BMJ Open

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Journal:	*BMJ Open*
Manuscript ID	bmjopen-2020-036995
Article Type:	Protocol
Date Submitted by the Author:	14-Jan-2020
Complete List of Authors:	Sommer, Jana; German Diabetes Center, Leibniz Center for Diabetes Research at the Heinrich Heine University Düsseldorf, Institute for Health Services Research and Health Economics; Heinrich Heine University Düsseldorf, Institute for Health Services Research and Health Economics, Centre for Health and Society, Faculty of Medicine Dyczmons, Jan; German Diabetes Center, Leibniz Center for Diabetes Research at the Heinrich Heine University Düsseldorf, Institute for Health Services Research and Health Economics; Heinrich Heine University Düsseldorf, Institute for Health Services Research and Health Economics, Centre for Health and Society, Faculty of Medicine Grobosch, Sandra; German Diabetes Center, Leibniz Center for Diabetes Research at the Heinrich Heine University Düsseldorf, Institute for Health Services Research and Health Economics; Heinrich Heine University Düsseldorf, Institute for Health Services Research and Health Economics, Centre for Health and Society, Faculty of Medicine Gontscharuk, Veronika; Heinrich Heine University Düsseldorf, Institute for Health Services Research and Health Economics, Centre for Health and Society, Faculty of Medicine; German Diabetes Center, Leibniz Center for Diabetes Research at the Heinrich Heine University Düsseldorf, Institute for Health Services Research and Health Economics Vomhof, Markus; German Diabetes Center, Leibniz Center for Diabetes Research at the Heinrich Heine University Düsseldorf, Institute for Health Services Research and Health Economics; Heinrich Heine University Düsseldorf, Institute for Health Services Research and Health Economics, Centre for Health and Society, Faculty of Medicine Roden, Michael; German Diabetes Center, Leibniz Center for Diabetes Research at the Heinrich Heine University Düsseldorf, Institute for Clinical Diabetology; Heinrich Heine University Düsseldorf, Division of Endocrinology and Diabetology, Faculty of Medicine Icks, Andrea; Heinrich Heine University Düsseldorf, Institute for Health Services Research and Health Economics, Centre for Health and Society, Faculty of Medicine; German Diabetes Center, Leibniz Center for Diabetes Research at the Heinrich Heine University Düsseldorf, Institute for Health Services Research and Health Economics
Keywords:	Telemedicine < BIOTECHNOLOGY & BIOINFORMATICS, STATISTICS & RESEARCH METHODS, Protocols & guidelines < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Health economics < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, General diabetes <

	DIABETES & ENDOCRINOLOGY, QUALITATIVE RESEARCH

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Preferences of people with type 2 diabetes for tele-medical lifestyle programmes in Germany: Protocol of a discrete choice experiment

Jana Sommer[1,2,3] *, Jan Dyczmons[1,2,3,] Sandra Grobosch[1,2,3], Veronika Gontscharuk[1,2,3], Markus Vomhof[1,2,3], Michael Roden[,3,4,5], and Andrea Icks[1,2,3]

[1] Institute for Health Services Research and Health Economics, German Diabetes Center (DDZ), Leibniz Center for Diabetes Research at the Heinrich Heine University, Auf´m Hennekamp 65, 40225 Duesseldorf, Germany

[2] Institute for Health Services Research and Health Economics, Centre for Health and Society, Medical Faculty, Heinrich Heine University, Moorenstraße 5, 40225 Duesseldorf, Germany

[3] German Center for Diabetes Research (DZD), Ingolstaedter Landstraße 1, 85764 Neuherberg, Germany

[4] Institute for Clinical Diabetology, German Diabetes Center (DDZ), Leibniz Center for Diabetes Research at the Heinrich Heine University, Auf´m Hennekamp 65, 40225 Duesseldorf, Germany

[5] Division of Endocrinology and Diabetology, Medical Faculty, Heinrich Heine University, Moorenstraße 5, 40225 Duesseldorf, Germany

* Corresponding author

Jana Sommer *, Dr., jana.sommer@hhu.de, Phone: +49 211 8106503

Word count: 3956; Abstract: 267, Number of figures: 1, Number of tables: 1, Number of supplementary material: 1

ABSTRACT

Introduction

Tele-medical lifestyle programmes provide an opportunity to improve the adherence to lifestyle-changing programmes for people with type 2 diabetes mellitus (T2DM). When implementing new programmes into standard care, it is important to consider patients' preferences in order to maximise their success. This study aims to examine the preferences of people with T2DM with respect to tele-medical lifestyle programmes alongside a randomised-controlled trial (RCT).

Methods and analysis

We outline the protocol of the development and assessment of a discrete choice experiment (DCE) to examine patient preferences in a tele-medical lifestyle programme with regard to the functions of the online portal, communication, responsibilities, group activities, and time requirements. To develop the design of the DCE, we conducted pilot work involving health care experts and in particular people with T2DM using cognitive pretesting. The final DCE is being implemented alongside a RCT investigating whether participation in a tele-medical lifestyle intervention programme sustainably improves the HbA_{1c} values of people with T2DM. Preferences are being assessed before and after participants complete the programme. About 850 members of a large German statutory health insurance are being recruited to participate. The DCE data will be analysed using regression analysis.

Ethics and dissemination

The DCE study has been approved by the ethics committee of the medical faculty of the Heinrich Heine University Duesseldorf, registration number 2018-242-ProspDEuA, registered on December 6th, 2018. The TeLIPro trial is registered at the U. S. National Library of Medicine, registration number NCT03675919, registered on September 15th, 2018. We aim to disseminate our results in peer-reviewed journals, at national and international conferences, and among interested patient groups and the public.

Strengths and limitations of this study

- We use a DCE to assess the preferences of people with T2DM participating in a tele-medical lifestyle programme, before and after they complete the programme.
- DCE data enable us to retrieve relative preference weights from which we can learn which characteristics of a tele-medical lifestyle programme are most important to the participants.
- Since the DCE was developed on the basis of the TeLIPro trial, the transferability of the DCE to other tele-medical lifestyle programmes is limited.

Keywords

Patient preferences, discrete choice experiment, lifestyle changes, Type 2 diabetes mellitus, tele-medical coaching, lifestyle intervention, preference elicitation, preference assessment, lifestyle changing programme

INTRODUCTION

The prevalence of diagnosed diabetes in the world is continuously increasing[1]. In 2019, more than 9.5 million adults were diagnosed with diabetes in Germany, most of them with type 2 diabetes mellitus (T2DM)[2]. The health expenditures of people diagnosed with diabetes are about twice as high as those of people without diabetes. Approximately two thirds of the total expenditures for the medical treatment of diabetes in Germany are incurred for the treatment of diabetes-related comorbidities[3]. Besides demographic aging, a lifestyle characterised by little physical activity and a high caloric diet is assumed to be largely responsible for the increasing prevalence of T2DM[2].

Lifestyle programmes as part of T2DM treatment

Besides antihyperglycemic treatment, an effective T2DM therapy includes programmes aimed at lifestyle changes, including changes in dietary habits and improvements in physical activity. Since these programmes have significantly reduced T2DM participants' haemoglobin A_{1c} (HbA_{1c}) levels, they may help to reduce the progression of the disease[4–8]. Thus, lifestyle programmes for improving diabetes self-management have been included in clinical guidelines and international position statements for the treatment of people with T2DM[9–11]. Although education tools and disease management programmes are available for all patients in Germany, some patients may have difficulties implementing a successful lifestyle change in everyday life in the long term[12].

Tele-medical health programmes as an effective, easy-access treatment approach

Tele-medical health programmes use digital health technologies to offer up-to-date easy access and most notably a location-independent way to support patients in managing their diabetes and integrating a healthier lifestyle into their daily lives. Besides technical aids such as apps, internet platforms, and mobile measurement devices, a personal health coach is often an

integral part of such a programme[13–16]. The health coach evaluates the digital health data that are obtained and derives recommendations (e.g., to increase physical activity or implement a healthy diet). A proof of concept study showed that participation in a tele-medical health intervention programme that focused on eating behaviour, but also included support from a personal health coach, led to significant reductions in HbA_{1c}, weight, blood pressure, and other cardiovascular risk factors in people with T2DM. Furthermore, a reduction in the medication demand, using the medication effect score which is based on the potency and dosage of diabetes medication, and the insulin demand was achieved, also quality of life and eating behaviour improved significantly[14].

Patient preferences as an essential part of patient centeredness

Although digital health technologies and coaching approaches play an increasingly important role in diabetes care,[13–19] little is known about the underlying decision-making process regarding the participation and adherence of the target groups to tele-medical lifestyle programmes. One promising approach to examine why some people participate and succeed in lifestyle-changing programmes and others do not is to ask patients about their preferences for different aspects of these programmes. Preferences answer the question of which alternative is most favourably evaluated by patients (e.g., which type of lifestyle programme is preferred). According to Scholl et al., the consideration of patient preferences is an essential part of patient centeredness[20]. Moreover, consideration of patients' preferences has shown a significant, albeit small, positive effect on treatment outcomes, (e.g., drug adherence)[21–23]. An increasingly popular method for eliciting patient preferences in health care is the discrete choice experiment (DCE),[24–28] a stated preference method. The DCE methodology – based on the Random Utility Theory – allows researchers to estimate and contrast the relative strengths of preferences across a range of particular attributes. To date, studies using a DCE to elicit preferences in people with diabetes have mostly examined their preferences regarding

treatment[29–23] and lifestyle changes[234–36]. Thus, there remains a need for a clarification of patients' preferences regarding the relative importance of attributes with respect to tele-medical lifestyle programmes and coaching approaches (e.g., involvement of the coach, internet platforms, mobile measurement instruments, or type of support). Knowledge of these preferences and identification of groups of patients with similar preferences may be helpful for designing more tailored, patient-centred tele-medical lifestyle programmes.

Contribution to the field & Aims

With this study, we aim (i) to measure preferences of people with T2DM regarding tele-medical lifestyle programmes and (ii) to compare participants' preferences before and after the intervention so that we have the preferences of uninformed naive programme participants and informed experienced programme participants. The former will help to address new programme participants when implementing tele-medical lifestyle programmes into standard health care, whereas the latter will provide information about changes over the course of the intervention. We also aim (iii) to study possible preference heterogeneity. Finally, we aim (iv) to investigate whether tele-medical lifestyle programme preferences are able to predict programme success because a match between programme preferences and content might increase adherence to the programme. The results will contribute to improving future patient-centred lifestyle programmes so that they are better aligned with the preferences of potential participants.

METHODS AND ANALYSIS

The investigation of patient preferences for tele-medical lifestyle programmes will be performed alongside a randomised-controlled trial (RCT) of the Tele-medical Lifestyle intervention Programme TeLIPro[37]. Next, we briefly describe the TeLIPro Health

Programme and the RCT, and then we outline the assessment of patient preferences via a DCE in detail.

The TeLIPro Health Programme

TeLIPro (TeLIPro Health Programme - Active with Diabetes) is a tele-medical lifestyle programme in Germany designed to help people with T2DM implement a healthy lifestyle through patient-centred and personal care[37]. Participants receive tele-medical devices, access to a secured tele-medical online portal, and tele-medical coaching from a personal health coach who supports and accompanies them for the duration of the programme. The programme is intended to improve blood glucose levels and therefore to improve or maintain the health status and the quality of life of the participants in the long-term. Ultimately, this should minimise the risk for concomitant and secondary diseases. The integration of the technology also supports the scalability of the programme, enabling it to meet the individual preferences and needs of the participants.

The RCT: The TeLIPro trial

The TeLIPro trial is aimed at assessing whether participation in the TeLIPro Health Programme can improve HbA_{1c} levels through lifestyle changes in people with T2DM in Germany.

Participants

For the RCT, 850 participants are currently being recruited from within the members of a German statutory health insurance (Allgemeine Ortskrankenkasse, Rhineland/Hamburg, AOK) via informational letters and reminder telephone calls. Inclusion criteria consist of a T2DM diagnosis (International Statistical Classification of Diseases and Related Health Problems, 10th Revision: E11), age between 18 and 67 years, $HbA_{1c} \geq 6.5\%$, Body Mass Index (BMI) $\geq$ 27 kg/m², and a willingness to participate in the study. Exclusion criteria consist of factors that would prevent successful participation in the programme, e.g., acute infections or chronic

illnesses, addictions, acute depression, dementia, acute chemotherapy or cortisone therapy, and paralysis. Also excluded are women who are pregnant or breastfeeding as well as individuals who take weight-influencing medication, who have quit smoking in the last 3 months or plan to quit, who have already taken part in a study in the last 6 months, or who have insufficient knowledge of the German language. Recruitment for the TeLIPro trial began in the last quarter of 2018 and is anticipated until December 2019. Participants are being randomised (1:1) into two groups: the intervention group (IG) and the control group (CG).

Intervention Group

Participants of the IG are given a scale, a step counter, access to a tele-medical online portal, a data hub for transmitting the measured values to the online portal, a glucose meter with test strips for the self-monitoring of blood glucose, and tele-medical telephone coaching from a personal health coach in addition to routine care. For the IG, the measures of blood glucose are recorded continuously, and pedometer data and weight (on a daily or weekly basis) are automatically transmitted to the online portal by the devices. The data can be viewed by both the participant and the coach. If a previously determined target value is exceeded or not reached, an alert is triggered, and the coach may decide to intervene. In addition to the monitoring function, the online portal provides information to support the change in lifestyle and enable participants to manage their illness autonomously. Furthermore, functions are available for communication and information exchange between the actors who are involved: participant and coach, as well as the attending general practitioner (GP) or relatives with the participant's consent. Therefore, it is easy to exchange information and adapt the therapy. The intervention will last 12 months.

Control Group

Participants of the CG are not accompanied by a coach. Except for this, they receive the same components of the programme as the IG.

Outcomes

The primary outcome may depend on how long the participants have had diabetes. Therefore, the study sample was divided into two subgroups. The primary outcome for participants with a duration of diabetes of < 5 years is remission after a period of 12 months after baseline defined as an HbA_{1c} level < 6.5%[38]. The hypothesis is that the remission rate 12 months after baseline will be 11% in the IG and 5% in the CG. The primary outcome for participants with a duration of diabetes of ≥ 5 years is the HbA_{1c} level. It is hypothesised that the HbA_{1c} level will be reduced by 0.5% for the IG and 0.2% for the CG 12 months after baseline. The secondary outcomes are cardiovascular risk factors (blood pressure, HDL/LDL cholesterol, total cholesterol, and triglycerides), health-related quality of life, depressive symptoms, eating habits, exercise behaviour, antihyperglycaemic treatment, and blood pressure medication.

Data collection

After participants are recruited for the TeLIPro trial, they are given detailed information about the programme and provide informed consent. Participants register in the online portal and are asked for sociodemographic factors (sex, age, employment status, education) and the duration of their diabetes. Afterwards, the intervention begins. Participants are given devices and the IG is contacted by the personal health coach. In the online portal, all participants answer questionnaires about their health-related quality of life (Short-Form-Health Survey 12; SF-12), impairment due to depressive symptoms (German version of the Centre for Epidemiological Studies-Depression Scale; CES-D Scale), eating behaviour (German version of the Three-Factor Eating Questionnaire; FEV), and exercise behaviour (Global Physical Activity Questionnaire, GPAQ)[39-42] at baseline, 3 months, 6 months, 9 months, 1 year (completion

of the intervention), 15 months (follow-up phase), and 18 months (follow-up phase) after baseline. If a questionnaire is not answered within two weeks, participants are reminded by a telephone call from the online portal service staff. A total of up to three telephone calls are attempted, followed by a reminder e-mail. On a quarterly basis, also the attending GP is asked for the participants' HbA_{1c} level, weight, BMI, fasting blood glucose, blood pressure, triglycerides, HDL/LDL cholesterol, antihyperglycaemic treatment, and blood pressure medication. Body weight is recorded weekly, and walked steps are recorded daily by the devices for both groups. For the IG, blood glucose is monitored daily.

Development of the DCE

The first step in developing a DCE is to define the research problem under consideration (e.g., measuring patient preferences for tele-medical lifestyle programmes) and to adequately transfer it into an experimental framework[43–44]. The task comprises the identification and selection of attributes that reflect all characteristics relevant for a decision in the context of the research problem. The attributes (e.g., cost or duration of treatment) of the research problem are further specified by different levels (e.g., cost of $50 or $500 and 2, 3, or 4 hours). To construct an experimental design, the levels of the attributes are systematically varied and presented in a series of choice sets each with the same number of alternatives (typically two alternatives). By standard economic theory, it is assumed that individuals will choose the alternative that maximises their utility. The preference weights for attributes and levels (part-worth preference weights) constitute the overall utility of an alternative. Thus, observed choices provide information about the relative weights of preferences for attributes and levels as well as about the overall utility of each alternative[45]. We are primarily interested in the preferences of participants who already decided to participate in a tele-medical coaching programme. Thus, we did not include an opt-out option because respondents have already chosen to participate in TeLIPro. To identify and select attributes and levels, we followed the

current literature on the development of DCEs and implemented the following steps: (i) compilation of evidence, (ii) consultation of experts, (iii) consultation of people with diabetes as relevant actors, (iv) pretest, and (v) pilot test[46–47].

Compilation of evidence

First, we conducted a literature search to identify attributes used in DCEs to elicit preferences regarding lifestyle changes, coaching, and devices (see the online supplementary material). Based on the literature search, we summarised attributes regarding how comfortable the devices are to wear, the handling of the devices, the frequency of contact with the GP or the health coach, emotional support during the programme, responsibility for the physical activity schedule or diet schedule, and the time investment. We did not include monetary costs in our summary, because payments for the provision of health care in Germany are normally paid directly by the statutory health insurance, and therefore monetary costs are less relevant than the time investment for preferences regarding tele-medical lifestyle programmes.

Consultation of experts

Second, we discussed the attributes with health care experts (see acknowledgments) to ensure that the health care perspective, telehealth, and the clinical perspective were incorporated in the DCE. This process leads to a preliminary list of attributes (i) considering any possible attribute thought to be relevant to tele-medical lifestyle programmes for people with T2DM, (ii) including attributes with a special relevance for TeLIPro in order to best adapt patient preferences to the intervention envisaged in the project, and (iii) including those who could be realistically described in the choice scenario and were potentially amenable to change. This resulted in a list of seven attributes with 2-5 levels: the functions and handling of the online portal, the contacts to coach compared to GP contacts, the transfer of knowledge about a healthier lifestyle, emotional support, exercise plan, nutrition plan, and the total time required

for the programme. This list formed the basis for the DCE design. The alternative attributes: communication between coach and doctors, competence of the coach, total number of contacts to coach, duration of the programme, intensity of the exercise programme, and exercise in groups or individually were used in the pretest.

Consultation of people with diabetes/Pretest

Third, we conducted qualitative interviews in the form of a cognitive pretest with five individuals with diabetes (December 2018 and January 2019). Participants were recruited from the self-help group (n=2) at the German Diabetes Center in Duesseldorf, Germany, and a specialised diabetes care practice (n=3) in Leverkusen, Germany, by email or personal contact. They participated on a voluntary basis and gave written informed consent prior to being included in the study. The interviewers were two researchers from the Institute for Health Services Research and Health Economics. Interviews were conducted face-to-face at the German Diabetes Center, the diabetes care practice, and the participants' homes. All interviews were logged and audiotaped. The individual interviews were conducted in order to ensure that (i) the most important attributes were included in the DCE, (ii) none of the chosen attributes was dominant, (iii) proper levels were appointed to each of the attributes, and (iv) the task and the wording used in the questionnaire were comprehensible and feasible[44–45]. For the qualitative interviews, we developed a guideline based on cognitive pre-testing, including think-aloud methods, demand techniques (understanding individual words), paraphrasing (reproducing tasks), and sorting techniques (attributes were presented to participants on cards, and participants sorted them by personal relevance). In the first part of the interview, we introduced respondents to TeLIPro, and the questionnaire was presented piece by piece. To obtain more insight into how respondents understood the choice task, they were asked to think aloud during the interview. In addition, respondents were told to identify attributes and levels they did not understand or found hard to grasp and to provide suggestions for improvement. In

the second part, all seven attributes of the DCE were presented on separate paper cards. Respondents were asked whether they could think of any other attributes that were important but had not been included so far. If so, the interviewer wrote these new attributes on blank cards, and respondents were asked what they considered important about these attributes and what kinds of levels of the attribute they could think of. If no more new attributes were mentioned, the additional cards with the six alternative attributes were laid out and explained to the respondents by the interviewer. Next, respondents were asked if they would swap one or more of the six alternative attributes or – if new attributes were mentioned – if they would swap the new attributes with one or more of the seven attributes in the programme. Two researchers reviewed the interviews and adjusted the DCE after an internal discussion. The attribute 'emotional support' was swapped with 'group activities', which was also modified to include the non-exercise group activities. The attribute 'frequency of contacts' was changed to 'communication between coach and doctors'. It asks if the coach and doctors have contact with each other instead of the patient to doctor and patient to coach ratios. The attribute named "the transfer of knowledge about a healthier lifestyle" was changed to "responsibility for getting acquainted with a healthier lifestyle" The level '4 hours per week' was removed from the attribute 'total time required' because it was deemed unrealistic by respondents. The attributes 'exercise plan' and 'nutrition plan' were merged into 'responsibility for setting goals to exercise and menu schedule' because both attributes targeted the domain of autonomy, and the majority of the respondents swapped out one of these attributes. The description of the task concerning the selection of the choice sets was also rephrased to be more precise. This reduction in the number of attributes to six and the number of levels to two to four ensured an efficient design while also allowing the number of choice sets to be limited to a practicable number to prevent a mental burden that was too high for the participants. It was ensured that one combination of levels reproduced the actual TeLIPro health programme.

Pilot test

Fourth, we presented the revised DCE to the members of the self-help group (n=10) at one of their monthly meetings. On a pilot test, they answered a paper-pencil version of the DCE questionnaire and were asked at the end of the questionnaire if they had any suggestions for improvement. On the basis of these results, the attributes and levels as well as their descriptions in the questionnaire were not changed. The DCE instructions concerning the selection of the choice sets was again rephrased to clarify that the most preferred or least disliked programme of the two had to be chosen. The final six attributes with their corresponding levels are shown in Table 1.

Table 1: Final attributes and corresponding levels included in the DCE

Attributes	**Descriptions**	**Levels**
The functions and handling of the online portal	During the coaching programme, you are provided with different devices to measure your weight, your blood glucose, and the steps you have walked. These devices automatically transfer your data to an online portal that you and your coach can access. The range of functions and the handling of the online portal can differ for different programmes. The more functions the online portal offers, the more complex the handling becomes.	Extensive functions and more complex handling Less extensive functions and easier handling
Communication between coach and doctors	Coaching programmes can differ on the basis of whether your coach and your doctors communicate about your treatment, the programme goals you have set, and your data in the online portal.	My coach and my doctors do not communicate My coach and my doctors do communicate
Responsibility for getting acquainted with a healthier lifestyle	Coaching programmes can provide you with information about various opportunities for lifestyle changes.	I receive information from my doctor I receive information from my coach

		I search for information myself
Group activities	Some coaching programmes contain activities in groups of 10-15 participants each. The activities include sports activities, cooking together, and also the exchanging of experiences by the group members in an online forum.	*No* group activities Group activities
Responsibility for setting goals to exercise and menu schedule	One part of the coaching programme is setting goals to exercise and eat well.	My coach sets my goals I set my goals independently My coach and I set my goals together
Total time required	Coaching programmes may differ in the amount of time you have to spend on the programme. This includes the time spent fulfilling your movement goals, talking to your coach, changing your diet, and using your devices correctly. The time required for potential group activities is not included.	12 hours per week 10 hours per week 8 hours per week 6 hours per week

DCE questionnaire design

The combination of the attributes in the different scenarios of the DCE and the compilation of the scenarios was based on the number and levels of the attributes as well as other content and statistical requirements. SAS macros (SAS version 9.4) were used to define the optimal number of choice sets[48]. Particular care was taken to ensure that combinations of levels were realistic. The number of total choice sets takes respondents' cognitive capacity into account. The efficient factorial fractional design (*D*-error=0.12) consisted of 12 unique choice tasks. To control for the reliability of the choices that were made, choice set 7 was repeated as choice set 13, resulting in a total of 13 choice sets.

Assessment of the DCE

Initially, respondents are provided with an extensive explanation of the meanings of all attributes and levels as well as information on how to deal with a choice set, accompanied by an example. Afterwards, respondents are told that they need to choose between two lifestyle programmes in the following choice sets. They are told that 13 choice sets are best suited for determining what type of lifestyle programme is preferred. Respondents are told to always choose their personally best-suited or least-rejected lifestyle programme and that there are no right or wrong answers. They are also reminded that they can always opt for a programme with all the features listed. Every choice task is accompanied by the invitation: 'Please select the coaching programme that suits you best'. Then both programmes (Programmes A and B) are presented (see Figure 1) followed by the question: 'Which programme do you prefer? (Please tick the appropriate box)'. Figure 1 presents an example of a choice task as included in the questionnaire. The DCE is measured before the start of the intervention and after 1 year when the intervention has been completed. Data collection for the DCE began in January 2019 and is anticipated to take place until December 2020.

- *Please insert Figure 1 here* -

Data analysis

To derive the preferences of people with T2DM regarding tele-medical lifestyle programmes (i.e. relative preference weights for attributes and levels), the obtained baseline DCE data will be analysed using a conditional logit model. Preference weights describe the relative strength of each attribute and level in comparison with all other attributes and levels, respectively. Furthermore, the preference weights will be expressed as time equivalents (willingness to invest time) by calculating the trade-off or marginal rates of substitution between attributes and the attribute that focuses on the time required by the programme. Because the IG and CG do not differ at baseline, the analysis is based on the full sample. To investigate differences in

preferences before and after participation in the programme, the preference weights of unexperienced, naive programme participants and experienced participants will be compared descriptively and analysed using time equivalents. The analysis will be outlined separately for the IG and the CG as experiences during the intervention phase differ substantially.

To investigate possible preference heterogeneity, we will conduct a latent class analysis (LCA) using the baseline data (full sample). The number of classes is determined by the Bayesian information criterion as well as an examination of the interpretation of the latent classes. The following covariates will be incorporated into the LCA: sociodemographic factors (sex, age, employment status, and education), disease-related characteristics (HbA_{1c} level, duration of diabetes, BMI), exercise behaviour, depressive symptoms, and health-related quality of life. Finally, we will investigate the causal effect of latent classes of preferences at the beginning of the study on programme success at the end of the study. This will be done by means of an LCA with a distal outcome, where programme success is regressed on latent preference classes. This approach will allow us to explore whether programme preferences differ with respect to distal outcomes such as programme success. This type of analysis may lead to additional information about heterogeneity in the (study) population.

Patient and Public involvement

Patient involvement during the various stages of the development of the DCE (qualitative interviews, pilot tests) ensured that the research question relied on the actual preferences of people with T2DM participating in tele-medical lifestyle programmes.

ETHICS AND DISSEMINATION

The DCE study has been approved by the ethics committee of the medical faculty of the Heinrich Heine University committee of the Heinrich-Heine University Duesseldorf, registration number 2018-242-ProspDEuA, registered on December 6th, 2018. The TeLIPro

trial is registered at the U. S. National Library of Medicine, registration number NCT03675919, registered on September 15th, 2018. Patient consent to participate was obtained. Data analysis will be done according to the principles of good scientific research on DCEs developed by the International Society for Pharmacoeconomics and Outcome Research (ISPOR). We aim to disseminate our results in peer-reviewed journals and at national and international conferences to interested patient groups and the public.

ACKNOWLEDGEMENTS

We thank the team of the TeLIPro trial: the AOK Rhineland/Hamburg statutory health insurance (leader of the trial consortium), the German Institute for Telemedicine and Health Promotion GmbH (DITG), the Private Institute for Applied Care Research GmbH (inav), and the Association of Statutory Health Insurance Physicians of North Rhine-Westphalia (cooperation partner). We acknowledged the work of the DITG in programming and implementing the DCE at the online platform. We thank the diabetes care practice Kaltheuner, Schultens-Kaltheuner, Hannig, Marenbach, and Leverkusen and their staff for their support. We also thank the volunteers from the self-help group at the German Diabetes Center in Duesseldorf, Germany, and the diabetes care practice in Leverkusen, Germany for participation in this study.

AUTHOR STATEMENT

MV and AI contributed to the initial grant application. All authors contributed to the design of the study and are involved in the implementation of the project. JS wrote the first draft of the protocol. JS, JD, SG, VG, MV, MR, and AI contributed to the drafting and editing of the protocol. All authors read and approved the final protocol.

FUNDING

This work was supported by the Innovation Fund coordinated by the Innovation Committee of the Federal Joint Committee (funding period 2018 - 2021) grant number 01NVF17033 under the consortium leadership of the AOK Rhineland/Hamburg.

CONFLICTS OF INTEREST

The authors declare that they have no competing interests.

DATA STATEMENT

After the data are collected and the results are published, the data will be made available upon reasonable request.

SUPPLEMENTARY MATERIAL

Results of the literature review to identify attributes used in DCEs to elicit preferences regarding lifestyle changes, coaching, and devices.

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Figure 1: Example of a choice task used in the discrete choice experiment

First Choice

Please select the coaching programme that suits you best.

	Programme A	**Programme B**
The functions and handling of the online portal	**Extensive** and **complex**	**Less extensive** and **simple**
Communication between coach and doctors	My coach and my doctors **do not** communicate	My coach and my doctors **do** communicate
Responsibility for getting acquainted with a healthier lifestyle	I receive information from my **doctor**	I receive information from my **coach**
Group activities	No group activities	Group activities
Responsibility for the goals of the exercise and menu schedule	**My coach sets my goals**	**I set my goals independently**
Total time required	**10** hours per week	**8** hours per week
Which programme do you prefer? (Please tick the appropriate box)	☐	☐

Supplementary File

Results of the literature review to identify attributes used in DCEs to elicit preferences regarding lifestyle changes, coaching, and devices.

DCE Topic	Attribute	Levels	Reference
Devices	Comfort of wearing	- Warm and squeezing - Breathing and not squeezing - Comfortable - Uncomfortable	Bouman et al.,2016 [1] Bunge et al., 2010 [2]
Devices	Appearance	- Thick material and skin colored - Thin material and color of choice - Visible - Not visible	Bouman et al.,2016 [1] Bunge et al., 2010 [2]
Devices	Help Needed	- Help needed - Independently - No help needed while emptying your bowels - You need less help than you did previously - You need as much help as you did previously - You need more help than you did previously	Bouman et al.,2016 [1] Nafees et al.,2016 [3]
Devices	Duration of therapy	- 6 months - 15 months - 24 months	Bouman et al.,2016 [1]
Devices	Device Hygiene	- Hand washed, dries slowly - Machine washed, dries quickly - Mouthpiece can be washed, but not replaced - Mouthpiece can be replaced, but not washed - Mouthpiece can be cleaned with a dry cloth, but not washed or replaced	Bouman et al.,2016 [1] Hawken et al.,2017 [4]
Devices	Easy to Use	- 1 step - 2 to 3 steps - More than 4 steps - You will use an automatic pump (process requiring ~15 steps) - You will use a manual pump (process requiring ~30 steps)	Hawken et al.,2017 [4] Nafees et al.,2016 [3]
Devices	Flexibility of device handling	– Inhaler can be held in any position throughout inhalation process – Inhaler must be held in certain position throughout inhalation process	Hawken et al.,2017 [4]
Devices	Time to use per treatment	- 5 minutes - 10 minutes - 15 minutes - 25 minutes - 30 minutes - You will spend up to 30 minutes - You will spend up to 1 hour - You will spend up to 1.5 hours - You will spend up to 2 hours	Mohamed et al.,2015 [5] Nafees et al.,2016 [3]

DCE Topic	Attribute	Levels	Reference
Devices (Coaching)	Frequency of use	- None - 2 pills 3 times a day (6 pills per day) - 3 pills 4 times a day (12 pills per day) - 2 times per day - 3 times per day - Once every two days on average - Once every day on average - Twice a day on average - Three times a day on average - Once per day - Once per week - Once per month - Once per 3 months - Once per 6 months - Once per year	Marshall et al.,2017 [6] Mohamed et al.,2015 [5] Nafees et al.,2016 [3] Quaife et al.,2016 [7]
Coaching	Training of the IP (information provider)	- Counselor with specialized training in use of medications during pregnancy only - Family doctor with general health training	Hancock-Howard et al.,2012 [8]
Coaching	Method of counseling and waiting time	- Make an appointment and meet with the IP in person in 3 days - Call a telephone service and receive the information within 30-minutes	Hancock-Howard et al.,2012 [8]
Coaching	Knowing the IP	- You have met the IP before and they know your medical history - You have never met the IP	Hancock-Howard et al.,2012 [8]
Coaching	Confidence in the skills of the IP	- You have confidence in the skills of the IP - You know nothing about the skills of the IP	Hancock-Howard et al.,2012 [8]
Coaching	Helpfulness of information	- Enough information has been provided that you believe your question has been answered to your satisfaction - Some information has been provided to you, but your question has not been completely answered to your satisfaction	Hancock-Howard et al.,2012 [8]
Coaching	Time away from home/office/usual activities including travel	- More than four hours - 3–4 h - 1–2 h	Spinks et al.,2016 [9]
Coaching	Wait time to get result	- Up to three days - Up to one day - Less than four hours	Spinks et al.,2016 [9]
Coaching	Who reviews the result	- GP - Telederm dermatologist	Spinks et al.,2016 [9]
Coaching Diabetes	Feedback on physical activity performance	- Patient receives feedback on his or her individual performance - Patient's performance is compared with that of other patients	Ramirez et al.,2016 [10]
Coaching Diabetes	Physical activity behavior-change education	- Patient's doctor recommends the educational content - Patient specifies the type of educational content he or she wants to receive	Ramirez et al.,2016 [10]
Coaching Diabetes	Frequency of messaging	- Patient's doctor recommends how often patient should receive messages - Patient specifies how often he or she wants to receive messages	Ramirez et al.,2016 [10]

DCE Topic	Attribute	Levels	Reference
Lifestyle Diabetes	Menu schedule	- *Flexible* you set your own goals and develop your own menu schedule to reach these goals without the assistance of a lifestyle coach - *General* your lifestyle coach informs you about health and unhealthy foods, using food information and examples of recipes - *Elaborate* your lifestyle coach develops a menu schedule that meets your needs and wishes - Flexible: primarily based on the participants' own initiatives and ideas - General: includes general information on a healthy diet and provides example recipes - Elaborate: a patient tailored schedule that is completely prepared by the lifestyle coach - Flexible (you composed this schedule) - General (with information about diet and examples of recipes) - Elaborate (this schedule is composed for you and tailored to your needs)	Salampessy et al.,2015 [11] Veldwijk et al.,2013 [12] Wanders et al.,2014 [13]
Lifestyle Diabetes	Physical activity schedule	- Patient's doctor recommends physical activity goals - Patient selects his or her own personalized physical activity goals - *Flexible* you set your own goals and develop your own activity schedule to reach these goals without the assistance of a lifestyle coach - *General* your lifestyle coach informs you about what physical activities would be good for you, using information about physical activity and examples of exercises - *Elaborate* your lifestyle coach develops a physical activity schedule that meets your needs and wishes - Flexible: primarily based on the participants' own initiatives and ideas - General: includes general information on PA, and provides example exercises - Elaborate: a patient tailored schedule that is completely prepared by the lifestyle coach - Flexible (you composed this schedule) - General (with information about physical activity and examples of exercises) - Elaborate (this schedule is composed for you and tailored to your needs)	Ramirez et al.,2016 [10] Salampessy et al.,2015 [11] Veldwijk et al.,2013 [12] Wanders et al.,2014 [13]

DCE Topic	Attribute	Levels	Reference
Coaching Lifestyle Diabetes	Consultation Structure / Social support	- Family members learn how to offer support - Patient meets other patients so they can support one another - *Individual* the consultations of the lifestyle program are individually - *Consultation 5* the consultations of the lifestyle program are in groups of *5 other patients* - *Consultation 10* the consultations of the lifestyle program are in groups of *10 other patients* - Individually - Groups with 5 other T2DM patients - Groups with 10 other T2DM patients - individual - in a group with 5 other people - in a group with 10 other people	Ramirez et al.,2016 [10] Salampessy et al.,2015 [11] Veldwijk et al.,2013 [12] Wanders et al.,2014 [13]
Lifestyle Diabetes	Time spent on the program	- 2.5 hours per week - 4 hours per week	Van Gils et al.,2011 [14]
Lifestyle Diabetes	Arrangement physical activity lessons	- Individually with men and women - With people of the same gender	Van Gils et al.,2011 [14]
Lifestyle Diabetes	Group activity	- Only with people without diabetes - Only with other diabetes patients	Van Gils et al.,2011 [14]
Lifestyle Diabetes	Sports activity	- Walking/cycling - Fitness (treadmill, rowing machine, bicycle)	Van Gils et al.,2011 [14]
Lifestyle Diabetes	Counseling	- None - Physical therapist/sports teacher	Van Gils et al.,2011 [14]

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BMJ Open

Preferences of people with type 2 diabetes for tele-medical lifestyle programmes in Germany: Protocol of a discrete choice experiment

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2020-036995.R1
Article Type:	Protocol
Date Submitted by the Author:	25-Jun-2020
Complete List of Authors:	Sommer, Jana; German Diabetes Center, Leibniz Center for Diabetes Research at the Heinrich Heine University Düsseldorf, Institute for Health Services Research and Health Economics; Heinrich Heine University Düsseldorf, Institute for Health Services Research and Health Economics, Centre for Health and Society, Faculty of Medicine Dyczmons, Jan; German Diabetes Center, Leibniz Center for Diabetes Research at the Heinrich Heine University Düsseldorf, Institute for Health Services Research and Health Economics; Heinrich Heine University Düsseldorf, Institute for Health Services Research and Health Economics, Centre for Health and Society, Faculty of Medicine Grobosch, Sandra; German Diabetes Center, Leibniz Center for Diabetes Research at the Heinrich Heine University Düsseldorf, Institute for Health Services Research and Health Economics; Heinrich Heine University Düsseldorf, Institute for Health Services Research and Health Economics, Centre for Health and Society, Faculty of Medicine Gontscharuk, Veronika; Heinrich Heine University Düsseldorf, Institute for Health Services Research and Health Economics, Centre for Health and Society, Faculty of Medicine; German Diabetes Center, Leibniz Center for Diabetes Research at the Heinrich Heine University Düsseldorf, Institute for Health Services Research and Health Economics Vomhof, Markus; German Diabetes Center, Leibniz Center for Diabetes Research at the Heinrich Heine University Düsseldorf, Institute for Health Services Research and Health Economics; Heinrich Heine University Düsseldorf, Institute for Health Services Research and Health Economics, Centre for Health and Society, Faculty of Medicine Roden, Michael; German Diabetes Center, Leibniz Center for Diabetes Research at the Heinrich Heine University Düsseldorf, Institute for Clinical Diabetology; Heinrich Heine University Düsseldorf, Division of Endocrinology and Diabetology, Faculty of Medicine Icks, Andrea; Heinrich Heine University Düsseldorf, Institute for Health Services Research and Health Economics, Centre for Health and Society, Faculty of Medicine; German Diabetes Center, Leibniz Center for Diabetes Research at the Heinrich Heine University Düsseldorf, Institute for Health Services Research and Health Economics
Primary Subject Heading:	Research methods
Secondary Subject Heading:	Research methods, Diabetes and endocrinology, Health economics,

	Health services research
Keywords:	Telemedicine < BIOTECHNOLOGY & BIOINFORMATICS, STATISTICS & RESEARCH METHODS, Protocols & guidelines < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Health economics < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, General diabetes < DIABETES & ENDOCRINOLOGY, QUALITATIVE RESEARCH

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Preferences of people with type 2 diabetes for tele-medical lifestyle programmes in Germany: Protocol of a discrete choice experiment

Jana Sommer[1,2,3] *, Jan Dyczmons[1,2,3] Sandra Grobosch[1,2,3], Veronika Gontscharuk[1,2,3], Markus Vomhof[1,2,3], Michael Roden[3,4,5], and Andrea Icks[1,2,3]

[1] Institute for Health Services Research and Health Economics, German Diabetes Center (DDZ), Leibniz Center for Diabetes Research at the Heinrich Heine University, Auf´m Hennekamp 65, 40225 Duesseldorf, Germany

[2] Institute for Health Services Research and Health Economics, Centre for Health and Society, Medical Faculty, Heinrich Heine University, Moorenstraße 5, 40225 Duesseldorf, Germany

[3] German Center for Diabetes Research (DZD), Ingolstaedter Landstraße 1, 85764 Neuherberg, Germany

[4] Institute for Clinical Diabetology, German Diabetes Center (DDZ), Leibniz Center for Diabetes Research at the Heinrich Heine University, Auf´m Hennekamp 65, 40225 Duesseldorf, Germany

[5] Division of Endocrinology and Diabetology, Medical Faculty, Heinrich Heine University, Moorenstraße 5, 40225 Duesseldorf, Germany

* Corresponding author

Dr. Jana Sommer *, jana.sommer@uni-duesseldorf.de, Phone: +49 211 8106503

Word count: 4017; Abstract: 285, Number of figures: 1, Number of tables: 1, Number of supplementary material: 1

ABSTRACT

Introduction

Tele-medical lifestyle programmes for people with type 2 diabetes mellitus (T2DM) provide an opportunity to develop a healthier lifestyle and consequently to improve health outcomes. When implementing new programmes into standard care, considering patients' preferences may increase the success of the participants. This study aims to examine the preferences of people with T2DM with respect to tele-medical lifestyle programmes, to analyse whether these preferences predict programme success, and to explore the changes that may occur during a tele-medical lifestyle intervention.

Methods and analysis

We outline the protocol of the development and assessment of a discrete choice experiment (DCE) to examine patient preferences in a tele-medical lifestyle programme with regard to the functions of the online portal, communication, responsibilities, group activities, and time requirements. To develop the design of the DCE, we conducted pilot work involving health care experts and in particular people with T2DM using cognitive pretesting. The final DCE is being implemented within a randomised controlled trial (RCT) for investigating whether participation in a tele-medical lifestyle intervention programme sustainably improves the HbA_{1c} values in 850 members of a large German statutory health insurance with T2DM. Preferences are being assessed before and after participants complete the programme. The DCE data will be analysed using regression and latent class analyses (LCAs).

Ethics and dissemination

The DCE study has been approved by the ethics committee of the medical faculty of the Heinrich Heine University Duesseldorf, registration number 2018-242-ProspDEuA, registered on December 6th, 2018. The TeLIPro trial is registered at the U. S. National Library of Medicine, registration number NCT03675919, registered on September 15th, 2018. We aim to

disseminate our results in peer-reviewed journals, at national and international conferences, and among interested patient groups and the public.

Strengths and limitations of this study

- We are using a DCE to assess the preferences of people with T2DM participating in TeLIPro, a tele-medical lifestyle programme, before and after they complete the programme.
- Programme preferences may be used to further develop the TeLIPro Health Programme.
- DCE data will enable us to retrieve relative preference weights from which we can learn which components of a tele-medical lifestyle programme are most important to the participants.
- Since the DCE was developed on the basis of the TeLIPro trial, the transferability of the DCE to other tele-medical lifestyle programmes will be limited.

Keywords

Patient preferences, discrete choice experiment, lifestyle changes, Type 2 diabetes mellitus, tele-medical coaching, lifestyle intervention, preference elicitation, preference assessment, lifestyle changing programme

INTRODUCTION

The prevalence of diagnosed diabetes in the world is continuously increasing[1]. In 2019, more than 9.5 million adults were diagnosed with diabetes in Germany, most of them with type 2 diabetes mellitus (T2DM)[2]. Besides antihyperglycemic treatment, an effective T2DM therapy includes programmes aimed at lifestyle changes, including changes in dietary habits and improvements in physical activity. Since these programmes have significantly reduced T2DM participants' haemoglobin A_{1c} (HbA_{1c}) levels, they may help to reduce the progression of the disease[3–7]. Thus, lifestyle programmes have been included in clinical guidelines and international position statements for the treatment of people with T2DM[8–10].

Digital health technologies and coaching approaches are playing increasingly important roles in health care in diabetes[11–17]. Tele-medical health programmes offer up-to-date easy access and most notably a location-independent way to support patients in managing their diabetes, using technical aids such as apps, internet platforms, and mobile measurement devices and often including a personal health coach[11–14]. A proof of concept study showed that participation in a tele-medical health intervention programme that focused on eating behaviour, but also included support from a personal health coach, led to significant reductions in HbA_{1c}, weight, blood pressure, and other cardiovascular risk factors in people with T2DM[12].

Little is known about the underlying decision-making process regarding the participation and adherence of the target groups to tele-medical lifestyle programmes. One promising approach to examine why some people participate and succeed in lifestyle-changing programmes and others do not is to ask patients about their preferences for these programmes. As one integral part of the multidimensional concept of patient-centeredness[18], preferences determine which alternative is most favourably evaluated by patients (e.g., which type of lifestyle programme is preferred).

Preferences can be determined not only for entire programmes but also for different components that make up a programme (e.g., the duration or intensity of a programme). These components might be evaluated differently by participants. Multi-attribute methods, such as the discrete choice experiment (DCE)[19–21], can help to identify preferred components, which are important for achieving better programme outcomes. To date, studies using a DCE to elicit preferences in people with diabetes have mostly examined preferences regarding treatment[22–26] and lifestyle changes[27-29]. Thus, there remains a need to clarify patients' preferences regarding the relative importance of components with respect to tele-medical lifestyle programmes and coaching approaches (e.g., involvement of the coach, internet platforms, mobile measurement instruments, or type of support). Knowledge of these preferences and the identification of groups of patients with similar preferences may be helpful for identifying new programme participants and for developing new or adapting existing health programmes by designing them in a more tailored and preference-oriented way.

It is also important to ask whether preferences are associated with programme success. A match between the preference for and the content of a programme is likely to improve a participant's adherence to and willingness to participate in a programme and thus the success of the programme in the form of better outcomes. Studies in which participants were matched to entire lifestyle programmes in accordance with their preferences found significant, albeit small, positive effects on treatment outcomes[30–34]. To the best of our knowledge, associations between preferences for certain components of tele-medical lifestyle programmes and programme success have not been investigated in diabetes care using DCE methodology. Knowledge of which particular components contribute to the success of tele-medical lifestyle programmes may be helpful for modifying programmes accordingly.

Another question that arises is whether participants' preferences change while they are participating in a tele-medical lifestyle programme. In principle, preferences are assumed to be stable[35–37]. However, as expressed preferences depend on individual information and experience, they may change as participants receive more information about the programme and its components during participation. Similar effects have been found for preferences with regard to cancer screening. Detailed information about recommended invasive follow-up testing for individuals at risk had negative effects on individuals' decision to participate in a non-invasive screening[38]. Knowledge of changes in preferences in individuals with diabetes participating in tele-medical lifestyle programmes would be helpful for adapting the components of a programme as it progresses.

Contribution to the field & Aims

With this study, we aim (i) to measure the preferences of people with T2DM regarding tele-medical lifestyle programmes and coaching approaches and to analyse the heterogeneity of these preferences, (ii) to investigate whether preferences predict programme success, and (iii) to compare participants' preferences before and after the intervention.

METHODS AND ANALYSIS

Patient preferences for tele-medical lifestyle programmes and coaching approaches are being elicited with a DCE in individuals who are participating in a randomised-controlled trial (RCT) for testing the effectiveness of the tele-medical lifestyle intervention programme TeLIPro[39]. Participants of the RCT are also taking part in the DCE. The DCE uses the infrastructure of the RCT for data collection. However, the DCE does not influence the RCT, the selection of participants, or the randomised assignment of the participants. In the following, we first

describe the TeLIPro Health Programme briefly. After this, we outline the development of the DCE and its assessment within the RCT.

The TeLIPro Health Programme

TeLIPro (TeLIPro Health Programme - Active with Diabetes) is a tele-medical lifestyle programme in Germany designed to help people with T2DM implement a healthy lifestyle through patient-centred and personal care[39]. Participants receive tele-medical devices, access to a secured tele-medical online portal, and tele-medical coaching from a personal health coach who supports and accompanies them for the duration of the programme. The programme is intended to improve blood glucose levels and therefore to improve or maintain the health status and the quality of life of the participants in the long-term. Ultimately, this should reduce the risk for concomitant and secondary diseases. The integration of the technology also supports the scalability of the programme, enabling it to meet the individual preferences and needs of the participants.

Development of the DCE to measure patient preferences

To measure preferences, we are employing a DCE, a stated preference method, which is the predominant method for eliciting patient preferences in all fields of health care[40–44]. The DCE methodology – based on the Random Utility Theory – allows researchers to estimate and contrast the relative strengths of preferences across a range of particular attributes. The first step in developing a DCE is to define the research problem under consideration (e.g., measuring patient preferences for tele-medical lifestyle programmes) and to adequately transfer it into an experimental framework[19–20]. The task comprises the identification and selection of attributes that reflect all characteristics relevant for a decision in the context of the research problem. The attributes (e.g., cost or duration of treatment) of the research problem are further specified by different levels (e.g., cost of $50 or $500 and 2, 3, or 4 hours). To

construct an experimental design, the levels of the attributes are systematically varied and presented in a series of choice sets each with the same number of alternatives (typically two alternatives). By standard economic theory, it is assumed that individuals will choose the alternative that maximises their utility. The preference weights for attributes and levels (part-worth preference weights) constitute the overall utility of an alternative. Thus, observed choices provide information about the relative weights of preferences for attributes and levels as well as about the overall utility of each alternative[45]. We are primarily interested in the preferences of participants who already decided to participate in a tele-medical coaching programme. Thus, we did not include an opt-out option because respondents have already chosen to participate in TeLIPro. To identify and select attributes and levels, we followed the current literature on the development of DCEs and implemented the following steps: (i) compilation of evidence, (ii) consultation of experts, (iii) consultation of people with diabetes as relevant actors, (iv) pretest, and (v) pilot test[46–47].

Compilation of evidence

First, we conducted a literature search to identify attributes used in DCEs to elicit preferences regarding lifestyle changes, coaching, and devices (see the online supplementary material). Based on the literature search, we summarised attributes regarding how comfortable the devices are to wear, the handling of the devices, the frequency of contact with the GP or the health coach, emotional support during the programme, responsibility for the physical activity schedule or diet schedule, and the time investment. We did not include monetary costs in our summary, because payments for the provision of health care in Germany are normally paid directly by the statutory health insurance, and therefore monetary costs are less relevant than the time investment for preferences regarding tele-medical lifestyle programmes.

Consultation of experts

Second, we discussed the attributes with health care experts (see acknowledgments) to ensure that the health care perspective, telehealth, and the clinical perspective were incorporated in the DCE. This process leads to a preliminary list of attributes (i) considering any possible attribute thought to be relevant to tele-medical lifestyle programmes for people with T2DM, (ii) including attributes with a special relevance for TeLIPro in order to best adapt patient preferences to the intervention envisaged in the project, and (iii) including those who could be realistically described in the choice scenario and were potentially amenable to change. This resulted in a list of seven attributes with 2-5 levels: the functions and handling of the online portal, the contacts to coach compared to GP contacts, the transfer of knowledge about a healthier lifestyle, emotional support, exercise plan, nutrition plan, and the total time required for the programme. This list formed the basis for the DCE design. The alternative attributes: communication between coach and doctors, competence of the coach, total number of contacts to coach, duration of the programme, intensity of the exercise programme, and exercise in groups or individually were used in the pretest.

Consultation of people with diabetes/Pretest

Third, we conducted qualitative interviews in the form of a cognitive pretest with five individuals with diabetes (December 2018 and January 2019). Participants were recruited from the self-help group (n=2) at the German Diabetes Center in Duesseldorf, Germany, and a specialised diabetes care practice (n=3) in Leverkusen, Germany, by email or personal contact. They participated on a voluntary basis and gave written informed consent prior to being included in the study. The interviewers were two researchers from the Institute for Health Services Research and Health Economics. Interviews were conducted face-to-face at the German Diabetes Center, the diabetes care practice, and the participants' homes. All interviews were logged and audiotaped. The individual interviews were conducted in order to ensure that (i) the most important attributes were included in the DCE, (ii) none of the chosen attributes

was dominant, (iii) proper levels were appointed to each of the attributes, and (iv) the task and the wording used in the questionnaire were comprehensible and feasible[19,45]. For the qualitative interviews, we developed a guideline based on cognitive pre-testing, including think-aloud methods, demand techniques (understanding individual words), paraphrasing (reproducing tasks), and sorting techniques (attributes were presented to participants on cards, and participants sorted them by personal relevance). In the first part of the interview, we introduced respondents to TeLIPro, and the questionnaire was presented piece by piece. To obtain more insight into how respondents understood the choice task, they were asked to think aloud during the interview. In addition, respondents were told to identify attributes and levels they did not understand or found hard to grasp and to provide suggestions for improvement. In the second part, all seven attributes of the DCE were presented on separate paper cards. Respondents were asked whether they could think of any other attributes that were important but had not been included so far. If so, the interviewer wrote these new attributes on blank cards, and respondents were asked what they considered important about these attributes and what kinds of levels of the attribute they could think of. If no more new attributes were mentioned, the additional cards with the six alternative attributes were laid out and explained to the respondents by the interviewer. Next, respondents were asked if they would swap one or more of the six alternative attributes or – if new attributes were mentioned – if they would swap the new attributes with one or more of the seven attributes in the programme. Two researchers reviewed the interviews and adjusted the DCE after an internal discussion. The attribute 'emotional support' was swapped with 'group activities', which was also modified to include the non-exercise group activities. The attribute 'frequency of contacts' was changed to 'communication between coach and doctors'. It asks if the coach and doctors have contact with each other instead of the patient to doctor and patient to coach ratios. The attribute named "the transfer of knowledge about a healthier lifestyle" was changed to "responsibility for getting acquainted with a healthier lifestyle" The level '4 hours per week' was removed from the

attribute ‘total time required’ because it was deemed unrealistic by respondents. The attributes ‘exercise plan’ and ‘nutrition plan’ were merged into ‘responsibility for setting goals to exercise and menu schedule’ because both attributes targeted the domain of autonomy, and the majority of the respondents swapped out one of these attributes. The description of the task concerning the selection of the choice sets was also rephrased to be more precise. This reduction in the number of attributes to six and the number of levels to two to four ensured an efficient design while also allowing the number of choice sets to be limited to a practicable number to prevent a mental burden that was too high for the participants. It was ensured that one combination of levels reproduced the actual TeLIPro health programme.

Pilot test

Fourth, we presented the revised DCE to the members of the self-help group (n=10) at one of their monthly meetings. On a pilot test, they answered a paper-pencil version of the DCE questionnaire and were asked at the end of the questionnaire if they had any suggestions for improvement. On the basis of these results, the attributes and levels as well as their descriptions in the questionnaire were not changed. The DCE instructions concerning the selection of the choice sets was again rephrased to clarify that the most preferred or least disliked programme of the two had to be chosen. The final six attributes with their corresponding levels are shown in Table 1.

Table 1: Final attributes and corresponding levels included in the DCE

Attributes	Descriptions	Levels
The functions and handling of the online portal	During the coaching programme, you are provided with different devices to measure your weight, your blood glucose, and the steps you have walked. These devices automatically transfer your data to an online portal that you and your coach can access. The range of	Extensive functions and more complex handling Less extensive functions and easier handling

	functions and the handling of the online portal can differ for different programmes. The more functions the online portal offers, the more complex the handling becomes.	
Communication between coach and doctors	Coaching programmes can differ on the basis of whether your coach and your doctors communicate about your treatment, the programme goals you have set, and your data in the online portal.	My coach and my doctors do not communicate My coach and my doctors do communicate
Responsibility for getting acquainted with a healthier lifestyle	Coaching programmes can provide you with information about various opportunities for lifestyle changes.	I receive information from my doctor I receive information from my coach I search for information myself
Group activities	Some coaching programmes contain activities in groups of 10-15 participants each. The activities include sports activities, cooking together, and also the exchanging of experiences by the group members in an online forum.	*No* group activities Group activities
Responsibility for setting goals to exercise and menu schedule	One part of the coaching programme is setting goals to exercise and eat well.	My coach sets my goals I set my goals independently My coach and I set my goals together
Total time required	Coaching programmes may differ in the amount of time you have to spend on the programme. This includes the time spent fulfilling your movement goals, talking to your coach, changing your diet, and using your devices correctly. The time required for potential group activities is not included.	12 hours per week 10 hours per week 8 hours per week 6 hours per week

DCE questionnaire design

The combination of the attributes in the different scenarios of the DCE and the compilation of the scenarios was based on the number and levels of the attributes as well as other content

and statistical requirements. SAS macros (SAS version 9.4) were used to define the optimal number of choice sets[48]. Particular care was taken to ensure that combinations of levels were realistic. The number of total choice sets takes respondents' cognitive capacity into account. The efficient factorial fractional design (*D*-error=0.12) consisted of 12 unique choice tasks. To control for the reliability of the choices that were made, choice set 7 was repeated as choice set 13, resulting in a total of 13 choice sets.

Assessment of the DCE within the RCT

The collecting of the DCE data is integrated into the collecting of the RCT data. Therefore, all RCT participants are asked to respond to the DCE. Next, we first describe the RCT, and then we describe the assessment of the DCE.

The RCT: The TeLIPro trial

The trial is aimed at assessing whether participating in the tele-medical lifestyle programme TeLIPro can improve the HbA_{1c} levels of people with T2DM. According to the sample size calculation computed for the RCT, 850 participants were recruited from within the members of a German statutory health insurance (Allgemeine Ortskrankenkasse, Rhineland/Hamburg, AOK) via informational letters and reminder telephone calls. Inclusion criteria consist of a T2DM diagnosis, age between 18 and 67 years, $HbA_{1c} \geq 6.5\%$, Body Mass Index (BMI) ≥ 27 kg/m², and a willingness to participate in the study. Participants are given detailed information about the programme and provide informed consent. Exclusion criteria consist of factors that would prevent successful participation in the programme, e.g., acute infections, addictions or dementia, as well as insufficient knowledge of the German language. Participants are being randomised (1:1) into an intervention group (IG) and control group (CG). Participants of the IG are given a scale, a step counter, access to a tele-medical online portal, a data hub for transmitting the measured values to the online portal, a glucose meter with test strips for the

self-monitoring of blood glucose, and tele-medical telephone coaching from a personal health coach in addition to routine care. The number and duration of interactions between the health coach and the individuals in the IG are determined by the needs of the participants (on average 14 interactions over the course of the intervention with a duration of 10–30 minutes each). The health coach encourages the participant, and they set goals together (i.e., behavioural changes concerning physical activity and eating). For the IG, the measures of blood glucose are recorded continuously, and pedometer data and weight (on a daily or weekly basis) are automatically transmitted to the online portal by the devices. The data can be viewed by both the participant and the coach. If a previously determined target value is exceeded or not reached, an alert is triggered, and the coach may decide to intervene. In addition to the monitoring function, the online portal provides information to support the change in lifestyle and enable participants to manage their illness autonomously, for example, text-based information on illness, nutrition, exercise, motivation, and health parameters. Furthermore, functions are available for communication and information exchange between the actors who are involved: participant and coach, as well as the attending general practitioner (GP) or relatives with the participant's consent. Therefore, it is easy to exchange information and adapt the therapy. The intervention will last 12 months. Participants of the CG are not accompanied by a coach. Except for this, they receive the same components of the programme as the IG. Participants register in the online portal and are asked for sociodemographic factors (sex, age, employment status, education) and the duration of their diabetes. Afterwards, the intervention begins. Participants are given devices and the IG is contacted by the personal health coach. In the online portal, all participants answer questionnaires about their health-related quality of life (Short-Form-Health Survey 12; SF-12), impairment due to depressive symptoms (German version of the Centre for Epidemiological Studies-Depression Scale; CES-D Scale), eating behaviour (German version of the Three-Factor Eating Questionnaire; FEV), and exercise behaviour (Global Physical Activity Questionnaire, GPAQ)[49-52] at baseline, 3 months, 6

months, 9 months, 1 year (completion of the intervention), 15 months (follow-up phase), and 18 months (follow-up phase) after baseline. If a questionnaire is not answered within two weeks, participants are reminded by a telephone call from the online portal service staff. On a quarterly basis, the participants' HbA_{1c} level, BMI, fasting blood glucose, blood pressure, triglycerides, HDL/LDL cholesterol, antihyperglycemic treatment, and blood pressure medication are assessed by asking the attending GP. Body weight is recorded weekly, and walked steps are recorded daily by the devices for both groups. For the IG, blood glucose is monitored daily. The primary outcome is the HbA_{1c} level. Secondary outcomes include cardiovascular risk factors, health-related quality of life, and medication. The analysis of the effectiveness and health economic evaluation of the TeLIPro trial will be the topic of a later publication.

Assessment of the DCE

To address the DCE, respondents are provided with an extensive explanation of the meanings of all attributes and levels as well as information on how to deal with a choice set, accompanied by an example. Afterwards, respondents are told that they need to choose between two lifestyle programmes in the following choice sets. They are told that 13 choice sets are best suited for determining what type of lifestyle programme is preferred. Respondents are told to always choose their personally best-suited or least-rejected lifestyle programme and that there are no right or wrong answers. They are also reminded that they can always opt for a programme with all the features listed. Every choice task is accompanied by the invitation: 'Please select the coaching programme that suits you best'. Then both programmes (Programmes A and B) are presented (see Figure 1) followed by the question: 'Which programme do you prefer? (Please tick the appropriate box)'. Figure 1 presents an example of a choice task as included in the questionnaire. The DCE is measured before the start of the intervention and after 1 year when the intervention has been completed. Data collection for the DCE began in January 2019 and is anticipated to take place until December 2020.

- *Please insert Figure 1 here* -

Data analysis for the DCE

To derive the preferences of people with T2DM regarding tele-medical lifestyle programmes (i.e. relative preference weights for attributes and levels), the obtained baseline DCE data will be analysed using a conditional logit model. Preference weights describe the relative strength of each attribute and level in comparison with all other attributes and levels, respectively. Furthermore, the preference weights will be expressed as time equivalents (willingness to invest time) by calculating the trade-off or marginal rates of substitution between attributes and the attribute that focuses on the time required by the programme. To investigate possible preference heterogeneity, we will conduct a latent class analysis (LCA). The number of classes is determined by the Bayesian information criterion as well as an examination of the interpretation of the latent classes. The following covariates will be incorporated into the LCA: sociodemographic factors (sex, age, employment status, and education), disease-related characteristics (HbA_{1c} level, duration of diabetes, BMI), exercise behaviour, depressive symptoms, and health-related quality of life. Because the IG and CG are not expected to differ at baseline due to randomisation, the analysis will be based on the full sample.

We will investigate the effect of latent classes of preferences at the beginning of the study on programme success at the end of the study. This will be done by means of an LCA with a distal outcome, where programme success is regressed on latent preference classes. This approach will allow us to explore whether programme preferences differ with respect to distal outcomes such as programme success. This type of analysis may lead to additional information about heterogeneity in the (study) population.

To investigate changes due to participation, preference weights before and after participation in the programme will be compared descriptively and analysed using time equivalents. The

analysis will be outlined separately for the IG and the CG as their experiences during the intervention phase will differ substantially.

Sample size calculation for the DCE

As no initial estimates about parameter values in the target population are available, we applied a rule of thumb to determine the sample size instead of a parametric approach. According to de Bekker-Grob et al. [53], one frequently used rule of thumb suggests $N > 500c/(t * a)$, where c is the largest number of levels among attributes, t is the number of choice tasks, and a is the number of alternatives per choice task. This was later refined by Orne [54] to $N > 1000c/(t * a)$, which resulted in a sample size of $N = 167$ for our design. The recruitment of 850 participants for the RCT will likely lead to a large enough sample that can be stratified for the IG and CG.

Patient and Public involvement

Patient involvement during the various stages of the development of the DCE (qualitative interviews, pilot tests) ensured that the research question relied on the actual preferences of people with T2DM participating in tele-medical lifestyle programmes.

ETHICS AND DISSEMINATION

The DCE study has been approved by the ethics committee of the medical faculty of the Heinrich Heine University committee of the Heinrich-Heine University Duesseldorf, registration number 2018-242-ProspDEuA, registered on December 6th, 2018. The TeLIPro trial is registered at the U. S. National Library of Medicine, registration number NCT03675919, registered on September 15th, 2018. Patient consent to participate was obtained for the RCT as well as for the DCE. Data analysis will be done according to the principles of good scientific research on DCEs developed by the International Society for Pharmacoeconomics and

Outcome Research (ISPOR). We aim to disseminate our results in peer-reviewed journals and at national and international conferences to interested patient groups and the public.

ACKNOWLEDGEMENTS

We thank the team of the TeLIPro trial: the AOK Rhineland/Hamburg statutory health insurance (leader of the trial consortium), the German Institute for Telemedicine and Health Promotion GmbH (DITG), the Private Institute for Applied Care Research GmbH (inav), and the Association of Statutory Health Insurance Physicians of North Rhine-Westphalia (cooperation partner). We acknowledged the work of the DITG in programming and implementing the DCE at the online platform. We thank the diabetes care practice Kaltheuner, Schultens-Kaltheuner, Hannig, Marenbach, and their staff from Leverkusen, Germany, for their support. We also thank the volunteers from the self-help group at the German Diabetes Center in Duesseldorf, Germany, and the diabetes care practice in Leverkusen, Germany for participation in this study.

AUTHOR STATEMENT

MV and AI contributed to the initial grant application. All authors contributed to the design of the study and are involved in the implementation of the project. JS wrote the first draft of the protocol. JS, JD, SG, VG, MV, MR, and AI contributed to the drafting and editing of the protocol. All authors read and approved the final protocol.

FUNDING

This work was supported by the Innovation Fund coordinated by the Innovation Committee of the Federal Joint Committee (funding period 2018 - 2021) grant number 01NVF17033 under the consortium leadership of the AOK Rhineland/Hamburg.

CONFLICTS OF INTEREST

The authors declare that they have no competing interests.

DATA STATEMENT

After the data are collected and the results are published, the data will be made available upon reasonable request.

SUPPLEMENTARY MATERIAL

Results of the literature review to identify attributes used in DCEs to elicit preferences regarding lifestyle changes, coaching, and devices.

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Caption of Figures

Figure 1: Example of a choice task used in the discrete choice experiment.

First Choice

Please select the coaching programme that suits you best.

	Programme A	Programme B
The functions and handling of the online portal	**Extensive** and **complex**	**Less extensive** and **simple**
Communication between coach and doctors	My coach and my doctors **do not** communicate	My coach and my doctors **do** communicate
Responsibility for getting acquainted with a healthier lifestyle	I receive information from my **doctor**	I receive information from my **coach**
Group activities	No group activities	Group activities
Responsibility for the goals of the exercise and menu schedule	**My coach sets my goals**	**I set my goals independently**
Total time required	**10** hours per week	**8** hours per week
Which programme do you prefer? (Please tick the appropriate box)	☐	☐

Supplementary File

Results of the literature review to identify attributes used in DCEs to elicit preferences regarding lifestyle changes, coaching, and devices.

DCE Topic	Attribute	Levels	Reference
Devices	Comfort of wearing	- Warm and squeezing - Breathing and not squeezing - Comfortable - Uncomfortable	Bouman et al.,2016 [1] Bunge et al., 2010 [2]
Devices	Appearance	- Thick material and skin colored - Thin material and color of choice - Visible - Not visible	Bouman et al.,2016 [1] Bunge et al., 2010 [2]
Devices	Help Needed	- Help needed - Independently - No help needed while emptying your bowels - You need less help than you did previously - You need as much help as you did previously - You need more help than you did previously	Bouman et al.,2016 [1] Nafees et al.,2016 [3]
Devices	Duration of therapy	- 6 months - 15 months - 24 months	Bouman et al.,2016 [1]
Devices	Device Hygiene	- Hand washed, dries slowly - Machine washed, dries quickly - Mouthpiece can be washed, but not replaced - Mouthpiece can be replaced, but not washed - Mouthpiece can be cleaned with a dry cloth, but not washed or replaced	Bouman et al.,2016 [1] Hawken et al.,2017 [4]
Devices	Easy to Use	- 1 step - 2 to 3 steps - More than 4 steps - You will use an automatic pump (process requiring ~15 steps) - You will use a manual pump (process requiring ~30 steps)	Hawken et al.,2017 [4] Nafees et al.,2016 [3]
Devices	Flexibility of device handling	– Inhaler can be held in any position throughout inhalation process – Inhaler must be held in certain position throughout inhalation process	Hawken et al.,2017 [4]
Devices	Time to use per treatment	- 5 minutes - 10 minutes - 15 minutes - 25 minutes - 30 minutes - You will spend up to 30 minutes - You will spend up to 1 hour - You will spend up to 1.5 hours - You will spend up to 2 hours	Mohamed et al.,2015 [5] Nafees et al.,2016 [3]

DCE Topic	Attribute	Levels	Reference
Devices (Coaching)	Frequency of use	- None - 2 pills 3 times a day (6 pills per day) - 3 pills 4 times a day (12 pills per day) - 2 times per day - 3 times per day - Once every two days on average - Once every day on average - Twice a day on average - Three times a day on average - Once per day - Once per week - Once per month - Once per 3 months - Once per 6 months - Once per year	Marshall et al.,2017 [6] Mohamed et al.,2015 [5] Nafees et al.,2016 [3] Quaife et al.,2016 [7]
Coaching	Training of the IP (information provider)	- Counselor with specialized training in use of medications during pregnancy only - Family doctor with general health training	Hancock-Howard et al.,2012 [8]
Coaching	Method of counseling and waiting time	- Make an appointment and meet with the IP in person in 3 days - Call a telephone service and receive the information within 30-minutes	Hancock-Howard et al.,2012 [8]
Coaching	Knowing the IP	- You have met the IP before and they know your medical history - You have never met the IP	Hancock-Howard et al.,2012 [8]
Coaching	Confidence in the skills of the IP	- You have confidence in the skills of the IP - You know nothing about the skills of the IP	Hancock-Howard et al.,2012 [8]
Coaching	Helpfulness of information	- Enough information has been provided that you believe your question has been answered to your satisfaction - Some information has been provided to you, but your question has not been completely answered to your satisfaction	Hancock-Howard et al.,2012 [8]
Coaching	Time away from home/office/usual activities including travel	- More than four hours - 3–4 h - 1–2 h	Spinks et al.,2016 [9]
Coaching	Wait time to get result	- Up to three days - Up to one day - Less than four hours	Spinks et al.,2016 [9]
Coaching	Who reviews the result	- GP - Telederm dermatologist	Spinks et al.,2016 [9]
Coaching Diabetes	Feedback on physical activity performance	- Patient receives feedback on his or her individual performance - Patient's performance is compared with that of other patients	Ramirez et al.,2016 [10]
Coaching Diabetes	Physical activity behavior-change education	- Patient's doctor recommends the educational content - Patient specifies the type of educational content he or she wants to receive	Ramirez et al.,2016 [10]
Coaching Diabetes	Frequency of messaging	- Patient's doctor recommends how often patient should receive messages - Patient specifies how often he or she wants to receive messages	Ramirez et al.,2016 [10]

DCE Topic	Attribute	Levels	Reference
Lifestyle Diabetes	Menu schedule	- *Flexible* you set your own goals and develop your own menu schedule to reach these goals without the assistance of a lifestyle coach - *General* your lifestyle coach informs you about health and unhealthy foods, using food information and examples of recipes - *Elaborate* your lifestyle coach develops a menu schedule that meets your needs and wishes - Flexible: primarily based on the participants' own initiatives and ideas - General: includes general information on a healthy diet and provides example recipes - Elaborate: a patient tailored schedule that is completely prepared by the lifestyle coach - Flexible (you composed this schedule) - General (with information about diet and examples of recipes) - Elaborate (this schedule is composed for you and tailored to your needs)	Salampessy et al.,2015 [11] Veldwijk et al.,2013 [12] Wanders et al.,2014 [13]
Lifestyle Diabetes	Physical activity schedule	- Patient's doctor recommends physical activity goals - Patient selects his or her own personalized physical activity goals - *Flexible* you set your own goals and develop your own activity schedule to reach these goals without the assistance of a lifestyle coach - *General* your lifestyle coach informs you about what physical activities would be good for you, using information about physical activity and examples of exercises - *Elaborate* your lifestyle coach develops a physical activity schedule that meets your needs and wishes - Flexible: primarily based on the participants' own initiatives and ideas - General: includes general information on PA, and provides example exercises - Elaborate: a patient tailored schedule that is completely prepared by the lifestyle coach - Flexible (you composed this schedule) - General (with information about physical activity and examples of exercises) - Elaborate (this schedule is composed for you and tailored to your needs)	Ramirez et al.,2016 [10] Salampessy et al.,2015 [11] Veldwijk et al.,2013 [12] Wanders et al.,2014 [13]

DCE Topic	Attribute	Levels	Reference
Coaching Lifestyle Diabetes	Consultation Structure / Social support	- Family members learn how to offer support - Patient meets other patients so they can support one another - *Individual* the consultations of the lifestyle program are individually - *Consultation 5* the consultations of the lifestyle program are in groups of *5 other patients* - *Consultation 10* the consultations of the lifestyle program are in groups of *10 other patients* - Individually - Groups with 5 other T2DM patients - Groups with 10 other T2DM patients - individual - in a group with 5 other people - in a group with 10 other people	Ramirez et al.,2016 [10] Salampessy et al.,2015 [11] Veldwijk et al.,2013 [12] Wanders et al.,2014 [13]
Lifestyle Diabetes	Time spent on the program	- 2.5 hours per week - 4 hours per week	Van Gils et al.,2011 [14]
Lifestyle Diabetes	Arrangement physical activity lessons	- Individually with men and women - With people of the same gender	Van Gils et al.,2011 [14]
Lifestyle Diabetes	Group activity	- Only with people without diabetes - Only with other diabetes patients	Van Gils et al.,2011 [14]
Lifestyle Diabetes	Sports activity	- Walking/cycling - Fitness (treadmill, rowing machine, bicycle)	Van Gils et al.,2011 [14]
Lifestyle Diabetes	Counseling	- None - Physical therapist/sports teacher	Van Gils et al.,2011 [14]

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