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Article

Development of a salutogenic intervention for healthy eating among Dutch type 2 diabetes mellitus patients

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Summary

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. 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. 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. 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.

Lay Summary

Healthy eating can be difficult for people with the disease type 2 diabetes. This article describes how a programme aimed at helping type 2 diabetes patients to eat healthily was developed. The draft version of the programme was based on a theoretical framework that aims to understand what creates health in everyday life, and on conversations with type 2 diabetes patients and healthcare providers. The draft programme was adjusted based on the feedback of type 2 diabetes patients, healthcare providers and scientists. This resulted in a 12-week, group-based programme that enables people to think about who they are and what they want by setting health goals and sharing experiences. Attention was also paid to disease knowledge, disease acceptance, nutritional skills, dealing with stress, self-identity and social support. The group sessions began following an individual intake session, with a booster session held 3 months after the intervention. By involving everybody, we were able to develop a programme that takes into account the preferences, needs and priorities of all stakeholders. It is important to describe the development and the content of programmes encouraging healthy eating to determine their quality and effectivity.

Key words: type 2 diabetes, salutogenesis, multicomponent intervention, participatory research, diet

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 (Evert *et al.*, 2014)] is effective for improving glycaemic control and other metabolic biomarkers in type 2 diabetes mellitus (T2DM) patients (Gregg *et al.*, 2012; Steven *et al.*, 2016; Taylor, 2013). 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 (Neuenschwander *et al.*, 2019; Pan *et al.*, 2019; Schwingshackl *et al.*, 2018). 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 (Caro-Bautista *et al.*, 2020; Coster and Norman, 2009; Franz *et al.*, 2015; Norris *et al.*, 2005), and sustaining health effects appears to be even more difficult (Coster and Norman, 2009; Franz *et al.*, 2007, 2015; Turk *et al.*, 2009).

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. (Ganiyu *et al.*, 2013; Mohammed and Sharew, 2019)]; 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 (Van Woerkum and Bouwman, 2014). Within the cognitive–psychological tradition, the social world is seen from *within* the individual (Van Woerkum and Bouwman, 2014); 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 (Bisogni *et al.*, 2012; Lawton *et al.*, 2007; Lundkvist *et al.*, 2010). Eating is a chain of activities, embedded in a social context that influence why, when and what we eat (Higgs, 2015). 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 (Van Woerkum and Bouwman, 2014). Without considering contextual influences on eating behaviour, the relevance of interventions to everyday life as well as their long-term effectiveness are limited (Swan *et al.*, 2015).

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 (Antonovsky, 1979, 1996). 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 (Wells *et al.*, 2012).

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 (Antonovsky, 1996). 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 (Polhuis *et al.*, 2020a) was a systematic review to indicate and assess effective characteristics of salutogenic-oriented lifestyle interventions for T2DM patients. In Study II (Polhuis *et al.*, 2020b), 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 (Polhuis, 2020a, b). 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 Annexe I), and regarding the intervention content (i.e. input for intervention sessions and tailoring) (Supplementary Annexe II). 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.

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 (Academie voor Leefstijl en Gezondheid, 2020); 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 HbA1c 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, HbA1c and self-efficacy, and secondarily to improve body mass index (BMI), and SoC. HbA1c 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 Annexe III 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 Annexe IV.

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 Annexe V.

DISCUSSION

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 (Montgomery *et al.*, 2008). 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 (Montgomery *et al.*, 2008). In salutogenesis, self-identity is regarded as a crucial resource for coping and possibly as even a necessary precondition for a strong SoC (Antonovsky, 1979). 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 (Super *et al.*, 2016). 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 (Calder *et al.*, 2020; McClain *et al.*, 2009). The limited available evidence is mostly cross-sectional and/or focussed on proximal indicators of healthy eating rather than healthy eating itself (Strachan and Brawley, 2009). 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 (Bisogni *et al.*, 2012; Hartmann-Boyce *et al.*, 2018). In addition, a 'healthy-eater identity' has been shown to be a significant predictor of healthy eating behaviour, even after controlling for nutrition knowledge (Strachan and Brawley, 2009). Moreover, an experimental study that encouraged participants to identify as a healthy eater led to more healthy food consumption (Brouwer and Mosack, 2015). Regarding T2DM, self-identity has been demonstrated to be an intervening variable for most self-management behaviours, including diet (Brouwer and Mosack, 2012). 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 (Bandura, 1971). Both observational (Kelly *et al.*, 2016) and experimental research (Seib *et al.*, 2018) 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 (Strychar *et al.*, 2012). Useful strategies to promote dietary self-efficacy include stress management, goal setting and goal evaluation (Prestwich *et al.*, 2014). 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 (Song *et al.*, 2017; Stopford *et al.*, 2013). Evidence showed that the effect of social support on glycaemic control may be mediated sequentially by self-efficacy and adherence to self-management (Shao *et al.*, 2017). 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 (Calder *et al.*, 2020; Komro *et al.*, 2016). 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 (Calder *et al.*, 2020; Green *et al.*, 2009; Wells *et al.*, 2012). 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) (Moher *et al.*, 2010; World Health Organization, 2020). 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' (Calder *et al.*, 2020; Springett, 2001). 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 (Green *et al.*, 2009; Wells *et al.*, 2012). 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 (Mittelmark *et al.*, 2017), 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 (Hart, 2003; Van Hoek *et al.*, 2017), 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 (Boutron *et al.*, 2008); however, this statement lacks items regarding the reporting of an intervention's developmental process. No ideal evaluation method exists for multicomponent interventions (Minary *et al.*, 2019). 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 (Minary *et al.*, 2019)]. Finally, we strongly recommend the use of salutogenesis for nutritional intervention development (and evaluation) to minimize the science-practice gap.

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CONFLICT OF INTEREST STATEMENT

The authors declare that they have no conflict of interests.

SUPPLEMENTARY MATERIAL

Supplementary material is available at *Health Promotion International* online.

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.

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