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EFFECTIVENESS OF A TARGETED LIFESTYLE INTERVENTION IN PRIMARY CARE ON DIET AND PHYSICAL ACTIVITY AMONG SOUTH ASIANS AT RISK OF DIABETES: 2-YEAR RESULTS OF A RANDOMISED CONTROLLED TRIAL

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Effectiveness of a targeted lifestyle intervention in primary care on diet and physical activity among South Asians at risk of diabetes; 2-year results of a randomised controlled trial

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ABSTRACT

Objectives. In South Asian populations, little is known about the effects of intensive interventions to reduce the risk of type 2 diabetes on health behaviour. We examined the effectiveness at 2 years of a culturally-targeted lifestyle intervention on diet, physical activity and determinants of behaviour change among South Asians at risk of diabetes.

Design. Randomised controlled trial with de facto masking

Setting. Primary care.

Participants. A total of 536 18-60 year old South Asians at risk of diabetes (i.e. with impaired glucose tolerance, impaired fasting glucose, or relatively high insulin resistance) were randomised to the intervention (n=283) or a control (n=253) group. Data of 314 participants (n= 165 intervention, n=149 control) were analysed.

Interventions. The culturally-targeted intervention consisted of individual counselling using motivational interviewing (6-8 sessions in the first 6 months plus 3-4 booster sessions), a family session, cooking classes, and a supervised physical activity programme. The control group received generic lifestyle advice.

Outcome measures. We compared changes in physical activity, diet and social-cognitive underlying determinants between the two groups at 2-year follow-up.

Results. At 2-year follow-up participants in the intervention group were more moderately-to-vigorously active than at baseline but, compared with changes in the control group, the difference was not significant (change min/week 142.9 versus 0.5, p=0.672). Also, no significant difference was found between the two groups in changes on any of the components of the diet or the social-cognitive determinants of diet and physical activity.

Conclusions. The culturally-targeted lifestyle intervention led to high drop-out and was not effective in promoting healthy behaviour among South Asians at risk of diabetes. Given the

high *a priori* risk, we recommend to develop new strategies, preferably more accessible, to promote healthy behaviour.

Trial registration: NTR1499; www.trialregister.nl/trialreg/admin/rctview.asp?TC=1499

Strengths and limitations of this study

- The intensive intervention in this trial was culturally targeted, based on a needs assessment and formative research, to characteristics of South Asians living in the Netherlands.
- This study reports on physical activity, diet as well as the determinants of behaviour change, thus contributing to the yet limited knowledge about the effects of intensive interventions on behavioural measures among South Asians.
- Potential selection related to the relatively low participation and high drop-out from the trial may have led to a biased estimate of intervention effects.
- We assessed the intervention effects on health behaviours with selfreported measures, which may be influenced by various reporting biases.

BACKGROUND

Diet and physical activity are key modifiable risk factors for type 2 diabetes mellitus (T2D), and interventions targeting these behaviours can help to prevent or postpone this disease [1-5]. Efficacy trials have shown that, in high-risk individuals, the onset of T2D may be prevented or postponed through individual diet counselling and physical activity guidance through reduction in weight and waist circumference [2-5]. Trials in a standard care setting aimed at promoting a healthy diet and physical activity have yielded similar, albeit more modest, results [6-8].

South Asian migrants and their offspring (hereafter referred to as 'South Asians') living in high-income countries are, in particular, at high risk for T2D [9-13]. Strategies targeting diet and physical activity have been implemented to reduce this increased risk among these populations. However, the trials evaluating intensive diet counselling and physical activity guidance in South Asian populations in the UK and in the Netherlands yielded only moderate results in terms of the reduction of weight and waist circumference [14-15].

One of the reasons for the moderate results could be that, in these trials, the interventions implemented do not lead to the intended changes in dietary behaviour and physical activity. However, little is known about the effects of intensive interventions on behavioural measures among South Asians [16]. These measures not only include dietary behaviour and physical activity, but also social-cognitive determinants (such as self-efficacy) as a result of which changes in these behaviours occur [17-19].

Therefore, the present study aims to analyse the effectiveness of an intervention among South Asians living in the Netherlands aimed at preventing T2D, with regard to changes in dietary habits, physical activity, and the social-cognitive determinants of behaviour change. Whereas our earlier study described the effects of this intervention on weight and other metabolic outcomes after one year [14], the effects on behavioural measures have not yet been investigated. In that intervention, motivational interviewing and tailored risk information were used to address social-cognitive factors underlying dietary behaviour and physical activity, including risk perception, attitudes, social support, and self-efficacy. The intervention was based on a needs assessment and formative research, and targeted to characteristics of South Asians living in the Netherlands.

METHODS

Study population

All those included in the present investigation were participants of the DHIAAN study: this is a randomised controlled trial (no. NTR1499) investigating the effectiveness of a culturally-targeted intensive lifestyle intervention to prevent T2D and cardiovascular risk factors among South Asian Surinamese in primary care [20]. The primary outcomThe term South Asian Surinamese (or Hindustani Surinamese) refers to people of South Asian ancestral origin and their offspring who migrated to the Netherlands via Suriname. The South Asian Surinamese are descendants of the labourers from North India (Uttar Pradesh, Uttaranchal, and West Bihar) who were indentured between 1873 and 1917. The two large migration waves of South Asian Surinamese to the Netherlands were caused mainly by the political situation in Suriname. The first wave took place at the time of the independence of Suriname in 1975 and the second wave (at the time of Desi Bouterse's coup) in February 1980 [21].

Details of the DHIAAN study, including changes to the original protocol, and the process of adapting the lifestyle intervention for the social-cultural and social-cognitive determinants of South Asian Surinamese, are already published [20,22]. In brief, 2307 South Asian Surinamese (aged 18-60 years) living in The Hague (the Netherlands), were screened via general practices between 18 May 2009 and 11 October 2010 (Fig. 1). To achieve a high response rate, a culturally-targeted intensive recruitment strategy was used that was proven feasible in the pilot of the DHIAAN study [20]. General practitioners (GPs) sent each potential participant an invitation, together with a reply card that could be returned if further contact was not wanted. Invitees who did not respond received a written reminder and were also contacted by telephone.

All potential participants were requested to fill out a brief questionnaire, undergo a physical examination, and provide a fasting blood sample. The 968 participants who were invited and screened between 18 May 2009 and 18 April 2010 also took an oral glucose tolerance test (75 g).

Inclusion in the trial

Screened participants with impaired fasting glucose (fasting glucose of 5.6-6.9 mmol/l), impaired glucose tolerance (2-hour post-load glucose of 7.8-11.0 mmol/l), a glycated haemoglobin (HbA1c) level of ≥ 42 mmol/mol , and/or a value of ≥ 2.39 for the homeostasis model assessment-insulin resistance (HOMA-IR) were invited to participate in the trial [20] (Fig. 1).

Excluded was anyone who was already involved in a lifestyle programme, was pregnant, had a chronic disease that made participation in the intervention impossible, and/or used drugs that interfered with plasma glucose levels. Also excluded were participants with newly diagnosed T2D (i.e. a fasting glucose ≥7.0 mmol/l, a 2-h post-load glucose ≥11.0 mmol/l, or a HbA1c level ≥48 mmol/mol); these persons were referred to regular clinical care.

As described previously in more detail [14,20], 536 people were randomly assigned to either the intervention or the control group using a computer-generated randomisation list (simple randomisation). Family or household members (defined by postal code and house number) were assigned to the same group. Participants were informed about the procedures for the arm of the trial that they were assigned to; the masking (de facto masking) of the two groups was maintained throughout the trial.

The study was approved by the Institutional Review Board of the Academic Medical Center, Amsterdam. All participants provided both oral and written informed consent.

Intervention group

All participants in the intervention group were offered a culturally-targeted lifestyle intervention [22]. The design of this intervention was in line with the design of the proven efficacious intervention used in the Study on Lifestyle Intervention and Impaired Glucose Tolerance Maastricht (SLIM), which aimed to evaluate the effect of that intervention on glucose tolerance in a European Dutch population [23]. For the present study, the latter intervention was culturally adjusted to the South Asian Surinamese population, as cultural adaptations are likely to promote the effectiveness of interventions among specific ethnic populations [24]. Both surface and deep structure adaptations were used to make the intervention attractive, appropriate and ultimately more potentially effective in the present study population [22].

The intervention was designed to be carried out by dieticians within their usual practice setting. The aim was to meet current national guidelines for diet and physical activity [25,26]. In the first 6 months, dieticians used motivational interviewing during 6-8 individual lifestyle counselling sessions, followed by 3-4 booster sessions over the following 18 months. The dieticians were trained in motivational interviewing, in which previous successes, skills and strengths of the client were highlighted to support self-efficacy [27]; dieticians were also familiar with the South Asian culture and dietary habits. Special attention was paid to generate appropriate risk perception, a positive attitude towards a healthy lifestyle, and the possible barriers and motivating factors specific to the South Asian population; these were elicited from the literature and focus group discussions [22].

In addition, dieticians offered a family session at the participant's home, with the aim to engage the family in supporting the individual participant in achieving dietary goals. Participants were also offered two group-based cooking classes to increase their self-efficacy in and to learn skills for adjusting traditional dishes to meet nutritional guidelines.

Furthermore, we offered a 20-week physical activity programme to all participants in the intervention group. This 'exercise on prescription' programme is described elsewhere [28-30]. Trained coaches monitored participation in the programme.

Control group

Participants in the control group were invited to join two group sessions led by student dieticians (at baseline and after 6 months). The sessions provided generic information about T2D and discussed current guidelines for diet and physical activity. These participants received two leaflets (at 3 and 9 months) with simple, generic lifestyle advice.

Data collection

Trial visits were planned for both groups at baseline, and after 1 and 2 years [20]. The invitation procedures for these visits were similar to the intensive procedures used during the screening. Participants who did not respond to the invitation for the follow-up visit were contacted by telephone and received a written reminder. In addition to written confirmation of their appointment, all participants received a text message reminder the day before their appointment.

During the visit, a trained interviewer conducted a face-to-face interview with each participant. Trained research staff used a standardised protocol for the physical examinations.

They measured weight on a mechanical scale (Seca 761, Hamburg, Germany) to the nearest 500 g and height was measured to the nearest 0.01 m. The anthropometric measurements were obtained twice and the means were used for analysis.

During all visits, all participants provided a fasting blood sample and were offered an oral glucose tolerance test. Measurements of fasting plasma glucose and 2-hour post-load glucose (oral glucose tolerance test, 75 g; hexokinase, Roche Diagnostics), HbA1c (high-performance liquid chromatography), and insulin (immunoassay, sandwich principle, Roche Diagnostics) were carried out according to a standardised protocol at the SHL Group (laboratory), Etten-Leur (the Netherlands). The HOMA-IR was calculated as glucose (mmol/l) multiplied by fasting insulin (mU/l) divided by 22.5 [31].

Data on participation were recorded by dieticians and obtained from the process data collected from participants during the first year [20].

Measurements and definitions

Physical activity, diet, and social-cognitive determinants of behaviour change were noted during the trial visits [23,32]. Physical activity was assessed with the Short Questionnaire to Assess Health-enhancing Physical Activity (SQUASH), supplemented with culturally-specific activities [33,34]. Three measures were defined: i) any versus no moderate-to-vigorous activity, ii) the total moderate-to-vigorous activity expressed in min/week, and iii) the total activity expressed in min/week.

Dietary intake was determined using questions based on the national guidelines for a healthy diet, supplemented with questions on group-specific dietary behaviours of the South Asian

population [22,25]. Fruit, vegetables, rice, and whole wheat intake was assessed with multi-item questions (with 3, 2, 2, and 11 items, respectively) to determine the quantity and frequency. Moreover, two single-item questions addressed the regularity of the meals. These aspects of the diet were dichotomised into meeting versus not meeting the guideline (Box 1).

Box 1. Categories used for meeting the dietary guidelines

	Meeting the guideline[a]
Fruit intake	2 pieces of fruit/day
Vegetable intake	200 g vegetables/day
Whole wheat intake	Almost exclusively whole wheat products
Regular eating pattern	3 meals/day at a regular time
Rice intake	Almost exclusively brown rice

[a]Derived from the current national guidelines for diet [25], with the exception of rice for which no guideline has been established.

Social-cognitive determinants of behaviour change

Risk perception consisted of measures of perceived susceptibility and two components of Leventhal's common-sense model of representations of illness and self-regulation [35], i.e. causal beliefs and perceived controllability by physical activity. Causal beliefs were measured with 12 statements about the perceived influence of certain behaviours or characteristics on the onset of diabetes, on a 3-point Likert scale. The statements concerned (a) general lifestyle beliefs related to seven general risk factors for diabetes, (b) three group-specific lifestyle beliefs (consumption of masala and large amounts of white rice and sugar) derived from our focus group discussions, and (c) two heredity beliefs (e.g. family history of diabetes and being a South Asian) [22, 36]. The general lifestyle beliefs related to overweight, unhealthy food, insufficient exercise, hypertension, age, and smoking were combined into a single factor based on the results of internal consistency analysis (n=6, α=0.63; a score of $\geq$ 4 indicating

'perceiving general lifestyle as a cause of type 2 diabetes mellitus'). Perceived controllability with physical activity was measured by a single item on a 5-point Likert scale. Perceived susceptibility was measured with a 3-item perceived susceptibility score, on a 5-point Likert scale (n=3, α=0.63) [37].

Internal consistency analysis resulted in three factors for attitudes towards physical activity and diet: direct (enjoyment and importance; n=4, α=0.64) and indirect attitude towards physical activity (possible consequences of increasing physical activity; n=7, α=0.67), and the attitude towards conventional healthy dietary behaviours (enjoyment and importance of a regular eating pattern and breakfast, fruit, vegetable, whole wheat intake; n=10, α=0.84). We also measured the attitudes (enjoyment and importance) towards two group-specific healthy dietary behaviours (replacing white rice with brown rice, and refusing snacks at parties).

Two factors were formed for social support: perceived social support for physical activity from other family members and close relatives (n=2, α=0.68), and perceived social support for the conventional healthy dietary behaviours (n=5, α=0.94). We also measured the perceived social support for physical activity from the spouse and the perceived social support for two group-specific healthy dietary behaviours (replacing white rice with brown rice, and refusing snacks at parties).

Self-efficacy was reflected in two combined factors: perceived self-efficacy for physical activity (n=5, α=0.73), and perceived self-efficacy for the conventional healthy dietary behaviours (n=5, α=0.66). Moreover, we measured self-efficacy expectations for two group-specific healthy dietary behaviours (replacing white rice with brown rice, and refusing snacks at parties).

The stages of change towards diet and physical activity were classified as being motivated or not motivated to change one's diet according to the Dutch guidelines, and physical activity within 6 months. The stage of change towards diet was measured for each specific dietary behaviour. One factor was formed for stage of change towards the conventional healthy dietary behaviours (n=5, α=0.73).

For analysis, we dichotomized all resulting variables, e.g. perceiving versus not perceiving having a family history of diabetes as cause. In addition, as the group-specific items (e.g. refusing snacks at parties) did not load on the aforementioned scales, we decided to include these in the analysis as single items.

Other factors

Age and gender were determined from the GPs' registries. Education level was measured at the initial screening. The categories for education level were low (primary education or less), intermediate (lower vocational training, lower secondary education, intermediate vocational training, and higher secondary education), and high (higher professional training or university). A family history of diabetes was defined as having a first- or second-degree family member with diabetes. Body mass index (BMI) was calculated as weight (kg)/height $(m)^2$.

Statistical analysis

In the current analysis we included all those who participated in both the baseline measurement and measurement at 2-year follow-up, and excluded anyone without data on physical activity or diet at baseline and/or at 2-year follow-up (Figure 1). This means that 314 participants remained for the present analysis: 165 in the intervention group with a mean

follow-up time of 22.1 (21.0-23.8) months and 149 in the control group with a mean follow-up time of 22.1 (21.3-23.2) months.

The means [standard errors (SE)], medians (IQR), or n (percentages) are used to describe the baseline characteristics of the remaining participants in both groups. Baseline differences between groups were checked using independent sample t-tests, Mann-Whitney U tests and chi-square tests. In addition, for those in the intervention group, their participation in elements of the intervention was described, i.e. dietary counselling, cooking classes, family sessions and/or the exercise programme.

Changes in physical activity, diet and the social-cognitive determinants of behaviour change are also described. For the continuous measures, the mean difference was determined in changes between baseline and 1 and 2-year follow-up, respectively. For the other measures, we determined the percentage of participants with a positive change (e.g. from non-adherence to adherence to the guideline for fruit intake) or a negative change (e.g. from a regular to an irregular meal pattern) at 1 and 2-year follow-up. Except for the belief that masala intake is a possible cause of diabetes, and the attitude towards refusing snacks at parties, positive changes were expected to positively influence lifestyle behaviour and health. Independent sample t-tests were used to compare the mean changes, and chi-square tests and (where relevant) Fisher's exact tests were used to compare the percentage positive and negative changes between the two groups. To avoid additional testing, this was only done for the changes at 2-year follow-up, as the present analysis focuses on the effects two years post-baseline.

In the present study we did not consider multiple imputations or more complex modelling of patterns of missingness. This decision was based on a comparison of the baseline characteristics between participants with and those without a measurement at 2-year follow-up. Apart from being younger and having a higher HOMA-IR, those who participated in the measurement at 2-year follow-up had baseline characteristics similar to those who dropped-out (Online supplement 1). Drop-out was similar in both groups [age and sex adjusted OR 1.02 (0.72-1.45)], and these differences did not vary by age or gender ($p>0.05$ for the interaction terms). In addition, we analysed different patterns of missingness in relation to the reported total physical activity, meal pattern and whole wheat consumption, using a pattern mixture model in the total study population and found no significant evidence for an effect (data not shown).

We did not perform multilevel analysis with the data on dieticians. In line with previous analyses of the DHIAAN data [14, 32], no evidence was found for dependencies between participants registered with the same dietician (data not shown). Furthermore, as only 29 people with family members in the study had follow-up data available, no multilevel analysis was performed on family data.

The SPSS 19.0 (SPSS Inc., Chicago, Illinois, USA) and R2.15.3 (R Foundation for Statistical Computing, 2009) were used for the analyses. A p-value <0.05 was considered to be statistically significant.

RESULTS

Baseline characteristics

At baseline, both groups were similar in terms of demographic characteristics and physical activity (Table 1 and 2). Most of the participants reported to be moderately-to-vigorously active: 82% of the intervention group and 79% of the control group (Table 2). Moreover, at baseline, similar proportions in both groups met the guidelines for fruit, whole wheat intake, a regular meal pattern, and use of brown rice. However, vegetable intake differed between the groups: 68% of the intervention group ate 200 g of vegetables/day compared with 56% of the control group. At baseline, the social-cognitive determinants (with the exception of enjoyment of snacks) were also similar in both groups (Table 3). The observed percentage of people with a positive response varied largely between the determinants. For example, ≥ 90% of both groups had a positive attitude toward physical activity and a healthy diet, whereas ≤ 50% of the population reported to experience social support from their partner regarding healthy behaviour.

Participation in the intervention

In the intervention group, 81.8% of the respondents participated in the intake for the individual lifestyle counselling sessions. Of this latter group, 94.8% attended at least one additional session, with a median number of eight sessions (IQR 4-9) per person (in addition to the initial intake visit). Moreover, 14.4% participated in a supplemental family session, 12.7% in the cooking classes and 26.3% in the supervised exercise sessions.

Effect of the intervention on physical activity and diet

Participants in the intervention group were more moderately-to-vigorously active at 2-year follow-up than at baseline but, compared with the change in the control groups, the difference

was not significant (Table 2). In addition, while more participants in the intervention group than in the control group met the guidelines for several dietary behaviours (e.g. whole wheat intake, eating brown rice and fruit) at 2-year follow-up, none of these changes significantly differed between the groups (Table 2).

Remarkably, a substantial percentage of people who were adherent to a specific guideline at baseline were no longer adherent 1 or 2 years later ('negative' change). For most behaviours this percentage is almost as high as the percentage 'positive' change.

Effect of the intervention on social-cognitive determinants of behaviour change

At 2-year follow-up, no significant difference was found between the two groups in any of the social-cognitive determinants of behaviour change (Table 3). A positive change was observed in several of the social-cognitive determinants of behaviour change among part of the intervention group and similar changes were observed in the control group. For instance, 22.4% of those in the intervention group who did not perceive themselves as susceptible at baseline, perceived themselves as susceptible to the onset of diabetes after 2 years; in the control group, this figure was 21.5% (p=0.941 for the difference between groups). Similar to the results for dietary behaviour and physical activity, remarkably high percentages of participants showed a 'negative' change in social-cognitive determinants.

DISCUSSION

This study examined the effect of a culturally-targeted intervention on behavioural measures on dietary behaviour and physical activity among a South Asian population at risk of T2D. At 2-year follow-up, no significant difference was found between the intervention and the control group in changes in any of the components of dietary and physical activity behaviour, or in the social-cognitive determinants underlying these behaviours. Notably, in both groups, the proportion of participants reporting a less healthy behaviour at 2-year follow-up almost equalled the proportion reporting a more healthy behaviour. The percentage of participants lost to follow-up was high.

Study Limitations

In addition to a relatively low response rate for the initial screening and for the baseline evaluation, a relatively high number of participants dropped-out of the study. This low participation rate limits the reach and potential impact that the intervention may have in practice. In addition, we are aware that selective drop-out may lead to a biased estimate of intervention effects. However, analysis of the characteristics of those who dropped-out and the evaluation of patterns of missingness provided no clear evidence on the direction in which our estimates may have been biased. This is in line with our previous analyses on the longitudinal DHIAAN data at 1-year follow-up, that showed no relevant contribution of multiple imputations to the interpretation of our data [14].

In the interpretation of tour results, it should also be noted that self-reported questionnaire data were used to assess the change in physical activity, diet and the determinants of behaviour change. We cannot exclude the possibility that our participants gave socially desirable answers [38]. As recommended, we added culturally-specific activities to the

physical activity questionnaire (such as yoga and dancing) to mitigate cultural differences in recommended physical activity [34]; nevertheless, the validity of this measurement may have been suboptimal. To measure diet, we included a limited number of questions on specific behaviours, which may be less reliable than biomarkers or a more complete measurement of food intake such as a food frequency questionnaire [39,40]. As a result, we may have missed more general positive changes in other aspects of the diet, potentially due to the intervention.

In addition, because the reference period for the physical activity and diet questionnaire spanned a few months, the answers may have been influenced by recall bias [39]. Although the effect of these types of bias apply to both groups, the effects could differ between the groups, e.g. due to the focus on certain behaviours during the intensive counselling in the intervention group. However, this seems very unlikely given the small differences between the two groups in reported changes. Therefore, we conclude that it is unlikely that these methodological limitations have substantially biased the present results.

Discussion of main findings

At 2-year follow-up we found that a culturally-targeted lifestyle intervention in primary care did not change the dietary behaviour and physical activity of this group of South Asian people at risk of T2D. This is in line with our observation of no effect of the intervention on weight status and other metabolic risk factors at 1-year follow-up [14]. However, a lack of effect on metabolic outcomes at one year does not rule out the possibility that the health behaviours or the underlying determinants may still change due to the intervention. The results of the present study clearly show that this was not the case. On the contrary, the health behaviour of a substantial number of participants even deteriorated. This was unexpected given the intensity of our intervention, an element previously shown to increase the effectiveness of

such a lifestyle programme [41]. Although changes in reported behaviour may also be the result of increased awareness among participants of their own (poor) diet and physical activity, the negative finding matches the weight gain reported for some participants after one year of follow-up [14].

There are several possible reasons for the lack of an effect of the intervention on health behaviour. First, despite being classified as being at risk for diabetes (i.e. impaired glucose tolerance, impaired fasting glucose, or relatively high insulin resistance) the participants were relatively healthy and health conscious. For instance, the mean BMI was lower compared to other, similar, populations [2-4, 6-8]. Moreover, a substantial part of our population met the guidelines for a healthy diet at baseline and indicated that they considered physical activity and a healthy diet important. These positive characteristics probably leave little room for improvement with an intervention aimed at a healthy lifestyle alone. To effectively reduce the burden of T2D among South Asians, future interventions should explore new strategies, e.g. focus on more specific forms of physical activity [42]. In addition, the low initial response rate in combination with the high drop-out rate raise the question whether an intensive intervention as employed in this study is the optimal approach to reach those in need in this high-risk population. More easily implemented interventions that reach a larger proportion of those with an increased risk of T2D seem necessary in order to effectively reduce the risk of T2D at population level.

Secondly, the intervention primarily addressed the individual and only marginally targeted the individual's environment. However, changes in the physical and social environment may influence the accessibility to and the social norm towards a healthy lifestyle, making it easier to make healthier lifestyle choices [18,43]. For instance, evidence from the EPODE

(Ensemble, Prévenons l'Obesité Des Enfants) approach suggests that environmental changes implemented by the private and public sectors are essential for behaviour change on the long term [44]. We attempted to make the intervention accessible by offering a local physical activity programme (involving the family) and having dieticians carry out the intervention as part of their dietician practice. However, we did not involve the private and public sectors to make adjustments to the immediate environment to facilitate healthier lifestyle choices, e.g. in local (South Asian) supermarkets or at work. In addition, involvement of the family at the start of the intervention (e.g. the family-based intervention among South Asians in the UK) [15], rather than in a separate family session, may have had greater impact as family influences can then be addressed more extensively. In that case the intervention might have benefited from support for the intended behaviour changes via changes in the environment. This explanation is supported by data from similar interventions in a primary care setting [6-8, 47] that also failed to positively change health behaviour. For instance, an intervention study in a Dutch primary care setting reported a significant difference between the groups only for physical activity and fibre intake [6].

Thirdly, although we purposefully invested in culturally targeting the intervention, the intervention as implemented may not have met the needs of our specific population. Cultural targeting was based on an analysis of the determinants of diet and physical activity in our study population; this led to the incorporation of both surface and deep structure elements in the intervention [22]. The process evaluation revealed that the majority of participants who attended the intervention perceived the materials as clear and attractive, and agreed that the advice given within the intervention matched their lifestyle (unpublished data). Moreover, although it was a challenge to motivate respondents to participate in the family meeting, cooking classes or the exercise programme, those who attended were enthusiastic. However,

these latter views may differ from those who did not participate and those who dropped-out. Therefore, the positive experiences do not exclude the possibility that incorporating different culturally-targeted elements in the intervention might have led to an effective intervention. More studies are needed to elucidate the specific elements which make cultural targeting effective in this population [46].

Conclusions

In this group of South Asians (aged 18-60 years) at risk of diabetes, a culturally-targeted lifestyle intervention was not effective in promoting healthy behaviour. At 2-year follow-up the changes in dietary behaviour, physical activity or underlying social-cognitive determinants in the intervention group did not differ from those in the control group. Given the high *a priori* risk and the specific characteristics of the target population, we recommend further research to determine whether an updated strategy, preferably more accessible for the target population, may change health behaviours through changes in the underlying social-cognitive determinants (e.g. social norms and self-efficacy) in this high-risk South Asian population.

Authors' contributions

EV and IV analyzed the data. EV contributed to the interpretation, and drafted the first version of the manuscript. IV and KS designed the study, contributed to the interpretation of the data, and edited the manuscript. VN, BM and MN gave advice for the design and interpretation. WB contributed to the analysis and interpretation. All authors reviewed the manuscript and approved the final version.

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Competing interests

All authors declare that they have no competing interests.

Data Sharing

No additional data supporting the present paper are available online. Data collected during the study, as described in doi: 10.1186/1471-2458-12-371 , after a collaboration agreement is signed. Researchers may contact i.g.vanvalkengoed@amc.nl or k.stronks@amc.nl.

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Table 1. Baseline characteristics of participants with a measurement of physical activity and diet at baseline and at 2-year follow-up measurement

	Intervention group, *N*=165	Control group, *N*=149	P-value
Male	75 (45.5)	77 (52.0)	0.245
Mean age (years)	44.9 (0.87)	44.7 (0.84)	0.970
Low education	16 (10.1)	20 (13.8)	0.315
Family history of diabetes	124 (77.5)	103 (71.5)	0.232
Mean body mass index	27.7 (0.32)	27.2 (0.30)	0.200
Mean fasting plasma glucose	5.3 (0.05)	5.3 (0.04)	0.109
Mean 2-h post-load glucose	6.1 (0.13)	6.0 (0.15)	0.368
Mean glycated haemoglobin	5.7 (0.03)	5.7 (0.03)	0.883
Median HOMA-IR	3.0 (2.2-4.1)	2.8 (2.1-3.9)	0.499

Data are presented as means (standard error), median (25th-75th percentile) or *n* (percentages); HOMA-IR, Homeostasis Model of Assessment-Insulin Resistance

Table 2. Effectiveness of intervention on physical activity and dietary behaviour among South Asians at risk of diabetes

	Intervention group, *N*=165			Control group, *N*=149			
	At T0	**ChangeT0-T1** [a]	**Change T0-T2**	**At T0**	**Change T0-T1** [a]	**ChangeT0-T2**	**p-value** [b]
Physical activity							
Any moderate-to-vigorous activity	135 (81.8)			118 (79.2)			
-Participants with positive change (%)		22 (17.1)	20 (13.4)		18 (14.9)	21 (12.7)	0.630
-Participants with negative change (%)		9 (7)	10 (6.7)		11 (9.1)	16 (9.7)	
Mean moderate-to-vigorous activity (min/week)	628.0 (62.7)			665.6 (72.0)			
-Changes		163.1 (71.6)	142.9 (74.9)		-34.3 (78.4)	0.5 (75.8)	0.672
Mean total activity (min/week)	2698.8 (83.4)			2451.3 (95.5)			
-Changes		83.1 (83.4)	-9.3 (84.8)		-174.8 (105.2)	2.9 (101.4)	0.297
Dietary intake [c]							
Fruit: 2 pieces /day (%)	71 (43.3)			55 (36.9)			0.680
-Participants with positive change (%)		20 (15.9)	28 (17.1)		16 (13.3)	30 (20.3)	
-Participants with negative change (%)		21 (16.7)	19 (11.6)		13 (10.8)	14 (9.5)	

Vegetables: 200 g/day (%)	112 (67.9)			48 (56.4) [d]			0.787
-Participants with positive change (%)		12 (9.3)	20 (12.1)		19 (15.8)	19 (12.8)	
-Participants with negative change (%)		17 (13.2)	17 (10.3)		14 (11.7)	12 (8.1)	
Whole wheat: almost exclusively (%)	11 (6.7)			11 (7.4)			0.667
-Participants with positive change (%)		8 (6.2)	25 (15.2)		14 (11.7)	20 (13.4)	
-Participants with negative change (%)		7 (5.4)	7 (4.2)		11 (9.2)	4 (2.7)	
Meal pattern: 3 meals/day at a regular times (%)	94 (57.3)			82 (55.4)			0.329
-Participants with positive change (%)		22 (17.3)	32 (19.5)		19 (16.0)	26 (17.6)	
-Participants with negative change (%)		12 (9.4)	11 (6.7)		7 (5.9)	17 (11.5)	
Brown rice: almost exclusively (%)	21 (12.8)			11 (7.4)			
-Participants with positive change (%)		10 (7.8)	12 (7.3)		6 (5.0)	19 (12.8)	0.264
-Participants with negative change (%)		7 (5.5)	6 (3.7)		5 (4.3)	6 (4.0)	

Data at T0 are presented as mean change (standard error) or n (percentages), changes from T0-T1 and T0-T2 are described as means (standard error) or number (percentage) with a positive change (e.g. from non-adherent to adherent to the guideline for fruit intake) or a negative change (e.g. from a regular to an irregular meal pattern) at one and two years.

[a] Of the 314 participants with a measurement at baseline and at 2-year follow-up, 279 also attended the measurement at 1-year follow-up (148 in the intervention group and 131 in the control group); [b] *P*-value for the intention-to-treat analysis of the difference in changes from T0 to T2 between the two groups; [c] Derived from the national guidelines for diet (30), with the exception of rice for which no guideline has been established; [d] significant difference between the groups at T0; T0, baseline measurement; T1, measurement after 1 year; T2, measurement after 2 years.

Table 3. Effectiveness of intervention on determinants of behaviour among South Asians at risk of diabetes (n=314)

		Intervention group, *N*=165			Control group, *N*=149			
		At T0	**ChangeT 0-T1** [a]	**Change T0-T2**	**At T0**	**Change T0-T1** [a]	**ChangeT0-T2**	**p-value** [b]
Risk perception	***Causal beliefs***							
	Perceiving 6 general risk factors as cause (%) [c]	110 (66.7)			103 (69.1)			
	-Participants with positive change (%)		20 (15.5)	32 (19.4)		24 (19.8)	33 (22.1)	0.818
	-Participants with negative change (%)		16 (12.4)	16 (9.7)		12 (9.9)	13 (8.7)	
	Perceiving consuming a lot of sugar as cause (%)	113 (68.5)			105 (70.5)			
	-Participants with positive change (%)		18 (14.1)	21 (12.7)		16 (13.2)	18 (12.1)	0.458
	-Participants with negative change (%)		32 (25.0)	34 (20.6)		16 (13.2)	23 (15.4)	
	Perceiving consuming a lot of white rice as cause (%)	95 (57.6)			86 (57.7)			
	-Participants with positive change (%)		25 (19.4)	35 (21.2)		33 (27.3)	39 (26.2)	0.552
	-Participants with negative change (%)		18 (14.0)	21 (12.7)		10 (8.3)	16 (10.7)	

Perceiving consuming masala as cause[d]	49 (29.9)			48 (32.4)			
-Participants with positive change (%)		11 (8.7)	22 (13.4)		17 (14.0)	19 (12.8)	0.569
-Participants with negative change (%)		27 (21.3)	29 (17.7)		17 (14.0)	20 (13.5)	
Perceiving being a South Asian as cause	122 (73.9)			104 (69.8)			
-Participants with positive change (%)		19 (14.7)	24 (14.5)		18 (14.9)	30 (20.1)	0.395
-Participants with negative change (%)		13 (10.1)	15 (9.1)		12 (9.9)	11 (7.4)	
Perceiving having a family history of T2D as cause	150 (90.9)			134 (89.9)			
-Participants with positive change (%)		8 (6.2)	12 (7.3)		10 (8.3)	12 (8.1)	0.798
-Participants with negative change (%)		9 (7.0)	13 (7.9)		4 (3.3)	9 (6.0)	
High susceptibility	63 (38.2)			71 (47.7)			
-Participants with positive change (%)		24 (18.6)	37 (22.4)		28 (23.1)	32 (21.5)	0.941
-Participants with negative change (%)		11 (8.5)	17 (10.3)		17 (14.0)	17 (11.4)	
High controllability belief by PA	146 (88.5)			132 (88.6)			
-Participants with positive change (%)		5 (3.9)	15 (9.1)		8 (6.6)	12 (8.1)	0.619
-Participants with negative change (%)		7 (5.5)	9 (5.5)		8 (6.6)	5 (3.4)	

Positive attitude	***PA***							
towards	**Direct**	160 (97.0)			143 (96.0)			
	-Participants with positive change (%)		3 (2.4)	4 (2.4)		3 (2.5)	4 (2.7)	1.0[e]
	-Participants with negative change (%)		2 (1.6)	0 (0.0)		1 (0.8)	0 (0.0)	
	Indirect	161 (97.6)			142 (95.3)			
	-Participants with positive change (%)		4 (3.1)	4 (2.4)		3 (2.5)	5 (3.4)	0.740[e]
	-Participants with negative change (%)		3 (2.3)	6 (3.6)		2 (1.7)	1 (0.7)	
	Diet							
	In general	161 (98.2)			148 (99.3)			
	-Participants with positive change (%)		2 (1.6)	2 (1.2)		1 (0.8)	1 (0.7)	1.0[e]
	-Participants with negative change (%)		2 (1.6)	1 (0.6)		2 (1.7)	1 (0.7)	
	Importance brown rice	76 (46.1)			62 (41.6)			
	-Participants with positive change (%)		34 (26.4)	40 (24.2)		30 (24.8)	39 (26.2)	0.739
	-Participants with negative change (%)		13 (10.1)	16 (9.7)		16 (13.2)	11 (7.4)	
	Importance snacks[d]	51 (31.5)			39 (26.4)			
	-Participants with positive change (%)		18 (14.5)	20 (12.3)		20 (16.8)	11 (7.4)	0.298
	-Participants with negative change (%)		25 (20.2)	31 (19.1)		19 (16.0)	26 (17.6)	

	Enjoyment brown rice	43 (27.0)			30 (20.5)		
	-Participants with positive change (%)		34 (27.6)	32 (20.4)		20 (17.2)	27 (18.5)	0.140
	-Participants with negative change (%)		10 (8.1)	15 (9.6)		7 (6.0)	6 (4.1)	
	Enjoyment snacks [d]	93 (58.1)			67 (45.6) [f]		
	-Participants with positive change (%)		25 (20.5)	22 (13.9)		24 (20.3)	19 (12.9)	0.147
	-Participants with negative change (%)		36 (29.5)	49 (31.0)		16 (13.6)	32 (21.8)	
Perceiving social support	***PA***							
	Partner	71 (43.0)			66 (44.3)		
	-Participants with positive change (%)		18 (14.2)	28 (17.0)		13 (10.7)	22 (14.8)	0.730
	-Participants with negative change (%)		13 (10.2)	16 (9.7)		11 (9.1)	12 (8.1)	
	Others	103 (62.4)			99 (66.4)		
	-Participants with positive change (%)		26 (20.3)	30 (18.2)		19 (15.7)	28 (18.8)	0.205
	-Participants with negative change (%)		18 (14.1)	15 (9.1)		16 (13.2)	23 (15.4)	
	Diet							
	In general	98 (59.8)			85 (57.0)		
	-Participants with positive change (%)		21 (16.5)	28 (17.1)		19 (16.1)	27 (18.1)	0.090
	-Participants with negative change (%)		21 (15.5)	35 (21.3)		27 (22.9)	18 (12.1)	

	Brown rice	44 (26.8)			41 (27.5)			
	-Participants with positive change (%)		28 (22.2)	26 (15.9)		17 (14.4)	31 (20.8)	0.473
	-Participants with negative change (%)		12 (9.5)	24 (14.6)		22 (18.6)	18 (12.1)	
	Refusing snacks	48 (29.3)			45 (30.2)			
	-Participants with positive change (%)		30 (23.6)	37 (22.6)		18 (15.1)	37 (25.0)	0.389
	-Participants with negative change (%)		13 (10.2)	29 (17.7)		25 (21.0)	18 (12.2)	
Perceiving self-efficacy	***PA***	109 (66.1)			103 (69.1)			
	-Participants with positive change (%)		22 (17.2)	28 (17.0)			25 (16.8)	0.973
	-Participants with negative change (%)		24 (18.8)	19 (11.5)			16 (10.7)	
	Diet							
	In general	151 (91.5)			136 (91.3)			
	-Participants with positive change (%)		4 (3.1)	7 (4.2)		7 (5.8)	10 (6.7)	0.334[e]
	-Participants with negative change (%)		2 (1.6)	3 (1.8)		7 (5.8)	4 (2.7)	
	Brown rice	56 (33.9)			38 (25.5)			
	-Participants with positive change (%)		28 (21.7)	26 (15.9)		29 (24.0)	27 (18.1)	0.669
	-Participants with negative change (%)		22 (17.1)	20 (12.2)		13 (10.7)	14 (9.4)	

	Refusing snacks	98 (60.5)			101 (69.7)		
	-Participants with positive change (%)		25 (20.0)	40 (24.8)		25 (21.4)	27 (18.9)	0.359
	-Participants with negative change (%)		11 (8.8)	15 (9.3)		14 (12.0)	18 (12.6)	
Stage of change-	***PA within 6 months***	99 (59.3)			105 (69.5)		
motivated to	-Participants with positive change (%)		26 (15.8)	33 (20.0)		16 (10.7)	21 (14.1)	0.076
change	-Participants with negative change (%)		43 (26.1)	30 (18.2)		44 (29.5)	18 (12.1)	
	Diet within 6 months							
	In general	153 (92.7)			135 (90.6)		
	-Participants with positive change (%)		7 (5.4)	7 (4.2)		8 (6.6)	10 (6.7)	0.334[e]
	-Participants with negative change (%)		1 (0.8)	3 (1.8)		4 (3.3)	4 (2.7)	
	Brown rice	82 (49.7)			59 (39.6)		
	-Participants with positive change (%)		22 (17.2)	21 (12.7)		23 (19.0)	26 (17.4)	0.266
	-Participants with negative change (%)		13 (10.2)	30 (18.2)		17 (14.0)	19 (12.8)	

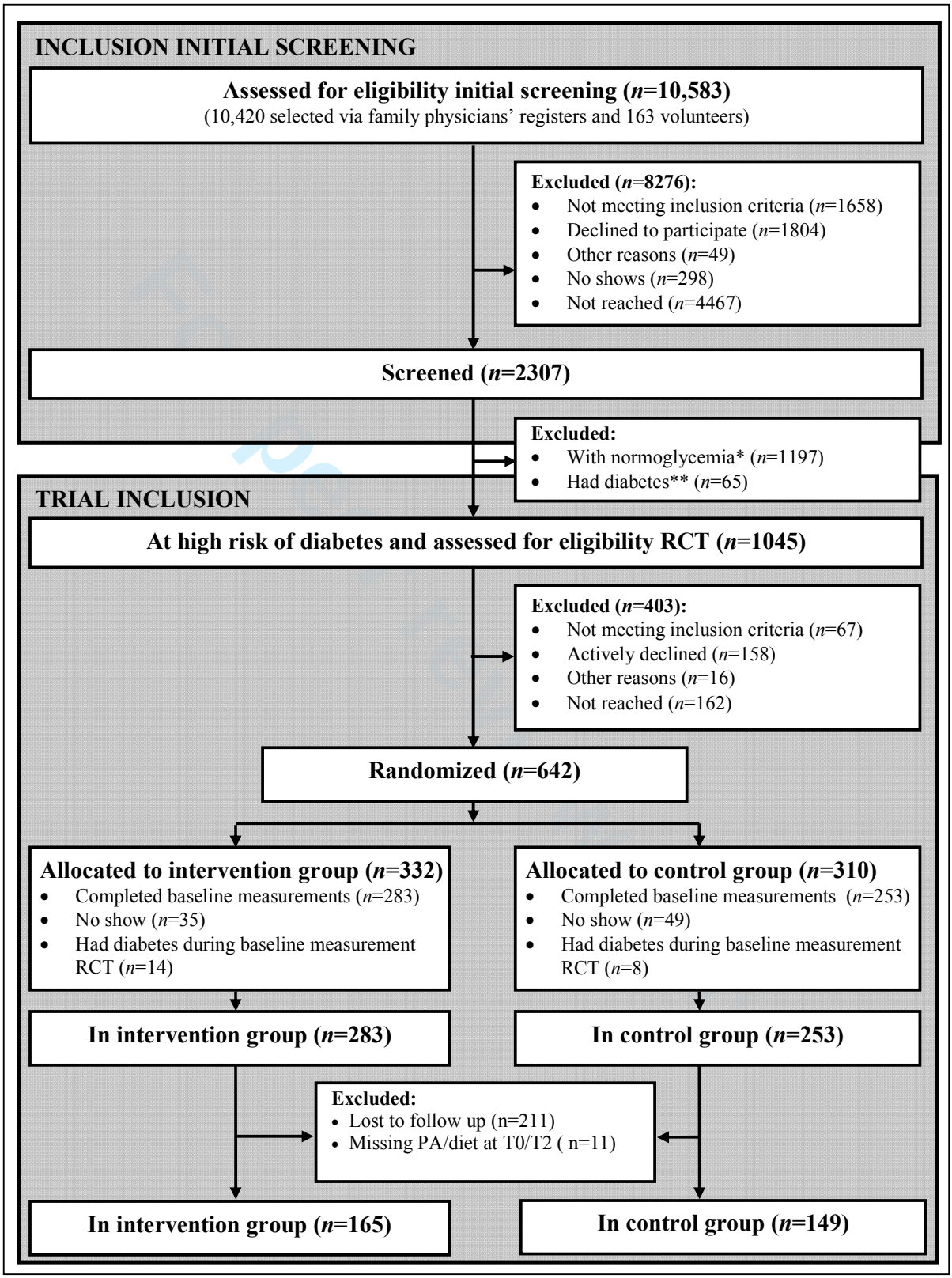
Data at T0 are presented as mean change (standard error) or n (percentages), changes from T0-T1 and T0-T2 are described as means (standard error) or number (percentage) with a positive change (e.g. from non-adherent to adherent to the guideline for fruit intake) or a negative change (e.g. from a regular to an irregular meal pattern) at one and two years. [a] Of the 314 participants with a measurement at baseline and after two years, 279 also attended the measurement at year 1 (148 in the intervention group and 131 in the control group); [b] *P*-value for the intention-to-treat analysis of the difference in changes from T0 to T2 between the intervention and control group; [c] Six common risk factors: overweight, too little exercise, unhealthy diet, age ≥ 35 years, smoking, and hypertension; [d] Except for the belief that masala intake is a possible cause of diabetes and the attitude towards refusing snacks at parties, an increase or positive change in the items measuring the determinants of behaviour change was expected to positively influence behaviour change; [e] Because of low

expected counts, a Fisher's exact test or chi-square test was done comparing the category positive change versus the rest; [f] Significant difference between the groups at T0; T0, baseline measurement; T1, measurement after 1 year; T2, measurement after 2 years; T2D, Type 2 diabetes mellitus; PA, physical activity.

Figure 1. Flow chart of inclusion of the study participants

*A fasting glucose of 5.5 mmol/L or lower, a 2-hour post-load glucose of 7.7 mmol/L or lower, a glycated haemoglobin level of 5.9% or lower and a value of 2.38 or lower for the homeostasis model assessment of estimated insulin resistance; ** a fasting glucose of 7.0 mmol/L or more, and/or a 2-hour post-load glucose of 11.1 mmol/L or more; RCT, randomized controlled trial; PA, physical activity; T0, baseline measurement; T2, measurement at 2-year follow-up

Figure 1- Flow chart of the study



SUPPLEMENT 1. Comparison of baseline characteristics, physical activity, dietary behaviour and motivational stage of participants in the present analysis and those who were excluded

	In present analysis (*N*=314)	Excluded (*N*=222)	p-value
Male	152 (48.6)	112 (50.5)	0.667
Mean age (years)	44.8 (0.6)	41.6 (0.7)	**0.001**
Low education	36 (11.8)	25 (11.6)	0.925
Family history of diabetes	227 (74.7)	171 (78.4)	0.318
Mean body mass index	27.3 (0.3)	27.4 (0.2)	0.889
Mean fasting plasma glucose	**5.3 (0.03)**	5.3 (0.04)	0.803
Mean 2-h post-load glucose	6.0 (0.1)	6.0 (0.1)	0.907
Mean glycated haemoglobin	5.7 (0.02)	5.6 (0.03)	0.092
Median HOMA-IR	3.0 (2.2-4.0)	3.2 (2.4-4.4)	**0.048**
Mean total activity (min/week)	2600.8 (64.6)	2663.6 (84.1)	0.490
Fruit: 2 pieces /day	126 (40.3)	97 (46.2)	0.179
Vegetables: 200 g/day	196 (62.4)	131 (62.4	0.993
Whole wheat: almost exclusively	22 (7.0)	11 (5.2)	0.414
Meal pattern: 3 meals/day at regular times	176 (56.4)	103 (49.0)	0.098
Brown rice: almost exclusively	32 (10.2)	24 (11.5)	0.649
Stage of change- motivated to change physical activity within 6 months	204 (65.0)	148 (66.7)	0.683
Stage of change: motivated to change diet within 6 months	288 (91.7)	188 (90.0)	0.489

Data are presented as means (standard error), median (interquartile range) or *n* (percentage); HOMA-IR, Homeostasis Model of Assessment-Insulin Resistance.

Checklist of Items for Reporting Trials of Nonpharmacologic Treatments*

Section	Item	Standard CONSORT Description	Extension for Nonpharmacologic Trials	Reported on Page No.
Title and abstract†	1	How participants were allocated to interventions (e.g., "random allocation," "randomized," or "randomly assigned")	In the abstract, description of the experimental treatment, comparator, care providers, centers, and blinding status	1-2
Introduction				
Background	2	Scientific background and explanation of rationale		4
Methods				
Participants†	3	Eligibility criteria for participants and the settings and locations where the data were collected	When applicable, eligibility criteria for centers and those performing the interventions	6-7
Interventions†	4	Precise details of the interventions intended for each group and how and when they were actually administered	Precise details of both the experimental treatment and comparator	8-9
	4A		Description of the different components of the interventions and, when applicable, descriptions of the procedure for tailoring the interventions to individual participants	8-9
	4B		Details of how the interventions were standardized	8-9
	4C		Details of how adherence of care providers with the protocol was assessed or enhanced	8
Objectives	5	Specific objectives and hypotheses		5
Outcomes	6	Clearly defined primary and secondary outcome measures and, when applicable, any methods used to enhance the quality of measurements (e.g., multiple observations, training of assessors)		9-13
Sample size†	7	How sample size was determined and, when applicable, explanation of any interim analyses and stopping rules	When applicable, details of whether and how the clustering by care providers or centers was addressed	Reference trial protocol

Randomization–sequence generation†	8	Method used to generate the random allocation sequence, including details of any restriction (e.g., blocking, stratification)	When applicable, how care providers were allocated to each trial group	7
Allocation concealment	9	Method used to implement the random allocation sequence (e.g., numbered containers or central telephone), clarifying whether the sequence was concealed until interventions were assigned		7
Implementation	10	Who generated the allocation sequence, who enrolled participants, and who assigned participants to their groups		7, references
Blinding (masking)†	11A	Whether or not participants, those administering the interventions, and those assessing the outcomes were blinded to group assignment	Whether or not those administering co-interventions were blinded to group assignment	7
	11B		If blinded, method of blinding and description of the similarity of interventions†	
Statistical methods†	12	Statistical methods used to compare groups for primary outcome(s); methods for additional analyses, such as subgroup analyses and adjusted analyses	When applicable, details of whether and how the clustering by care providers or centers was addressed	14-15
Results				
Participant flow†	13	Flow of participants through each stage (a diagram is strongly recommended)---specifically, for each group, report the numbers of participants randomly assigned, receiving intended treatment, completing the study protocol, and analyzed for the primary outcome; describe deviations from study as planned, together with reasons	The number of care providers or centers performing the intervention in each group and the number of patients treated by each care provider or in each center	Figure 1, trial protocol
Implementation of intervention†	New item		Details of the experimental treatment and comparator as they were implemented	16
Recruitment	14	Dates defining the periods of recruitment and follow-up		6,14
Baseline data†	15	Baseline demographic and clinical characteristics of each group	When applicable, a description of care providers (case volume, qualification, expertise, etc.) and centers (volume) in each group	Table1, supplement 1

Numbers analyzed	16	Number of participants (denominator) in each group included in each analysis and whether analysis was by "intention-to-treat"; state the results in absolute numbers when feasible (e.g., 10/20, not 50%)		13
Outcomes and estimation	17	For each primary and secondary outcome, a summary of results for each group and the estimated effect size and its precision (e.g., 95% confidence interval)		16,17, tables
Ancillary analyses	18	Address multiplicity by reporting any other analyses performed, including subgroup analyses and adjusted analyses, indicating those prespecified and those exploratory		15
Adverse events	19	All important adverse events or side effects in each intervention group		na
Discussion				
Interpretation†	20	Interpretation of the results, taking into account study hypotheses, sources of potential bias or imprecision, and the dangers associated with multiplicity of analyses and outcomes	In addition, take into account the choice of the comparator, lack of or partial blinding, and unequal expertise of care providers or centers in each group	18-19
Generalizability†	21	Generalizability (external validity) of the trial findings	Generalizability (external validity) of the trial findings according to the intervention, comparators, patients, and care providers and centers involved in the trial	18,21
Overall evidence	22	General interpretation of the results in the context of current evidence		22

*Additions or modifications to the CONSORT checklist. CONSORT = Consolidated Standards of Reporting Trials.
†This item was modified in the 2007 revised version of the CONSORT checklist.

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EFFECTIVENESS OF A TARGETED LIFESTYLE INTERVENTION IN PRIMARY CARE ON DIET AND PHYSICAL ACTIVITY AMONG SOUTH ASIANS AT RISK OF DIABETES: 2-YEAR RESULTS OF A RANDOMISED CONTROLLED TRIAL IN THE NETHERLANDS

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Effectiveness of a targeted lifestyle intervention in primary care on diet and physical activity among South Asians at risk of diabetes; 2-year results of a randomised controlled trial in the Netherlands

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ABSTRACT

Objectives. In South Asian populations, little is known about the effects of intensive interventions to reduce the risk of type 2 diabetes on health behaviour. We examined the effectiveness at 2 years of a culturally-targeted lifestyle intervention on diet, physical activity and determinants of behaviour change among South Asians at risk of diabetes.

Design. Randomised controlled trial with de facto masking

Setting. Primary care.

Participants. A total of 536 18-60 year old South Asians at risk of diabetes (i.e. with impaired glucose tolerance, impaired fasting glucose, or relatively high insulin resistance) were randomised to the intervention (n=283) or a control (n=253) group. Data of 314 participants (n= 165 intervention, n=149 control) were analysed.

Interventions. The culturally-targeted intervention consisted of individual counselling using motivational interviewing (6-8 sessions in the first 6 months plus 3-4 booster sessions), a family session, cooking classes, and a supervised physical activity programme. The control group received generic lifestyle advice.

Outcome measures. We compared changes in physical activity, diet and social-cognitive underlying determinants between the two groups at 2-year follow-up with independent sample t-tests, chi square tests and Fisher's exact tests.

Results. At 2-year follow-up participants in the intervention group were more moderately-to-vigorously active than at baseline but, compared with changes in the control group, the difference was not significant (change min/week 142.9 versus 0.5, p=0.672). Also, no significant difference was found between the two groups in changes on any of the components of the diet or the social-cognitive determinants of diet and physical activity.

Conclusions. The culturally-targeted lifestyle intervention led to high drop-out and was not effective in promoting healthy behaviour among South Asians at risk of diabetes. Given the

high *a priori* risk, we recommend to develop new strategies, preferably more acceptable, to promote healthy behaviour.

Trial registration: NTR1499; www.trialregister.nl/trialreg/admin/rctview.asp?TC=1499

Strengths and limitations of this study

- The intensive intervention in this trial was culturally targeted, based on a needs assessment and formative research, to characteristics of South Asians living in the Netherlands.
- This study reports on physical activity, diet as well as the determinants of behaviour change, thus contributing to the yet limited knowledge about the effects of intensive interventions on behavioural measures among South Asians.
- Low participation and high drop-out from the trial may indicate poor acceptability of the intervention, and may have led to a biased estimate of intervention effects.
- We assessed the intervention effects on health behaviours with self-reported measures, which may be influenced by various reporting biases.

BACKGROUND

Diet and physical activity are key modifiable risk factors for type 2 diabetes mellitus (T2D), and interventions targeting these behaviours can help to prevent or postpone this disease [1-5]. Efficacy trials have shown that, in high-risk individuals, the onset of T2D may be prevented or postponed through individual diet counselling and physical activity guidance through reduction in weight and waist circumference [2-5]. Trials in a standard care setting aimed at promoting a healthy diet and physical activity have yielded similar, albeit more modest, results [6-8].

South Asian migrants and their offspring (hereafter referred to as 'South Asians') living in high-income countries are, in particular, at high risk for T2D [9-13]. Strategies targeting diet and physical activity have been implemented to reduce this increased risk among these populations. However, the trials evaluating intensive diet counselling and physical activity guidance in South Asian populations in the UK and in the Netherlands yielded only moderate results in terms of the reduction of weight and waist circumference [14-15].

One of the reasons for the moderate results could be that, in these trials, the interventions implemented do not lead to the intended changes in dietary behaviour and physical activity. However, little is known about the effects of intensive interventions on behavioural measures among South Asians [16]. These measures not only include dietary behaviour and physical activity, but also social-cognitive determinants (such as self-efficacy) as a result of which changes in these behaviours occur [17-19].

Therefore, the present study aims to analyse the effectiveness of an intervention among South Asians living in the Netherlands aimed at preventing T2D, with regard to changes in dietary habits, physical activity, and the social-cognitive determinants of behaviour change. Whereas our earlier study described the effects of this intervention on weight and other metabolic outcomes after one year [14], the effects on behavioural measures have not yet been investigated. In this intervention, motivational interviewing and tailored risk information were used to address social-cognitive factors underlying dietary behaviour and physical activity, including risk perception, attitudes, social support, and self-efficacy. The intervention was based on a needs assessment and formative research, and targeted to characteristics of South Asians Surinamese, who are the descendants of contract labourers who migrated to Surinam mostly from North India.

METHODS

Study population

All those included in the present investigation were participants of the DHIAAN study: this is a randomised controlled trial (no. NTR1499) investigating the effectiveness of a culturally-targeted intensive lifestyle intervention to prevent T2D and cardiovascular risk factors among South Asian Surinamese in primary care [20]. The term South Asian Surinamese refers to people of South Asian ancestral origin and their offspring who migrated to the Netherlands via Suriname. The South Asian Surinamese are descendants of the labourers from North India (Uttar Pradesh, Uttaranchal, and West Bihar) who were indentured between 1873 and 1917. The two large migration waves of South Asian Surinamese to the Netherlands were caused mainly by the political situation in Suriname. The first wave took place at the time of the independence of Suriname in 1975 and the second wave (at the time of Desi Bouterse's coup) in February 1980 [21].

Details of the DHIAAN study, including changes to the original protocol, and the process of adapting the lifestyle intervention for the social-cultural and social-cognitive determinants of South Asian Surinamese, are already published [20,22]. In brief, 2307 South Asian Surinamese (aged 18-60 years) living in The Hague (the Netherlands), were screened via general practices between 18 May 2009 and 11 October 2010 (Fig. 1). To achieve a high response rate, a culturally-targeted intensive recruitment strategy was used that was proven feasible in the pilot of the DHIAAN study [20]. General practitioners (GPs) sent each potential participant an invitation, together with a reply card that could be returned if further contact was not wanted. Invitees who did not respond received a written reminder and were also contacted by telephone.

All potential participants were requested to fill out a brief questionnaire, undergo a physical examination, and provide a fasting blood sample. The 968 participants who were invited and screened between 18 May 2009 and 18 April 2010 also took an oral glucose tolerance test (75 g). Thereafter, the oral glucose tolerance test was discontinued for practical reasons. Due to the shorter duration of a screening with a single measurement, a greater number of people could be screened within the extended recruitment period [20].

Inclusion in the trial

Screened participants with impaired fasting glucose (fasting glucose of 5.6-6.9 mmol/l), impaired glucose tolerance (2-hour post-load glucose of 7.8-11.0 mmol/l), a glycated haemoglobin (HbA1c) level of ≥ 42 mmol/mol , and/or a value of ≥ 2.39 for the homeostasis model assessment-insulin resistance (HOMA-IR) were invited to participate in the trial [20] (Fig. 1).

Excluded was anyone who was already involved in a lifestyle programme, was pregnant, had a chronic disease that made participation in the intervention impossible, and/or used drugs that interfered with plasma glucose levels. Also excluded were participants with newly diagnosed T2D (i.e. a fasting glucose ≥7.0 mmol/l, a 2-h post-load glucose ≥11.0 mmol/l, or a HbA1c level ≥48 mmol/mol); these persons were referred to regular clinical care.

As described previously in more detail [14,20], 536 people were randomly assigned to either the intervention or the control group using a computer-generated randomisation list (simple randomisation). Family or household members, defined by postal code and house number, were assigned to the same group. Participants were informed about the procedures for the arm

of the trial that they were assigned to; the masking (de facto masking) of the two groups was maintained throughout the trial.

The study was approved by the Institutional Review Board of the Academic Medical Center, Amsterdam. All participants provided both oral and written informed consent.

Intervention group

All participants in the intervention group were offered a culturally-targeted lifestyle intervention [22]. The design of this intervention was in line with the design of the proven efficacious intervention used in the Study on Lifestyle Intervention and Impaired Glucose Tolerance Maastricht (SLIM), which aimed to evaluate the effect of that intervention on glucose tolerance in a European Dutch population [23]. In line with that and other interventions in this field, the theoretical starting point of our intervention was the notion that motivation for behaviour change is driven by personal determinants, including attitudes, social influences and self-efficacy. In our intervention, we used the technique of motivational interviewing to address these personal determinants [22]. In addition, the technique could address other factors (e.g. stress) if relevant for the individual's behaviour. We also involved the family members in the intervention to strengthen the participants to cope with social pressure to eat sweet and fat products (see below) .

To address the socio-cultural influences that affect these personal determinants, we culturally adapted the intervention as used in the SLIM study to the South Asian Surinamese population. We have described the theoretical framework underlying the intervention and adaptations in detail elsewhere [22]. In short, the aim was to enhance the cultural sensitivity of the intervention, as this is likely to promote the effectiveness of interventions among specific

ethnic populations [24]. We based our definition of cultural sensitivity on that of Resnicow: 'the extent to which ethnic/cultural characteristics, experiences, norms, values, behavioural patterns and beliefs of a target population as well as relevant historical, environmental and social forces are incorporated in the design, delivery and evaluation of targeted health promotion interventions' [25]. Cultural adaptations are divided into two major dimensions: surface structure, which involves matching interventions materials and message to the observable behaviour characteristics that are shared by the target population, and deep structure adaptations, which target the social or cultural values underlying these behaviours. We used both type of adaptations, e.g. a study logo based on the design of the Surinamese flag and propositions on culturally held ideas regarding DM for the family session respectively, to make the intervention attractive, appropriate and ultimately more potentially effective in the present study population [22]. These adaptations were based on formative research, including literature review, focus groups and the experiences in a pilot study [22]. The intervention was designed to be carried out by dieticians within their usual practice setting. The aim was to meet current national guidelines for diet and physical activity [26,27]. In the first 6 months, dieticians used motivational interviewing during 6-8 individual lifestyle counselling sessions, followed by 3-4 booster sessions over the following 18 months. The dieticians were trained in motivational interviewing, in which previous successes, skills and strengths of the client were highlighted to support self-efficacy [28]. All dieticians were also familiar with the South Asian culture and dietary habits; three had South Asian roots themselves, and the other three had experience working within the South Asian community. On the basis of the aforementioned formative research, we identified four goals that seem to be particularly important for promoting the effectiveness of the intervention, and for addressing the barriers and motivating factors that appeared to be relevant in this South Asian population. These were: 1. generating appropriate risk perception and conviction that diabetes

can be prevented or at least postponed, 2. generating a positive attitude towards a healthy lifestyle, 3. mobilizing social support by involving participants' families in the intervention, and 4. creating the conviction that healthy eating can also be tasty [22].

In line with these goals, dieticians as well as the written materials paid specific attention to the issues of risk perception (e.g. by stressing the modifiability of risk factors for T2D), and positive attitude towards diet and PA (e.g. by giving suggestions for healthy eating based on traditional foods). In addition, dieticians offered a family session at the participant's home, with the aim to engage the family in supporting the individual participant in achieving dietary goals. Finally, participants were offered two group-based cooking classes to learn skills for adjusting traditional dishes to meet nutritional guidelines, thereby also increasing their self-efficacy.

We also offered a 20-week physical activity programme to all participants in the intervention group. This 'exercise on prescription' programme is described elsewhere [29-31]. Trained coaches monitored participation in the programme.

Control group

Participants in the control group were invited to join two group sessions led by student dieticians (at baseline and after 6 months). The sessions provided generic information about T2D and discussed current guidelines for diet and physical activity. These participants received two leaflets (at 3 and 9 months) with simple, generic lifestyle advice. The group sessions and leaflets were not targeted to characteristics of the target population.

Data collection

Trial visits were planned for both groups at baseline, and after 1 and 2 years [20]. The invitation procedures for these visits were similar to the intensive procedures used during the screening. Participants who did not respond to the invitation for the follow-up visit were contacted by telephone and received a written reminder. In addition to written confirmation of their appointment, all participants received a text message reminder the day before their appointment.

During the visit, a trained interviewer conducted a face-to-face interview with each participant in Dutch or, optionally, in Sarnami (Surinamese dialect based on North Indian dialects). At baseline, two participants in the trial asked to be interviewed in Sarnami. Trained research staff used a standardised protocol for the physical examinations. They measured weight on a mechanical scale (Seca 761, Hamburg, Germany) to the nearest 500 g and height was measured to the nearest 0.01 m. The anthropometric measurements were obtained twice and the means were used for analysis.

During all visits, all participants provided a fasting blood sample and were offered an oral glucose tolerance test. Measurements of fasting plasma glucose and 2-hour post-load glucose (oral glucose tolerance test, 75 g; hexokinase, Roche Diagnostics), HbA1c (high-performance liquid chromatography), and insulin (immunoassay, sandwich principle, Roche Diagnostics) were carried out according to a standardised protocol at the SHL Group (laboratory), Etten-Leur (the Netherlands). The HOMA-IR was calculated as glucose (mmol/l) multiplied by fasting insulin (mU/l) divided by 22.5 [32].

Data on participation were recorded by dieticians and obtained from the process data collected from participants during the first year [20].

Measurements and definitions

Physical activity, diet, and social-cognitive determinants of behaviour change were noted during the trial visits [23,33]. Physical activity was assessed with the Short Questionnaire to Assess Health-enhancing Physical Activity (SQUASH), supplemented with culturally-specific activities [34,35]. Three measures were defined: i) any versus no moderate-to-vigorous activity, ii) the total moderate-to-vigorous activity expressed in min/week, and iii) the total activity expressed in min/week.

Dietary intake was determined using questions based on the national guidelines for a healthy diet, supplemented with questions on group-specific dietary behaviours of the South Asian population [22,26; Online supplement 1]. Fruit, vegetables, rice, and whole wheat intake was assessed with multi-item questions (with 3, 2, 2, and 11 items, respectively) to determine the quantity and frequency. Moreover, two single-item questions addressed the regularity of the meals. These aspects of the diet were dichotomised into meeting versus not meeting the guideline (Box 1).

Box 1. Categories used for meeting the dietary guidelines

	Meeting the guideline[a]
Fruit intake	2 pieces of fruit/day
Vegetable intake	200 g vegetables/day
Whole wheat intake	Almost exclusively whole wheat products
Regular eating pattern	3 meals/day at a regular time
Rice intake	Almost exclusively brown rice

[a]Derived from the current national guidelines for diet [26], with the exception of rice for which no guideline has been established.

Social-cognitive determinants of behaviour change

Risk perception consisted of measures of perceived susceptibility and two components of Leventhal's common-sense model of representations of illness and self-regulation [36], i.e. causal beliefs and perceived controllability by physical activity. Causal beliefs were measured with 12 statements about the perceived influence of certain behaviours or characteristics on the onset of diabetes, on a 3-point Likert scale. The statements concerned (a) general lifestyle beliefs related to seven general risk factors for diabetes, (b) three group-specific lifestyle beliefs (consumption of masala and large amounts of white rice and sugar) derived from our focus group discussions, and (c) two heredity beliefs (e.g. family history of diabetes and being a South Asian) [22, 37]. The internal consistency of items was estimated with Crohnbach's alpha (α) , and an α above 0.6 considered to be moderate and above 0.8 good. The general lifestyle beliefs related to overweight, unhealthy food, insufficient exercise, hypertension, age, and smoking were combined into a single factor based on the results of internal consistency analysis(n=6, α=0.63; a score of ≥ 4 indicating 'perceiving general lifestyle as a cause of type 2 diabetes mellitus'). Perceived controllability with physical activity was measured by a single item on a 5-point Likert scale. Perceived susceptibility was measured with a 3-item perceived susceptibility score, on a 5-point Likert scale (n=3, α=0.63) [38].

Internal consistency analysis resulted in three factors for attitudes towards physical activity and diet: direct (enjoyment and importance; n=4, α=0.64) and indirect attitude towards physical activity (possible consequences of increasing physical activity; n=7, α=0.67), and the attitude towards conventional healthy dietary behaviours (enjoyment and importance of a regular eating pattern and breakfast, fruit, vegetable, whole wheat intake; n=10, α=0.84). We also measured the attitudes (enjoyment and importance) towards two group-specific healthy dietary behaviours (replacing white rice with brown rice, and refusing snacks at parties).

Two factors were formed for social support: perceived social support for physical activity from other family members and close relatives (n=2, α=0.68), and perceived social support for the conventional healthy dietary behaviours (n=5, α=0.94). We also measured the perceived social support for physical activity from the spouse and the perceived social support for two group-specific healthy dietary behaviours (replacing white rice with brown rice, and refusing snacks at parties).

Self-efficacy was reflected in two combined factors: perceived self-efficacy for physical activity (n=5, α=0.73), and perceived self-efficacy for the conventional healthy dietary behaviours (n=5, α=0.66). Moreover, we measured self-efficacy expectations for two group-specific healthy dietary behaviours (replacing white rice with brown rice, and refusing snacks at parties).

The stages of change towards diet and physical activity were classified as being motivated or not motivated to change one's diet according to the Dutch guidelines, and physical activity within 6 months. The stage of change towards diet was measured for each specific dietary behaviour. One factor was formed for stage of change towards the conventional healthy dietary behaviours (n=5, α=0.73).

Because of the skewness of the variables, we dichotomized all resulting variables, e.g. perceiving versus not perceiving having a family history of diabetes as cause. In addition, as the group-specific items (e.g. refusing snacks at parties) did not load on the aforementioned scales, we decided to include these in the analysis as single items.

Other factors

Age and gender were determined from the GPs' registries. Country of birth, duration of residence, low education level (primary education or less), having paid work were measured at the initial screening. Low family income (≤net 998 euros/month) was determined at baseline. A family history of diabetes was defined as having a first- or second-degree family member with diabetes. Body mass index (BMI) was calculated as weight (kg)/height $(m)^2$.

Statistical analysis

In the current analysis we included all those who participated in both the baseline measurement and measurement at 2-year follow-up, and excluded anyone without data on physical activity or diet at baseline and/or at 2-year follow-up (Figure 1). This means that 314 participants remained for the present analysis: 165 in the intervention group with a mean follow-up time of 22.1 (95%-confidence interval (95%CI): 21.0-23.8) months and 149 in the control group with a mean follow-up time of 22.1 (95%CI : 21.3-23.2) months.

We described the baseline characteristics of the remaining participants in both groups. Continuous variables were described using means (95%CIs). Continuous variables that were not normally distributed, based on visual inspection, skewness and kurtosis values, were described with a median and interquartile range (IQR). Baseline differences in continuous variables between the intervention and control group were checked using independent sample t-tests and ,where relevant, Mann-Whitney U tests. Categorical variables were described by reporting the n (percentage) with a certain characteristic. Group differences were tested with chi-square tests.

In addition, for those in the intervention group, their participation in elements of the intervention was described. We calculated the percentage who participated in the intake for the individual lifestyle counselling, and of this group the percentage who attended at least one

more session after the intake. We also report the median (IQR) number of sessions attended (in addition to the initial intake visit) within this group. Finally we determined the percentage participating in cooking classes, family sessions and/or the supervised exercise programme. Changes in physical activity, diet and the social-cognitive determinants of behaviour change are also described. For the continuous measures, the change was determined between baseline and 1 and 2-year follow-up, respectively. As the changes appeared normally distributed (based on visual inspection, and the skewness and kurtosis values), we report the mean changes in the intervention and control group. For the categorical measures, we determined the percentage of participants with a positive change (e.g. those who changed from non-adherent to adherent to the guideline for fruit intake) or a negative change (e.g. those who changed from a regular to an irregular meal pattern) at 1 and 2-year follow-up. The remaining participants had not changed their behaviour for that specific measure. Except for the belief that masala intake is a possible cause of diabetes, and the attitude towards refusing snacks at parties, positive changes were expected to positively influence lifestyle behaviour and health. Independent sample t-tests were used to compare the mean changes between the intervention and control group in continuous measures. Chi square tests were used to compare the percentage positive and negative changes between the two groups. Where expected counts per cell were low, we merged the 'negative change' and 'unchanged' categories, and compared the percentage 'positive change' across groups with a Fisher's exact test. As the present analysis focuses on the effects two years post-baseline, only the full p values for the differences at 2 years are reported.

In the present study we did not consider multiple imputations or more complex modelling of patterns of missingness. This decision was based on a comparison of the baseline characteristics between participants with and those without a measurement at 2-year follow-

up (Online supplement 2). Apart from being younger and having a higher HOMA-IR, those who participated in the measurement at 2-year follow-up had baseline characteristics similar to those who dropped-out. We used logistic regression to examine differences in drop-out across groups. Drop-out was similar in both groups [age and sex adjusted OR 1.02 (95%CI: 0.72-1.45)], and these differences did not vary by age or gender ($p>0.05$ for the interaction terms). In addition, we previously analysed different patterns of missingness in relation to the reported total physical activity, meal pattern and whole wheat consumption, using a pattern mixture model in the total study population and found no significant evidence for an effect of missingness on our outcomes (data not shown).

In the current paper, we did not perform multilevel analysis with the data on dieticians. In line with previous analyses of the DHIAAN data [14, 33], no evidence was found for dependencies between participants registered with the same dietician (data not shown). We analyzed this with two-level regression models (individual and dietician) with a random intercept at the level of the dietician. Furthermore, as only 29 people with family members in the study had follow-up data available (intervention n=18, control n=11), no multilevel analysis was performed on family data. Analysis of reported total physical activity, meal pattern and whole wheat consumption after exclusion of all people with family members in the study showed similar results to the analysis in the full population (data not shown).

The SPSS 19.0 (SPSS Inc., Chicago, Illinois, USA) and R2.15.3 (R Foundation for Statistical Computing, 2009) were used for the analyses. A p-value <0.05 was considered to be statistically significant.

RESULTS

Baseline characteristics

At baseline, both groups were similar in terms of demographic characteristics and physical activity (Table 1). Most of the participants reported to be moderately-to-vigorously active: 82% of the intervention group and 79% of the control group. Moreover, at baseline, similar proportions in both groups met the guidelines for fruit, whole wheat intake, a regular meal pattern, and use of brown rice. However, vegetable intake differed between the groups: 68% of the intervention group ate 200 g of vegetables/day compared with 56% of the control group. At baseline, the social-cognitive determinants (with the exception of enjoyment of snacks) were also similar in both groups. The observed percentage of people with a positive response varied largely between the determinants. For example, ≥ 90% of both groups had a positive attitude toward physical activity and a healthy diet, whereas ≤ 50% of the population reported to experience social support from their partner regarding healthy behaviour.

Participation in the intervention

In the intervention group, 81.8% of the respondents participated in the intake for the individual lifestyle counselling sessions. Of this latter group, 94.8% attended at least one additional session, with a median number of eight sessions (IQR: 4-9) per person. Moreover, 14.4% participated in a supplemental family session, 12.7% in the cooking classes and 26.3% in the supervised exercise sessions.

Effect of the intervention on physical activity and diet

Participants in the intervention group were more moderately-to-vigorously active at 2-year follow-up than at baseline but, compared with the change in the control groups, the difference was not significant (Table 2). In addition, while more participants in the intervention group

than in the control group met the guidelines for several dietary behaviours (e.g. whole wheat intake, eating brown rice and fruit) at 2-year follow-up, none of these changes significantly differed between the groups (Table 2).

Remarkably, a substantial percentage of people who were adherent to a specific guideline at baseline were no longer adherent 1 or 2 years later ('negative' change). For most behaviours this percentage is almost as high as the percentage 'positive' change.

Effect of the intervention on social-cognitive determinants of behaviour change

At 2-year follow-up, no significant difference was found between the two groups in any of the social-cognitive determinants of behaviour change (Table 3). A positive change was observed in several of the social-cognitive determinants of behaviour change among part of the intervention group and similar changes were observed in the control group. For instance, 22.4% of those in the intervention group who did not perceive themselves as susceptible at baseline, perceived themselves as susceptible to the onset of diabetes after 2 years; in the control group, this figure was 21.5% (p=0.941 for the difference between groups). Similar to the results for dietary behaviour and physical activity, remarkably high percentages of participants showed a 'negative' change in social-cognitive determinants.

DISCUSSION

This study examined the effect of a culturally-targeted intervention on dietary behaviour and physical activity among a South Asian population at risk of T2D. At 2-year follow-up, no significant difference was found between the intervention and the control group in changes in any of the components of dietary and physical activity behaviour, or in the social-cognitive determinants underlying these behaviours. Notably, in both groups, the proportion of participants reporting a less healthy behaviour at 2-year follow-up almost equalled the proportion reporting a more healthy behaviour. The percentage of participants lost to follow-up was high.

Study Limitations

In addition to a relatively low response rate for the initial screening and for the baseline evaluation, a relatively high number of participants dropped-out of the study. This low participation rate limits the reach and potential impact that the intervention may have in practice. In addition, we are aware that selective drop-out may lead to a biased estimate of intervention effects. However, analysis of the characteristics of those who dropped-out and the evaluation of patterns of missingness provided no clear evidence on the direction in which our estimates may have been biased. This is in line with our previous analyses on the longitudinal DHIAAN data at 1-year follow-up, that showed no relevant contribution of multiple imputations to the interpretation of our data [14]. Nevertheless, it seems fair to consider the high drop-out rate as a sign that for many participants the intervention did not meet their perceived needs.

In the interpretation of our results, it should also be noted that self-reported questionnaire data were used to assess the change in physical activity, diet and the determinants of behaviour

change. We cannot exclude the possibility that our participants gave socially desirable answers [39], potentially influenced by an increase in awareness after the start of the intervention. As recommended, we added culturally-specific activities to the physical activity questionnaire (such as yoga and dancing) to mitigate cultural differences in recommended physical activity [35]; nevertheless, the validity of this measurement may have been suboptimal. To measure diet, we included a limited number of questions on specific behaviours, which may be less reliable than biomarkers or a more complete measurement of food intake such as a food frequency questionnaire [40,41]. As a result, we may have missed more general positive changes in other aspects of the diet, potentially due to the intervention.

In addition, because the reference period for the physical activity and diet questionnaire spanned a few months, the answers may have been influenced by recall bias [40]. Although the effect of these types of bias apply to both groups, the effects could differ between the groups, e.g. due to the focus on certain behaviours during the intensive counselling in the intervention group. However, this seems very unlikely given the small differences between the two groups in reported changes. Therefore, we conclude that it is unlikely that these methodological limitations have substantially biased the present results.

Discussion of main findings

At 2-year follow-up we found that a culturally-targeted lifestyle intervention in primary care did not change the dietary behaviour and physical activity of this group of South Asian people at risk of T2D. This is in line with our observation of no effect of the intervention on weight status and other metabolic risk factors at 1-year follow-up [14]. However, a lack of effect on metabolic outcomes at one year does not rule out the possibility that the health behaviours or the underlying determinants may still change due to the intervention. The results of the

present study suggest that this was not the case. On the contrary, the health behaviour of a substantial number of participants even deteriorated. This was unexpected given the intensity of our intervention, an element previously shown to increase the effectiveness of such a lifestyle programme [42]. Although changes in reported behaviour may also be the result of increased awareness among participants of their own (poor) diet and physical activity, the negative finding matches the weight gain reported for some participants after one year of follow-up [14].

There are several possible reasons for the lack of an effect of the intervention on health behaviour. First, despite being classified as being at risk for diabetes (i.e. impaired glucose tolerance, impaired fasting glucose, or relatively high insulin resistance) the participants were relatively healthy and health conscious. For instance, the mean BMI was lower compared to other, similar, populations [2-4, 6-8]. Moreover, a substantial part of our population met the guidelines for a healthy diet at baseline and indicated that they considered physical activity and a healthy diet important. These positive characteristics probably leave little room for improvement with an intervention aimed at a healthy lifestyle alone. To effectively reduce the burden of T2D among South Asians, future interventions should explore new strategies, e.g. focus on more specific forms of physical activity [43]. In addition, the low initial response rate in combination with the high drop-out rate raise the question whether an intensive intervention as employed in this study is the optimal approach to reach those in need in this high-risk population. It suggests that, despite all efforts to adapt the intervention, the current design is not attractive and acceptable to the target population. More acceptable interventions that reach a larger proportion of those with an increased risk of T2D seem necessary in order to effectively reduce the risk of T2D at population level. This might include more community-engaged interventions. Broader involvement from the community as a whole, perhaps in an

even earlier phase of the project or in different aspects, might improve the acceptability and enhance the response to the intervention. Nevertheless, the current project builds on a long tradition of health interventions by the Municipal Health Service of the Hague (B.M). Moreover, we have tried to engage community members and professionals in the adaptation of the intervention during the pilot [20].

Secondly, the intervention primarily addressed the individual and only marginally targeted the individual's environment. However, changes in the physical and social environment may necessary to influence the accessibility to and the social norm towards a healthy lifestyle, making it easier to make healthier lifestyle choices [18,44]. For instance, evidence from the EPODE (Ensemble, Prévenons l'Obesité Des Enfants) approach suggests that environmental changes implemented by the private and public sectors are essential for behaviour change on the long term [45]. We attempted to make the intervention accessible by offering a local physical activity programme, and having dieticians carry out the intervention as part of their dietician practice. However, we did not involve the private and public sectors to make adjustments to the immediate environment to facilitate healthier lifestyle choices, e.g. in local (South Asian) supermarkets or at work. In that case the intervention might have benefited from support for the intended behaviour changes via changes in the environment. This explanation is supported by data from similar interventions in a primary care setting [6-8, 46] that also failed to positively change health behaviour. For instance, an intervention study in a Dutch primary care setting reported a significant difference between the groups only for physical activity and fibre intake [6]. At the same time, we should be cautious in our expectations. Previous research indicates that the dietary patterns of South Asian Surinamese are rather robust across acculturation strategies. More specifically, South-Asian Surinamese participants reported significantly higher intakes of rice (staple food) and chicken

(complementary food) and significantly lower intakes of red meat and vegetables (complementary foods) and cookies and sweets (accessory food) as compared to the host population [47]. The robustness of these patterns probably suggest that a single intervention will not suffice to change these patterns. .

Thirdly, the intervention as implemented may not have met the needs of our specific population. This might partly be due to a suboptimal implementation of the targeted intervention. We, for example, found that the adapted counselling method– using the principles of motivational interviewing - had not been fully applied during the sessions of the dieticians [48]. The difficulties that we experienced with application of this method have also been reported in other studies [e.g. 49]. Hence, one might question whether professionals in practice can be expected to show motivational interviewing skills in this kind of interventions as long as these skills are not a fully integrated part of the baseline qualifications of these professionals. Moreover, although we purposefully invested in culturally targeting the intervention, and the majority of participants perceived the materials as clear and attractive, we cannot rule out the possibility that further investments, or investments in other elements could have improved the effectiveness of the interventions. This also applies to the choice for the technique of motivational interviewing. The experiences of some dieticians seemed to indicate that this technique was less effective for this South Asian origin population, as some participants preferred a more directive style and 'just wanted a list what to do or what to eat' [48]. Additionally, few participants took up the offer of a family session. This seems in contrast with the success of family oriented sessions in a comparable trial among South Asians in the UK [15]. This difference between both trials might indicate the importance of involvement of the family from the start of the intervention, rather than in a separate family session [47]. On the other hand, it might also reflect real differences between the South Asian

population in the UK and that in the Netherlands. As the latter have migrated via Surinam, a former Dutch colony, this might have led to a situation where they have been more adapted to the host culture than the South Asians in the UK. More studies are needed to elucidate the specific elements which make cultural targeting effective in this population [50].

Conclusions

In this group of South Asians (aged 18-60 years) at risk of diabetes, a culturally-targeted lifestyle intervention was not effective in promoting healthy behaviour. At 2-year follow-up the changes in dietary behaviour, physical activity or underlying social-cognitive determinants in the intervention group did not differ from those in the control group. Given the high *a priori* risk and the specific characteristics of the target population, we recommend further research to determine whether an updated strategy, preferably more acceptable for the target population, may change health behaviours through changes in the underlying social-cognitive determinants (e.g. social norms and self-efficacy) in this high-risk South Asian population.

Authors' contributions

EV and IV analyzed the data. EV contributed to the interpretation, and drafted the first version of the manuscript. IV and KS designed the study, contributed to the interpretation of the data, and edited the manuscript. VN, BM and MN gave advice for the design and interpretation. WB contributed to the analysis and interpretation. All authors reviewed the manuscript and approved the final version.

Competing interests

All authors declare that they have no competing interests.

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Data sharing statement

No additional data supporting the present paper are available online. Data collected during the study, as described in doi: 10.1186/1471-2458-12-371, after a collaboration agreement is signed. Researchers may contact i.g.vanvalkengoed@amc.nl or k.stronks@amc.nl.

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Table 1. Baseline characteristics of participants with a measurement of physical activity and diet at baseline and at 2-year follow-up measurement

		Intervention group, *N*=165	Control group, *N*=149
Socio-demographic	**Male**	75 (45.5)	77 (52.0)
	Mean age (years)	44.9 (43.5-46.5)	44.7 (43.1-46.4)
	Low education	16 (10.1)	20 (13.8)
	Paid work	115 (70.6)	104 (70.3)
	Family income ≤net 998 euros/month	18 (2.3)	14 (10.0) [a]
	Country of birth (Netherlands)	14 (8.5)	14 (9.5)
	Mean duration of residence (years)	28.8 (28.2-30.4)	27.9 (26.4-29.4)
	Family history of diabetes	124 (77.5)	103 (71.5)
Metabolic	**Mean body mass index**	27.7 (27.1-28.3)	27.2 (26.6-27.8)
	Mean fasting plasma glucose	5.3 (5.2-5.4)	5.3 (5.3-5.4)
	Mean 2-h post-load glucose	6.1 (5.8-6.3)	6.0 (5.7-6.2)
	Mean glycated haemoglobin	5.7 (5.6-5.8)	5.7 (5.6-5.7)
	Median HOMA-IR	3.0 (2.2-4.1)	2.8 (2.1-3.9)
Physical activity	**Any moderate-to-vigorous activity**	135 (81.8)	118 (79.2)
	Mean moderate-to-vigorous activity (min/week)	628.0 (504.1-751.9)	665.6 (523.2-807.9)
	Mean total activity (min/week)	2698.8 (2534.2-2863.5)	2451.3 (2262.7-2640.0)
Dietary intake [b]	**Fruit: 2 pieces /day (%)**	71 (43.3)	55 (36.9)
	Vegetables: 200 g/day (%)	112 (67.9)	48 (56.4) [c]
	Whole wheat: almost exclusively (%)	11 (6.7)	11 (7.4)
	Meal pattern: 3 meals/day at a regular times (%)	94 (57.3)	82 (55.4)
	Brown rice: almost exclusively (%)	21 (12.8)	11 (7.4)
Risk perception	**Causal beliefs**		
	-Perceiving 6 general risk factors as cause (%) [d]	110 (66.7)	103 (69.1)
	-Perceiving consuming a lot of sugar as cause (%)	113 (68.5)	105 (70.5)
	-Perceiving consuming a lot of white rice as cause (%)	95 (57.6)	86 (57.7)
	-Perceiving consuming masala as cause [d]	49 (29.9)	48 (32.4)
	-Perceiving being a South Asian as cause	122 (73.9)	104 (69.8)
	-Perceiving having a family history of T2D as cause	150 (90.9)	134 (89.9)
	High susceptibility	63 (38.2)	71 (47.7)
	High controllability belief by physical activity	146 (88.5)	132 (88.6)
Positive attitude towards	**Physical activity**		
	-Direct	160 (97.0)	143 (96.0)

	-Indirect	161 (97.6)	142 (95.3)
	Diet		
	-In general	161 (98.2)	148 (99.3)
	-Importance brown rice	76 (46.1)	62 (41.6)
	-Importance snacks	51 (31.5)	39 (26.4)
	-Enjoyment brown rice	43 (27.0)	30 (20.5)
	-Enjoyment snacks	93 (58.1)	67 (45.6) [c]
Perceiving social support	**Physical activity**		
	-Partner	71 (43.0)	66 (44.3)
	-Others	103 (62.4)	99 (66.4)
	Diet		
	-In general	98 (59.8)	85 (57.0)
	-Brown rice	44 (26.8)	41 (27.5)
	-Refusing snacks	48 (29.3)	45 (30.2)
Perceiving self-efficacy	**Physical activity**	109 (66.1)	103 (69.1)
	Diet		
	-In general	151 (91.5)	136 (91.3)
	-Brown rice	56 (33.9)	38 (25.5)
	-Refusing snacks	98 (60.5)	101 (69.7)
Stage of change- motivated to change	**Physical activity within 6 months**	99 (59.3)	105 (69.5)
	Diet within 6 months		
	-In general	153 (92.7)	135 (90.6)
	-Brown rice	82 (49.7)	59 (39.6)

Data are presented as means (95%-confidence interval), median (25th-75th percentile) or *n* (percentage); HOMA-IR, Homeostasis Model of Assessment-Insulin Resistance ; T2D, type 2 diabetes mellitus ; [a] Estimated net income was not reported by 54 (17.0%) of participants. Differences between groups were, therefore, not assessed. [b] Derived from the national guidelines for diet (30), with the exception of rice for which no guideline has been established; [c]Significant difference between the groups at baseline (T0); [d] Six common risk factors: overweight, too little exercise, unhealthy diet, age ≥ 35 years, smoking, and hypertension.

Table 2. Effectiveness of intervention on physical activity and dietary behaviour among South Asians at risk of diabetes

		Changes in intervention group, *N*=165		Changes in control group, *N*=149		
		At T1 [a,b]	At T2 [a]	At T1 [a,b]	At T2 [a]	p-value T2 [c]
Physical activity	**Any moderate-to-vigorous activity**					
	Participants with positive change (%)	22 (17.1)	20 (13.4)	18 (14.9)	21 (12.7)	0.630
	Participants with negative change (%)	9 (7)	10 (6.7)	11 (9.1)	16 (9.7)	
	Mean moderate-to-vigorous activity (min/week)	163.1 (21.5-304.7)	142.9 (-5.26-291.0)	-34.3 (-189.6-120.9)	0.5 (-149.5-150.6)	0.672
	Mean total activity (min/week)	83.1 (-82.9-249.2)	-9.3 (-177.2-158.4)	-174.8 (-383.2-33.5)*	2.9 (-197.9-203.7)	0.297
Dietary intake [d]	**Fruit: 2 pieces /day (%)**					
	Participants with positive change (%)	20 (15.9)	28 (17.1)	16 (13.3)	30 (20.3)	0.680
	Participants with negative change (%)	21 (16.7)	19 (11.6)	13 (10.8)	14 (9.5)	
	Vegetables: 200 g/day (%)					
	Participants with positive change (%)	12 (9.3)	20 (12.1)	19 (15.8)	19 (12.8)	0.787
	Participants with negative change (%)	17 (13.2)	17 (10.3)	14 (11.7)	12 (8.1)	
	Whole wheat: almost exclusively (%)					
	Participants with positive change (%)	8 (6.2)	25 (15.2)	14 (11.7)	20 (13.4)	0.667
	Participants with negative change (%)	7 (5.4)	7 (4.2)	11 (9.2)	4 (2.7)	
	Meal pattern: 3 meals/day at a regular times (%)					
	Participants with positive change (%)	22 (17.3)	32 (19.5)	19 (16.0)	26 (17.6)	0.329
	Participants with negative change (%)	12 (9.4)	11 (6.7)	7 (5.9)	17 (11.5)	
	Brown rice: almost exclusively (%)					
	Participants with positive change (%)	10 (7.8)	12 (7.3)	6 (5.0)	19 (12.8)	0.264
	Participants with negative change (%)	7 (5.5)	6 (3.7)	5 (4.3)	6 (4.0)	

[a]Changes from T0-T1 and T0-T2 are described as number (percentage of total population) with a positive change (e.g. from non-adherent to adherent to the guideline for fruit intake) or a negative change (e.g. from a regular to an irregular meal pattern) at one and two years. The remaining participants had not changed their dietary intake or physical activity. For continuous measures a mean change (95%-confidence interval) is given.
[b] Of the 314 participants with a measurement at baseline and at 2-year follow-up, 279 also attended the measurement at 1-year follow-up (148 in the intervention group and 131 in the control group); [c] *P*-value for the intention-to-treat analysis of the difference in changes from T0 to T2 between the two groups; [d] Derived from the national guidelines for diet (30), with the exception of rice for which no guideline has been established; T0, baseline measurement; T1, measurement after 1 year; T2, measurement after 2 years.

Table 3. Effectiveness of intervention on determinants of behaviour among South Asians at risk of diabetes (n=314)

		Changes in intervention group, *N*=165		Changes in control group, *N*=149		
		At T1 [a,b]	At T2 [a]	At T1 [a,b]	At T2 [a]	p-value T2 [c]
Risk perception	**Causal beliefs**					
	-Perceiving 6 general risk factors as cause (%) [d]					
	Participants with positive change (%)	20 (15.5)	32 (19.4)	24 (19.8)	33 (22.1)	0.818
	Participants with negative change (%)	16 (12.4)	16 (9.7)	12 (9.9)	13 (8.7)	
	-Perceiving consuming a lot of sugar as cause (%)					
	Participants with positive change (%)	18 (14.1)	21 (12.7)	16 (13.2)	18 (12.1)	0.458
	Participants with negative change (%)	32 (25.0)	34 (20.6)	16 (13.2)	23 (15.4)	
	-Perceiving consuming a lot of white rice as cause (%)					
	Participants with positive change (%)	25 (19.4)	35 (21.2)	33 (27.3)	39 (26.2)	0.552
	Participants with negative change (%)	18 (14.0)	21 (12.7)	10 (8.3)	16 (10.7)	
	-Perceiving consuming masala as cause [e]					
	Participants with positive change (%)	11 (8.7)	22 (13.4)	17 (14.0)	19 (12.8)	0.569
	Participants with negative change (%)	27 (21.3)	29 (17.7)	17 (14.0)	20 (13.5)	
	-Perceiving being a South Asian as cause					
	Participants with positive change (%)	19 (14.7)	24 (14.5)	18 (14.9)	30 (20.1)	0.395
	Participants with negative change (%)	13 (10.1)	15 (9.1)	12 (9.9)	11 (7.4)	
	-Perceiving having a family history of T2D as cause					
	Participants with positive change (%)	8 (6.2)	12 (7.3)	10 (8.3)	12 (8.1)	0.798
	Participants with negative change (%)	9 (7.0)	13 (7.9)	4 (3.3)	9 (6.0)	
	High susceptibility					
	Participants with positive change (%)	24 (18.6)	37 (22.4)	28 (23.1)	32 (21.5)	0.941
	Participants with negative change (%)	11 (8.5)	17 (10.3)	17 (14.0)	17 (11.4)	
	High controllability belief by physical activity					
	Participants with positive change (%)	5 (3.9)	15 (9.1)	8 (6.6)	12 (8.1)	0.619
	Participants with negative change (%)	7 (5.5)	9 (5.5)	8 (6.6)	5 (3.4)	
Positive attitude towards	**Physical activity**					
	-Direct					

	Participants with positive change (%)	3 (2.4)	4 (2.4)	3 (2.5)	4 (2.7)	1.0[f]
	Participants with negative change (%)	2 (1.6)	0 (0.0)	1 (0.8)	0 (0.0)	
	-Indirect					
	Participants with positive change (%)	4 (3.1)	4 (2.4)	3 (2.5)	5 (3.4)	0.740[f]
	Participants with negative change (%)	3 (2.3)	6 (3.6)	2 (1.7)	1 (0.7)	
	Diet					
	-In general					
	Participants with positive change (%)	2 (1.6)	2 (1.2)	1 (0.8)	1 (0.7)	1.0[f]
	Participants with negative change (%)	2 (1.6)	1 (0.6)	2 (1.7)	1 (0.7)	
	-Importance brown rice					
	Participants with positive change (%)	34 (26.4)	40 (24.2)	30 (24.8)	39 (26.2)	0.739
	Participants with negative change (%)	13 (10.1)	16 (9.7)	16 (13.2)	11 (7.4)	
	-Importance snacks[d]					
	Participants with positive change (%)	18 (14.5)	20 (12.3)	20 (16.8)	11 (7.4)	0.298
	Participants with negative change (%)	25 (20.2)	31 (19.1)	19 (16.0)	26 (17.6)	
	-Enjoyment brown rice					
	Participants with positive change (%)	34 (27.6)	32 (20.4)	20 (17.2)*	27 (18.5)	0.140
	Participants with negative change (%)	10 (8.1)	15 (9.6)	7 (6.0)	6 (4.1)	
	-Enjoyment snacks[d]					
	Participants with positive change (%)	25 (20.5)	22 (13.9)	24 (20.3)	19 (12.9)	0.147
	Participants with negative change (%)	36 (29.5)	49 (31.0)	16 (13.6)	32 (21.8)	
Perceiving social support	**Physical activity**					
	-Partner					
	Participants with positive change (%)	18 (14.2)	28 (17.0)	13 (10.7)	22 (14.8)	0.730
	Participants with negative change (%)	13 (10.2)	16 (9.7)	11 (9.1)	12 (8.1)	
	-Others					
	Participants with positive change (%)	26 (20.3)	30 (18.2)	19 (15.7)	28 (18.8)	0.205
	Participants with negative change (%)	18 (14.1)	15 (9.1)	16 (13.2)	23 (15.4)	
	Diet					
	-In general					
	Participants with positive change (%)	21 (16.5)	28 (17.1)	19 (16.1)	27 (18.1)	0.090
	Participants with negative change (%)	21 (15.5)	35 (21.3)	27 (22.9)	18 (12.1)	
	-Brown rice					
	Participants with positive change (%)	28 (22.2)	26 (15.9)	17 (14.4)	31 (20.8)	0.473
	Participants with negative change (%)	12 (9.5)	24 (14.6)	22 (18.6)	18 (12.1)	

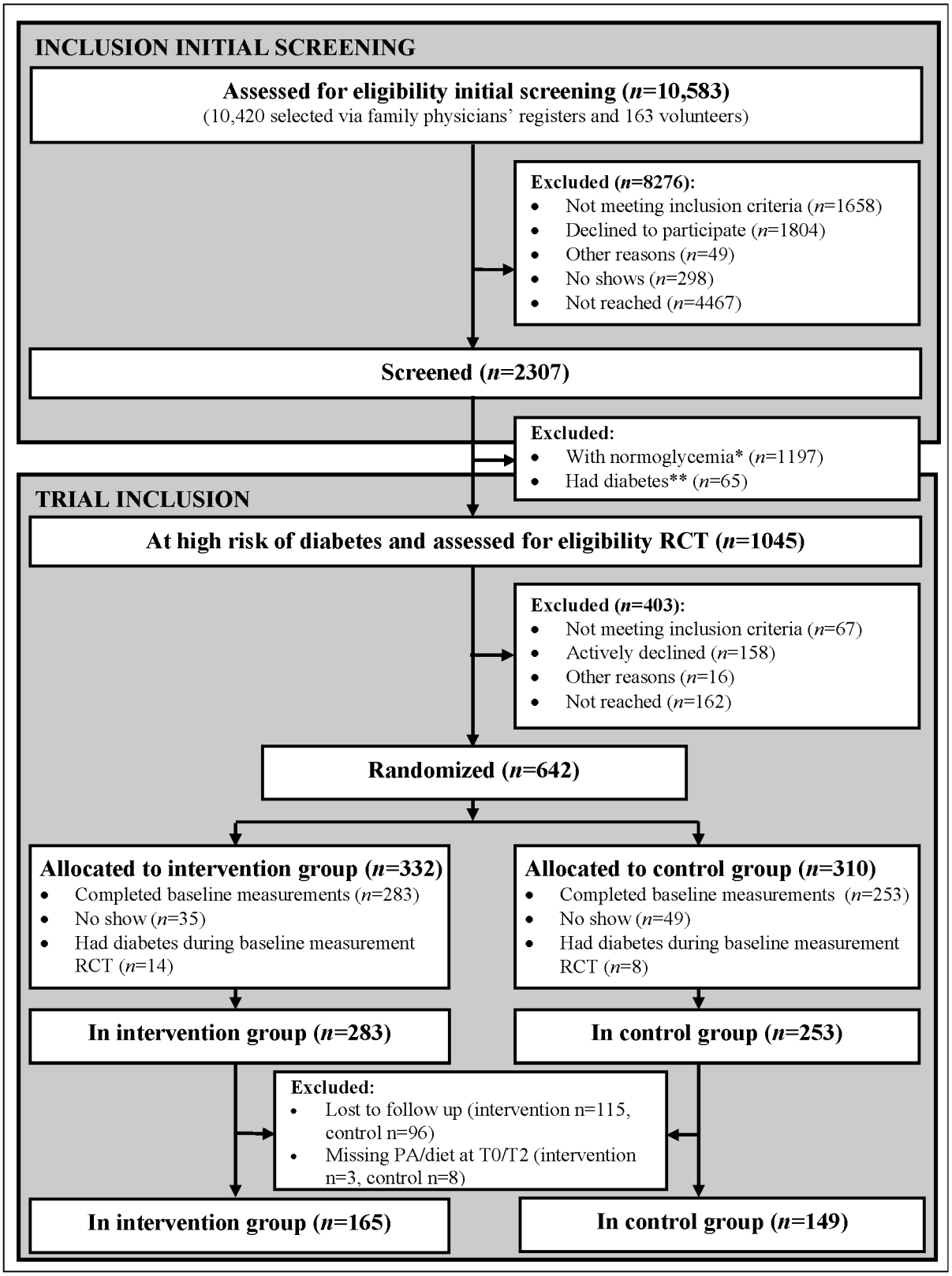
	-Refusing snacks					
	Participants with positive change (%)	30 (23.6)	37 (22.6)	18 (15.1)*	37 (25.0)	0.389
	Participants with negative change (%)	13 (10.2)	29 (17.7)	25 (21.0)	18 (12.2)	
Perceiving self-efficacy	**Physical activity**					
	Participants with positive change (%)	22 (17.2)	28 (17.0)	18 (14.9)	25 (16.8)	0.973
	Participants with negative change (%)	24 (18.8)	19 (11.5)	14 (11.6)	16 (10.7)	
	Diet					
	-In general					
	Participants with positive change (%)	4 (3.1)	7 (4.2)	7 (5.8)	10 (6.7)	0.334[f]
	Participants with negative change (%)	2 (1.6)	3 (1.8)	7 (5.8)	4 (2.7)	
	-Brown rice					
	Participants with positive change (%)	28 (21.7)	26 (15.9)	29 (24.0)	27 (18.1)	0.669
	Participants with negative change (%)	22 (17.1)	20 (12.2)	13 (10.7)	14 (9.4)	
	-Refusing snacks					
	Participants with positive change (%)	25 (20.0)	40 (24.8)	25 (21.4)	27 (18.9)	0.359
	Participants with negative change (%)	11 (8.8)	15 (9.3)	14 (12.0)	18 (12.6)	
Stage of change-motivated to change	**Physical activity within 6 months**					
	Participants with positive change (%)	26 (15.8)	33 (20.0)	16 (10.7)	21 (14.1)	0.076
	Participants with negative change (%)	43 (26.1)	30 (18.2)	44 (29.5)	18 (12.1)	
	Diet within 6 months					
	-In general					
	Participants with positive change (%)	7 (5.4)	7 (4.2)	8 (6.6)	10 (6.7)	0.334[f]
	Participants with negative change (%)	1 (0.8)	3 (1.8)	4 (3.3)	4 (2.7)	
	-Brown rice					
	Participants with positive change (%)	22 (17.2)	21 (12.7)	23 (19.0)	26 (17.4)	0.266
	Participants with negative change (%)	13 (10.2)	30 (18.2)	17 (14.0)	19 (12.8)	

[a] Changes from T0-T1 and T0-T2 are described as number (percentage of total population) with a positive change (e.g. from non-adherent to adherent to the guideline for fruit intake) or a negative change (e.g. from a regular to an irregular meal pattern) at one and two years. The remaining participants had not changed their dietary intake or physical activity. [b] Of the 314 participants with a measurement at baseline and at 2-year follow-up, 279 also attended the measurement at 1-year follow-up (148 in the intervention group and 131 in the control group); [c] *P*-value for the intention-to-treat analysis of the difference in changes from T0 to T2 between the intervention and control group; [d] Six common risk factors: overweight, too little exercise, unhealthy diet, age ≥ 35 years, smoking, and hypertension; [e] Except for the belief that masala intake is a possible cause of diabetes and the attitude towards refusing snacks at parties, an increase or positive change in the items measuring the determinants of behaviour change was expected to positively influence behaviour change; [f] Because of low expected counts, a Fisher's exact test or chi-square test was done comparing the category positive change versus the rest; T0, baseline measurement; T1, measurement after 1 year; T2, measurement after 2 years; T2D, Type 2 diabetes mellitus.

Figure 1. Flow chart of inclusion of the study participants

*A fasting glucose of 5.5 mmol/L or lower, a 2-hour post-load glucose of 7.7 mmol/L or lower, a glycated haemoglobin level of 5.9% or lower and a value of 2.38 or lower for the homeostasis model assessment of estimated insulin resistance; ** a fasting glucose of 7.0 mmol/L or more, and/or a 2-hour post-load glucose of 11.1 mmol/L or more; RCT, randomized controlled trial; PA, physical activity; T0, baseline measurement; T2, measurement at 2-year follow-up

Figure 1- Flow chart of the study



Supplement 1. Questionnaire
Below are the questions on dietary behavior (in Dutch) from the questionnaire at baseline, T1, T2 of the DHIAAN study. Participants were interviewed by a trained interviewer. Answer cards with the answer categories for each question were provided.

1. Risicoperceptie

Allereerst volgen er een aantal vragen over het risico op diabetes. Ik lees steeds een situatie voor en kunt u antwoorden of deze situatie uw risico op diabetes verhoogt of niet verhoogt?
Als u het niet weet, kunt u dat ook zeggen.

INT Als verhoogd risico onduidelijk is, dan aangeven dat dit hetzelfde is als meer kans

1.1

Heeft u een verhoogd risico op diabetes als u:	Ja	Weet niet	Nee
Van Hindostaans-Surinaamse afkomst bent?	☐	☐	☐
Veel witte rijst eet?	☐	☐	☐
Weinig beweegt?	☐	☐	☐
Ongezond eet?	☐	☐	☐
Familie heeft met diabetes?	☐	☐	☐
Ouder dan 35 jaar bent?	☐	☐	☐
Een hoge bloeddruk heeft?	☐	☐	☐
Rookt?	☐	☐	☐
In het verleden zwangerschapsdiabetes heeft gehad?	☐	☐	☐
Veel masala eet?	☐	☐	☐
Overgewicht heeft?	☐	☐	☐
Veel suiker eet?	☐	☐	☐

Bent u het eens of oneens met de volgende stellingen. Misschien vindt u deze stellingen op elkaar lijken, maar geef toch elke keer het antwoord dat u het meest van u op toepassing vindt.
INT: Gebruik antwoordkaart 1 voor vragen 1.2 t/m 1.4

1.2 Het is aannemelijk dat ik diabetes zal krijgen
☐ Helemaal mee eens
☐ Mee eens
☐ Niet mee eens/Niet mee oneens
☐ Niet mee eens
☐ Helemaal niet mee eens

1.3 Mijn kans op het krijgen van diabetes in de komende paar jaren is groot
☐ Helemaal mee eens
☐ Mee eens
☐ Niet mee eens/Niet mee oneens
☐ Niet mee eens
☐ Helemaal niet mee eens

1.4	Ik heb het gevoel dat ik ooit in mijn leven diabetes zal krijgen	☐ Helemaal mee eens ☐ Mee eens ☐ Niet mee eens/Niet mee oneens ☐ Niet mee eens ☐ Helemaal niet mee eens

6. Voeding 1

De volgende vragen gaan over uw huidige eetpatroon.

6.1 **INT**	Hoeveel dagen van de week eet u fruit? **Het gaat hierbij niet alleen om vers fruit, ook fruit uit blik of glas tellen mee**	☐ Elke dag, 7 keer per week ☐ 5 of 6 dagen per week ☐ 4 dagen per week of minder
6.2 dag **INT**	Hoeveel fruit eet u dan per dag? **Als één stuk fruit telt 1 (sinaas)appel, 1 banaan 2 mandarijnen of een schaaltje kleiner fruit zoals aardbeien. Het gaat niet alleen om vers fruit, ook fruit uit blik of glas tellen mee.**	☐ 2 stuks fruit of meer per ☐ 1 stuks fruit per dag ☐ ik eet (bijna) nooit fruit
6.3	Hoe vaak drinkt u vruchtensappen, vers of uit pak of fles? Siroop moet u niet meetellen.	☐ Vaak (dagelijks) ☐ Soms ☐ Nooit (< 1 keer per week)
6.4	Hoe vaak eet u, tussendoor of bij uw maaltijd rauwkost of salade?	☐ 6 – 7 keer per week ☐ 3 – 5 keer per week ☐ 1-2 keer per week of minder
6.5 **INT**	Hoeveel dagen van de week eet u groenten? **Alle groenten tellen mee, ook voorgesneden groeten, Diepvriesgroenten en groenten uit pot of blik.** **(Bij deze vraag telt rauwkost *niet* mee)**	☐ Elke dag, 7 keer per week ☐ 5 of 6 dagen per week ☐ 4 dagen per week of minder ☐ (Bijna) nooit
6.6	Hoe vaak per week eet u een ochtendmaaltijd (ontbijt)?	☐ 6 – 7 keer per week ☐ 3 – 5 keer per week ☐ 1 – 2 keer per week

☐ Nooit, ik eet geen ochtendmaaltijd (ontbijt)

6.7 Hoe vaak per week eet u een middagmaaltijd (lunch)?

☐ 6 – 7 keer per week
☐ 3 – 5 keer per week
☐ 1 – 2 keer per week
☐ Nooit, ik eet geen middagmaaltijd (lunch)

6.8 Hoe ziet uw maaltijdpatroon er op een dag uit?

☐ Regelmatig maaltijdpatroon (ontbijt, lunch, avondmaaltijd)
☐ Vast maaltijdpatroon (alleen lunch en avondmaaltijd)
☐ Onregelmatig maaltijdpatroon (soms ontbijt, lunch, avondmaaltijd)

6.9 Hoe vaak per week eet u rijst?

☐ 6 – 7 keer per week
☐ 3 – 5 keer per week
☐ 1 – 2 keer per week
☐ < 1 keer per week / (bijna) nooit

6.10 Welk soort rijst eet u?

☐ Altijd witte rijst
☐ Meestal witte rijst, af en toe zilvervliesrijst
☐ Even vaak witte rijst als zilvervliesrijst
☐ Meestal zilvervliesrijst, af en toe witte rijst
☐ Altijd zilvervliesrijst
☐ Ik eet (bijna) nooit rijst

6.11 Hoe vaak per week eet u brood zoals: sneetjes brood, puntjes, broodjes, bolletjes en broodvervangers beschuit, crackers, rijstwafels?

☐ 6 – 7 keer per week
☐ 3 – 5 keer per week
☐ 1 – 2 keer per week
☐ < 1 keer per week / (bijna) nooit

6.12 Als u brood of broodvervangers eet, welke soorten waren dat dan?

INT: Gebruik Antwoordkaart 8

	Nooit	Soms	Vaak	Altijd		Weet niet
'Gewone' knäckebröd, beschuit, matzes, crackers of rijstwafel	☐	☐	☐	☐		☐
Volkoren knäckebröd, beschuit, matzes of crackers	☐	☐	☐	☐		☐
Croissant	☐	☐	☐	☐		☐
Witte krenten-, rozijnen-, muesli- bolletjes	☐	☐	☐	☐		☐
Volkoren krenten-, rozijnen-, mueslibolletjes	☐	☐	☐	☐		☐
Wit brood	☐	☐	☐	☐		☐
Rogge-, volkoren- of mueslibrood	☐	☐	☐	☐		☐
Bruin brood	☐	☐	☐	☐		☐
'gewone' ontbijtkoek	☐	☐	☐	☐		☐
Volkoren ontbijtkoek	☐	☐	☐	☐		☐

INT **Als respondent niet weet of hij/zij een volkoren of gewoon brood of broodvervanger eet, dan aangeven dat 'witte' of 'gewone' producten het meest standaard zijn. Als respondent het dan echt niet weet → weet niet invullen.**

6.13 Bent uw binnen uw huishouden verantwoordelijk voor het bereiden van de warme maaltijd?

☐ Altijd
☐ Meestal
☐ Af en toe
☐ Bijna nooit
☐ Nooit

7. Voeding 2

De volgende vragen gaan over hoe belangrijk of onbelangrijk u voeding en bepaalde aspecten van voeding vindt.

7.1 Hoe belangrijk is het eten van gezonde voeding voor u?

INT: Gebruik Antwoordkaart 9

☐ Heel belangrijk
☐ Belangrijk
☐ Niet belangrijk/niet onbelangrijk
☐ Niet belangrijk
☐ Totaal niet belangrijk

Ik ga nu een aantal van de aanbevelingen van het Voedingscentrum noemen. Misschien bent u ermee bekend. Allereerst is, volgens het Voedingscentrum, dagelijks 3 hoofdmaaltijden en maximaal 4 keer tussendoor eten het meest optimaal. Daarnaast adviseert het Voedingscentrum om tenminste twee ons groente en twee stuks fruit per dag te eten. Tot slot is het belangrijk voldoende voedingsvezel te eten. Dit kan, onder andere, door de voorkeur te geven aan volkoren brood en zilvervliesrijst in plaats van wit brood en witte rijst.

INT Dus: Volkoren producten zijn bijvoorbeeld bruin brood i.p.v. wit brood of roti van volkoren bloem i.p.v. witte bloem

Bij de volgende vragen willen we weten hoe belangrijk of onbelangrijk u de bovengenoemde adviezen vindt.

7.2

INT: Gebruik Antwoordkaart 9

Stelling	Heel belangrijk	Belangrijk	Niet belangrijk/ Niet onbelangrijk	Niet belangrijk	Totaal niet belangrijk
Het dagelijks eten van een ontbijt, vind ik..	☐	☐	☐	☐	☐
Het regelmatig eten, dat wil zeggen 3 keer per dag een maaltijd, vind ik (ontbijt + lunch + diner)	☐	☐	☐	☐	☐
Elke dag 2 ons groente eten vind ik	☐	☐	☐	☐	☐
Elke dag 2 stuks fruit eten vind ik	☐	☐	☐	☐	☐
Het eten van zilvervliesrijst, vind ik	☐	☐	☐	☐	☐

7.2 vervolg

Stelling	Heel belangrijk	Belangrijk	Niet belangrijk/ Niet onbelangrijk	Niet belangrijk	Totaal niet belangrijk	N.v.t.*
Het eten van volkoren producten, vind ik	☐	☐	☐	☐	☐	-
Elk hapje aannemen bij feestjes en/of religieuze bijeen-komsten, vind ik	☐	☐	☐	☐	☐	☐

*** INT: N.v.t. Alleen invullen als resp. nooit naar een feestje en religieuze bijeenkomst gaat.**

Ik noem opnieuw dezelfde aspecten uit de voeding. Wilt u nu aangeven of dit plezierig of onplezierig vindt om te doen?

INT: Gebruik Antwoordkaart 10

7.3

Stelling	Plezierig	Een beetje plezierig	Niet plezierig/ niet onplezierig	Een beetje onplezierig	Onplezierig	N.v.t.*
Het dagelijks eten van een ontbijt, vind ik	☐	☐	☐	☐	☐	-
Het regelmatig eten, dat wil zeggen 3 keer per dag een maaltijd, vind ik	☐	☐	☐	☐	☐	-
Elke dag 2 ons groente eten, vind ik	☐	☐	☐	☐	☐	-
Elke dag 2 stuks fruit eten, vind ik	☐	☐	☐	☐	☐	-
Het eten van zilvervliesrijst, vind ik	☐	☐	☐	☐	☐	-
Het eten van volkoren producten, vind ik	☐	☐	☐	☐	☐	-
Elk hapje aannemen bij feestjes en/of religieuze bijeenkomsten, vind ik	☐	☐	☐	☐	☐	☐

*** INT: N.v.t. Alleen invullen als resp. nooit naar een feestje en religieuze bijeenkomst gaat.** ***De volgende uitspraken gaan over uw familieleden en of zij u stimuleren om gezonde voeding te eten. Ik ga nu verschillende elementen uit de voeding opnemen, kunt u mij zeggen hoe vaak familieleden u stimuleren om dat te doen? Ik bedoel hiermee familieleden die voor u belangrijk zijn en die u regelmatig ziet of spreekt.***

INT: Gebruik Antwoordkaart 11

7.4

Wordt u gestimuleerd door familieleden om..	**Ja, heel vaak**	**Ja, vaak**	**Ja, af en toe**	**Nee, bijna nooit**	**Nee, nooit**	**N.v.t.***
Iedere dag te ontbijten?	☐	☐	☐	☐	☐	-
Regelmatig te eten (d.w.z. 3 hoofdmaaltijden per dag)?	☐	☐	☐	☐	☐	-
Meer groente te eten?	☐	☐	☐	☐	☐	-
Meer fruit te eten?	☐	☐	☐	☐	☐	-
Vaker zilvervliesrijst i.p.v. witte rijst te eten?	☐	☐	☐	☐	☐	-
vaker volkoren producten te eten?	☐	☐	☐	☐	☐	-
Hapjes af te slaan bij feestjes en/of religieuze bijeenkomsten	☐	☐	☐	☐	☐	☐

*** INT: N.v.t. Alleen invullen als resp. nooit naar een feestje en religieuze bijeenkomst gaat.**

De volgende vragen gaan over een aantal elementen uit de voeding. Kunt u bij de volgende aspecten aangeven in hoeverre het u het zou lukken als u vanaf vandaag dit aspect van voeding wilt verbeteren om dat ook op iedere dag te doen.

<u>Met iedere dag bedoelen we 7 dagen in de week</u>.

INT: Gebruik Antwoordkaart 12

7.5

Lukt het u om..	**Lukt me zeker wel**	**Dat lukt me waarschijnlijk wel**	**Dat lukt misschien wel/ misschien niet**	**Dat lukt me waarschijnlijk niet**	**Dat lukt me zeker niet**	**N.v.t.***
Iedere dag te ontbijten	☐	☐	☐	☐	☐	-
Ik eet regelmatig (dat wil zeggen 3 hoofdmaaltijden per dag)	☐	☐	☐	☐	☐	-
Iedere dag 2 ons groenten te eten	☐	☐	☐	☐	☐	-
Iedere dag 2 stuks fruit te eten	☐	☐	☐	☐	☐	-
zilvervliesrijst i.p.v. witte rijst te eten	☐	☐	☐	☐	☐	-
volkorenproducten i.p.v. witte producten te eten	☐	☐	☐	☐	☐	-
Hapjes af te slaan bij feestjes en/of religieuze bijeenkomsten	☐	☐	☐	☐	☐	☐

*** INT: N.v.t. Alleen invullen als resp. <u>nooit</u> naar een feestje en religieuze bijeenkomst gaat.**

De volgende vraag gaat over wat u in de toekomst van plan bent met betrekking tot uw voeding. Hierna lees ik enkele uitspraken op die daar mee te maken hebben. Kunt u zeggen welke uitspraak het beste bij u past?

INT: Gebruik Antwoordkaart 13

7.6 Ik noem nu enkele stellingen op. Kunt u steeds aangeven welke antwoordoptie het beste bij u past?

	Ja, **al 6 maanden of langer**	**Ja,** **Sinds kort (minder dan 6 maanden)**	**Nee,** **Maar van plan binnen 1 maand te gaan doen**	**Nee,** **Maar van plan binnen 6 maanden te gaan doen**	**Nee,** **Ook niet van plan**
	JA >6 maanden	*JA < 6 maanden*	*NEE, maar wel* *<1 maand*	*NEE, maar wel* *<6 maanden*	*NEE*
Ik ontbijt iedere dag	☐	☐	☐	☐	☐
Ik eet regelmatig (dat wil zeggen 3 hoofdmaaltijden per dag)	☐	☐	☐	☐	☐
Ik eet iedere dag 2 ons groente	☐	☐	☐	☐	☐
Ik eet iedere dag 2 stuks fruit	☐	☐	☐	☐	☐
Ik eet zilvervliesrijst i.p.v witte rijst	☐	☐	☐	☐	☐
Ik eet volkorenproducten i.p.v. witte producten	☐	☐	☐	☐	☐

SUPPLEMENT 2. Comparison of baseline characteristics, physical activity, dietary behaviour and motivational stage of participants in the present analysis and those who were excluded

	In present analysis (*N*=314)	Excluded (*N*=222)	p-value
Male	152 (48.6)	112 (50.5)	0.667
Mean age (years)	44.8 (43.6-46.0)	41.6 (40.2-43.0)	**0.001**
Low education	36 (11.8)	25 (11.6)	0.925
Family history of diabetes	227 (74.7)	171 (78.4)	0.318
Mean body mass index	27.3 (27.0-27.9)	27.4 (26.7-27.9)	0.889
Mean fasting plasma glucose	5.3 (5.2-5.4)	5.3 (5.2-5.4)	0.803
Mean 2-h post-load glucose	6.0 (5.8-6.2)	6.0 (5.8-6.3)	0.907
Mean glycated haemoglobin	5.7 (5.6-5.7)	5.6 (5.6-5.7)	0.092
Median HOMA-IR	3.0 (2.2-4.0)	3.2 (2.4-4.4)	**0.048**
Mean total activity (min/week)	2600.8 (2473.5-2728.0)	2663.6 (2497.8-2829.3)	0.490
Fruit: 2 pieces /day	126 (40.3)	97 (46.2)	0.179
Vegetables: 200 g/day	196 (62.4)	131 (62.4	0.993
Whole wheat: almost exclusively	22 (7.0)	11 (5.2)	0.414
Meal pattern: 3 meals/day at regular times	176 (56.4)	103 (49.0)	0.098
Brown rice: almost exclusively	32 (10.2)	24 (11.5)	0.649
Stage of change- motivated to change physical activity within 6 months	204 (65.0)	148 (66.7)	0.683
Stage of change: motivated to change diet within 6 months	288 (91.7)	188 (90.0)	0.489

Data are presented as means (95%-confidence interval), median (interquartile range) or *n* (percentage);

HOMA-IR, Homeostasis Model of Assessment-Insulin Resistance.

Checklist of Items for Reporting Trials of Nonpharmacologic Treatments*

Section	Item	Standard CONSORT Description	Extension for Nonpharmacologic Trials	Reported on Page No.
Title and abstract†	1	How participants were allocated to interventions (e.g., "random allocation," "randomized," or "randomly assigned")	In the abstract, description of the experimental treatment, comparator, care providers, centers, and blinding status	1-2
Introduction				
Background	2	Scientific background and explanation of rationale		4
Methods				
Participants†	3	Eligibility criteria for participants and the settings and locations where the data were collected	When applicable, eligibility criteria for centers and those performing the interventions	6-7
Interventions†	4	Precise details of the interventions intended for each group and how and when they were actually administered	Precise details of both the experimental treatment and comparator	8-9
	4A		Description of the different components of the interventions and, when applicable, descriptions of the procedure for tailoring the interventions to individual participants	8-9
	4B		Details of how the interventions were standardized	8-9
	4C		Details of how adherence of care providers with the protocol was assessed or enhanced	8
Objectives	5	Specific objectives and hypotheses		5
Outcomes	6	Clearly defined primary and secondary outcome measures and, when applicable, any methods used to enhance the quality of measurements (e.g., multiple observations, training of assessors)		9-13
Sample size†	7	How sample size was determined and, when applicable, explanation of any interim analyses and stopping rules	When applicable, details of whether and how the clustering by care providers or centers was addressed	Reference trial protocol

Randomization–sequence generation†	8	Method used to generate the random allocation sequence, including details of any restriction (e.g., blocking, stratification)	When applicable, how care providers were allocated to each trial group	7
Allocation concealment	9	Method used to implement the random allocation sequence (e.g., numbered containers or central telephone), clarifying whether the sequence was concealed until interventions were assigned		7
Implementation	10	Who generated the allocation sequence, who enrolled participants, and who assigned participants to their groups		7, references
Blinding (masking)†	11A	Whether or not participants, those administering the interventions, and those assessing the outcomes were blinded to group assignment	Whether or not those administering co-interventions were blinded to group assignment	7
	11B		If blinded, method of blinding and description of the similarity of interventions†	
Statistical methods†	12	Statistical methods used to compare groups for primary outcome(s); methods for additional analyses, such as subgroup analyses and adjusted analyses	When applicable, details of whether and how the clustering by care providers or centers was addressed	14-15
Results				
Participant flow†	13	Flow of participants through each stage (a diagram is strongly recommended)---specifically, for each group, report the numbers of participants randomly assigned, receiving intended treatment, completing the study protocol, and analyzed for the primary outcome; describe deviations from study as planned, together with reasons	The number of care providers or centers performing the intervention in each group and the number of patients treated by each care provider or in each center	Figure 1, trial protocol
Implementation of intervention†	New item		Details of the experimental treatment and comparator as they were implemented	16
Recruitment	14	Dates defining the periods of recruitment and follow-up		6,14
Baseline data†	15	Baseline demographic and clinical characteristics of each group	When applicable, a description of care providers (case volume, qualification, expertise, etc.) and centers (volume) in each group	Table1, supplement 1

Numbers analyzed	16	Number of participants (denominator) in each group included in each analysis and whether analysis was by "intention-to-treat"; state the results in absolute numbers when feasible (e.g., 10/20, not 50%)		13
Outcomes and estimation	17	For each primary and secondary outcome, a summary of results for each group and the estimated effect size and its precision (e.g., 95% confidence interval)		16,17, tables
Ancillary analyses	18	Address multiplicity by reporting any other analyses performed, including subgroup analyses and adjusted analyses, indicating those prespecified and those exploratory		15
Adverse events	19	All important adverse events or side effects in each intervention group		na
Discussion				
Interpretation†	20	Interpretation of the results, taking into account study hypotheses, sources of potential bias or imprecision, and the dangers associated with multiplicity of analyses and outcomes	In addition, take into account the choice of the comparator, lack of or partial blinding, and unequal expertise of care providers or centers in each group	18-19
Generalizability†	21	Generalizability (external validity) of the trial findings	Generalizability (external validity) of the trial findings according to the intervention, comparators, patients, and care providers and centers involved in the trial	18,21
Overall evidence	22	General interpretation of the results in the context of current evidence		22

*Additions or modifications to the CONSORT checklist. CONSORT = Consolidated Standards of Reporting Trials.
†This item was modified in the 2007 revised version of the CONSORT checklist.