kitchen scale […] I gain weight and my insulin

levels go up; they are not all that good.
Group 3; line 626-630

Participant 21 experienced the programme as confronting but did not talk in a reflective or introspective way that was typical for the others. Participant 21 did not mention the typical error-and-trial experiments with corresponding personal reflections and lessons learned nor issues related to interoceptive ability that seemed important for the others. In addition, contrary to the other participants, participant 21's coping strategies were more externally-focused with limited acknowledgement for his own individual responsibility for his health (e.g. his wife has to 'unlearn' things).

Participant 21: Well, I found it valuable [*to discover*] that calories exist, [*and*] that you have to take that into account. I found it valuable that I had to exercise more, I knew that, but now I was forced to face the facts.
Coach: Which facts and did you also get new insights about yourself?
Participant 21: No, no, no, I've known myself longer than today. No, no.
Group 3; line 646-654

Coach: Could your partner help you in some way to continue to work towards your goals?
Participant 21: Well, by not tempting me. She shouldn't bring in things that are bad for me. She can eat that herself. But if she offers it to me, that's a step too far. […] So she has to unlearn offering me something that is not good for me.
Group 3; line 997-998

Theme integration

Theme 1 described that the participants experienced SALUD as a positive, enjoyable and sociable experience, which invited an active learning process (theme 2). The learning process is characterised by realistically self-set goals, and trial-and-error experiments, which led to developing health-promoting strategies and mobilising new tools/resources. The learning process was experienced as meaningful because it led to a better overall grip on health and life (theme 3). Three aspects were fundamental in this: 1) positive self-confrontation aroused more awareness *why* one was making certain health choices; 2) a better understanding of mind-body connections; and 3) positive changes in the participants' social environment. The positive, encouraging approach and peer-support (theme 1) seemed important for participants to be able to cope with the self-confronting aspect of programme (theme 3). The meaningful learning process in its turn contributed to the positive evaluation of the SALUD-programme (theme 1). A deviant experience reveals that active and reflective engagement is a vital prerequisite for an impactful experience with the SALUD-programme, because without, the SALUD-programme is just a pleasant, sociable gathering (**Figure 8.1** summarizes the shared experiences of the participants with the SALUD-programme and the interlinkages between the themes).

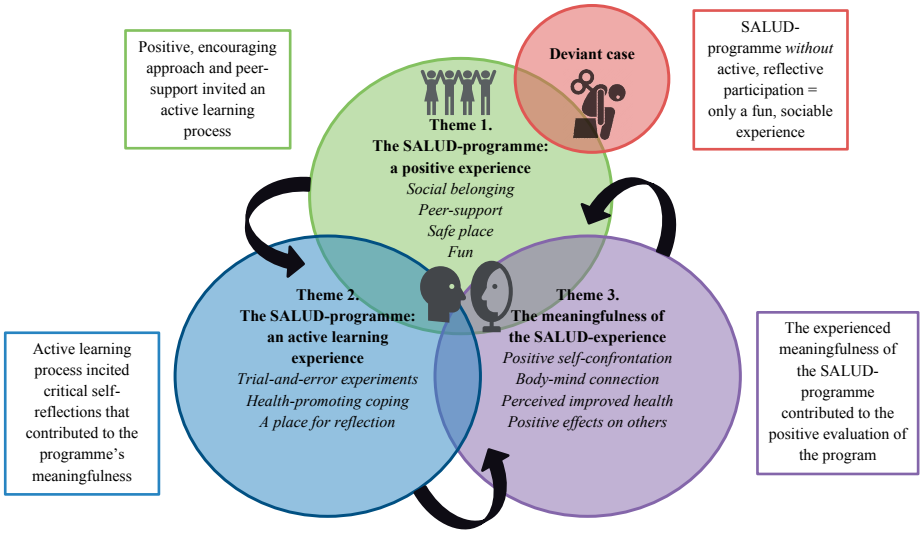

Figure 8.1 Schematic integration of the three themes summarizing the experience of the participants with the SALUD-programme.

8.4 Discussion and conclusion

Participants experienced the SALUD-programme as a positive and meaningful learning process, in which they developed new coping strategies, gained new self-insights and perceived improved overall health. The learning process was experienced as meaningful as it led to a better overall grip on health and life. Three aspects were fundamental in this. First of all, the participants declared that positive self-confrontation was important for changing eating behaviours. The positive self-confrontation aroused more awareness *why* one was making certain health choices. This finding is important because confrontational health-experiences have the potential to invoke sustainable dietary improvements [19–21].

Second, the participants talked about better understanding of mind-body connections. Participants used self-monitoring blood glucose as a feedback-strategy to explore body-mind connections. Indeed, self-monitoring glucose has been proven to be an effective strategy to enhance and sustain health among people with T2DM [22,23]. This study adds to that evidence by indicating that instructions for self-monitoring strategies need to extend beyond mere technical instructions; these strategies should be integrated within a broader, meaningful context, emphasising their role as a tool rather than a standalone goal. However, some participants expressed they would have liked more concrete steering regarding self-monitoring blood glucose, for example by receiving a glucose monitor at the start of the programme or more detailed instructions how to use a glucose monitor in combination with SALUD. The role of self-monitoring blood glucose in the SALUD-programme is something to further consider to facilitate active engagement with the programme.

Third, the participants talked about the positive changes in the participants' social environment. Participants mentioned that their participation in the SALUD-programme enabled social support from family and partners. In addition, some participants inspired family members to start improving their health. The peer-support during SALUD was considered important for disease acceptance, which is important because victim-blaming and stigma is common among people with T2DM and this can negatively impact T2DM self-management [24]. In addition to peer-support, the positive, encouraging approach seemed important to cope with the self-confronting aspect of the SALUD-programme. Self-reflection and introspection can be demanding. The coach had the challenging responsibility to keep the delicate balance between the health-promoting and health-damaging aspects of self-confrontation: moderate discomfort is good, but excessive discomfort may cause participants to disengage. An imbalance between beneficial and damaging aspects of self-confrontation might have played a role in the deviant-experience. Similar to the others, the deviant-case mentioned that the programme was self-confronting, but he was not actively and reflectively participating in a learning process. Perhaps the deviant-case needed more time and/or guidance to work through the experienced self-confrontation before being able to engage actively in a learning process. To a certain extent, this sentiment appears to be echoed by other participants, as all groups indicated a preference for a longer voluntary follow-up period (6 instead of 3 months).

Another interesting finding is that meaningful peer-support and social connectedness was established via a web-based programme. The fact that the deviant-case considered the programme still as a positive experience further exemplifies the positive atmosphere maintained throughout the programme. Recent research also demonstrated that in-person interventions adapted for web-based delivery appear to be equally effective as delivery in-person [25,26]. The SALUD participants generally preferred the web-based format for reasons of saving time and travelling costs, but also for feeling more comfortable at home. However, the groups recommended a combination between in-person and web-based sessions because the participants would enjoy meeting each other in-person.

These three fundamental identified aspects for a meaningful learning process are in line with the self-tuning model for health-promoting coping [27]. Both the current findings and self-tuning model emphasise three important mechanisms for developing health promoting coping: 1) unlock an 'inner drive' by positive self-confrontation to catalyze health-promoting learning process; 2) compassionate, authentic and accepting social support; and 3) sensing and being mindfully present (body-mind connections) [27]. According to the self-tuning model, these mechanisms contribute to self-tuning: a health-promoting competence of continuous '*exploring, sensing, reflecting, and thus reacting to a situation with increasingly more adaptive coping*' [27]. The self-tuning model has evolved from investigating job engagement and burn-outs [27]. The current study suggests that the self-tuning model could be applied in a broader health-setting.

Finally, the findings are in line with previous studies that demonstrated that the factors driving healthy eating are different from factors driving unhealthy eating [13]. For example, an extensive systematic review demonstrated that demographic determinants -age, gender, socioeconomical status- do not predict weight-loss maintenance [22]. The most important determinants for successful healthy eating and weight-loss maintenance appear to be those that relate to coping abilities, such as problem-solving, self-efficacy and SoC [13,22,23]. Contrary to demographic determinants, coping abilities can be trained and enhanced. The present study suggests that this requires a supportive, positive, safe and reflective environment.

Strengths and limitations

An important strength is that all SALUD participants who finished the programme participated in the focus groups. A second strength is the use of the objects, because these objects allowed participants to share their experiences in their own way. A limitation is that the experiences of the participants allocated to the control-group in the SALUD-RCT were not qualitatively assessed, which would have provided an in-depth understanding of the SALUD-programme. Finally, it is important to note that the coach who guided the focus groups is not a researcher. A qualitatively trained/experienced researcher might have handled the group conversations differently. However, the SALUD coach was experienced in guiding group conversations and the established group dynamics during the programme were not interfered by adding a new person to the group.

Conclusion

The present evaluation complements the quantitative evaluation of the SALUD-programme by uncovering aspects that are difficult to measure quantitively: a learning process for health-promoting coping and the contextual factors that are important for facilitating such learning process. The results highlight the importance of peer-support in a supportive, positive, safe and reflective environment for the T2DM health-care sector. The evaluation also yielded the following points of the SALUD-programme that sought further consideration: the follow-up trajectory, adding in-person sessions to the programme, and the role of self-monitoring blood glucose within the programme. These aspects may be adjusted to further optimize the SALUD-programme in order to maximize the chance of inciting an active learning process of all kinds of future participants.

Acknowledgements: We are extremely grateful for all the participants; without you the study would not have been possible. A special thank you for Annemone Siffels for her assistance in transcribing the focus groups and the assistance in the initial steps of the data analysis as part of the MSc thesis.

Funding: This study received funding from the Edema-Steernberg Foundation. The Edema-Steernberg Foundation is a Dutch non-profit organisation that stimulates multidisciplinary nutritional research.

Authors' contributions: Kristel CMM Polhuis: conceptualization, data curation; data analysis; methodology; data visualization; Writing - original draft. Lenneke Vaandrager: supervision; data analysis; writing - review & editing. Laura I. Bouwman: supervision; data analysis; writing - review & editing. Maria A Koelen: supervision; data analysis; writing - review & editing.

Competing interest: The authors declare no conflict of interest.

Supplementary Tables

Supplementary Table 1 Final coding list in alphabetical order. Normal codes are allocated to category codes (= secondary themes; in **bold**). Category codes as well as merging of codes has been indicated in the 'comment' column. The number behind the (category) code indicates how often the code was applied. Definitions of the (category) codes are explained under 'code description'.

Code	Comment	Code description
Active learning (62)	*Category code*	Describes aspects that show that participants were actively involved in a learning process towards behavioural change.
Active learning: Confrontation and introspection (3)		Participant explains that reflecting on eating behaviours and lifestyle requires introspection and is confrontational.
Active learning: experimental learning (11)	*Merged with Experimental learning - incorporating unhealthy foods, and 'Experimental learning – SMBG'.*	Describes trial-and-error experiments participants did to better understand their bodies: responsiveness of blood sugar to certain foods, finding a sensible balance between 'pleasure' and 'healthy' foods, trying out new recipes, etc.
Active learning: future coping (24)		Concrete formulation coping strategies/action plans participants indicated to use after the end of the program when confronted to challenges.
Active learning: new coping strategy (14)		Concrete new coping strategies participants have developed and used during the program.
Active learning: reflective mindset (11)	*Merged with reflective thinking (1), and ' revalue balance (1)'.*	Participants explains what they learned about the process of revaluing the balance between healthy and unhealthy behaviours during the program.
Behavioural effects (16)	*Category code*	The perceived effects of the program on lifestyle related behaviour.
Behavioural effects: blood glucose measuring (1)		Participant self-monitors blood glucose regularly.
Behavioural effects: goal achievement (6)		Participant explained (s)he reached her personal health goal during the program.
Behavioural effects: more physical activity (3)		Participant experienced more physical activity because of the program.
Behavioural effects: observed health behavioural change (6)		The partner of the participant explains (s)he noticed a remarkable positive change in health behaviour.
Effects on Autonomy (39)	*Category code*	Describes the perceived effects of the program on the participant's autonomy.
Effects on Autonomy: autonomy (25)	*Merged with autonomy (19) (merged with 'doing (2)), ' no autonomy (2)'.'introspection - not yet enough autonomy (1)', 'observed autonomy (2)', and 'turning point - increased autonomy (3)'.*	Describes the (increased) capacity of the participant to act according to his/her health motivations.
Effects on Autonomy: self-compassion (1)		Describes that a participant noticed self-compassion.
Effects on Autonomy: SOC-comprehensibility (8)		Describes the extent to which stimuli a person is confronted with make cognitive sense.

Code	Comment	Code description
Effects on Autonomy: SOC-manageability (7)		Describes the extent to which an individual perceives resources that are available t them as adequate enough to meet the demands of the stimuli they face.
Effects on Autonomy: SOC-meaningfulness (5)		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.
Effects on nutritional behaviour (23)	*Category code*	Describes the perceived effects of the program on the participant's eating behaviour.
Effects on nutritional behaviour: adding vegetables (1)		Describes that the participant adds vegetables to standard meals as a consequence of the program.
Effects on nutritional behaviour: cooking (1)		Describes that the participant partakes more often in cooking as a consequence of the program.
Effects on nutritional behaviour: drinking more water (1)		Describes that the participant drinks more water as a consequence of the program
Effects on nutritional behaviour: eating less sugar (1)		Describes that the participant is limited sugar intake as a consequence of the program.
Effects on nutritional behaviour: Food literacy (10)		Describes an increase in food literacy, e.g. improvement in nutritional knowledge, skills to judge food products, healthy snack strategies, preparing new recipes, etc.
Effects on nutritional behaviour: Mindful eating (4)		Describes that the participant is more mindful while eating foods, i.e. pays attention to the food, taste, satiety signals when eating.
Effects on nutritional behaviour: more regular eating pattern (2)		Describes that the participant has a more regular eating program because of the program.
Effects on nutritional behaviour: swapping foods (4)		Describes that the participant changed unhealthy foods for healthier alternatives.
Embedding in everyday life (27)	*Category code*	Describes the extent the program is embedded (or not) in the participant's everyday life.
Embedding in everyday life: awareness (20)	*Merged with awareness – shame (1)*	Describes that the participant notices an increased daily life; both regarding why making certain choices as well as feelings of shame regarding T2DM.
Embedding in everyday life: habit (3)	*Merged with 'Embedding behaviour change in everyday life: turning points - becomes a habit (1)'.*	Describes that the participant notice that new healthier habits are developing/developed.
Embedding in everyday life: integration everyday life (2)		Describes that study participation requires rather small changes that are easily implemented rather than drastic changes.
Embedding in everyday life: everyday life always changing (2)		Participants explains that the everyday life fluctuates and that is experienced as a challenge for maintaining health enhancing behaviour.
Embedding in everyday life: turning point (2)	*Merged with 'turning points (1)'.*	Participant explains that (s)he notices new healthier behaviours become automatic, enjoyable, habitual because of the program.
Impact on others (9)	*Category code*	Describes the perceived effects of the program on the participant's social network.

Code	Comment	Code description
Impact on others: impact on others – positive (8)	*Merged with 'impact on others (1)'.*	Participant notice that their behavioural changes have positive influence on the behaviours of their close social environment (partner, family, co-workers).
Impact on others: turning point - partners on same page again (1)		Partner of participant explains that the program brought them one the same page again health-wise.
Mobilizing resources (12)	*Category code*	Participant start using an existing (internal or external) resource in a health-promoting way.
Mobilizing resources: facilitating external influences – summer (4)		Participant experience good weather/the summer season as a facilitating factor for performing healthy behaviours.
Mobilizing resources: mobilizing social support (1)		Describes that informing your close social network facilitates sticking to your health intentions.
Mobilizing resources: smartwatch (2)		Describes active use of smart watch for motivation and awareness of health behaviours.
Mobilizing resources: strengthening resources (3)		Participant experiences program as reactivating health-related knowledge in a structural way.
Mobilizing resources: cooking books to increase vegetable intake (2)		Rediscovering of old cooking books and use them to increase vegetable intake.
New resources (8)	*Category code*	Participant found or created a new resources that assists in health promoting coping.
New resources: Food app (1)		Participant describes (s)he discovered a new app that makes it easier for him/her to make healthy food choices.
New resources: Making own cooking book (1)		Participants made own cooking book with new healthy recipes.
New resources: peer model (3)		Participant gained new helpful insights for managing lifestyle from T2DM peer model.
New resources: Reflection booklet (2)		Participant created a reflection diary to reflect on health behaviour and keep motivated.
New resources: walk - reflection moment (1)		Participant describes that (s)he uses daily walk as moment of reflection on lifestyle.
Passive participation (8)	*Category code*	Describes a passive attitude towards changing health behaviours – external factors are responsible or praised.
Passive participation: future - no concrete coping strategy (4)		Participant does not describe (a) concrete coping strategy for reaching/maintaining goals after program's end.
Passive participation: No reflectivity (2)	*Merged with 'lack of reflexivity (1)'..*	Participant is not reflective on own influence on reaching goals.
Passive participation: passive coping (2)		Describes a passive coping strategy, i.e. external influence determine whether the participant will be able to reach goals or not – low locus of control.
Peers (19)	*Category code*	Describes the role of peer support in the program.
Peers: peer learning (9)	*Merged with: Peers: peer learning - sharing recipes (1). Merged with 'group interactions'(1).*	Describes that participants learn from each other by sharing experiences as well as practical tips and recipes.

Code	Comment	Code description
Peers: peer support (12)		Describes that participants feel motivated, inspired and less alone by listening to stories from peers.
Peers: perspective coach on different groups (1)		Describes how the coach experienced a strong social cohesion in all groups as well as that the peer-connectedness developed in different ways among the groups.
Personal experience program (46)	*Category code*	Describes in general terms the personal perception of the program.
Personal experience program: general experience – positive (7)		Describes a positive evaluation of the program.
Personal experience program: learning process (1)		Describes the program as a learning process.
Personal experience program: turning point – flourishing (1)		Describes how one of the participants evolved from caterpillar to butterly.
Personal experience program: turning point - revalue balance (1)		Describes the program as a tool of revaluing balance in lifestyle related behaviours.
Personal experience program: object (19)		Describes the object that the participant brought to the session.
Personal experience program: Reason behind object (21)		Describes the reason why the object represented their experiences with the program.
Personal experience program: recommend salud (4)		Describes whether or not the participant would recommend the program to others.
Personal experience program: goal not achieved (1)		Describes an experienced lack of effectiveness of the program.
Physical effects (7)	*Category code*	Describes the perceived effects of the program on the participant's physical health status.
Physical effects: decrease medication use (2)		Participant mentions less T2DM medication use because of the program.
Physical effects: improved blood values (5).		Participant mentions improved blood glucose values because of the program.
Physical effects: hypo (1)		Participant noticed that blood values become too low.
Physical effects: weight loss (2)		Participant mentions weight loss because of the program.
Physical effects: feeling less bloated (1)		Participant mentions feeling less bloated because of the program.
Physical effects: Sleep (1)		Participant mentions improved sleep quality because of the program.
Points to improve (24)	*Category code*	Aspects that could be improved according to the participants.
Points to improve: follow-up trajectory (5)		Describes suggestions for a different (longer) follow-up trajectory.
Points to improve: off and online sessions (4)		Describes that a combination of off- and online session would be preferrable.
Points to improve: blood glucose monitor (3)		Describes the need to provide a blood glucose monitor and clear instruction how to use in the program.

Code	Comment	Code description
Points to improve: manual (5)	*Merged with 'manual- background knowledge more information diabetes physiology (2)', and 'more info on stress and relaxation (1)'.*	Describes that a manual in which the program is outlined and provides background information is provided would be beneficial to receive at the start of the program.
Points to improve: hire mindfulness expert (2)	*Merged with 'Points to improve: coach – mindfulness (1)'.*	Participants suggest to hire a mindfulness expert for the mindfulness session as the coach seems uncomfortable during the mindfulness exercises.
Points to improve: duration - too long (2)		Describes that participants found the duration of some sessions too long.
Points to improve: break out rooms (1)		Describes the need to work more often in break-out rooms (participant one-to-one).
Points to improve: dietician more often in program (1)		Describes the need to involve the dietician earlier and more often in the program.
Points to improve: earlier involvement partner (1)		Describes the need to involve partners of participants earlier in the program.
Psychosocial effects (14)	*Category code*	Describes the perceived effects of the program on the participant's psychosocial health.
Psychosocial effects: interoceptive ability (8)		Describes increased ability to identify, access, understand, and respond appropriately to the patterns of internal signals
Psychosocial effects: better coping with stress (3)		Participants notice more effective coping with psychosocial stress.
Psychosocial effects: disease acceptance (4)		Participants notice increased disease acceptance of T2DM.
Social support (15)	*Category code*	Describes the role of the participant's personal social network for the effectiveness of the program.
Social support: social support – partner (6)		Describes the beneficial influence of the partner for health goal achievement.
Social support: social support – motivation (5)		Describes the beneficial role of feeling supported by your social network for reaching health goals.
Social support: lack of partner support (3)		Describes that it is difficult if your partner does not support you in reaching your goals.
Social support: social support - not needed (1)		Participant does not find social support necessary.
Stressors (15)	*Category code*	Describes types of experienced challenge for working and reaching health goals.
Stressors: Corona (3)		Describes the negative influence of COVID-19 infection/lock-down on goal achievement.
Stressors: winter (3)	*Merged with 'Stressors: rainy weather'.*	Describes that the winter season is perceived as challenge as it discourages physical activity.
Stressors: late night snacking (2)		Describes that late night snacking is a difficult challenge for participants.
Stressors: arthrosis (1)		Describes that arthrosis complicates exercise/physical activity.
Stressors: disagreements about food (1)		Describes that disagreements at the dinner table are a challenge for sticking to eating goals.

Code	Comment	Code description
Stressors: vegetable intake (1)		Describes that dislike of vegetables makes it challenging to eat healthy.
Stressors: disappointment in self (1)		Feeling like a failure/disappointment in self when you are not able to stick to your goal is perceived as a challenge.
Stressors: everyday life as stressor (1)		Participants explains that the everyday life fluctuates and that is experienced as a challenge for maintaining health enhancing behaviour.
Stressors: stress (1)		Participant foresee that setbacks and accompanying stress as challenge for maintaining health behaviours.
Stressors: The end of program (1)		Participants perceive end of the program as challenge – no external control/ social pressure to work on goals.
Valued aspects (51)	*Category code*	Aspects that the participants appreciated.
Valued aspects: coach (19)		Describes that participants valued the coach.
Valued aspects: peer support (9)	*Merged with group format (4), group chat (1), and social pressure (3).*	Describes that the participants valued the peer-group format.
Valued aspects: safe place (7)	*Merged with duration – good,'group dynamic', and 'social cohesion'.*	Describes that participants valued that they felt safe and comfortable during the sessions.
Valued aspects: online format – positive (6)	*Merged with online - comfortable in own environment, and 'online format - multi tasking'.*	Describes that participants valued that the program was online: they felt comfortable from their own home, it safed travelling time/costs, and allowed for multi-tasking.
Valued aspects: reading nutrition labels (4)		Describes that participants valued the session the coach included on reading and understanding nutrition labels.
Valued aspects: variation in program (3)		Describes that the participants valued the variety of topics in the program and the broad/ holistic approach.
Valued aspects: place for reflection (2)		Describes that the participants valued that the program offers a moment of reflection in the week.
Valued aspects: positive approach (1)		Describes that the participants valued the positive encouraging approach of the program.
Valued aspects: type of eater (1)		Describes that the participants valued the session the coach included on testing your type of eater.
Valued aspects: dietician (1)		Describes that the participants valued the session with the dietician.
Valued aspects: frequency (1)		Describes the participants valued the once-a-week frequency of the program (i.e. intensity).
Valued aspects: cooking workshop (1)		Describes the participants valued the cooking workshop.
Independent codes (37)	*Category code*	Describes independent codes – not used for further qualitative analysis.
Technical interruptions (15)		Describes technical interruptions in the conversations (participants with internet connection problems, problems logging-in, problems with muting microphone).
Snack (18)		Describes the snack participants brought to the session.

Code	Comment	Code description
Informed consent (4)		Participant consented with participation in focus group.

Supplementary Table 2 Preliminary themes. The (category) codes were allocated to one of the three preliminary themes: perceived effects, coping, and program evaluation. The category codes (secondary themes) can be interpretated as sub-themes. Merging of codes has been indicated under 'comment'. The independent codes are not used for further analysis.

Preliminary themes	Code	Comment
Perceived effects	**Effects on nutritional behaviour (23)**	
	Effects on nutritional behaviour: adding vegetables (1)	
	Effects on nutritional behaviour: cooking (1)	
	Effects on nutritional behaviour: drinking more water (1)	
	Effects on nutritional behaviour: eating less sugar (1)	
	Effects on nutritional behaviour: Food literacy (10)	
	Effects on nutritional behaviour: Mindful eating (4)	
	Effects on nutritional behaviour: more regular eating pattern (2)	
	Effects on nutritional behaviour: swapping foods (4)	
	Behavioural effects (16)	
	Behavioural effects: blood glucose measuring (1)	

Preliminary themes	Code	Comment
	Behavioural effects: goal achievement (6)	
	Behavioural effects: more physical activity (3)	
	Behavioural effects: observed health behavioural change (6)	
	Physical effects (7)	
	Physical effects: improved blood values (8)	Merged with 'Physical effects: decrease medication use (2)', and 'Physical effects: hypo (1)'.
	Physical effects: weight loss (2)	
	Physical effects: feeling less bloated (1)	
	Physical effects: Sleep (1)	
	Psychosocial effects (53)	Category code 'perceived effects on autonomy (39)' merged with 'psychosocial effects (13)'.
	Effects on Autonomy: autonomy (25)	Merged with autonomy (19) (merged with 'doing (2)), 'no autonomy (2)', 'introspection - not yet enough autonomy (1)', 'observed autonomy (2)', and 'turning point - increased autonomy (3)'.
	Effects on Autonomy: self-compassion (1)	
	Effects on Autonomy: SOC-comprehensibility (8)	
	Effects on Autonomy: SOC-manageability (7)	
	Effects on Autonomy: SOC-meaningfulness (5)	
	Psychosocial effects: interoceptive ability (8)	
	Psychosocial effects: better coping with stress (3)	
	Psychosocial effects: disease acceptance (4)	
	Effect on others (9)	
	Impact on others: impact on others – positive (8)	Merged with 'impact on others (1)'.
	Impact on others: turning point - partners on same page again (1)	
Coping	**Active learning (62)**	
	Active learning: Confrontation and introspection (3)	
	Active learning: experimental learning (11)	Merged with 'Experimental learning - incorporating unhealthy foods', and 'Experimental learning – SMBG'.
	Active learning: future coping (24)	
	Active learning: new coping strategy (14)	
	Active learning: reflective mindset (11)	Merged with 'reflective thinking (1)', and 'Active learning: revalue balance (1)'.

Preliminary themes	Code	Comment
	Mobilizing resources (28)	Category code 'Social support (15)' merged with mobilizing resources (13); because of the rediscovery of importance social support
	Social support (16)	Moved ''Mobilizing resources: mobilizing social support (1)' to category code social support.
	Social support: social support – partner (6)	
	Social support: social support – motivation (5)	
	Mobilizing resources: mobilizing social support (1)	
	Social support: lack of partner support (3)	
	Social support: social support - not needed (1)	
	Mobilizing resources: smartwatch (2)	
	Mobilizing resources: strengthening resources (3)	
	Mobilizing resources: cooking books to increase vegetable intake (2)	
	Mobilizing resources: facilitating external influences – summer (4)	
	New resources (8)	Category code 'peers (20)' merged with 'new resources (8)'; peer support is one of the new resources.
	Peers (19)	'New resources: peer model (3)' moved under 'peers'.
	Peers: peer learning (9)	Merged with 'Peers: peer learning - sharing recipes (1)'.
	Peers: peer support (12)	
	Peers: perspective coach on different groups (1)	
	New resources: peer model (3)	
	New resources: Reflection booklet (2)	Merged with 'New resources: walk - reflection moment (1)'.
	New resources: Food app (1)	
	New resources: Making own cooking book (1)	
	Stressors (15)	
	Stressors: Corona (3)	
	Stressors: winter (3)	Merged with 'Stressors: rainy weather'.
	Stressors: late night snacking (2)	
	Stressors: everyday life as stressor (2).	Merged with 'Stressors: The end of program? (1)'.
	Stressors: arthrosis (1)	
	Stressors: disagreements about food (1)	
	Stressors: vegetable intake (1)	

Preliminary themes	Code	Comment
	Stressors: disappointment in self (1)	
	Stressors: stress (1)	
	Passive participation (8)	
	Passive participation: future - no concrete coping strategy (4)	
	Passive participation: No reflectivity (2)	Merged with 'lack of reflexivity (1)'.
	Passive participation: passive coping (2)	
Program evaluation	**Personal experience program (46)**	
	Personal experience program: general experience – positive (14)	Merged with 'Personal experience program: learning process (1)', 'Personal experience program: recommend salud (4)', 'Personal experience program: turning point – flourishing (1)', and 'Personal experience program: turning point - revalue balance (1)'.
	Personal experience program: Reason behind object (21)	Merged with 'Personal experience program: object (19)'.
	Personal experience program: goal not achieved (1)	
	Embedding in everyday life (27)	
	Embedding in everyday life: awareness (20)	Merged with 'awareness – shame (1)'.
	Embedding in everyday life: habit (5)	Merged with 'Embedding behaviour change in everyday life: turning points - becomes a habit (1)', and 'Embedding in everyday life: turning point (2) – Merged with 'turning points'.
	Embedding in everyday life: integration everyday life (2)	
	Embedding in everyday life: everyday life always changing (2)	
	Valued aspects (51)	
	Valued aspects: coach (19)	
	Valued aspects: peer support (9)	Merged with 'group format (4)', 'group chat (1)', and 'social pressure (3)'.
	Valued aspects: safe place (7)	Merged with 'duration – good', 'group dynamic', and 'social cohesion'.
	Valued aspects: online format – positive (6)	Merged with 'online - comfortable in own environment' and 'online format - multi tasking'.
	Valued aspects: reading nutrition labels (4)	
	Valued aspects: variation in program (3)	
	Valued aspects: place for reflection (2)	
	Valued aspects: positive approach (1)	
	Valued aspects: type of eater (1)	
	Valued aspects: dietician (1)	
	Valued aspects: frequency (1)	

Preliminary themes	Code	Comment
	Valued aspects: cooking workshop (1)	
	Points to improve (24)	
	Points to improve: follow-up trajectory (5)	
	Points to improve: manual (5)	Merged with manual- background knowledge, 'more information diabetes physiology (2)', and 'more info on stress and relaxation (1)'.
	Points to improve: off and online sessions (4)	
	Points to improve: blood glucose monitor (3)	
	Points to improve: hire mindfulness expert (2)	Merged with 'Points to improve: coach – mindfulness (1)'.
	Points to improve: duration - too long (2)	
	Points to improve: break out rooms (1)	
	Points to improve: dietician more often in program (1)	
	Points to improve: earlier involvement partner (1)	
	Independent codes (37)	
	Technical interruptions (15)	No used in further analysis.
	Snack (18)	No used in further analysis.
	Informed consent (4)	No used in further analysis.

Supplementary Table 3 Overview analysis steps: from codes, to secondary themes, preliminary themes and final themes.

Final themes	Preliminary themes	Secondary themes	Codes
Theme 1: The SALUD program: a positive experience	Program evaluation	*Personal experience program*	General experience – positive Reason behind object
		Embedding in everyday life	Awareness Habit Integration everyday life
		Valued aspects	Coach Peer support Safe place Web-based format-positive Place for reflection Positive approach
Theme 2: The SALUD program: a learning experience	Coping	*Active learning*	Confrontation and introspection Experimental learning Future coping New coping strategy Reflective mindset
		Mobilized resources	Smartwatch Strengthening resources Cooking boos to increase vegetable intake Facilitating external influences – summer
		Social support	Social support-partner Social support-motivation Mobilizing social support Lack op partner support Social support – not needed
		New resources	Peer learning Peer support Peer model Reflection booklet Food app Making own cooking book
		Stressors	Corona Winter Late-night snacking Arthrosis Disagreements about food Vegetable intake Disappointment in self Stress
		Embedding in everyday life	Everyday life always changing
	Perceived effects	*Behavioural effects*	Goal achievement
Theme 3: The significance of the SALUD-experience	Perceived effects	*Effects on nutritional behaviour*	Adding vegetables Cooking Drinking more water Eating less sugar Food literacy Mindful eating More regular eating pattern Swapping foods
		Behavioural effects	Blood glucose measuring Goal achievement Observed behavioural change

Final themes	Preliminary themes	Secondary themes	Codes
		Physical effects	Improved blood values Weight loss Feeling less bloated Sleep
		Psychosocial effects	Effects on autonomy Interoceptive ability Better coping with stress Disease acceptance
		Effects on others	Impact on others – positive Partners on same page again
	Coping	*Passive participation*	Future – no concrete coping strategy No reflectivity Passive coping
	General evaluation	*Points to improve*	Follow-up trajectory Manual Off-and online sessions Blood glucose monitor

Supplementary Table 4 Analysis of the objects and symbolism.

Category	Interpretation researcher	Object	Participant	Participant's reasoning behind the object
Goal achievement	Goal achievement Resource mobilization	Smartwatch (1/2)	*1*	Although the participant has had this smart watch for 1,5 years, the participant only started to use it since the program. It symbolizes that the participant was able to effective use this watch to work on his goals.
	Goal achievement	Bottle opener (1/1)	*4*	Symbolizes the fact that the participant was able to achieve his goals during the program. One of these goals was consuming less alcohol, hence the bottle opener.
	Goal achievement Social support	'Dopper' water bottle (1/2)	*6*	Symbolizes the fact that the participant was able to achieve his goal (consuming more water). Furthermore symbolizes social support with this partner he introduced 'Dopper Time': certain times at the day they remined each other to drink water together
	Goal achievement Active coping New resource	Glucose meter (1/2)	*7*	Symbolizes what the participant achieved his goals regarding T2DM blood values. He has used this tool during the program to get to know his body, and now that his blood values are healthy again, he wants to leave this object behind.
	Goal achievement New resource	Smartwatch (1/2)	*8*	The participant started to monitor stress, sleep, steps and heart rate with the smart watch as a tool to reflect on these data. In addition, it motivates him as well as reminds him to move by giving notifications.
	Goal achievement Active coping	Cookbook (500 salads) (1/2)	*11*	Preparing vegetables is challenging for this participant, and this cooking book made it easier way to incorporate more vegetables in his diet. It symbolizes anticipation and active coping, as he is finding ways to work on his goals in his daily life, even if that takes some adjusting.
	Goal achievement New resource	Smartwatch (1/2)	*12*	Symbolizes that the participant is being more aware of his goals and how much exercise he gets in a day. He uses the watch as a tool to reflect on his physical activity of the whole week.
	Working on goals Active coping	Diabetes cookbook (1/2)	*13*	Usually the participant cooks recipes by heart, but from now on she wants to utilize this cookbook more. It symbolizes motivation for the future and to keep working on her health goals.
	Reflection Resource mobilization	Nutrition labels (1/2)	*14*	Learning how to read nutrition labels was an important insight/skill for this participant that helped her a lot to improve dietary intake. 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.
	Goal achievement	Mobile (1/1)	*16*	The participant uses the mobile as alarm clock. One of her goals was improving her sleep, and during the program she was able to work on that goal.
	Goal achievement Resource mobilization	Radio (1/2)	*19*	It symbolizes relaxation, because whenever this participant listens to music from this radio he feels calmer and more at ease (which was one of her goals).
	No goal achievement	Kitchen scale (1/1)	*21*	Symbolizes that the participant was not able to reach his health goals: the participant gained weight and his insulin levels increased.
Active coping	Goal achievement Resource mobilization	Smartwatch (2/2)	*1*	Although the participant has had this smart watch for 1,5 years, they only started to use it since the start of the study. It symbolizes that the participant was able to effective use this watch to work on his goals.

Category	Interpretation researcher	Object	Participant	Participant's reasoning behind the object
	Goal achievement Active coping New resource	Glucose meter (2/2)	*7*	Symbolizes what the participant achieved his goals regarding T2DM blood values. He has used this tool during the program to get to know his body, and now that his blood values are healthy again, he wants to leave this object behind.
	Goal achievement New resource	Smartwatch (2/2)	*8*	The participant started to monitor stress, sleep, steps and heart rate with the smart watch as a tool to reflect on these data. In addition, it motivates him as well as reminds him to move by giving notifications.
	Goal achievement Active coping	Cookbook (500 salads) (2/2)	*11*	Preparing vegetables can be challenging for this participant, and this cooking book made it easier way to incorporate more vegetables in his diet. It symbolizes anticipation and active coping, as he is finding ways to work on his goals in his daily life, even if that takes some adjusting.
	Goal achievement New resource	Smartwatch (2/2)	*12*	Symbolizes that the participant is being more aware of his goals and how much exercise he gets in a day. He uses the watch as a tool to reflect on his physical activity of the whole week.
	Working on goals Active coping	Diabetes cookbook (2/2)	*13*	Usually the participant cooks recipes by heart, but from now on she wants to utilize this cookbook more. It symbolizes motivation for the future and to keep working on her health goals.
	Reflection Resource mobilization	Nutrition labels (2/2)	*14*	Learning how to read nutrition labels was an important insight/skill for this participant that helped her a lot to improve dietary intake. 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.
	Goal achievement Resource mobilization	Radio (2/2)	*19*	It symbolizes relaxation, because whenever this participant listens to music from this radio he feels calmer and more at ease.
	Reflection New resource	Notebook (1/2)	*18*	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.
Confronting learning process	Confrontation, Reflection	Clothing brush (1/1)	*3*	Symbolizes an important insight of the participant: the longer you wait to deal with something unhealthy behaviors, 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).
	Confrontation Reflection	Walnut (1/2)	*5*	It symbolized the "hard nut" the participant had to crack during the meetings, because thinking about what you want and what is good for you is confronting but in a good way. On the other hand it also symbolized the "happy nut" (happy note), because the meetings with the group were fun.
	Reflection	One hiking shoe (1/1)	*15*	Symbolizes the fact that the participant knows he is not yet where he wants to be (only 1 shoe instead of a pair); he is on the right track and half way there.
	Reflection Balance	Notebook (1/1)	*17*	The cover of the notebook says: revalue balance, which symbolizes how she was finding her right balance again regarding lifestyle behaviors. She used the notebook during the sessions to make notes.
	Reflection New resource	Notebook (2/2)	*18*	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.

Category	Interpretation researcher	Object	Participant	Participant's reasoning behind the object
Control of health/ life	Control Motivation	Lifestyle wheel (1/1)	*10*	The wheel symbolized everything that was discussed during the program (nutrition, movement, connection, relaxation, sleep) and it symbolizes that you are behind the steering wheel; you are in control of your health.
	Control	Wheel (1/1)	*14*	Participant feels as if she gives more direction to her life now.
	Reflection	Golf ball (1/1)	*20*	Golf is an individual sport, and if something goes wrong you can only blame yourself. The same can be said about your blood sugar levels. It symbolizes that if you forget some things, it can have large consequences.
Social belonging	Peer support Safe place	Table sugar (1/1)	*2*	Symbolizes the connection between the participants. Having diabetes ("sugar disease") is what brought them together and allowed them to connect on an emotional level. The participant found it important to meet people that are going through the same.
	Fun	Walnut (2/2)	*5*	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 thinking about what you want is confronting.
	Working on goals Social support	'Dopper' water bottle (2/2)	*6*	This specific bottle being reminded to the program because of the word 'mindfulness' printed on the bottle. The bottle also symbolizes support from his family: together with this partner he introduced 'Dopper Time' certain times at the day they remined each other to drink water together. Furthermore, it symbolized goal achievement.
	Group feeling Fun	Chalk/crayons (1/1)	*9*	At first, the participant did not really liked the session, and hence started to draw during parts she found boring. As the intervention went on, she started to like the group more and more and she was happy that she stayed in the program.
	Peer support Motivation	Stick (1/1)	*5*	Symbolizes that the group acted as the ' stick behind the door'; fact that when you are in a group and (frequently) meet, you experience social pressure to work on your goals. This was experienced as motivating by the participant.

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9

Chapter 9

General discussion

9.1 Integration of findings

The overarching aim of this dissertation is to gather new insights for optimising the Dutch T2DM care. To accomplish this, the salutogenic model of health (SMH) is used to develop (Chapters 2-6) and evaluate (Chapters 7 and 8) an innovative intervention programme to enable healthy eating among people with T2DM: the SALUD programme (**Table 9.1**). The salutogenic perspective broadens the research lens on dietary programmes for T2DM by focussing on the context of healthy eating in everyday life and the interactions between the individual and one's (physical and social) environment.

There were three objectives in this research project: 1) establish what a salutogenic intervention entails; 2) determine how to develop a salutogenic intervention for enabling healthy eating among people with T2DM and 3) assess the use of a salutogenic intervention for people with T2DM. In this chapter, the findings are integrated by reflecting on the three overall objectives (§9.1 to §9.4). Thereafter, the (methodological) strengths and limitations of this dissertation are discussed (§9.5). This is followed by overall conclusions and a set of recommendations for practice and research (§9.6). The chapter ends with a final take-home message (§9.7).

9.2 Theoretical contributions to the salutogenic model of health

A recent systematic review points out that dietary interventions based on (health-behavioural) theories seem more effective at improving health; however, the use of theory is an exception rather than a standard practice in dietary research [1]. In addition, there is little diversity in theories used within dietary interventions (social-cognitive theory being the theory most frequently applied), revealing a need to explore the use of other theoretical health models [1]. This dissertation adds to the scientific literature by investigating the use of a socioecological theoretical model for promoting healthy eating practice: the SMH. However, at the time this research project began, limited salutogenic interventions were performed [2], and consensus on a clear formulation, definition or operationalisation of the SMH for interventions was lacking [3].

Hence, the first objective of this research project was to establish the minimum criteria that salutogenic interventions should follow. Therefore, three key principles for salutogenic interventions were operationalised: the participant as a whole, the participant's active involvement, and the participant's individual learning process (Chapter 2). For the first time, the SMH was explicitly translated in guiding principles for a salutogenic intervention for enabling healthy eating among people with T2DM. This paragraph reflects on the operationalisation of the SMH and distinguishing aspects of a salutogenic intervention for T2DM in order to provide a clear understanding of the phenomenon 'salutogenic intervention'.

Table 9.1 Summary of the chapters.

Chapter	Research aim	Methods	Main findings
		1) Theory operationalisation	
2	a. Operationalisation of the SMH for salutogenic interventions	Systematic literature review.	• Three salutogenic principles were operationalised to three criteria for salutogenic interventions: the participant as a whole, the participant's active involvement, and the participant's individual learning process. The criteria were applied to systematic literature review.
		2) Development of the SALUD programme	
2	b. To describe the characteristics and assess the effectiveness of RCTs comparing salutogenic-oriented interventions with standard T2DM.	Systematic literature review.	• The characteristics of the effective salutogenic-oriented interventions included: 1) development based on participatory research, 2) culturally targeted and 3) delivered in 10–20 sessions 4) in group settings. • Most interventions that were salutogenic-oriented were found to improve physical health, psychosocial health or both.
3	To explore how and why the eating practices of adults with T2DM (low socioeconomic position in particular) are developed over the life course.	Interpretative phenomenological analysis of in-depth life course interviews.	• Healthy eating requires a reflective, positive attitude towards life and supportive psychosocial resources. A stress-free mind, a flexible approach to eating, and feeling supported seem crucial for healthy eating. • Identified moments for dietary change are experiencing confrontation with ill-health, when becoming a parent and after psychological therapy. • Identified moments under which dietary change is difficult or impossible: losing a loved one, depression, and suffering from (physical) pain.
4	To examine the relationships between mental health and lifestyle behaviours among people with T1DM and T2DM.	Analysis of covariance of and logistic regressions based on cross-sectional survey data.	• People with T2DM with flourishing mental health had a diet more in line with dietary guidelines and were more physically active compared to those with T2DM and moderate mental health. • The associations of flourishing mental health with diet and physical activity were not significant in people with T1DM. • No significant associations between mental health and respectively smoking and alcohol consumption were found neither among people with T1DM nor among people with T2DM.
5	To describe the developmental process, structure and content of the SALUD intervention.	a. Theory operationalisation. b. Integration of previous findings. c. Validation by focus groups with people with T2DM, health-care professionals and scientists.	• Healthy eating is a complex social phenomenon that requires an intervention that includes strategies to develop self-identity, social support, food literacy, disease acceptance and stress management. • A comprehensive salutogenic intervention (the SALUD programme) to enable healthy eating among people with T2DM that is based on the preferences, needs and priorities of all stakeholders. • A comprehensive and transparent description of the developmental process of the SALUD programme.

Chapter	Research aim	Methods	Main findings
6	To outline the study in which the SALUD programme is compared with the Dutch usual care for T2DM.	Study protocol description.	• The outline of the RCT study that describes the quantitative and qualitative effect analysis of a salutogenic, web-based intervention programme on healthy eating and wellbeing in people with T2DM.
		3) Evaluation of the SALUD programme	
7	To evaluate the effects of the SALUD programme primarily on food literacy, and secondarily on dietary quality, and psychosocial- and physical health.	Linear mixed model analysis of RCT.	• The SALUD programme was statistically effective for enhancing SoC, which implies that self-identity and social support are important strategies for strengthening SoC. • The results are promising for food literacy, diet quality and body weight, as both groups improved in these outcomes with consistently greater improvements in the intervention group, albeit not statistically significant.
8	To gain insight in how participants experienced the content and meaning of the SALUD programme.	Thematic analysis of focus groups.	• Participants experienced the SALUD programme as a positive and meaningful learning process, in which they developed new coping strategies, gained new self-insights and perceived improved overall health. • Contextual factors that seemed crucial for inciting a learning process for healthy eating are: an emotionally safe place, positive and encouraging interactions, peer support and a holistic and reflective approach to healthy eating. • Psychosocial health effects were mostly emphasised, but improved physical health was mentioned as well. • The deviant case demonstrated that active and reflective engagement with the programme is a vital prerequisite for the programme to be impactful.

Note: **SMH** = salutogenic model of health; **RCT** = randomised controlled trial; **T2DM** = type 2 diabetes mellitus; **T1DM** = type 1 diabetes mellitus; **SoC** = sense of coherence.

9.2.1 Reflections on the three operationalised salutogenic principles

1) The participant as a whole

One aspect that distinguishes the SALUD programme from previous T2DM programmes is that SALUD adopted a holistic approach for healthy eating [4–6]. A salutogenic intervention considers physical and psychosocial health as equally important. However, Chapter 2 shows that even the interventions which complied with the salutogenic principles seem to have had a stronger focus on physical than psychosocial health. The SALUD programme is evaluated primarily on dietary practices in everyday life as well as on physical and psychosocial health (Chapter 6). Content-wise, a holistic programme implies an introspective approach for healthy eating (Chapters 3, 5 and 8*)*. Chapter 3 demonstrates the strong temporal influence of past experiences on present eating behaviour. In order to improve eating behaviour, one has to critically reflect on how eating behaviour developed over time and assess the circumstances when it was easy or difficult to eat healthy (Chapters 3, 5 and 8). In addition, Chapter 3 also underscores the importance of the timing of a dietary intervention programme: offering a dietary programme at the right moment in life seems important for the success of the programme. Turning points for healthy eating only seem to occur when someone is not facing (too many) stressors at the same time (Chapter 3). Chapter 8 reveals that the participants found introspection and reflecting on one self as well as on previous life-experiences is imperative for personal learning processes during the SALUD programme. These findings are supported by previous qualitative studies that also identified the need for T2DM interventions that 'convey compassion and listening, try to make sense of root causes and contextual factors, focus on whole-person health and action planning, and foster reflection and experimentation within others' [7–9].

2) The participant's active involvement

The second distinguishing aspect of the SALUD programme compared to previous literature is that the SALUD programme is set up as a flexible programme: there was room for participants to steer the content and focus of the programme. Contrary to most (T2DM) lifestyle interventions, the SALUD participants were entirely in control of the nature of the goal they wanted to work on. The fact that participants consider the SALUD programme as a positive and meaningful experience (Chapter 8) may be attributed to the extensive participatory approach of the SALUD programme (Chapter 5). Chapter 2 shows that active involvement of participants in (the development of) the programme results in more successful interventions. According to Antonovsky, to experience control about one's health process is a source experience for developing SoC [10]. Antonovsky explained that life experiences that fuel the meaning are experiences in which:

> 'we have taken part in choosing to undergo that experience, in judging whether the rules of the game are legitimate, and in solving the problems and tasks posed by the experience. When others decide everything for us ... we are reduced to being objects. A world thus experienced as being indifferent to what we do comes to be seen as a world devoid of meaning' ([11], p. 92).

Antonovsky refers to this type of experiences as one of participation in shaping outcomes. Experiences in shaping outcomes are comparable to what self-determination theory refers to as the psychological need for autonomy [12]. Autonomy is experienced when people feel they contribute to decision-making and feel in control of the behaviour. In self-determination theory, autonomy is considered critical for internalising a motivation for initiating and sustaining new behaviours (e.g. moving from external motivation to intrinsic motivation and regulation) [12]. The findings of this dissertation support the notion that actively participating in deciding which route the intervention programme takes is important for a meaningful learning experience (Chapter 8).

3) The participant's active learning process

The third distinguishing aspect of the SALUD programme was that it prioritised individual learning processes over traditional education and knowledge transfer. It seems that the SALUD programme successfully incited an active learning process, because the participants talked about setting realistic goals, developing health-promoting coping strategies and mobilizing new tools/ resources to work on these goals (Chapter 8). This learning process required frequent reflective evaluation of the trial-and-error experiments the participants conducted. All participants except one were able to reach their goals during the programme, and the drop-out rate of the program was low (Chapters 8 and 9). Taken alltogether, it seems that the SALUD programme was successful in providing people a good load-balance experience (i.e. providing a good balance between the demands made upon one and one's resources), which is a source experience for developing strong SoC, particularly for developing manageability (or self-efficacy) over a task [10].

Self-monitoring blood glucose is considered an important resource (a SRR) in the active learning process of several SALUD participants (Chapter 8). It was used to become more aware of body-mind interactions and to reaching and evaluating their goal progress. From a salutogenic perspective, self-monitoring may be a means to provide some consistency in coping with T2DM in everyday life. Consistent experiences contribute specifically to the *comprehensibility* component of SoC [10]. In addition, self-monitoring can help in experiencing a feeling of mastery over healthy eating. This relates to the basic human psychological need of *competence* in self-determination theory, and the concept of self-efficacy in social-cognitive theory [12]. In this sense, self-monitoring blood glucose also contributes to the *manageability* component of the SoC.

However, a (salutogenic) learning process is more than reflection on the personal goal progress; it also requires substantial self-reflection. The SALUD participants confirmed this as they described the SALUD programme as a positive self-confronting experience that was considered useful in their personal learning process to healthier eating. Introspective and reflective overthinking of what is truly important to who they are as a person helped to discover *why* one was making certain health choices, which in turn helped the participants to change behaviours in line with

health goals (Chapter 8). This relates directly to the *meaningfulness* component of the SoC: participants were motivated to undergo this self-confrontational process (which is not necessarily easier) because it was considered a challenge deserving of active engagement, which is reflected by the active learning the participants talked about (*comprehensibility/manageability*).

9.2.2 Optimising our operationalisation

The operationalisation of these three salutogenic principles was useful in developing a salutogenic intervention. It resulted in a programme that was characterised by a holistic, flexible, encouraging and supportive approach to healthy eating (Chapter 8). Our operationalisation of the SMH also seems to resonate with our scientific peers, because other researchers used it as input for a further elaboration of defining salutogenic interventions [13]. However, based on the present findings and the (a posteriori) research experiences, our operationalisation can be further optimised by adding two additional salutogenic principles:

The participant's need for emotional closeness with others

The first additional principles concerns the crucial role of social relatedness and support in the salutogenic learning process (Chapters 2, 3, 5 and 8). From a theoretical perspective, social support is considered a vital coping resource in the SMH and experiencing emotional closeness is considered an important experience for developing strong SoC [14,15]. Social support has also a central place in developing autonomous motivation in self-determination theory: the psychological need of relatedness (i.e. sense of belonging with others) [12]. Chapter 2 reveals that goal-setting only seems to result in effective health improvements *if* combined with social support, particularly for adults with T2DM in socially-disadvantaged situations [16,17]. Participants with T2DM in this research project also indicated a need for social support for healthy eating (Chapters 3, 5 and 8). Chapter 8 explains why social support was important for the participants: experiencing emotional closeness and relatedness with others that have T2DM aided self-acceptance of the disease and getting rid of feelings of shame or guilt. In addition, participants indicated that being in a group of peers motivated to keep on track with goals. Finally, participants learned a lot from each other's experiences with coping with T2DM. These aspects were considered focal to the learning process of the participants (Chapter 8). The importance of emotional (peer) support is also emphasised by several other studies [7–9]. In addition, longitudinal observational research shows that involving in social activities as such is important for overall health, as more frequent social activity was significantly associated with prolonged overall survival in older people [18]. Therefore, based on the findings of Chapters 3, 5 and 8, an additional principle could be recommended for developing salutogenic interventions: the participant's need for emotional closeness with others.

Positively encouraging the participant

Secondly, the positive and encouraging approach of a salutogenic programme should be more explicitly emphasised, particularly because SALUD participants found the authentic

and encouraging attention extremely important for being able to work on healthy eating goals (Chapter 8). The positive and encouraging approach made participants feel safe and invited them to participate in an active learning process. It also led to more self-compassion and the ability to deal with self-confronting feelings regarding (ill)health. Finally, the positive and encouraging approach also made the SALUD programme enjoyable. This is an important finding in itself, because a growing body of research suggests that positive emotions may be key to sustaining health as people age [19]. Research suggests that positive emotions can elicit a positive effect via three pathways: facilitating performing health-promoting behaviours, direct physiological benefits and an attenuated reactivity to and quicker recovery from stress [19]. The importance of positive and encouraging communication is observed in several recent studies about the factors that contribute to dietary change after T2DM diagnosis [7,8]. In addition, health care professionals voiced that establishing an authentic personal connection is necessary to gain the client's trust and promote healthy eating among clients with T2DM [20,21]. Therefore, the second additional principle that is recommended for developing salutogenic interventions is: positively encouraging the participant. This principle of positive encouragement encompasses the nature, tone an setting of the social interactions that define a salutogenic programme (Chapters 3, 5 and 8).

9.2.3 Summary remarks

Altogether, this dissertation contributed to a better theoretical understanding and definition of the phenomenon 'salutogenic intervention'. Our operationalisation of the SMH resulted in a dietary programme that was characterized by a holistic, flexible, encouraging and supportive approach to healthy eating. This characterisation is what distinguishes the SALUD programme from most previous T2DM dietary programs. Based on the a posteriori experiences, the initial operationalisation is further specified, and this operationalisation is recommended for future research (**Table 9.2**).

Table 9.2 Recommended guiding principles for future salutogenic interventions. The a priori operationalization (principle 1 to 3) has been complemented with two a posteriori principles that were formulated based on the evaluation of the SALUD programme (principles 4 and 5).

Principle	Explanation
1. The participant as a whole	In salutogenesis, health is a complex concept incorporating multiple aspects of wellbeing that relate to the whole person. According to Antonovsky, researchers should focus on human beings with T2DM, instead of focussing solely on the disease and its physical health consequences [15] This necessitates the suggestion of T2DM lifestyle interventions that aim to improve multiple aspects of health and wellbeing, including the physical, mental, social and spiritual dimensions.
2. The participant's active involvement	Understanding the unique life story and current life situation of adults with T2DM is important for providing meaningful care; however, these are often not taken into account in current interventions [22]. Adjusting lifestyle intervention strategies to the individual's priorities, motivations and capabilities increases the chance of accomplishing meaningful and active participation in the interventions [23].

Principle	Explanation
3. The participant's individual learning process	Salutogenesis complements traditional information-providing approaches by supporting individuals in a learning process to develop self-identity. Antonovsky regarded self-identity as a crucial resource for coping as the image one has of oneself influences one's relationship with the world ([15]; 109–110). A learning process focussed on self-identify may lead to the discovery of individual internal and external resources that can be used to facilitate coping with T2DM-specific challenges, including the physiological defects, psychological consequences and implementation of structural changes in daily routines.
4. The participant's need for emotional closeness with others	Experiencing emotional relatedness with peers and feeling emotionally safe in a salutogenic interventions programme is crucial in order to incite an effective individual learning process that contributes to strong SoC [14].
5. The participant's need for positive encouragement	A positive and encouraging approach emphasises that stressors and tension are part of normal experience. In addition, a positive and encouraging approach comprises to compliment participants on (small) personal successes and achievements and to normalises failures as part of a learning process. Positive and encouraging communication and interactions are vital for enabling engagement in an individual learning process.

9.3 From theory to intervention: healthy eating in everyday life

This paragraph reflects on the second objective of this dissertation: how to develop a salutogenic intervention to enable healthy eating among people with T2DM. The three operationalised salutogenic principles set the direction of the SALUD programme. In addition, the content of the SALUD programme was informed by investigating resources that contribute to healthy eating in everyday life via a qualitative (Chapters 3 and 5) and quantitative approach (Chapter 4). This paragraph reflects first on resources for healthy eating in everyday life that were investigated during this developmental process. Thereafter, reflections on the developmental procedure are discussed.

9.3.1 Resources for healthy eating in everyday life

This dissertation indicates that a main resource for healthy eating is a reflective, positive attitude to face the continuous challenges in the process of dietary change (Chapter 3). More concretely, this translates to a flexible and creative approach to eating in everyday life with the following characteristics (Chapter 3):

- prioritising healthy eating, but not obsessing about dieting and weight loss;
- incorporating 'unhealthy' foods in a healthy way;
- a focus on what one should and could eat more of (e.g. vegetables) rather than what one could not eat (e.g. limiting added sugar intake);
- being creative with foods and experiencing joy in this process (e.g. replacing snacks with healthy alternatives and experimenting with new recipes).

A flexible and creative approach to eating is the opposite of a weight loss diet: it is non-prescriptive, non-judgemental, cherishing the importance of enjoyment of food and paying attention

to the situational and temporal (life course) complexity of eating. This flexible and creative approach counterbalances the medicalisation of eating, a process in which everyday activities are problematised over time or certain behaviours are framed as deviant and become a legitimate target for health care interventions [24,25]. The experiences of the SALUD participants confirm that a flexible and creative approach to eating was useful to eat healthier. Increased awareness of body-mind interactions was considered important for a flexible and creative approach to healthy eating (Chapter 8). Research shows that increased awareness of body-mind interactions, for example mindful or intuitive eating, is associated with lower body weight [26] as well as with lower risk of poor glycaemic control (regardless of BMI) in people with T2DM [27]. Although there is little experimental evidence that it supports actual dietary quality [28], mindful and intuitive eating is positively related to psychological wellbeing, body appreciation, self-esteem and life satisfaction [29], aspects that have also been identified in the present dissertation as essential for enabling healthy eating along the life course (Chapters 3 and 8).

Self-monitoring blood glucose is an important resource (a SRR) for becoming aware of body-mind interactions (Chapters 2 and 8). SALUD participants considered self-monitoring blood glucose as an aid in discovering one's own personalised nutrition guidelines: what does and what does not work, and under which circumstances (Chapter 8). Some participants indicate that they would have liked to receive a little more help with self-monitoring blood glucose (Chapter 8*).* However, there is some conflict between a flexible and creative approach to eating and self-monitoring blood glucose. Self-monitoring blood glucose can be used as a feedback-strategy to explore body-mind connections, which were considered beneficial for eating practices. However, overfocussing on self-monitoring blood glucose and meticulously tracking dietary eating can lead to medicalising eating and dieting – which is in contrast with a flexible and creative approach to eating. There is a delicate balance between using self-monitoring blood glucose as an aid to understand one's body better and fixating about blood glucose values, and this distinction indicates that people with T2DM need more than just a technical instruction on how to conduct blood glucose self-measurements.

Another important identified resource for healthy eating is flourishing mental health (Chapter 3, 4 and 5). This is in line with previous research: an increasing amount of research demonstrates that maintaining a healthy lifestyle improves mental wellbeing, and better mental health supports a healthy lifestyle [30–36]. On the other hand, psychological stress (i.e. depression, emotional stress, work stress, and life adversities) plays an important role in the pathogenesis of T2DM and cardiovascular complications [37]. In the context of this dissertation, effective stress management strategies, disease acceptance and feeling emotionally supported by others are factors that contribute to flourishing mental health (Chapters 3, 5 and 8). Evidence shows that SoC predicts mental health [38,39] and salutogenic interventions seem particularly effective for improving mental health [13]. This evidence seems to be supported by the findings of this dissertation: the SALUD programme resulted in increased SoC (Chapter 7), improved wellbeing

and healthier dietary practices (Chapter 8) (the effects of the SALUD programme are elaborately discussed in §9.4). Hence, a salutogenic intervention may result in increased SoC, which in turn contributes to mental health, as well as vice versa. Together, this interplay between SoC and mental health facilitates making healthier dietary choices.

Altogether, these resources for healthy eating provide a new perspective on what food literacy exactly is or should be. Food literacy is defined in this dissertation as one's capability to navigate one's food environment in a healthy way. Several important adjustments concerning navigating in different food situations described by the participants (such as flexible and creative approaches to eating and awareness of body-mind interactions) do not really have a place in the food literacy questionnaire that has been used [40]. Hence, these present findings may be useful for further developing (quantitative) food literacy measures.

Reflections on resources that were *not* found

Remarkably, the participants in this research project – independent of socioeconomic status – do not indicate nutritional knowledge and motivation (or the lack of it) as essential resources for healthy eating (Chapter 3, 5 and *8*). In fact, the majority of participants had a good-to-adequate understanding of healthy eating and its importance for T2DM. This finding is in line with previous research that emphasised that the lack of nutritional knowledge is not the decisive factor explaining food behaviour [7,34]. In addition, an extensive systematic review demonstrates that demographic determinants - age, gender, socioeconomic status - do *not* predict maintained weight loss [41]. It is important to note that the majority of the participants in this dissertation had T2DM already for several years and most already visited a dietician in the past (Chapter 3). Hence, from these findings, it can be derived that the current Dutch T2DM care succeeded in providing the participants sufficient knowledge on nutrition and T2DM and their interrelations. Undoubtedly, nutritional knowledge is necessary for healthy eating and T2DM self-management. However, these findings emphasise that T2DM care that is strictly educational is not effective enough to enable healthy eating. This emphasis is reflected by the findings in Chapter 3: nine of the seventeen interviewed participants displayed a coping style in which people acknowledged their own influence on their health and succeeded in implementing radical dietary changes (referred to as the 'healthy copers' in Chapter 3). The other participants may benefit from more supportive and reflective dietary guidance.

It is also remarkable that the resources that have been identified in this dissertation are mostly at the individual level, not the collective/societal level. This may be because people can more easily identify what they need on the individual level than on the collective/societal level (Chapter 3, 5 and 8), and that the interventions assessed for the development of the SALUD programme are individually-oriented as well (Chapter 2). It could also be that people consider health more an individual than a societal responsibility. Over the last 100 years, medical scientists and psychologists have shifted their attention away from human behaviour as a predictable response to

instincts, habits and neurological mechanisms, and towards an idealisation of human agency that implies people can autonomously choose to act to maintain or regain their health [24]. Adding human agency as new ingredient to behavioural models led to an emphasis on individual choice and responsibility for health [24]. This focus on agency explains why most behavioural-health theories are more individually oriented. The emphasis on individual responsibility resonates with currently predominant neoliberalist views on society and politics that favour privatisation, reduced government intervention in labour markets, trade and health care [42]. The individualist stance in neoliberal perspectives offers little space to support a view that health is primarily created by systemic and environmental structures, including the dominant economic structure and the psychological stress people experience from such neoliberal economic systems [42].

Nevertheless, the accelerating effect of the obesogenic environment on incidence of chronic diseases such as T2DM is undeniable [43]. In addition, Chapter 3 shows that adverse childhood experiences, followed by an unequal share of hardship in later life, deprive people from developing strong psychosocial resources important for both managing emotional stress and healthy eating. Previous research shows that socioeconomic status was highly associated with both T2DM and childhood adversities [44], suggesting an unequal division of health-promoting resources and experiences between relatively low and high socioeconomic status. These findings argue for greater consideration of the environmental and systemic influences on eating behaviour for people with T2DM.

An important strength of the SMH is that, contrary to most health behaviour theories, it adopts a systems approach to health. After all, Antonovsky was a sociologist, and even for the more individually-oriented aspects of coping behaviour, such as the SoC, the foundations of the SMH lay in the source experiences that *society* does (or does not) provide (**Figure 1.3** and [10]). The SMH focuses on the *interaction* between the individual and the (social) environment, and acknowledges the influence of structural variables on human agency. According to the SMH, there is (*in addition to* an individual responsibility) a collective, societal responsibility to provide experiences and resources that contribute to developing individual strong SoC and health along the life course. In order to combat the T2DM epidemic effectively, dietary programmes such as SALUD should be simultaneously complemented by structural changes that contribute to healthier ways of organising Dutch society, such as offering healthy meals at schools and investing in healthy work settings.

9.3.2 Reflections on the developmental process of the SALUD programme

The SALUD programme is based in the integration of five (quantitative and qualitative) sources (Chapter 5). These results were summarised and integrated, which resulted in a first concept of the SALUD programme (Chapter 5). However, as can be seen in **Box 9.1**, the participatory developmental process made me very aware of my own position and influence in this research project, particularly, at the moment when the first concept of the SALUD programme was drafted.

Was this programme 'good enough'? Were the explorative preparatory findings interpreted as the participants truly intended? Or were the findings of the preparatory studies interpreted *too much* through a salutogenic lens? Were the elements that fit the SMH particularly overemphasised? Were aspects that did not fit within salutogenic framework ignored?

Box 9.1 Personal reflections during developmental process

The life course interviews in particular had a lasting effect on me. Connecting with strangers on a deep personal and emotional level was a beautiful and often emotional experience. The participants shared their entire life story with me: the good, the bad and the ugly. This made it sometimes impossible for me to stay in my role of objective scientist and only ask questions that related specifically to the research. These interviews felt like conversations between one human to another, instead of scientist to participant.

I often felt a bit uncomfortable when I left, because participants shared so much with me, and I so little (of myself) with them. I wanted to help them with their grief, sadness or their own feelings of hopelessness, and sometimes I felt hopeless too. It was therefore really nice to call the participants one week after the interviews to ask how they were doing and to reflect on our conversations. These phone calls provided me an extra opportunity to thank them. Most participants told me during these phone calls that they appreciated the interview because someone took the time to sincerely listen to them.

Something else I experienced was that the interviews also led to reflection on my own relationship with food and health. I became aware that things that were considered difficult for the participants were relatively easy for me. For example, I have always enjoyed cooking, and I exercise mostly because I simply enjoy it. I became increasingly aware of the differences in age, health, lifestyle, and socioeconomic environment between me and the participants, and this made me quite uncomfortable in the beginning. Was I not too different from the participants? Does that not limit me in my ability to truly understand them? Who am I, as a young and healthy researcher, to decide what people with T2DM really need? Sometimes I questioned whether I was the right person to conduct the interviews and the research project in general. This questioning led me to investigate my own eating practices and how they developed over time. My conclusion was that I just had more luck regarding the opportunities I was offered and the lack of setbacks and misfortunes in my life. This realisation made me very grateful and humble for my own experiences and luck but more importantly, it also helped me to connect with the participants in spite of our differences. If I have been in their shoes, I probably would have made similar decisions, which revealed to me something about to the true nature of human beings.

Questions like those above indicated the need for an additional 'validation step' in the programme's development, which is described in detail in Chapter 5. Instead of suggesting a completely different intervention approach (Chapter 5), additional suggestions and slight alterations were suggested by the different stakeholders. Nevertheless, this validation step was important for the programme development, because it was a way to check and correct for the researcher's subjective translation of the expressed needs and priorities of the stakeholders. With this step, the 'rightness' of the programme increased, as it caused a shift from the researcher's sole subjective interpretation to a more shared, intersubjective interpretation of what the programme should look like. Completely correcting for the subjective interpretations of researchers is impossible, and this correction is also not needed. The validation step was not perfect (several ways to improve such a 'validation check' to reach intersubjectivity are discussed in Chapter 5). Nevertheless, it could be argued that *any* attempt to correct and check for subjective interpretation of researchers is beneficial for the quality and rightness (validity) of an intervention programme.

Are people with T2DM motivated to change their eating practices?

Operationalisation of the SMH resulted in a developmental approach in which participants were actively involved. In turn, the developmental approach resulted in a flexible intervention programme in which participants had total control on which goal they wanted to work on. The SALUD programme was perceived as a positive and meaningful experience (Chapter 8), which may be attributed to the extensive participatory approach of the SALUD programme (Chapters 5 and 8). However, to play devil's advocate, it seems obvious that people like a programme they are allowed to fill in and steer themselves. Questions were frequently discussed throughout the developmental process: Do people know what they need to improve health? Are people actually willing to sacrifice unhealthy, ingrained and enjoyable habits to become healthier?

The life course interviews in Chapter 3 provide valuable insights on these questions: the (in) ability to eat healthily should be considered in light of the a life course perspective. Chapter 3 distinguishes different coping styles for healthy eating. Irrespective of the type of the coping style, all participants found health important, and none of the participants were careless about their diets (no one was eating unhealthy 'on purpose'). There were differences in *how* important their (physical) health was in relation to other aspects of life, and, thus, the individual willingness to 'sacrifice' habits or to invest conscious effort to become healthier (e.g. happy vs healthy coping; Chapter 3). However, the inability to change dietary practices (i.e. passive coping) seems to be explained mostly by not having the psychosocial strength, stability and support at that moment due to having a considerable and unequal share of life adversities (Chapter 3). A meta-analysis shows that adverse childhood experiences increased the risk of T2DM by 32% [44]. When dealing with an overwhelmingly stressful life-event, most people need their full capacity and coping abilities to carry on with 'normal' everyday life. Because of this, diet simply becomes an afterthought.

In addition, the evaluation studies also support that most people with T2DM want to eat healthier: participants voluntarily committed to a scientific study that included a considerable investment of time. The drop-out rate of 4.5% during the SALUD programme was relatively low compared to other web-based programmes for T2DM (generally between 7.4% and 79.8%) [45]. Considering the non-prescriptive nature of the SALUD programme, dietary change requires an active effort of the participants inside- and outside the programme. Nevertheless, the SALUD participants found healthier ways of organising eating and dietary intake in their everyday life (Chapters 7 and 8). Altogether, these studies indicate that most people with T2DM are motivated to improve dietary practices and find their (physical) health of vital importance. Coping styles regarding eating behaviour after T2DM diagnosis seem more determined by previous life experiences, current living conditions and the systemic influences underlying these than personal motivation.

9.3.3 Summary remarks

To sum up, the salutogenic principles underly the programme's design, but they did not dictate the intervention programme's content. A strength of this dissertation is that theory is combined with the voices of relevant stakeholders. Investigating individual perspectives on healthy eating and what makes dietary change easier or more difficult helped in uncovering several important resources for healthy eating in everyday life (§9.3.1). This investigation also revealed that most people with T2DM are motivated to improve dietary behaviour, but there are individual differences in how important healthy eating is at that moment in comparison with other aspects of life. This motivation depends heavily on temporal influences and the access to (psychosocial) resources for healthy eating.

9.4 The SALUD programme: success or failure?

Here I discuss the third objective of this research project: evaluating the effectiveness of a salutogenic intervention for healthy eating among people with T2DM. The effect evaluation of the SALUD programme consists of two parts: a quantitative (Chapter 7) and a qualitative evaluation (Chapter 8). In **Table 9.3**, the effect findings of the two chapters are compared.

Table 9.3 Summary of the findings of the quantitative and qualitative effects of the SALUD programme.

		SALUD programme's effectiveness	
Outcomes	*Quantitative perspective (Chapter 7)*		*Qualitative perspective (Chapter 8)*
Dietary practices	Food literacy	• Significant improvement over time. • No significant intervention effect.	• Identification of existing and new resources and how to apply these in a health promoting way. • Improved awareness of body-mind interactions. • Developing and applying concrete coping strategies for healthy eating.
	Diet quality	• Significant improvement over time. • No significant intervention effect.	
Psychosocial health	SoC	• Significant improvement over time. • Significant intervention*time effect.	• Positive self-confrontation (meaningfulness) • Active learning process (manageability/meaningfulness) • Feeling more in control over health and life (manageability/comprehensibility)
	QoL	• Significant improvement over time. • No significant intervention effect.	• Participants enjoyed the programme and found it meaningful. • Participants felt more calm and more self-compassionate and indicated improved disease acceptance.
	Self-efficacy	• No effects.	• Feeling more in control over health and life. • Developing and applying concrete coping strategies for healthy eating.
Physical health	Body weight, BMI, and Waist circumference	• Significant improvement over time. • No significant intervention effect.	• Several participants indicated considerable weight loss, others did not and one indicated weight-gain. • A few participants indicated lowered T2DM medication use.
	Hip circumference and WHR	• No effects.	• Perceived improved general health. • Partners noticed improved health and healthier behaviours of the participants.

Note: **SoC** = sense of coherence; **QoL** = quality of life; **BMI** = body mass index; **WHR** = waist-hip ratio.

Both chapters fulfil a different role in the evaluation of the SALUD programme and were useful and complementary to each other. Chapter 7 provides an indication of the 'net' effects of the programme on dietary practices, health and wellbeing. The net effect is that the SALUD programme was statistically effective for enhancing SoC, although a difference in baseline SoC between the groups complicates the interpretation of this finding. In addition, there were trends over time for food literacy, diet quality and body weight, as in both groups these outcomes significantly improve with consistently larger improvements in the intervention group that seem to persist during follow-up, though these improvements are not statistically significant. This lack of statistical significant intervention results leaves open the possibility that the observed improvements on dietary practices and health were caused by others things than the SALUD programme, such as seasonality effects or the attention of the researchers in times of social-isolation due the COVID-19 pandemic.

Chapter 8 provides further details and context to the net effects demonstrated in Chapter 7. This chapter shows that participants experienced the SALUD programme as a positive and meaningful learning process, in which they developed new coping strategies, gained new self-insights, perceived improved overall health and felt more in control of their health and lives. In addition, the participants noticed they were more aware of mind-body interactions, which resulted for example in eating more mindfully and paying closer attention to hunger and satiety signals. For the most part, psychosocial health effects are emphasised, but improved physical effects are mentioned, as well. Contextual factors that seem crucial for inciting a learning process for healthy eating include: an emotionally safe place, a positive and encouraging coach, peer support, and a holistic and reflective approach to healthy eating. These findings are supported by other studies regarding dietary change after T2DM diagnosis [7–9].

9.4.1 To determine the success of the SALUD programme

To answer the question whether the SALUD programme was a success or not is difficult because the answer depends on the paradigm from which it is assessed. A positivist and an interpretivist perspective have been applied to assess the use of the SALUD programme. My personal view on the SALUD programme is displayed in **Box 9.2**.

Positivist paradigm: the SALUD programme is ineffective.

In clinical care, a positivist paradigm is predominant, which is reflected by the linear evidence-based approaches to evaluate the success of interventions [46]. A linear evidence-based approach starts with designing interventions and determining their effectiveness (e.g. via RCT); consequently, the use for practice is promoted [46]. Success indicators are primarily defined from a biomedical view on health, such as body weight and blood values. The SALUD programme seems particularly effective for wellbeing/mental health and, to a lesser extent, physical health. This effectiveness is in line with previous research: salutogenic interventions seem to especially improve mental health [13,47]. However, substantial weight loss has metabolic benefits that can positively affect T2DM management: weight loss can normalise hepatic insulin responsiveness and β-cell recovery of acute insulin secretion by removing excess fat from the liver and pancreas [48]. Hence, from a biomedical-positivist paradigm, the lack of statistical improvements of (physical) health could imply that the SALUD programme is ineffective: without statistically significant weight loss, a programme is considered unsuccessful in improving the health of people with T2DM.

Box 9.2 Personal view on the SALUD program

The different perspectives on the success of the SALUD program exemplify the fascinating and innovative nature of interdisciplinary research, but also highlight its inherent challenges. Conclusions solely based on one perspective or the other should be avoided, as reality is rarely black or white. The answer lies somewhere in between. Policymakers, clients, health professionals and (even) scientists often seek one-size-fits-all solutions, but the reality is that they simply do not exist.

I am acutely aware that my own positive experiences during this research project may influence my objectivity, and it is essential for me to navigate this challenge appropriately. Consequently, the quantitative results and discussions with my supervisors, who had a distant involvement in the SALUD program, became even more critical. They helped me to delineate the boundaries between my subjective perception and the objective reality of the phenomenon known as the 'SALUD program'.

While I wish I could substantiate the effectiveness of the SALUD program with more compelling statistical evidence, I genuinely believe it is an effective program for certain individuals. I have witnessed impressive and measurable results in several participants, and all participants expressed great positivity towards the program. The coach shared valuable experiences with me, and both the coach and I observed personal growth in the participants throughout the program (albeit to varying degrees). For all involved parties - the participants, the coach and myself - the SALUD program has been a remarkable experience. However, these positives do not seem to resonate strongly enough on a group level to achieve statistical significance. We also offered the SALUD program to the control group (results not included in this dissertation), and we observed similar positive outcomes in terms of health benefits and participant experiences, which strengthens me in this opinion. SALUD is not a magic bullet, but rather a complementary option among the existing treatment choices for people with T2DM.

Interpretivist paradigm: the SALUD programme is effective.

From an interpretivist perspective, the answer is more positive. Good care is by definition context-dependent. In that regard, it is extremely important that the participants experienced the SALUD programme as positive and meaningful for their health. Participants described the programme as 'positive self-confrontation' that was perceived as useful in their personal learning processes to healthier eating. Previous research shows that confrontational health experiences have the potential to invoke sustainable dietary improvements [9,49–52].

In addition, both studies indicate that SALUD participants found healthier ways of organising eating and dietary intake in their everyday lives. Chapter 8 provides 'content' on *how* participants

improved their dietary intake: participants described concrete coping strategies as well as resources that facilitated dietary adjustments. These 'hows' make it less likely that the observed quantitative improvements in dietary behaviour, psychosocial and physical health are coincidental.

Furthermore, both chapters indicate that health and wellbeing improved, most notably in the considerably beneficial effect on SoC. As mentioned before, research has shown that, in the general population, SoC is associated with good physical health and wellbeing [47,53,54] and, in T2DM, with better HbA_{1c} and less T2DM-related complications [55–58]. However, there is some debate as to whether SoC is a stable or changeable orientation [11,15]. Research has shown that SoC is solid and stable over time [59], but it can be altered due to major life events and interventions [60–63], although little is known about the duration of these changes [13]. As SoC generally does not seem to change unexpectedly, it is quite interesting that time and the SALUD programme jointly contributed to the improvement in SoC in the SALUD participants. Although the interpretation is somewhat complicated by a baseline difference, the SALUD participants improved their SoC, on average, by 5.9 points versus 0.1 points in the control group. An average group improvement in SoC of >5 points after following a certain treatment/therapy is considered a substantial improvement [13]. In addition, the difference between the SALUD and control group was sustained at the three-month follow-up measurements, which suggests a more permanent change rather than a temporal, accidental fluctuation. However, a longer study duration is needed to provide more clarity on this.

Finally, based on both chapters, it can be argued that the SALUD programme invests in important preconditions for enabling long-term healthy eating. Investing in SoC, autonomy, personal meaning and wellbeing seem to be necessary first steps to be able to eat more healthily, which may explain why the effects of the SALUD programme on dietary behaviour became more apparent during the three-month follow-up measurements. It might take longer for a salutogenic programme to evoke effects on body weight, blood glucose and HbA_{1c}, because the SALUD programme invests in skills and resources that facilitate long-term healthy eating. The SALUD participants described the increase in SoC as knowing better what one wants (*meaningfulness*) and how to give direction to that knowledge (*manageability*). A recent meta-analysis demonstrated that autonomous motivation (*meaningfulness*) and perceived competence (*manageability*) predicted health behaviour, and these variables simultaneously mediated the effects of interventions on health behaviours [64]. SoC has been shown to be an important predictor of healthier dietary patterns [65–67], while related concepts regarding proactive coping ability and personal agency have been demonstrated to be important for healthy eating [33,41,68,69]. Regarding T2DM, a meta-analysis shows that many theory-based interventions based on conditions supporting the individual's experience of autonomy, and competence led to beneficial treatment outcomes regarding HbA_{1c}, weight loss and physical activity [70]. Hence, from a salutogenic-interpretivist perspective, the positive and meaningful experiences of the participants and the beneficial effects on SoC and dietary practices could indicate that the SALUD programme is a success.

Rather than proving either of the paradigms right (they both are), this dissertation argues that, in judging the success of dietary programmes, it could be questioned whether a linear evidence-based approach is appropriate. The SALUD programme heavily depends on personal agency and empowerment. Hence, the programme is not a fixed entity, but always the result of a situated co-production process [46]. In this situated co-production process, many situational and uncontrollable factors besides the SALUD intervention programme play a role in the programme's effectiveness, for example, the coach (who the participants highly appreciated) and the temporal context in which the SALUD programme is evaluated (amidst the COVID-19 pandemic). In the RCT, the entire configuration of SALUD intervention programme and applied context is evaluated, not *just* the SALUD programme. It is not possible to dissect the effect of the programme theory or separate 'active' intervention components, such as group-format, intervention topics or coach.

In intervention programmes where situated co-production processes occur (which seems inevitable in aiming sustainable dietary change), more attention may be directed to studying how the programme works (i.e. the *process* and *context* of dietary change). An alternative evaluation approach of interventions is realist evaluation. Realist evaluation is based on an iterative procedure whereby successive case studies are conducted and the mechanisms that are activated by the intervention to produce its effects in a given context are (qualitatively) investigated [71]. Realist evaluation does not necessarily exclude RCTs in evaluating dietary (behavioural change) programs; rather, it allows for a combination of qualitative and quantitative methods in order to help in the interpretation of the health outcome and contextual factors, similarly to what has been done in this dissertation. This approach is typically referred to as 'realist-RCT' [71]. However, there is ongoing debate about whether RCTs – a research design fundamentally based on a positivist ontological and epistemological positioning – can be adapted to be used for interventions that are based on situated co-production processes [72,73]. For example, a mechanism in RCT is equated to *intervention components*, but in programmes such as SALUD, a mechanism refers to the resources and opportunities created by the intervention that are taken up (or not) by people in different contexts. As a consequence, intervention programmes work in different ways for different people, because people respond to resources offered by the intervention in different ways [72]. It is not the programme that is effective, but all people involved in the programme who make the programme effective. Realist-RCT can be a valuable methodology to assess a range of questions regarding implementation, context, mechanisms, and outcomes, but it requires precise and meticulous integration and interpretation of quantitative and qualitative findings.

Interventions that include situated co-production also raise the question of what should be considered a success outcome. An effect evaluation that is only focussed on physical health outcomes and statistical significance may not be enough. For example, overemphasising body weight as success has the pitfall of focussing too rigidly on caloric intake. Diets can be extremely

effective in improving health in the short term, but research consistently shows that most people regain the initial weight loss or, in the long term, even more weight [74–76]. Even more important, a diet focussed on weight loss can become a health-damaging stressor that leads to psychological distress, depression, lower self-esteem and disordered eating behaviours [33,75,77]. Hence, a strict diet may seem a success at first, but can develop in a health-damaging stressor over time.

A more context and process-oriented effect evaluation implies a broader re-evaluation of the importance of psychological and behavioural outcomes in addition to biological health outcomes [78]. The human need to experience meaningfulness in everyday life activities appeared to be central. Another important outcome that appeared important for healthy eating is having the psychosocial strength, stability and support at the moment to eat in line with health intentions (Chapter 3). This is supported by Chapter 4, as well as by previous research [30–36]: a state of flourishing mental health contributes to self-managing a healthy lifestyle among people with T2DM. Although longer follow-up studies are needed to assess how SoC, wellbeing, lifestyle and physical health relate to each other in the process of establishing dietary change, alternative success outcomes (besides HbA_{1c} or weight) of dietary interventions are recommended to consider. In the context of T2DM, examples could be increased SoC, finding personal meaning in healthy eating or T2DM self-management and displaying a more flexible and positive relation with food. These indices can be measured quantitatively, but this dissertation demonstrates that a complementary qualitative evaluation may lead to a more comprehensive understanding.

9.4.2 Summary remarks

Together, Chapters 7 and 8 provide a more complete picture of the SALUD programme's effectiveness and future potential than when only focussing on these studies separately. Obviously, the SALUD programme (and its evaluation) is not perfect and could be further improved; however, overall, the findings shed light on the potential of salutogenic dietary programmes for people with T2DM. The current dissertation (together with other process-oriented studies [27,28,64,70]) supports that salutogenic strategies can result in improved health, wellbeing and (eventually) weight loss. Together, these results suggest that centring the personal meaningfulness of eating contributes to healthier eating. Important questions that should be debated – also with regard to reimbursement of interventions from health insurance – include how we evaluate dietary interventions, and when those interventions can be considered a success. Positivist and interpretivist paradigms have different perspectives on dietary intervention success. Considering that care is context-specific, biomedical-positivist views on successful dietary interventions may be complemented by investigating the contextual process during a dietary programme (via qualitative investigation) and a re-evaluation of psychological and behavioural health outcomes in the process of dietary change. **Table 9.4** summarises the combined effectiveness assessment of the SALUD programme.

Table 9.4 Summary of the effect assessment of the SALUD programme.

	Assessment of the SALUD programme
What?	• The SALUD programme resulted in a statistically significant (time*intervention) effect on sense of coherence and (perceived) health, wellbeing and dietary improvements.
Why?	• The SALUD programme is perceived as a positive and meaningful experience for healthy eating behaviour.
How?	• The holistic approach to healthy eating of the SALUD programme resulted in an active and reflective learning process for healthy eating.
Under which circumstances?	• Crucial contextual factors for inciting a learning process for healthy eating are: an emotionally safe place, social support and a positive and encouraging approach. • Active and reflective engagement with the program is a vital prerequisite for the programme to be impactful.

9.5 Strengths and limitations

9.5.1 Strengths

The research project described in this dissertation has several strengths. First of all, this dissertation describes an interdisciplinary study in which two different scientific perspectives on T2DM, health and healthy eating are brought together. Consequently, mixed research methodologies have been applied in both the development and evaluation phase of the intervention programme, providing a more comprehensive understanding of what constitutes an effective intervention for people with T2DM.

Second, the dissertation is theory-based. Theory operationalisation is clarified and the use of theory is also reflected upon. The dissertation contributes to the SMH by providing a better understanding of the phenomenon 'salutogenic intervention'. Furthermore, this dissertation contributes to the nutritional science literature by evaluating the use of an integrated and socioecological theoretical model (= SMH) for dietary programmes.

Third, extensive time has been dedicated to the development of the intervention programme and the development of the intervention has been extensively described. Both the intervention development and the study protocol have been published to maximise transparency and reproducibility of the research project. The advantages of publishing a study protocol is that it forces researchers to really think through the details of their research, and to adhere to a priori study plans/design. Furthermore, publishing the developmental process and the study protocol enables scientific peers to review and evaluate the quality of the theory operationalisation, the subjective choices the researcher(s) made during the process and any a posteriori changes to the study plans/design.

Fourth, the SALUD study is executed as intended (Chapter 6, 7 and 8*)*, albeit with a slightly smaller sample size. In addition, the intervention participants recognised and appreciated salutogenic orientation of the SALUD programme, and the drop-out rate (= 4.5%) was relatively low compared to other T2DM programmes [45]. This all testifies to good fidelity of the delivery

of the SALUD programme and thus indicates high internal validity of the SALUD study.

Fifth, this dissertation has applied a participatory, bottom-up approach in both the development of the SALUD programme and in the SALUD programme itself. This approach increases the external validity of the programme: the fit of the program with the real everyday life context. More importantly, genuinely listening to the needs of the participants was a central research principle, as this is an ethical and respectful way of involving participants in scientific research.

9.4.2 Limitations

The current dissertation also has a number of limitations. First of all, the RCT study was underpowered, which complicates the interpretation of the statistical analysis. Therefore, a replication study with a (considerably) larger sample size seems useful. Establishing a successful recruitment strategy is key in this regard. In this research project, recruitment via health care providers was not very successful, despite including aspects that have been previously identified as facilitating factors in recruiting strategies, such as frequent reminders and a brief recruitment procedure [79]. Getting health care professionals on board was difficult (reasons included being too busy, generally not having enough time an various factors stemming from the COVID pandemic). In addition, only a small amount of the recruiting health care providers actively recruited (and an even smaller part *successfully* recruited participants). The COVID lockdown periods, which overlapped with the period during which the evaluation research was conducted, did not help.

Second, the follow-up period of the SALUD programme is relatively short, which limits drawing conclusions on the sustainability of the health effects. This limitation is unfortunate because the SALUD programme is designed to invest precisely in skills needed for sustainable dietary change. In this (time-bound) research project, there was a trade-off between time for programme development and time for evaluation. The SALUD participants voiced the need of a longer follow-up trajectory, as well (Chapter 8). This message indicates that the programme did not succeed in establishing an autonomous regulation of healthy eating behaviour among all participants.

Third, this dissertation did not measure HbA_{1c} or another T2DM-related biomarker. It would be interesting to assess the SALUD programme's effect on T2DM blood measures. However, it is not expected that such an assessment would alter the present conclusions, because the SALUD programme seems particularly effective for psychosocial wellbeing. Based on the current findings, it is hypothesised that for sustainable healthy eating, attention is first needed for psychosocial wellbeing and coping abilities before physical health effects appear. Hence, medical T2DM indicators of physical health become more important when assessing the long-term effects of the SALUD programme in a possible follow-up study.

Fourth, Chapter 4 demonstrates that flourishing mental health is important for healthy lifestyle

behaviours of people with T2DM. In addition, SoC is an important predictor of mental health [38,39] and salutogenic interventions seem particularly effective for improving mental health [13]. In retrospect, it might have been interesting to include mental health as a study outcome and to explore associations between SoC and mental health more deeply. Although quality of life and mental health are not synonymous, Chapter 7 indicates that the effects of the SALUD program are stronger on SoC than on quality of life, which may indicate that SoC is a precondition for having flourishing mental health. More research is needed to further elucidate the relationships between SoC, mental health, and healthy eating after a salutogenic intervention.

Fifth, people with T2DM in disadvantaged socioeconomic situations were less represented in the evaluation of the SALUD programme (Chapters 7 and 8), which limits the generalisability of the present conclusions to this group. It seems likely that external resources such as high food prices and food availability are more important in socioeconomic disadvantaged situations than what has been observed in this dissertation [34].

Finally, the SALUD programme was developed *before* and evaluated *during* the COVID-19 pandemic. The COVID-19 pandemic can be seen as an extreme and collective stressor, which caused an unique situation in which the everyone's everyday lives was were disturbed due to lock down measures and social isolation. The added complexity to everyday life due to the COVID-19 pandemic may have made it more difficult for some of the SALUD participants to implement healthy eating changes. Indeed, research shows that for people with T2DM, the COVID-19 pandemic led to increased mental stress, overeating, reduced exercise and weight gain, although the effects on glycaemic control are not univocal [80–84]. On the other hand, the COVID-19 context might have added meaningfulness to the SALUD experience, as many people with T2DM found themselves having to manage T2DM with minimal or absent support from health care providers during the COVID-19 pandemic [85]. In addition, it was a time in which it was difficult to meet new people and to organise social gatherings. Nevertheless, the SALUD program was unquestionably evaluated in an extraordinary context, which may have influenced the external validity of the evaluation studies.

9.6 Conclusions and recommendations

Objective 1: Establish what a salutogenic intervention entails.

The first conclusion of this dissertation is that a salutogenic intervention distinguishes from traditional strategies by its holistic, flexible, encouraging and supportive approach to healthy eating. The research project contributed to a more comprehensive understanding of what salutogenic interventions entail. For the first time, the SMH was explicitly translated in guiding principles for a salutogenic intervention (**Table 9.2**). These principles were applied, evaluated and reflected upon, and they can be used for future research.

Objective 2: Determine how to develop a salutogenic intervention for enabling healthy eating among people with T2DM.

The second conclusion is that salutogenic interventions requires a participatory developmental approach that prioritises that participants can steer the intervention to topics that are most important to them. This open, unstructured developmental process uncovered important resources for healthy eating for people with T2DM in everyday life: a flexible and creative approach to eating, flourishing mental state, self-monitoring blood-glucose, disease acceptance, stress management and social support. This process also revealed that the (in)ability to eat healthily should be considered in light of the life course perspective: temporal influences and access to (psychosocial) resources strongly impact eating behaviour.

Objective 3: Assess the use of a salutogenic intervention for people with T2DM.

Finally, this research project delivered a concrete, web-based, and salutogenic dietary programme for people with T2DM. The salutogenic orientation of the SALUD programme resonated with the participants resulting in increased SoC. The combined qualitative and quantitative evaluation supports the conclusion that the SALUD participants found healthier ways of organising eating and dietary intake in their everyday lives. The findings argue that centring meaningfulness of healthy eating in everyday life can effectively contribute to the process of dietary change, improved health, wellbeing and (eventually) weight loss. Together, this dissertation advocates for a greater emphasis in T2DM health care on reflexivity, psychosocial well-being and social support in dietary guidance of people with T2DM. Thus, salutogenic dietary programmes for people with T2DM is an interesting and promising avenue to further explore.

9.6.1 Practical recommendations for the Dutch T2DM primary care

This section addresses the overarching aim of this dissertation: gathering insights for optimisation of the Dutch T2DM care. The previous paragraphs show that healthy eating is a complex social phenomenon that requires a strategy that consists of multiple elements. Recently, there has been increased political interest in implementing lifestyle as an integral part in health care in the Netherlands: the Dutch Ministry of Health, Welfare and Sports agreed to make funds available for a broad 'lifestyle coalition' from 2023 onwards (*Coalitie Leefstijl in de Zorg;* [86,87]). Based on this dissertation, the following insights can be derived of the SALUD programme to further optimise patient-centred T2DM care in the Netherlands:

1. Use a health-based rather than a weight-based dietary strategy.

This dissertation argues for investment in salutogenic, (= holistic, *health*-based) rather than *weight*-based approaches for sustainable dietary change. This dissertation shows that a health-based strategy translates to guiding people to a flexible and creative approach to healthy eating, through which eating becomes (again) a more integral and normal aspect of everyday life. In this regard, a flexible and creative approach to healthy eating can avoid the health-damaging aspects of dieting among people with T2DM. Based on this dissertation, a flexible and creative

approach to healthy eating also requires attention to strategies that contribute to flourishing mental health (particularly social support, disease acceptance and stress management strategies). In the context of T2DM, self-monitoring blood glucose can help in understanding one's body better, although it seems that technical instructions need to be complemented with reflective and holistic guidance for a flexible and creative approach to healthy eating.

2. Listen to personal stories.

Unique to the SMH is the central role of experiencing meaningfulness in everyday life activities. Meaningfulness in the SMH refers to the quality of the motivation rather than to the quantity of motivation to engage in a behaviour. Self-determination theory also advocates that the type/quality of motivation (extrinsic vs intrinsic) is more important than the amount of motivation [88]. However, a difference is that the SMH defines meaningfulness on a deeper level: meaningfulness is more than experiencing autonomy or self-efficacy; it is about experiencing autonomy *while* being acknowledged and seen by others. Throughout the dissertation's chapter, the importance of feeling seen and acknowledged by others is considered important for healthy eating, as well as guiding people with T2DN towards more physical activity within the health care sector [89]. It can be argued that providing room for sharing and listening to personal experiences in a health care setting is an important aspect in itself for lifestyle change. At the very least, it is a way to acknowledge the client and make the client feel seen. However, sharing and listening to stories can be even more powerful; for example, discussing and investigating the temporal and contextual influences on eating behaviour together with a client can have a beneficial effect on disease acceptance (Chapter 8). If a health care provider is able to understand the everyday life world of the client, (s)he may find a way to frame healthy eating in a way that is meaningful for the client. When a client prioritises diet less than a health care provider wishes to see, it might be worthwhile to investigate why this is the case. Incorporating reflective tools such as timeline exercise (as used in Chapter 3) may be useful in stimulating clients to reflect on and share experiences. Giving space to sharing and listening to personal stories may offer a bridge between the objective, biomedical world and the subjective, everyday world in which people live.

3. Value authentic interactions in T2DM health care.

This dissertation shows that, for people with T2DM, authentic interactions that are characterised by open, non-judgemental and positively encouraging communication are extremely important to be able to work on health goals. Opening-up and sharing personal life stories requires a setting in which clients feel (emotionally) safe (Chapter 8). Talking about health and eating behaviour is not easy, because many people with T2DM feel ashamed about their disease or feel that they failed when they regained weight after a previous attempt at dieting (Chapter 3). Health care professionals have also voiced that establishing an authentic personal connection is necessary to promote healthy eating among clients with T2DM [20,21]. In addition, boosting positive emotions of clients with T2DM seems to be something important on its own. At the very least, discouraging approaches, guilt trips, and shaming or scaring clients should be avoided [33].

Lifestyle coaches in particular are encouraged to maximise the enjoyability of the programme they offer. In the SALUD programme, participants specifically enjoyed group-sharing, positive encouragement/compliments of the coach, mindful eating exercises and fun little home exercises, such as collaboratively creating a cook book.

However, currently the Dutch T2DM health care organisation does not offer enough room for these delicate interactions between professional and client, nor does it value the importance of these interactions enough due to strict protocols, limited time available for consultations and a biomedical-oriented focus. This is frustrating, both for people with T2DM as well as for professionals. Both parties deserve a health care system that acknowledges the importance of these intangible and delicate aspects for meaningful and effective T2DM care.

4. Consider the timing of (dietary) interventions in light of the life course.
For some people, a T2DM diagnosis opens up a window of opportunity for dietary change, but not for all. Change depends on one's life circumstance and the (psychosocial) resources that are available at that time. However, life is everchanging: someone might not be in an ideal situation to work on dietary change today, but they might be tomorrow or next year. Therefore, it is important for health care providers to remain curious about their patients: the majority wants to become healthier if the circumstances allow for this. In addition, it is important to consider the timing of referral to a dietician or dietary/lifestyle programme, because the success of the referral depends on the client's current phase of life. If a client is temporarily not in the right circumstances to actively change dietary practices, care could be dedicated to discussing more immediately pressing issues. Within the limits of current health care systems, this could be done by investing in a mutual relationship based on trust by simply asking how someone is doing. Small acts of kindness, such as giving compliments and showing interest, can have a big impact on a client's health.

5. Facilitate trust and social connectedness.
This dissertation displays the importance of social support in the process of dietary change. Connecting to, sharing with and learning from peers is considered one of the most valued aspects of the SALUD programme. However, T2DM consultations are typically individual. Hence, it would be interesting to explore ways in which the health care system facilitates people with T2DM to connect in a meaningful way. One way of doing this is during (group) lifestyle interventions. This dissertation shows that investing in mutual trust among group members and the coach is essential for enabling high quality peer support. In the SALUD programme, the first session was dedicated to 'building trust' and social connectedness, and this was something which was invested in continuously for every subsequent session. Hence, 'just' putting people in a group is not enough: establishing mutual trust and social connectedness should be an explicit priority in a (dietary) intervention. In addition to lifestyle interventions, another way to facilitate peer support is via walking groups under supervision of a health care provider or a T2DM 'role' model. T2DM

walking groups already exist in the Netherlands: since 2015, the *Bas van de Goor Foundation* has organised the yearly National Diabetes Challenge: an initiative that organises walking groups that train together towards a walk of a maximum of fifteen kilometres by training once a week in the group and twice a week individually [90]. Walking stimulates a spontaneous and informal setting for self-reflective thinking [91] and sharing personal stories [89]. Adding walking groups to the SALUD programme may amplify the programme's health effects. This addition might be a way to break through the established biomedical health care protocols and offer room for a holistic, flexible and supportive approach to guide dietary change among people with T2DM.

9.6.2 But who's going to pay for it?

Although a cost-benefits analysis is beyond the scope of this dissertation, the afore mentioned recommendations do not necessarily result in more consultations/time per client, nor extra time from the health care provider, nor more (collective) health care costs. These recommendations suggest a different emphasis within care, such as the type of conversations and the quality of the interactions. The recommendations argue for a more flexible and spontaneous interpretation of the T2DM health care system. In addition, organising care in groups may be very time-efficient. In an ideal scenario, peer support groups are a shared responsibility between health care professional and clients. For example, a health care professional – a practice nurse, dietician or lifestyle coach – is involved in setting up the peer support groups, and an experienced participant takes over this role over time. The health care professional checks in with the group from time to time. However, implementing peer support into T2DM care does require that the organisation of peer support activities is recognised as an integral part of the job of the health care professional: it should be a paid activity during working hours, not something extra on top of the (already overloaded) workload. This is for example why most GP practices find it difficult to offer the National Diabetes Challenge as a permanent service, because the walking groups depend largely on motivated health care professionals that organise the National Diabetes Challenge 'for free' [92]. In addition to GPs and practice nurses, this dissertation shows that lifestyle coaches can assist in organising peer-supportive and reflective activities for people with T2DM. Lifestyle coaching is an up-and-coming profession in the Netherlands, and lifestyle coaches are specifically skilled in coaching techniques. In other words, practice nurses and GPs do not have to take on an extra responsibility and additional training courses. A final argument for taking the leap to more salutogenic-oriented care is the current care is not effective enough: medical consultations are also a waste of money and time if a client does not feel safe, understood or supported.

9.6.3 Recommendations for science

Based on the research work described in this dissertation, the following set of recommendations is recommended for future research:

1. Stimulate interdisciplinary research in social and nutritional sciences.

From my experience, working within two research disciplines broadens the horizon of a researcher

tremendously. It makes one aware of different research paradigms, differences in research priorities and different views on how research should be conducted. In addition, working within two disciplines exposes researchers to a broader array of research methodologies, both quantitative and qualitative. This exposure forces researchers to assess and reflect how they relate to these different paradigms. Combining different paradigms can lead to synergy: optimising the application of already available knowledge and stimulating creativity in new research ideas and strategies. At the same time, operating in different paradigms is also a challenge: in practice, scientists do not always seem to understand each other equally well due to differences in communication, unawareness of being of part of a certain paradigm and incomprehension of different views. Researchers with interdisciplinary-training may bring different disciplines (and researchers) closer together, which seems highly needed for complex issues such as treating and preventing chronic diseases such as T2DM [33,93]

2. Take your time for intervention development.

Researchers have a great deal of power in knowledge creation by formulating the research questions, deciding on the analytical frame and determining what should be included in an intervention and what not. When developing an health-promoting intervention, I recommend 1) a clear theory operationalisation; 2) a combination of qualitative and quantitative research to gather insights for the programme's content and structure; 3) a participatory approach to integrate the explorative findings; 4) a validation step to correct for researchers' subjective interpretations; and 5) a transparent and detailed description of the intervention's developmental process, content and the study protocol. These steps demonstrate good scientific practice as they force researchers to critically self-reflect and enable critical inspections of scientific peers. In addition, sharing personal doubts, questions and uncertainties with fellow scientists/colleagues is essential throughout developing an intervention programme. Finally, I emphasise the importance to reserve enough time for the practical implementation of an intervention and ensuring facilitating resources in an early stage, such as the METC procedure, participant recruitment and communication, particularly in time-bound projects such as most (Dutch) PhD projects. Specifically, participant recruitment via health care providers requires a continuous effort of the researcher(s) to motivate and engage recruiters – a time-consuming task. Recruitment via local newspapers was more successful in this research project. A recent systematic review indicated that web-based recruitment strategies are superior in regard to time and cost-effectiveness compared to 'off-line' recruitment strategies [95]. Hence, these type of strategies are advised to consider for future research.

3. Use both quantitative and qualitative methods for intervention evaluation.

This dissertation demonstrates that combining quantitative and qualitative methods enables a more comprehensive understanding of the effectiveness of the intervention as well as of crucial contextual factors. This understanding is particularly important for salutogenic interventions, because RCTs are not designed to evaluate these type of interventions and because there are

continuous interactions between intervention, implementation and everyday life context [46,94]. Information on the contextual factors and the mechanisms of an intervention is important for policy makers in order to adapt interventions into a specific context. Hence, both quantitative and qualitative effect assessment of multi-component interventions is recommended to inform policy makers as well as possible and to facilitate effective implementation in practice.

4. Re-evaluation of psychosocial health outcomes in health research.
This dissertation calls for further exploring the potential of interventions that focus on the process of behaviour change relative to its (immediate) outcomes. This focus also implies a re-evaluation of psychosocial and behavioural health outcomes in T2DM research [78]. Based on SMH and self-determination theory, alternative indices of success (besides HbA_{1c} or weight) could be increased SoC or perceived autonomy around T2DM self-management, finding personal meaning in eating healthfully and displaying a more flexible and positive relation to food and diet. To assess these alternative indices of success, standardised and validated quantitative instruments are needed (NB in Chapter 2, it was noticed there was great heterogeneity in the definitions and instruments used for psychosocial health). Considering that psychosocial and process-oriented outcomes are less straightforward than physical measures for dietary change, a combination of quantitative and qualitative measures may aid the interpretation of the success of a dietary intervention.

9.7 Take-home message

With this dissertation, I hope to provoke thought and discussion about the topic of healthy eating in T2DM care in order to contribute to its further improvement (**Box 9.3**). Healthy eating is a complex social phenomenon, and, thus, dietary change requires a different approach than pathogenic or medical issues. The dissertation provides a good illustration of the potential of an alternative, salutogenic approach to support people with T2DM in eating healthier. The findings encourage further investment in holistic, flexible and supportive dietary guidance centred around the personal meaningfulness of healthy eating in everyday life. Offering room for sharing and listening to personal stories and self-reflection as well as facilitating peer support is fundamental. More room for sharing and listening can help to make the T2DM care more effective and not necessarily more expensive. A more salutogenic-oriented T2DM care may also make the work of health care professionals regarding lifestyle guidance more meaningful and rewarding. It is interesting to further explore possibilities where salutogenic approach can be inserted to complement the current (biomedical) T2DM health care, e.g. within lifestyle intervention and walking groups, particularly, given the recent political interest in implementing lifestyle as integral part in health care in the Netherlands (*Coalitie Leefstijl in de Zorg).* Although these initiatives can only be applauded, it should be acknowledged that individual-oriented approaches are only a part of the solution. This dissertation emphasises that, for effective T2DM prevention and treatment, attention should be simultaneously given to the systemic and societal influences that impact one's opportunities to create healthy eating behaviours along the life course.

Box 9.3 Future perspectives

What was known before this research project?

Dietary interventions based on weight loss diets and performed in highly-controlled research settings can reverse T2DM. Dietary T2DM interventions that primarily focus on what people should (not) eat are not effective enough as people experience difficulties when they return from these clinical and controlled research settings to their everyday lives.

What does this research project add?

This research project adds to the literature by showing that dietary change in a real-world, everyday life setting requires a different approach than a pathogenic approach. This research project describes an alternative, salutogenic approach characterised by holistic, flexible and supportive dietary guidance and focusses on why people eat in everyday life.

How to proceed?

Previous research showed that internalising motivation for healthy eating leads to sustainable dietary changes. Therefore, it is recommended to explore and invest in dietary ways that not only focus on what people with T2DM should eat, but also why they eat. Offering space for listening to personal stories of clients and facilitating peer support within the Dutch T2DM health care system seem useful for enabling healthy eating in the everyday life.

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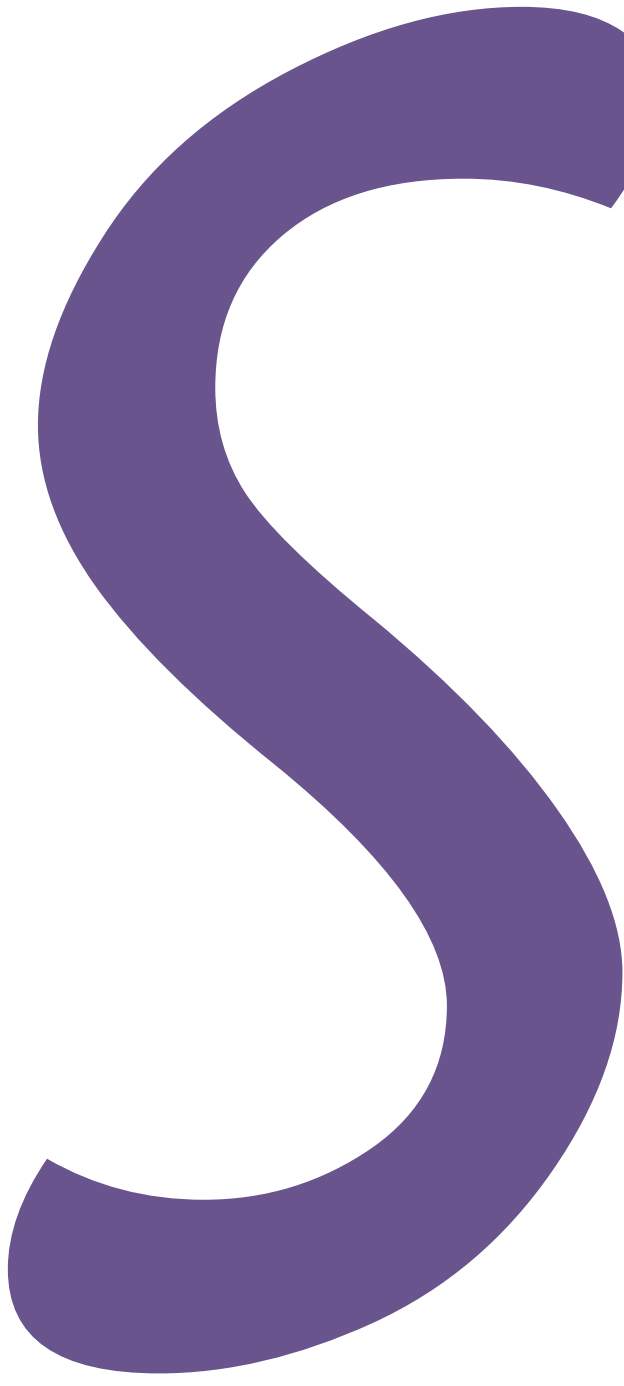


Summary

English summary

This doctoral dissertation describes an interdisciplinary research project that combines nutritional and social sciences in order to develop and evaluate a dietary intervention programme that enables healthy eating among people with type 2 diabetes mellitus (T2DM). T2DM is a disease that can potentially be reversed by improved dietary intake. Biomedical, pathogenic-oriented dietary interventions were able to reverse T2DM using strict diets in highly-controlled (research) settings. However, people seem to find it difficult to maintain these diets when they return to their everyday settings. The present dissertation uses the salutogenic model of health (SMH) to broaden the research lens on dietary programmes for T2DM by focussing on the everyday life context in which people with T2DM have to organise dietary change.

The overarching aim of this dissertation is to gather new insights for optimising the Dutch T2DM care. A mixed research design, using both quantitative and qualitative research methods is employed to investigate three research objectives: 1) to establish what a salutogenic intervention entails; 2) to determine how to develop a salutogenic intervention to enable healthy eating among people with T2DM; and 3) to assess the use of a salutogenic intervention for healthy eating among people with T2DM (**Chapter 1**). The salutogenic intervention that has been developed and evaluated in this dissertation is named the Salutogenic Intervention for Type 2 Diabetes (SALUD) programme. This dissertation starts with describing how the salutogenic intervention programme 'SALUD' was developed (**Chapters 2-6**), followed by its extensive effect evaluation (**Chapters 7 and 8**).

Developmental process of the SALUD programme

The developmental process started with operationalising the three key principles for salutogenic interventions: the participants as a whole, the participant's active involvement, and the participant's individual learning process (**Chapter 2**). In addition, these operationalised principles were applied in a literature search to provide some first insight on what a salutogenic intervention should look like. The findings show that most interventions that can, to a certain extent, be considered salutogenic were found to improve physical health or psychosocial health or both. The characteristics of the effective salutogenic-oriented interventions included 1) development based on participatory research, 2) the programme is culturally targeted, and 3) the programme is delivered in 10–20 sessions 4) within group settings. The chapter also uncovered important points to specify our operationalised salutogenic principles.

The second main step in the developmental process was to qualitatively investigate how and why the eating practices of adults with T2DM are developed over the life course via in-depth life course interviews (**Chapter 3**). This chapter demonstrates the strong temporal influence of past experiences on present eating behaviour. Adverse childhood experiences followed by an unequal share of hardship in later life deprive people from developing strong psychosocial

resources important for both managing emotional stress and healthy eating. Turning points along the life course that induced unhealthy eating are experiences that disturbed one's emotional stability through strong feelings of mental stress. Turning points that induce healthy eating are experiences that significantly change people's views on life, future health and (life) goals. One particularly powerful experience that can incite drastic and long-lasting dietary improvements is a confrontation with ill-health. A stress-free state-of mind, a flexible approach to eating, disease acceptance and feeling supported seem crucial for healthy eating practices.

The third main step of the developmental process describes a cross-sectional study based on web-based survey data that examines the relationships between mental health and lifestyle behaviours among people with T1DM and T2DM (**Chapter 4**). People with T2DM with flourishing mental health had a healthier diet and were more physically active compared to those with T2DM and moderate mental health. These associations were not found in people with T1DM.

Based on these steps, **Chapter 5** describes the participatory developmental process of the salutogenic intervention of people with T2DM: the SALUD programme. The chapter demonstrates clearly and transparently how five qualitative and quantitative sources were integrated in a coherent intervention programme via a qualitative process (i.e. focus groups). The integration resulted in a dietary programme that was characterised by a holistic, flexible, encouraging and supportive approach to healthy eating. This approach is what distinguishes the SALUD programme from most previous T2DM dietary programmes. The main strategies of the SALUD programme are focussed on guiding people towards developing self-identity and social support. In **Chapter 6,** the study protocol for the effect evaluation of the SALUD programme is outlined. The effect evaluation consists of a randomised controlled trial (RCT) in which the SALUD programme is compared with the Dutch usual care for T2DM and of a qualitative investigation regarding if, why, how and under which circumstances the SALUD programme does or does not work.

Evaluation of the SALUD programme

First, the outcomes of the RCT are discussed in **Chapter 7**. The SALUD programme is statistically effective for enhancing the sense of coherence, a measure that reflects a pervasive, enduring, though dynamic feeling of confidence towards life. The results are promising for food literacy, diet quality and body weight, as both groups improved in these outcomes with consistently greater improvements in the intervention group that seemed to sustain themselves at follow-up, albeit not to a statistically significant degree. Second, the qualitative investigation of how the participants experienced the content and meaning of the SALUD programme is discussed (**Chapter 8**). Participants experienced the SALUD programme as a positive and meaningful learning process, in which they developed new coping strategies, gained new self-insights and perceived improved overall health. Contextual factors that seemed crucial for inciting a learning process for healthy eating are an emotionally safe place, a positive and encouraging coach, peer support and a holistic and reflective approach to healthy eating. Psychosocial health effects were

mostly emphasised, but improved physical effects were mentioned, as well. The deviant case demonstrated that active and reflective engagement with the programme is a vital prerequisite for the programme to be impactful.

Overall conclusions and recommendations

The challenge throughout all chapters was to combine contrasting research approaches in a meaningful and fair way. **Chapter 9** describes the integration of and reflection upon the previous chapters. This reflection led to the three main conclusions:

1. A salutogenic intervention distinguishes itself from traditional strategies by its holistic, flexible, encouraging and supportive approach to healthy eating. This research project resulted in a more comprehensive understanding of what salutogenic intervention entails and clarity on its distinguishing characteristics.
2. A salutogenic intervention requires a participatory developmental approach. This open, dynamic developmental process uncovered important resources for healthy eating for people with T2DM in everyday life. This process also revealed that the (in)ability to eat healthily should be considered in light of the life course perspective: temporal influences and the access to (psychosocial) resources strongly impact eating behaviour.
3. A concrete, web-based and salutogenic dietary programme for people with T2DM is successfully delivered. The combined qualitative and quantitative evaluations argue that the salutogenic approach successfully supports people with T2DM in eating healthier. The findings imply the need to further invest in holistic, flexible and supportive dietary guidance that is centred around the personal meaningfulness of healthy eating in everyday life.

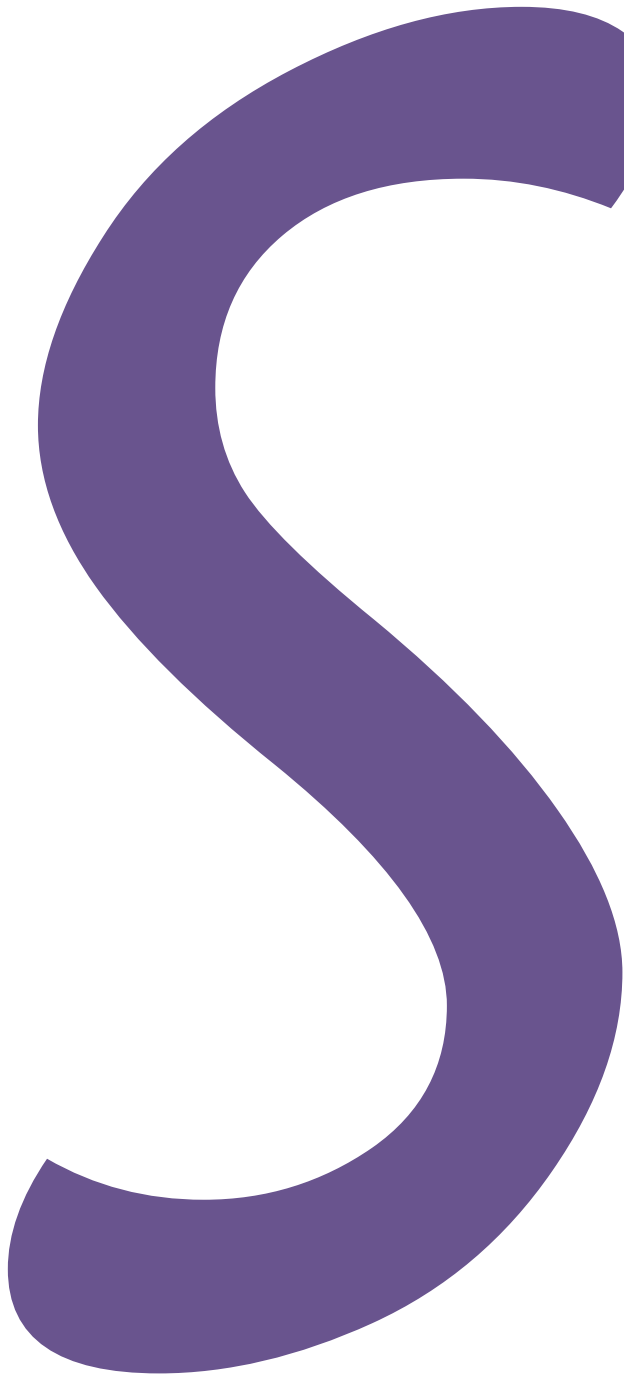
Together, this dissertation advocates for a greater emphasis in T2DM health care on reflexivity, psychosocial wellbeing and social support in dietary guidance of people with T2DM. Salutogenic dietary programmes for people with T2DM is an interesting and promising avenue to further explore. The traditional biomedical-positivist-oriented health care practice may be complemented by the following five salutogenic recommendations based on this dissertation:

1. **Use a health-based rather than a weight-based dietary strategy:** Investing in salutogenic, (= holistic, *health*-based) rather than *weight*-based approaches can lead to sustainable dietary change. A health-based strategy translates to guiding people to holistic, reflective and supportive guidance towards a flexible and creative approach to healthy eating.
2. **Listen to personal stories:** Giving space to sharing and listening to personal stories may offer a bridge between the objective, biomedical world and the subjective, everyday world people live in. Space for sharing and listening makes clients feel seen and acknowledged, and may offer opportunities to frame healthy eating to clients in meaningful ways.
3. **Value authentic interactions in T2DM health care:** People with T2DM find authentic attention extremely important for working on health goals. Opening up and sharing

personal life stories requires a setting in which clients feel (emotionally) safe.

4. **Consider the timing of (dietary) interventions in light of the life course:** Consider the (in)ability of a client to eat healthily in light of the life course perspective. This perspective implies that at certain times or phases in life, dietary change is easier or more difficult. Therefore, it is important to consider the timing of referral to a dietician or dietary/lifestyle programme. If a client is temporarily not in the right circumstances to actively change dietary practices, care could be dedicated to discussing the issues that are more pressing at that moment.
5. **Facilitate trust and social connectedness:** Connecting to, sharing with, and learning from peers is considered one of the most valued aspects of the SALUD programme. The health care system may benefit from creating opportunities for meaningful peer support. One way of doing this is during (group) lifestyle interventions. Another way is via walking groups under supervision of a health care professional or a T2DM 'role' model.

With this dissertation, I hope to provoke thought and discussion about the topic of healthy eating in T2DM care in order to contribute to its further improvement. Healthy eating is a complex social phenomenon and, thus, dietary change requires a different approach than pathogenic or medical issues. It is worthwhile to further explore possibilities where salutogenic approach can be inserted in order to complement the current (biomedical) T2DM health care, particularly given the recent political interest in implementing lifestyle as an integral part in healthcare in the Netherlands.



Samenvatting

Nederlandse samenvatting

In dit proefschrift wordt verslag gedaan van een interdisciplinair onderzoeksproject waarin voedings- en sociale wetenschappen zijn gecombineerd. Het overkoepelend doel van dit onderzoek is een bijdrage te leveren aan het verbeteren van de zorg voor mensen met diabetes mellitus type 2 (DMT2) (**hoofdstuk 1**). DMT2 is een ziekte waarbij het lichaam niet meer goed reageert op insuline. Insuline is een hormoon dat het suiker in het bloed regelt. Als het lichaam niet meer goed op insuline reageert, blijft er te veel suiker in het bloed achter. Te veel suiker in het bloed kan op termijn hart, bloedvaten, nieren, zenuwen of het netvlies beschadigen.

Gezonde voeding is belangrijk voor de behandeling van DMT2. Onderzoek laat zien dat gezonde voeding net zo effectief kan zijn als diabetesmedicatie en dat men zelfs helemaal kan genezen door een streng dieet. Tegelijkertijd blijkt uit onderzoek dat mensen het lastig vinden om eetgewoontes aan te passen en diëten vol te houden. In Nederland is steeds meer (politieke) aandacht voor een gezonde leefstijl als onderdeel van de gezondheidszorg. Het is nog niet duidelijk welke wat de beste manier is om leefstijl in te bedden in de gezondheidszorg. Dit proefschrift draagt bij aan deze discussie door het beschrijven van de ontwikkeling en evaluatie van een programma dat mensen met DMT2 ondersteunt om gezonder te gaan eten en leven, en om dat voor een langere tijd vol te houden.

Het onderzoeksproject gaat uit van het salutogene model van gezondheid. Dit model richt zich op factoren die de *gezondheid bevorderen*. Dit is een vernieuwend perspectief, omdat de traditionele gezondheidszorg zich voornamelijk richt op de factoren die *ziekte* veroorzaken. Het salutogene programma dat in dit proefschrift is ontwikkeld en geëvalueerd heet 'Salutogenic Intervention for Type 2 Diabetes' (afgekort: SALUD). Het onderzoeksproject bestaat uit twee fasen: het ontwikkelen van SALUD en de evaluatie van SALUD. In beide fasen zijn kwantitatieve en kwalitatieve onderzoeksmethoden gecombineerd.

Ontwikkeling van SALUD

De **hoofdstukken 2 t/m 6** beschrijven de ontwikkeling van SALUD. Het ontwikkelingsproces bestond uit drie stappen. De eerste stap was het vaststellen van de uitgangspunten van een salutogeen programma (**hoofdstuk 2**). Om een eerste indruk te krijgen hoe een salutogeen programma voor mensen met DMT2 eruit zou moeten zien is met behulp van literatuuronderzoek onderzocht in hoeverre bestaande leefstijlprogramma's voor mensen met DMT2 voldoen aan deze uitgangspunten. In totaal zijn 28 programma's geïdentificeerd en deze zijn met elkaar vergeleken wat betreft de ontwikkeling, inhoud, opzet en effectiviteit. De tweede stap in het ontwikkelingsproces van SALUD was het interviewen van mensen met DMT2 over hun levensloop om te onderzoeken hoe en waarom hun eetgewoonten zich ontwikkelden over de tijd (**hoofdstuk 3**). In dit hoofdstuk zijn zogenoemde levensloopkeerpunten van mensen beschreven die aanzetten tot gezond dan wel ongezond eten. Een moeilijke jeugd, gevolgd door veel tegenslagen in het

latere leven, gaven mensen minder kans om te investeren in belangrijke hulpbronnen om gezond te eten. Om gezond te kunnen eten blijken de volgende hulpbronnen belangrijk: een stressvrije geest, een flexibele houding ten opzichte van eten, acceptatie van DMT2 en het ervaren van steun uit de directe sociale omgeving. Stap drie van het ontwikkelingsproces van SALUD was het onderzoeken van verbanden tussen mentaal welzijn en leefstijl voor mensen met diabetes type 1 en type 2. Hierbij is gebruik gemaakt van een uitvoerige vragenlijst (**hoofdstuk 4**). Het bleek dat mensen met DMT2 met een goede mentale gezondheid een gezonder voedingspatroon hadden en meer bewogen dan mensen met DMT2 met een matige mentale gezondheid. Deze verbanden werden niet gevonden bij mensen met diabetes mellitus type 1.

Hoofdstuk 5 beschrijft hoe deze drie ontwikkelingsstappen uiteindelijke hebben geleid tot het online SALUD programma. SALUD onderscheidt zich van eerdere programma's voor mensen met DMT2 door een holistische, flexibele, aanmoedigende en ondersteunende benadering van gezonde voeding. In deze benadering wordt expliciet rekening gehouden met de betekenis van eten in het dagelijks leven. Door het SALUD programma krijgen mensen met DMT2 inzicht in wie ze zijn en hoe ze sociale steun kunnen organiseren.

Hoofdstuk 6 beschrijft het studieprotocol voor de effectevaluatie om de gezondheidseffecten van het SALUD programma vast te stellen. De effectevaluatie bestond uit twee delen:

1. een gerandomiseerde en gecontroleerde trial die de kwantitatieve effecten van SALUD op eetgewoonten, fysieke en psychosociale gezondheid meet;
2. groepsinterviews met de deelnemers van het SALUD programma om te onderzoeken of, waarom, hoe en onder welke omstandigheden het SALUD programma wel of niet werkt.

Effectiviteit van SALUD

In **hoofdstuk 7** zijn de kwantitatieve uitkomsten van de gerandomiseerde en gecontroleerde trial beschreven. De studie bestond uit 23 mensen die het SALUD programma volgden (experimentele groep) en 22 mensen die de gebruikelijke diabeteszorg volgden (de controlegroep). Beide groepen werden in totaal drie keer gemeten (aan het begin van de studie, na 12 weken en na 24 weken). De metingen bestonden uit lichamelijk onderzoek (gewicht en omtrek van buik en heup) en vragenlijsten over eetgedrag en mentale gezondheid. Uit de statistische analyses blijkt dat SALUD beter in staat is om de 'sense of coherence' te vergroten in vergelijking met de controlegroep. De sense of coherence is een maat die een "gevoel van samenhang" in het dagelijks leven weerspiegelt. De voedselvaardigheden, voedingsinname en het lichaamsgewicht verbeterden statistisch significant over de duur van het programma bij zowel de SALUD deelnemers als bij de deelnemers uit de controlegroep. Er kan niet met zekerheid worden gesteld dat deze verbeteringen in de SALUD-groep zijn veroorzaakt door SALUD of door toeval.

Hoofdstuk 8 beschrijft hoe de deelnemers het SALUD-programma hebben ervaren. Deelnemers

beschrijven het meedoen aan SALUD als een positief en zinvol leerproces, waarin zij nieuwe copingstrategieën ontwikkelden om gezonder te gaan eten, nieuwe zelfinzichten hebben verkregen en zich gezonder voelden. Deelnemers rapporteerden met name een verbetering van de mentale gezondheid, maar ook van de lichamelijke gezondheid, zoals gewichtsverlies, betere bloedsuikerwaarden en minder medicijngebruik. De deelnemers benadrukken dat voor het op gang brengen van dit leerproces de volgende contextuele factoren belangrijk zijn: een emotioneel veilige omgeving, een positieve en aanmoedigende coach, steun van lotgenoten en een holistische en reflectieve benadering van gezond eten.

Algemene conclusies en aanbevelingen

Dit onderzoekproject heeft met succes een concreet, online en salutogeen voedingsprogramma voor mensen met DMT2 ontwikkeld, uitgevoerd en geëvalueerd. Dit proefschrift beoogt een verbetering van de diabeteszorg door mensen met DMT2 aan te zetten tot nadenken en discussiëren over gezonde voeding in de alledaagse context.

Hoofdstuk 9 beschrijft de overkoepelende reflecties die tot de volgende hoofdconclusies leiden:

1. Een salutogeen programma onderscheidt zich van traditionele diabetesprogramma's door de holistische, flexibele, aanmoedigende en ondersteunende benadering van gezond eten. Dit onderzoeksproject heeft geresulteerd in meer duidelijkheid in de onderscheidende uitgangspunten van een salutogeen programma.
2. Een salutogeen programma vereist een open, dynamisch en participatief ontwikkelingsproces. Dit betekent samenwerken met de mensen waar het omgaat en gehoor geven aan de ervaringen en prioriteiten van mensen met DMT2. Zo'n open ontwikkelingsproces bracht belangrijke hulpbronnen in het dagelijks leven aan het licht voor gezond eten voor mensen met DMT2.
3. De gecombineerde kwantitatieve en kwalitatieve effectevaluatie pleit ervoor om verder te investeren in holistische, flexibele en ondersteunende begeleiding waarbij de persoonlijke en sociale betekenis van gezond eten in het dagelijks leven centraal staat.

Dit proefschrift geeft een stem aan wat mensen met DMT2 zelf belangrijk vinden in hun zorg: gezien en gehoord worden, sociale steun van lotgenoten ervaren en een holistische benadering van gezondheid en welzijn. De bevindingen noodzaken tot meer nadruk in de gezondheidszorg op reflexiviteit, psychosociaal welzijn en sociale steun bij gezondheidsbevordering voor mensen met DMT2. Het is de moeite waard om mogelijkheden te verkennen waar een salutogene gedachtengoed kan worden gebruikt om de huidige diabeteszorg verder te verbeteren. De volgende aanbevelingen voor de diabeteszorgpraktijk volgen uit dit onderzoek:

1. **Richt je op gezondheid in plaats van op (alleen) gewicht en suikerwaardes:** De deelnemers van SALUD waardeerden de holistische, reflectieve en ondersteunende begeleiding van

gezond eten. Dit dient zich te vertalen in een flexibele en creatieve benadering van gezond eten die makkelijk te implementeren is in het dagelijks leven.

2. **Luisteren naar persoonlijke verhalen:** Er is meer ruimte nodig voor delen van en luisteren naar persoonlijke verhalen van cliënten met DMT2. Dit geeft cliënten het gevoel dat ze gezien en gehoord worden.
3. **Waardeer oprechte interacties:** Het gesprek aangaan over eetgedrag/gewoontes is vaak lastig, want voor veel diabetescliënten is het een gevoelig en beladen onderwerp. Dit onderzoek geeft indicaties om dit op een goede manier te doen: het creëren van een omgeving waarin cliënten zich (emotioneel) veilig voelen en een positieve en aanmoedigende zorgverlener. Dit vereist investeren in een goede vertrouwensband tussen zorgverlener en client.
4. **Overweeg de timing van (voedings)interventies:** In bepaalde fasen in het leven is het aanpassen van eetgewoonten moeilijker of juist makkelijker. Het is daarom belangrijk om na te denken over het moment van doorverwijzing naar een diëtist of voedings-/leefstijlprogramma. Als een cliënt tijdelijk niet in de juiste omstandigheden verkeert om eetgewoonten te veranderen, is het beter om zorg te besteden aan het bespreken van de zaken die op dat moment belangrijker zijn.
5. **Vertrouwen en sociale verbondenheid bevorderen:** Contact maken met, delen met en leren van lotgenoten werd beschouwd als een van de meest gewaardeerde aspecten van SALUD. De gezondheidszorg kan baat hebben bij het creëren van mogelijkheden voor zinvolle ontmoetingsplekken voor en ondersteuning door lotgenoten. Dit kan bijvoorbeeld in (groeps)leefstijlinterventies of door het organiseren van wandelgroepen.

About the author

Curriculum Vitae

Christina Maria Martina Polhuis was born on 26 January 1993 in Hilversum, the Netherlands. She is named after her grandfather Christiaan Marinus Polhuis, both her grandmothers Maria Martina Koppejan and Maria Pas and her mother Leonie Maria Polhuis-Pas. However, in everyday life, she goes by Kristel. At 3 years old, she moved with her family from Hilversum to Leeuwarden, where she graduated from the *Stedelijk Gymnasium Leeuwarden* with her high school diploma in 2011.

Kristel always enjoyed learning and had a broad interest in a variety of topics, such as biology, health, philosophy, archaeology, arts and literature. Her interest in nutrition and how foods interact with the body was evoked by her severe food allergies. Kristel was fascinated by the fact that healthy nutrition is a relative concept: foods – like nuts – that are healthy to most people are extremely dangerous for her. In addition, Kristel always enjoyed helping her mother with grocery shopping and cooking (thanks to her mother, she thought that risotto, pilaf and gado-gado were part of the traditional Dutch cuisine). To learn more about the interactions between food and health, she moved to Wageningen to study nutrition and health at Wageningen University & Research (WUR) in 2011. She graduated with her BSc Nutrition and Health (thesis on the underlying mechanisms of altered taste perception and food preferences after roux-and-y gastric bypass surgery) in 2014 and her MSc degree Nutrition and Health in 2016 (thesis on optimal carbohydrate content for medium-chain and long-chain triglycerides metabolism and a second thesis on the effect of whole body vibration on physical activity, nutritional intake, sleep behaviour, cognition and mood). During her MSc study, she participated in a research honours track.

After her MSc graduation, she first worked as a research-assistant at the department of Nutrition and Health (WUR) on a project to develop a short food questionnaire (*de Eetscore*; a tool she later used in this PhD research). Thereafter, she worked as a junior-researcher at the Dutch Beer Institute (*Kennisinstituut Bier*). These jobs made Kristel realise that she wanted to do research she was entirely responsible for by herself. It was meant to be: she started her PhD research at the Social Sciences Group and at the department of Nutrition and Health at WUR in April 2017, which resulted in this dissertation. In her PhD research, Kristel finally had the opportunity to learn more about topics that she missed during her BSc/MSc studies: the social context embedding nutrition and health behaviour and how to study this. The most exciting aspect of this PhD project was that the project allowed for working with multiple scientific disciplines, which suits Kristel's natural curiosity and broad interests. During this PhD project, Kristel published several articles, presented at (inter)national conferences, supervised multiple BSc and MSc students (who wrote their theses as part of the project), coordinated a BSc course, and lectured in several courses offered by the chair group Health and Society.

Besides being a scientist Kristel is a group-fitness instructor since the age of 16. She started with an aerobics class and a variety of sports classes followed over the years. Currently, she teaches two times a week Pilates. Kristel considered this side job as essential for maintaining her health during this PhD trajectory.

Kristel is married to Erik Bouman. So, in fact, her name is not Kristel Polhuis after all: officially it is Christina Maria Martina Bouman-Polhuis. Kristel and Erik live a happy life in Wageningen together with their incredible daughters Isabel Leona Maria Bouman (2018) and Rosalie Petra Lena Bouman (2020). In her spare time, Kristel loves to spend time with her family, be outsides, cook, eat, exercise and read.

List of publications

(published and forthcoming)

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2020 **Polhuis, C.M.M.,** Bouwman, L.I., Vaandrager, L., Soedamah-Muthu, S.S., &

Koelen, M.A. Systematic review of salutogenic-oriented lifestyle randomised controlled trials for adults with type 2 diabetes mellitus. Patient Education and Counseling. https://doi.org/10.1016/j.pec.2019.10.017

2017 **Polhuis, C.M.M.,** Wijnen, A. H. C., Sierksma, A., Calame, W. & Tieland, M. The diuretic action of weak and strong alcoholic beverages in elderly men: A randomized diet-controlled crossover trial, Nutrients. 9, 7, 660, 10.3390/nu9070660

International conferences

- 8th Annual Conference of the Association of European Schools of Planning (AESOP): Sustainable Food Planning, Coventry, United Kingdom, **Presentation:** Back to basics: applying a salutogenic approach to understand the origins of healthful eating (2017)
- Salutogenesis Symposium at the 10th International Union for Health Promotion and Education (IUHPE), Trondheim, Norway, **Poster:** From diet to everyday-social life: everyday-life interviews with people with type 2 diabetes mellitus (2018)
- Nutrition Disparity and Equity conference: From differences to Potential, Wageningen, The Netherlands, **Presentation:** Turning points for healthful eating in people with type 2 diabetes mellitus and low social economic status (2020)
- Nutrition Disparity Network (NDN) conference: Values and Nutrition Equity, Wageningen, The Netherlands (online), **Workshop:** Values underlying nutrition sciences: the biomedical approach vs. the anti-diet movement (2021)
- European Federation of the Associations of Dietitians (EFAD), Europe (online), **Webinar:** An introduction to Salutogenesis: how to apply salutogenic principles in your dietetic practice? (2022)
- International Conference on Salutogenesis Advancing Salutogenesis towards thriving societies, Girona, Spain (online), **Workshop**: Discussing a salutogenic intervention for enabling healthy eating in adults with type 2 diabetes mellitus (2022)

National conferences

- VoedingNL, Congres Koolhydraten en insulinegevoeligheid, Utrecht, The Netherlands, Poster: Keerpunten en coping stijlen voor eetgedag van mensen met diabetes type 2 (2020)
- Health & Society Seminar: *From Ottawa to Wageningen: Building healthy societies in a planetary context*, Wageningen, The Netherlands (2023)

Awards

- Nomination Young Professional Award 2020, VoedingNL Congres Koolhydraten en insulinegevoeligheid, Utrecht, The Netherlands.

Kristel (C.M.M.) Polhuis
Wageningen School of Social Sciences (WASS)
Completed Training and Supervision Plan

Name of the learning activity	Department/Institute	Year	ECTS*
A) Project related competences			
Proposal writing	Health & Society (HSO), WUR, Wageningen, The Netherlands	2017	6.0
ETC Summer course: Public Health Assets	Department of Public Health, University of Alicante, Alicante, Spain	2017	8.0
Hermeneutic phenomenology methodology course	School of Nursing and Midwifery, Robert Gordon University, Aberdeen, Scotland	2018	2.1
Project and Time Management	Wageningen Graduate School (WGS), WUR, Wageningen, The Netherlands	2017	1.0
A life full of happiness and fulfilment	Massive Open Online Course (MOOC) via Coursera, Indian School of Business (India) and the University of Texas (Austin, United States of America)	2017	0.5
B) General research related competences			
WASS Introduction	Wageningen School of Social Sciences (WASS), WUR, The Netherlands	2017	1.0
Data Management Planning	WUR Library, WUR, The Netherlands	2017	0.4
Mobilising your scientific network	Wageningen Graduate School (WGS), WUR, The Netherlands	2017	1.0
Philosophy and Ethics of Food Science and Technology	Wageningen Graduate School (WGS), WUR, The Netherlands	2018	1.5
Edema-Steernberg PhD Literature discussion group (LDG) *"why do we eat what we eat?"*	Wageningen School of Social Sciences (WASS)/ VLAG graduate school, WUR, The Netherlands	2018-2020	1.0
'*Back to basics: applying a salutogenic approach to understand the origins of healthful eating*'	8th Annual Conference of the Association of European Schools of Planning (AESOP): *Sustainable Food Planning*, Coventry, United Kingdom	2017	1.0
'*The development of the D2SAL-intervention: a salutogenic intervention for enabling healthful eating among Dutch people with type 2 diabetes mellitus*'	WASS PhD Day, Wageningen, The Netherlands (online)	2020	1.0
'*From diet to everyday-social life: everyday-life interviews with people with type 2 diabetes mellitus*'	*Salutogenesis Symposium* at the 10th International Union for Health Promotion and Education (IUHPE), Trondheim, Norway	2018	1.0
'*Turning points for healthful eating in people with type 2 diabetes mellitus and low social economic status*'	Nutrition Disparity and Equity conference: *From differences to Potential*, Wageningen, The Netherlands	2019	1.0
Workshop: *Values underlying nutrition sciences: the biomedical approach vs. the anti-diet movement*	Nutrition Disparity Network (NDN) conference: *Values and Nutrition Equity*, Wageningen, The Netherlands (online)	2021	1.0
'*Keerpunten en coping stijlen voor eetgedag van mensen met diabetes type 2*'	VoedingNL, Congres *Koolhydraten en insulinegevoeligheid*, Utrecht, The Netherlands	2020	1.0
Webinar*: An introduction to Salutogenesis: how to apply salutogenic principles in your dietetic practice?*	European Federation of the Associations of Dietitians (EFAD), Europe (online)	2021	1.0

'*Discussing a salutogenic intervention for enabling healthy eating in adults with type 2 diabetes mellitus*'	International Conference on Salutogenesis *Advancing Salutogenesis towards thriving societies*, Girona, Spain (online)	2021	1.0
'*SALUD RCT-Study: healthy eating programme for people with type 2 diabetes*'	Health & Society Seminar: *From Ottawa to Wageningen: Building healthy societies in a planetary context*, Wageningen, The Netherlands	2023	1.0
Organising a guest lecture with prof. Lotte Holm – *Interdisciplinary approaches to food consumption, food and health*	Centre of Space, Place and Society (CSPS), Wageningen, The Netherlands	2017	1.0
Organising a guest lecture with dr. Joreintje Mackenbach – *How the environment influences food choices*	Centre of Space, Place and Society (CSPS), Wageningen, The Netherlands	2018	1.0
Organising a guest lecture with prof. Jane South – *Community-based approaches to health & wellbeing*	Centre of Space, Place and Society (CSPS), Wageningen, The Netherlands	2019	1.0
Hosting the HSO Seminar preceding the inaugural lecture of prof. Spencer Moore	HSO Seminar: *From Ottawa to Wageningen: Building healthy societies in a planetary context*, Wageningen, The Netherlands	2023	0.5
Reviewing a scientific paper	Journal: Acta Odontologica Scandinavica Journal: Health Promotion International Journal: Tijdschrift voor Gezonheidswetenschappen	2020-2023	3.0
C) Career related competences/personal development			
Nomination Young Professional Award 2020	VoedingNL Congres *Koolhydraten en insulinegevoeligheid*, Utrecht, The Netherlands	2020	1.0
Teaching activities Thesis supervision (13 BSc/MSc students) Lecture in course *Health Psychology* (2023) Tutor in course *Health Psychology* (2017 to 2023) Lecturer and tutor in course *Food Scapes* (2017) Coordinator, lecturer and tutor in course *Introduction Health & Society* (2022)	Health & Society (HSO), WUR, Wageningen, The Netherlands		4.0
Brain training	Wageningen Graduate School (WGS), WUR, Wageningen, The Netherlands	2017	0.3
Career Orientation	Wageningen Graduate School (WGS), WUR, Wageningen, The Netherlands	2022	1.5
Total			**44.8**

*One credit according to ECTS is on average equivalent to 28 hours of study load

Colophon

The research described in this dissertation was financially supported by the Edema-Steernberg Foundation: a charitable, non-profit organisation that encourages multidisciplinary nutrition research (registered with the Dutch Chamber of Commerce number 64 61 64 60; see www.wur.n/edemasteernberg).

Financial support from Wageningen University and the Edema-Steernberg Foundation for printing this dissertation is gratefully acknowledged.

Cover design	Leonie M. Polhuis-Pas and Dennis Hendriks
Lay-out	Dennis Hendriks | ProefschriftMaken.nl
Printed	ProefschriftMaken.nl (on FSC certified paper)