

Hybrid Evaluation of a Lifestyle Change Program to Prevent the Development of Type 2 Diabetes Among Individuals With Prediabetes: Intended and Observed Changes in Intervening Mechanisms

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Abstract

Background: Lifestyle interventions can prevent type 2 diabetes (T2D) by successfully inducing behavioral changes (eg, avoiding physical inactivity and sedentariness, increasing physical activity and/or healthy eating) that reduce body weight and normalize metabolic levels (eg, HbA1c). For interventions to be successful, it is important to influence “behavioral mechanisms” such as self-efficacy, which motivate behavioral changes. Theory-based expectations of how self-efficacy, chronic stress, and mood changed over time were investigated through a group-based behavior change intervention (PREMIT). At 8 intervention sites, PREMIT was offered by trained primary care providers in 18 group-sessions over a period of 36 months, divided into 4 intervention phases. Adherence to the intervention protocol was assessed. **Method:** Participants (n = 962) with overweight and prediabetes who had achieved $\geq 8\%$ weight loss during a diet reduction period and completed the intervention were categorized into 3 groups: infrequent, frequent, or very frequent group sessions attendance. The interactions between participation in the group sessions and changes in self-efficacy, stress, and mood were multivariate tested. Intervention sites were regularly asked where and how they deviated from the intervention protocol. **Results:** There was no increase in the participants’ self-efficacy in any group. However, the level of self-efficacy was maintained among those who attended the group sessions frequently, while it decreased in the other groups. For all participants, chronic stress and the frequency of attending group sessions were inversely related. Significant differences in mood were found for all groups. All intervention centers reported specific activities, additional to intervention protocol, to promote participation in the group sessions. **Conclusions:** The results suggest that the behavioral changes sought by trained primary care providers are related to attendance frequency and follow complex trajectories. The findings also suggest that group-based interventions in naturalistic primary care settings aimed at preventing T2D require formats and strategies that encourage participants to attend group sessions regularly.

Keywords

adherence, self-efficacy, prediabetes, behavior change, chronic stress, mood



Introduction

Common risk factors for developing type 2 diabetes (T2D) are sedentariness, insufficient physical activity (PA), and energy-dense diets with high saturated fat and added sugar, leading to overweight and obesity.^{1,2} T2D describes a combination of reduced insulin secretion and increased insulin resistance, and takes place insidiously by prediabetes, an intermediate stage between normal glucose metabolism and T2D.³⁻⁵

Sustained weight-loss, though challenging, can modify the progression of prediabetes to T2D.⁶⁻⁸ Complex, multidisciplinary behavioral interventions set in primary care have shown potential in supporting sustained weight-loss maintenance while being cost-effective.⁹⁻¹³ As T2D is considered a major public and primary health care challenge,¹⁴ it is imperative that public and primary health care providers have evidence- and theory-based information available to enable effective planning of primary care-based T2D prevention programs.^{15,16} Especially, as effectiveness of lifestyle interventions in real-world often falls short of efficacy shown in trial conditions.¹⁷

Identification and description of effective and adaptable behavior change techniques (BCTs) in lifestyle interventions¹⁸⁻²⁰ has contributed to improved implementation of programs in T2D prevention.^{16,21} The present study analyzed data from a “Prevention of diabetes through lifestyle Intervention and population studies in Europe and around²¹ the World” (PREVIEW-RCT).^{7,22} Principles of hybrid evaluation research were applied^{23,24} to examine changes in behavioral mechanisms that were expected to facilitate behavioral changes (eg, physical activity) that promote

body weight loss. Secondly, aspects influencing participation in intervention sessions were assessed. Details and theoretical background of the intervention plan has been published elsewhere.²¹

The PREMIT intervention design followed a program theory that included a behavioral mechanism change model and an action model to influence these mechanisms that could be delivered by trained primary care providers.²¹ In PREMIT, proven BCTs were applied to influence the behavioral mechanisms,¹⁸⁻²⁰ that is, to reduce stress, increase action self-efficacy in the initial intervention phases and coping self-efficacy in the later phases, and create a positive mood.^{25,26} Self-efficacy, in particular, is an important behavioral mechanism that describes the ability to perform goal-related behaviors and to overcome obstacles.^{27,28} Theories, such as the Theory of Planned Behavior,²⁹ the Social Cognitive Theory,³⁰ or the Transtheoretical Model (TTM),³¹ include self-efficacy as a key mechanism in regulation of feelings, thinking, and behaviors.³² Schwarzer and Renner³³ proposed to differentiate between action and coping self-efficacy, with action self-efficacy influencing the preparedness to start the behavior while coping self-efficacy influences perceptions of maintaining a behavior through challenges and barriers,³⁴ such as combining lifestyle change with work and family responsibilities.³⁵

Chronic stress (triggered by real or perceived threats) and mood (a state of broad positive and negative feelings) have been associated with likelihood of engaging with health behaviors.^{36,37} Increased chronic stress and negative mood have been associated with lower likelihood of achieving significant weight-loss³⁸⁻⁴⁰ or desired changes in the

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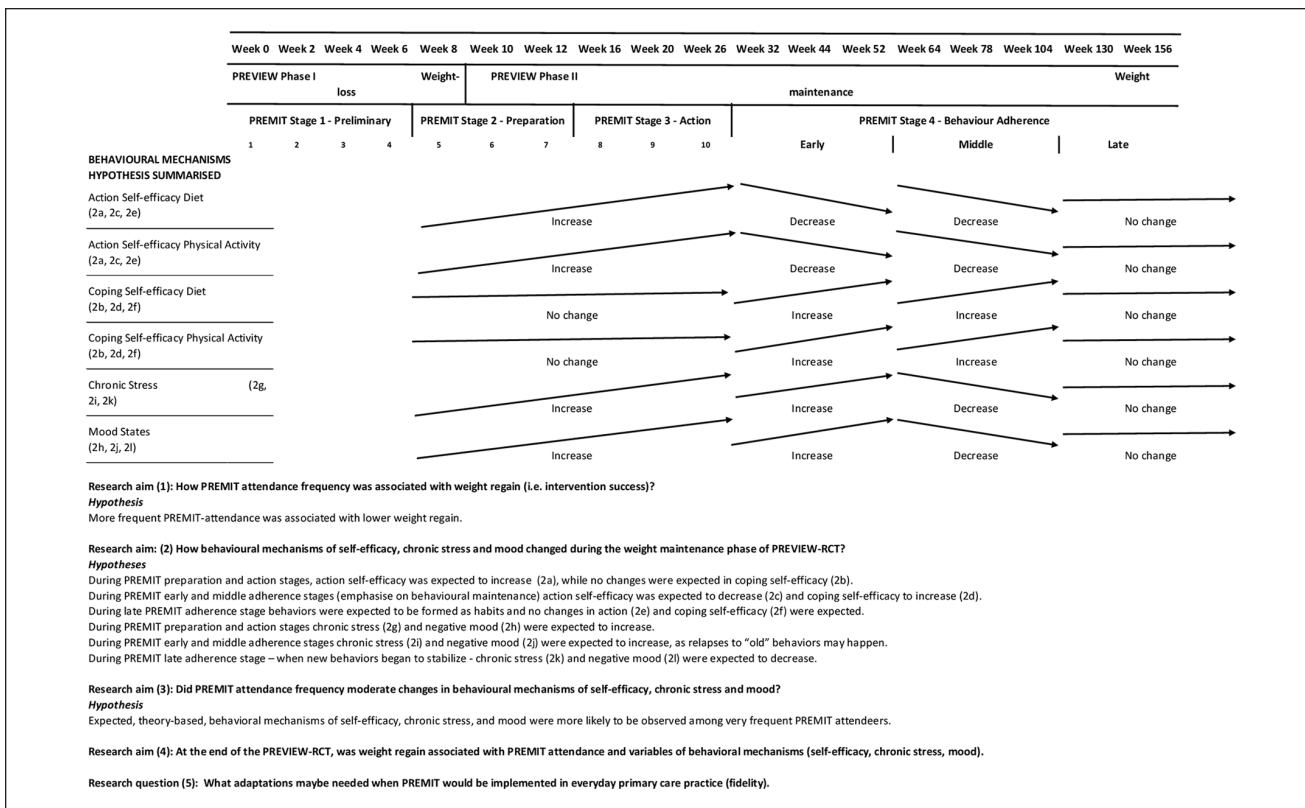


Figure 1. PREVIEW and PREMIT schedules with expected intervention pathways and summary of research aims.

volume of physical activity (PA) and of diet.^{41,42} Chronic stress and mood are bidirectional associated with PA. Increased chronic stress and negative mood have been linked with reduced PA and unhealthier diet. In turn, reduced PA and unhealthier diet are associated with increased chronic stress and negative mood.³⁷

Before lifestyle interventions (such as PREMIT) are applied on a larger scale by primary care providers in natural settings, the study here can provide hints on whether and how behavioral mechanisms change during a longer-term intervention and how variations in the intervention protocol affect the changes. This objective is in line with required frameworks for the development and evaluation of complex interventions.¹⁶ Detailed research aims and hypothesized behavioral mechanisms supporting weight-loss maintenance over the 34 months were included in Figure 1.

Methods

Study Design

PREVIEW-RCT included an 8-week weight-loss phase with low-energy diet (Cambridge Weight Plan™, UK) and a 148-week weight maintenance phase. To be eligible for the 148-week weight maintenance phase, participants were required

to achieve $\geq 8\%$ weight-loss and were randomized into 4 intervention arms, using a 2×2 diet and exercise factorial design.²² A 4-stage intervention (PREMIT) consisted 18 group sessions led by primary care providers trained in behavior modification techniques. PREMIT aligned with the phases of the PREVIEW RCT, was designed to motivate participants to change their lifestyle in order to further reduce their body weight or maintain the 8% weight loss already achieved (see Figure 1). PREMIT inputs were unspecific for the PREVIEW study arms, and participants were treated as a 1 group irrespective of the randomization.

The preliminary stage (stage 1) of PREMIT (Figure 1) concentrated on gain framing, that is, the message that while vulnerable to develop T2D, it may be possible to prevent or delay the onset of T2D.²¹ At preparation stage (stage 2) initiation of the diet and PA changes was supported. During action stage (stage 3) participants were enabled to perform independently the behaviors. At this stage, group contact with counsellors started to decrease. Action and coping self-efficacy were targeted during preparation and action stages. At adherence stage (stage 4), participants were supported to maintain the new behaviors, despite limited group counseling. Coping self-efficacy was targeted by up-skilling participants to master stressful and difficult situations.²¹

Participant Recruitment

Participants were recruited from 8 sites: Copenhagen, DK; Helsinki, FIN; Nottingham, UK; Maastricht, NL; Navarra, ES; Sofia, BG; Auckland, N Z; and Sydney, AUS. Recruitment was done through advertising in visual and print media and from referrals from local healthcare organizations. Prospective participants were pre-screened. Eligible participants were men and women aged 25 to 70 years with overweight or obesity ($BMI \geq 25 \text{ kg/m}^2$) and confirmed prediabetes following American Diabetes Association⁴³ guidance. The study protocol was reviewed by the Human Ethics Committees in each of the 8 participating sites and all participants provided written informed consent before enrollment.²²

Data Collection and Measurements

The data collection schedule is shown in Figure 1. Questionnaires were used to describe the participants socio-demographic status and to measure changes in the behavior mechanisms of interest: The European Social Survey and International Social Survey,⁴⁴ Self-efficacy (action and coping),⁴⁵ Profile Of Mood States Questionnaire (POMS),⁴⁶ and the Chronic stress Scale (PSS).⁴⁷

Implementation and fidelity to of the PREVIEW intervention and PREMIT tool was evaluated with a 10-item questionnaire based on the RE-AIM model.⁴⁸ Bodyweight, one of the main endpoints of the PREVIEW-RCT, was measured at the intervention sites using standardized scales. For further information please see the online Supplement (S1).

Statistical Analyses

Analyses for research aims 1 to 4 (hypotheses 1, 2a-n, 3). Analyses were based on participants who completed the trial. Missing data were imputed. Assumptions of data distributions were checked and 19 cases removed ($n=941$). Data transformations were performed for coping self-efficacy diet (SQRT(K-X)) and POMS (LG10(X)), but were not successful for the PSS scale.

Three groups were created depending on the PREMIT-attendance frequency, starting with session 2 and ending with session 17 (in sum 16 sessions, excluding sessions 1 and 18, as the study launch and conclusion). The groups were divided as; “infrequent attenders” (up to 9 sessions, $n=279/29.6\%$), “frequent attenders” (10-13 sessions, $n=400/42.6\%$), and “very frequent attenders” (14-16 sessions, $n=262/27.8\%$).

One-way Analysis of Variance (ANOVA) for weight change percentage for the PREVIEW maintenance phase (weeks 8 and 156) and PREMIT-attendance was calculated. Multivariate Analysis of Variance (MANOVA) was calculated for group session attendance and self-efficacy,

chronic stress, and mood with Pillai’s Criterion. Box’s test for equality of covariance matrices was significant ($F_{939, 1843375} = 1.3, P \leq .007$), but MANOVA analysis was completed as the Levene’s tests for individual dependent variables showed significant variation. Interaction effects were examined using simple effects analyses which examined each dependent variable (self-efficacy, mood, chronic stress) on each level of independent variable (time, PREMIT attendance frequency) using repeated (ANOVA) with Greenhouse-Geisser correction and 4 post hoc pairwise comparisons; weeks 8 to 26, weeks 26 to 52, weeks 52 to 104, and weeks 104 to 156, with Bonferroni adjusted p -value of $p \leq 0.007$.⁴⁹ Where appropriate, effect sizes were calculated.⁵⁰

A multiple regression analysis was fitted to explore variables associated with weight regain over and above group session attendance at week 156 of PREVIEW-RCT. Variables were entered in 2 blocks; block 1 (attendance frequency), block 2 (self-efficacy, stress, and mood). All the analyses were performed with SPSS 27[®] statistical program.

Mixed methods analyses of research aim 5. Answers from the study sites were collated using an Excel[®] spreadsheet. Descriptive and narrative methods were used to describe, for example, frequency of reported departures from the study protocol or occasions when participants were contacted outside scheduled group meetings.

Results

Participant Characteristics

Altogether 2022 participants entered the weight-loss phase of which 1856 (92%) started the weight maintenance phase, which was completed by 962 participants (48%). Main characteristics of the participants are shown in Table 1. The very frequent PREMIT attenders were significantly older ($M=56.7, SD=\pm 10.3, P < .001$) and were more likely to be retired ($N=92, \text{Std } R=4.5$). Infrequent attenders were more likely to live in 2 adult households with at least 1 child ($N=63, \text{Std } R=2.7$).

Means and standard deviations for self-efficacy, chronic stress, and mood, as well as results for group differences can be found in Table 2.

Intervention Success (Weight Regain)

The success of the PREMIT intervention was measured—among other endpoints—whether participants maintained weight loss at the end of the trial. Weight changes can be seen as an indirect indication of behavioral changes, which in turn were influenced by changes in behavioral mechanisms. PREMIT-attendance was associated with weight

Table 1. Socio-demographic Characteristics for All Participants and Classified by PREMIT Attendance Frequency.

Socio-demographic characteristics (M ± SD)/N (%)	All n=941 (%)	Infrequent attenders n=279 (%)	Frequent attenders n=400 (%)	Very frequent attenders n=262 (%)
Body weight (kg)				
Week 8	84.2 ± 16.1	84.7 ± 15.8	86.0 ± 16.7	83.7 ± 16.8
Week 26	83.9 ± 16.6	85.6 ± 16.6	83.5 ± 16.0	82.6 ± 17.4
Week 52	86.2 ± 17.7	88.3 ± 17.8	84.4 ± 15.8	84.3 ± 18.8
Week 104	89.0 ± 18.3	90.6 ± 18.0	89.4 ± 17.9	86.9 ± 19.1
Week 156	90.7 ± 18.7	92.3 ± 18.8	91.2 ± 17.9	88.4 ± 19.5
Weight change percentage				
Week 8-week 156	7.7 ± 7.6	8.9 ± 7.6	8.2 ± 7.4	5.6 ± 8.1
Age (years)	55.0 ± 10.0	53.2 ± 10.1	55.2 ± 9.5	56.7 ± 10.3
Sex (Female)	601 (63.9)	172 (61.6)	265 (66.3)	164 (62.6)
Ethnicity (Caucasian)	875 (93.0)	254 (91.0)	370 (92.5)	251 (95.8)
Education				
Up to secondary school	131 (13.9)	34 (12.2)	59 (14.8)	38 (14.5)
Secondary vocational	163 (17.3)	53 (19.0)	69 (17.3)	41 (15.6)
Higher vocational	181 (19.2)	47 (16.8)	84 (21.0)	50 (19.1)
University	352 (37.4)	91 (32.6)	144 (36.0)	117 (44.7)
Other	114 (12.1)	54 (19.4)	44 (11.0)	16 (6.1)
Marital status				
Married/civil partnership	699 (74.3)	211 (75.6)	305 (76.3)	183 (69.8)
Divorced, widowed, separated	131 (13.9)	37 (13.3)	54 (13.5)	40 (15.3)
Other (incl. single and missing)	111 (11.8)	31 (11.1)	41 (10.3)	39 (14.9)
Household				
1 adult	173 (18.4)	46 (16.5)	72 (18.0)	55 (21.0)
2 adults	448 (47.6)	130 (46.6)	199 (49.8)	119 (45.4)
3 or more adults	144 (15.3)	34 (12.2)	61 (15.3)	49 (18.7)
1 adult and at least 1 child	5 (0.5)	—	—	—
2 adults and at least 1 child	151 (16.0)	63 (22.6)	57 (14.2)	31 (11.8)
3 or more adults and at least 1 child	20 (2.1)	5 (1.8)	7 (1.8)	8 (3.1)
Employment				
Full-time study	607 (64.5)	188 (67.4)	247 (61.8)	139 (53.1)
Full- or part-time employment				
Economically not active (caring for family, unemployed)	81 (8.6)	28 (10.0)	43 (10.8)	10 (3.8)
Retired (wholly)	207 (22.0)	38 (13.6)	77 (19.3)	92 (35.1)
Other (including missing)	46 (4.8)	25 (9.0)	33 (8.3)	21 (8.0)

Only cells with 5 or more participants are shown.

regain (Welch $F_2=14.2$, $P<.001$, Cohen's $d=0.4$) with “very frequent” attenders ($M=8.9$, $SD=\pm 7.6$) having lower weight regain than “frequent” ($M=8.2$, $SD=\pm 7.4$, $P<.001$) or “infrequent” attenders ($M=5.6$, $SD=\pm 8.1$, $P<.001$).

Changes in Behavioral Mechanisms

A significant “time × attendance interaction” for self-efficacy, stress, mood was observed ($F_{48, 1832}=1.8$, $P\leq .007$, $\eta^2_p=.05$).

Action self-efficacy diet changes over time. Overall, significant differences over time were observed. *Post-hoc* pairwise comparisons indicated significant changes only during

the “early and middle PREMIT adherence stages” (see Table 2).

Action self-efficacy PA changes over time. Overall, significant differences over time were observed. *Post-hoc* pairwise comparisons indicated changes for “infrequent” and “frequent attenders” only during the “early PREMIT-adherence” stage (see Table 2).

Coping self-efficacy diet changes over time. Overall, significant differences over time were observed. *Post-hoc* pairwise comparisons indicated significant changes only during the “early PREMIT-adherence” stage for “frequent” and “infrequent attenders” (see Table 2).

Table 2. Summary of Change in Dependent Variables by Frequency of PREMIT Attendance.

Time points and groups	Variables					
	Action self-efficacy diet Range 1-4	Action self-efficacy PA Range 1-4	Coping self-efficacy diet Range 1-4	Coping self-efficacy PA Range 1-4	Chronic stress Range 0-40	Profile of mood states Range 0-232
Infrequent (n = 279) Frequent (n = 400) Very frequent (n = 262)						
Week 8—means and standard deviations						
All	3.2 ± 0.6	2.9 ± 0.6	3.3 ± 0.7	2.9 ± 0.7	12.0 ± 5.4	41.4 ± 24.7
Infrequent	3.2 ± 0.5	2.9 ± 0.7	3.3 ± 0.6	2.9 ± 0.7	11.9 ± 5.2	38.1 ± 22.6
Frequent	3.2 ± 0.5	2.9 ± 0.6	3.3 ± 0.7	3.0 ± 0.7	12.0 ± 5.3	42.0 ± 25.4
Very frequent	3.2 ± 0.6	2.9 ± 0.6	3.2 ± 0.7	2.9 ± 0.7	12.3 ± 5.8	44.7 ± 25.4
Week 26—means and standard deviations						
All	3.2 ± 0.5	2.9 ± 0.7	3.3 ± 0.7	2.9 ± 0.7	12.8 ± 5.8	42.9 ± 27.1
Infrequent	3.1 ± 0.5	2.8 ± 0.7	3.3 ± 0.6	2.9 ± 0.7	13.1 ± 5.9	42.9 ± 26.8
Frequent	3.3 ± 0.5	2.9 ± 0.7	3.4 ± 0.6	3.0 ± 0.7	12.6 ± 5.6	43.3 ± 28.8
Very frequent	3.3 ± 0.6	2.9 ± 0.7	3.3 ± 0.7	2.9 ± 0.7	12.9 ± 5.9	42.4 ± 24.8
Week 52—means and standard deviations						
All	3.1 ± 0.6	2.7 ± 0.7	3.1 ± 0.7	2.8 ± 0.7	13.6 ± 6.3	45.4 ± 29.1
Infrequent	3.0 ± 0.6	2.6 ± 0.7	3.0 ± 0.7	2.8 ± 0.7	13.8 ± 6.3	48.6 ± 3.3
Frequent	3.1 ± 0.6	2.7 ± 0.7	3.1 ± 0.7	2.8 ± 0.7	13.7 ± 6.6	45.5 ± 3.2
Very frequent	3.1 ± 0.6	2.8 ± 0.7	3.2 ± 0.6	2.8 ± 0.7	13.4 ± 5.9	42.0 ± 25.5
Week 104—means and standard deviations						
All	3.0 ± 0.6	2.7 ± 0.7	3.1 ± 0.7	2.7 ± 0.7	15.0 ± 6.6	48.4 ± 31.3
Infrequent	2.9 ± 0.6	2.6 ± 0.7	3.0 ± 0.7	2.7 ± 0.7	15.2 ± 6.3	48.9 ± 31.4
Frequent	3.0 ± 0.6	2.7 ± 0.7	3.1 ± 0.7	2.8 ± 0.7	14.8 ± 6.6	48.0 ± 31.9
Very frequent	2.8 ± 0.7	2.7 ± 0.7	3.0 ± 0.7	2.7 ± 0.7	14.9 ± 6.4	48.4 ± 3.2
Week 156—means and standard deviations						
All	2.9 ± 0.6	2.6 ± 0.7	3.0 ± 0.7	2.7 ± 0.7	14.4 ± 6.2	48.7 ± 31.8
Infrequent	2.9 ± 0.6	2.5 ± 0.7	3.0 ± 0.7	2.7 ± 0.7	13.9 ± 6.1	45.8 ± 29.0
Frequent	2.9 ± 0.6	2.6 ± 0.8	3.0 ± 0.7	2.8 ± 0.7	14.3 ± 6.3	48.8 ± 33.7
Very frequent	2.9 ± 0.7	2.6 ± 0.7	3.0 ± 0.7	2.8 ± 0.7	14.8 ± 6.2	51.7 ± 31.7
Simple effects ANOVA with repeated measures (Intervention behavioral mechanisms)						
Infrequent attenders	$F_{3,7} = 38.3, p \leq .007, \eta^2_p = .12$	$F_{3,7} = 33.2, p \leq .007, \eta^2_p = .11$	$F_{3,9} = 29.7, p \leq .007, \eta^2_p = .10$	$F_{3,8} = 12.0, p \leq .007, \eta^2_p = .04$	$F_{3,7} = 26.4, p \leq .007, \eta^2_p = .09$	$F_{3,7} = 12.7, p \leq .007, \eta^2_p = .04$
Frequent attenders	$F_{3,9} = 54.1, p \leq .007, \eta^2_p = .12$	$F_{3,9} = 32.5, p \leq .007, \eta^2_p = .08$	$F_{3,9} = 34.0, p \leq .007, \eta^2_p = .08$	$F_{3,9} = 17.7, p \leq .007, \eta^2_p = .04$	$F_{3,7} = 38.1, p \leq .007, \eta^2_p = .09$	$F_{3,9} = 6.5, p \leq .007, \eta^2_p = .02$
Very frequent attenders	$F_{3,8} = 30.5, p \leq .007, \eta^2_p = .11$	$F_{3,7} = 14.3, p \leq .007, \eta^2_p = .05$	$F_{3,9} = 11.3, p \leq .007, \eta^2_p = .04$	$F_{3,9} = 5.2, p \leq .007, \eta^2_p = .02$	$F_{3,8} = 26.3, p \leq .007, \eta^2_p = .09$	$F_{3,5} = 8.6, p \leq .007, \eta^2_p = .03$
Pairwise comparisons—PREMIT Preparation and Action Stages (Week 8-week 26)—Hypotheses 2a, 2b, 2g, 2h	$p = .088$ No change	$p = .346$ No change	$p = 1.00$ No change	$p = 1.00$ No change	$p \leq .001, d_{\text{repeated}} = .3$ increase	$p = .070$ No change
Infrequent attenders	$p = 1.00$ No change	$p = 1.00$ No change	$p = 1.00$ No change	$p = 1.00$ No change	$p = .061$ No change	$p = 1.00$ No change
Frequent attenders	$p = 1.00$ No change	$p = 1.00$ No change	$p = 1.00$ No change	$p = 1.00$ No change	$p = .302$ No change	$p = .609$ No change
Very frequent attenders	$p = 1.00$ No change	$p = 1.00$ No change	$p = 1.00$ No change	$p = 1.00$ No change	$p = .383$ No change	$p = .020$ No change
Pairwise comparisons—PREMIT Early Adherence Stage (week 26-week 52)—Hypotheses 2c, 2d, 2i, 2j	$p \leq .001, d_{\text{repeated}} = -.2$ decrease	$p \leq .001, d_{\text{repeated}} = -.3$ decrease	$p \leq .001, d_{\text{repeated}} = -.4$ decrease	$p = .208$ No change	$p \leq .001, d_{\text{repeated}} = .3$ increase	$p = .708$ No change
Infrequent attenders	$p \leq .001, d_{\text{repeated}} = -.2$ decrease	$p \leq .001, d_{\text{repeated}} = -.3$ decrease	$p \leq .001, d_{\text{repeated}} = -.3$ decrease	$p \leq .001, d_{\text{repeated}} = -.3$ decrease	$p = .646$ No change	$p = 1.00$ No change
Frequent attenders	$p \leq .001, d_{\text{repeated}} = -.4$ decrease	$p \leq .001, d_{\text{repeated}} = -.3$ decrease	$p = .191$ No change	$p = 1.00$ No change	$p = .001, d_{\text{repeated}} = .2$ increase	$p = 1.00$ No change
Very frequent attenders	$p \leq .001, d_{\text{repeated}} = -.4$ decrease	$p = .009$ No change	$p = 1.00$ No change	$p = 1.00$ No change	$p \leq .001, d_{\text{repeated}} = .2$ increase	$p = .400$ No change
Pairwise comparisons—PREMIT Middle Adherence Stage (week 52-week 104)—Hypotheses 2c, 2d, 2i, 2j	$p = .287$ No change	$p = 1.00$ No change	$p = 1.00$ No change	$p = .369$ No change	$p \leq .001, d_{\text{repeated}} = .2$ increase	$p = 1.00$ No change
Infrequent attenders	$p = .001, d_{\text{repeated}} = -.2$ decrease	$p = .088$ No change	$p = 1.00$ No change	$p = 1.00$ No change	$p \leq .001, d_{\text{repeated}} = .2$ increase	$p = .026$ No change
Frequent attenders	$p \leq .001, d_{\text{repeated}} = -.6$ decrease	$p = 1.00$ No change	$p = .051$ No change	$p = .117$ No change	$p \leq .001, d_{\text{repeated}} = .3$ increase	$p = .026$ No change
Very frequent attenders	$p \leq .001, d_{\text{repeated}} = -.6$ decrease	$p = 1.00$ No change	$p = 1.00$ No change	$p = 1.00$ No change	$p = .004, d_{\text{repeated}} = -.2$ decrease	$p = .155$ No change
Pairwise comparisons—PREMIT Late Adherence Stage week 104-week 156—Hypotheses 2e, 2f, 2k, 2l	$p = 1.00$ No change	$p = 1.00$ No change	$p = 1.00$ No change	$p = 1.00$ No change	$p = .511$ No change	$p = 1.00$ No change
Infrequent attenders	$p = 1.00$ No change	$p = 1.00$ No change	$p = 1.00$ No change	$p = 1.00$ No change	$p = 1.00$ No change	$p = 1.00$ No change
Frequent attenders	$p = 1.00$ No change	$p = 1.00$ No change	$p = 1.00$ No change	$p = 1.00$ No change	$p = 1.00$ No change	$p = .236$ No change
Very frequent attenders	$p = 1.00$ No change	$p = 1.00$ No change	$p = 1.00$ No change	$p = 1.00$ No change	$p = 1.00$ No change	$p = 1.00$ No change

Results for pairwise comparisons as hypothesised in **bold**.Abbreviations: d_{repeated} repeated measures; increase/decrease/increase; Significant decrease/Significant increase; No change, No significant change observed during the defined time period for within group.

Coping self-efficacy PA changes over time. Overall, significant differences over time were observed. *Post-hoc* pairwise comparisons indicated changes only for “frequent attenders” during the “early PREMIT adherence” stage (see Table 2).

Chronic stress changes over time. Significant differences over time were observed for all groups. *Post-hoc* pairwise comparisons indicated significant changes during all PREMIT-stages. For “infrequent attenders” chronic stress increased during the “preparation and action stages” and the “middle adherence stage” before decreasing during the “late adherence stage.” For “frequent attenders” chronic stress increased during the “early adherence” and the “middle adherence stages.” For very “frequent attenders,” chronic stress increased only during the “middle adherence stage” (see Table 2).

Mood changes over time. Significant differences over time were found, but none of the *post-hoc* pairwise comparisons were significant (see Table 2).

PREMIT-Attendance, Behavior Mechanisms, and Weight Regain

In a multiple regression analysis initially the frequency of PREMIT attendance was added to the model ($F_{1, 939} = 27.04$, $R^2 = .03$). Entering self-efficacy, stress, and mood at the next block indicated significant changes ($F_{6, 933} = 14.99$, $P \leq .007$, $R^2 = .09$). The complete model was significant ($P < .001$) and explained 11% of the total variance ($R^2 = .11$). Only PREMIT-attendance and action self-efficacy for healthy diet and for PA were significantly associated with weight change percentage at week 156 (Supplemental Table 1 (S2)).

Intervention Fidelity

Overall, intervention sites reported high fidelity to the study protocol, that is, implementing and delivering the intervention as described. Participants received the BCTs as described with the content of the PREMIT sessions as planned. Nevertheless, some changes to intervention protocol were reported to the extent that intervention sites offering additional support and incentives for continuing participation, over concerns of behavioral choices during the “weight-loss maintenance phase.” All intervention sites reported staying in contact with participants between scheduled group meetings. Six intervention sites reported holding at least 1 additional meeting. No clear pattern emerged for the themes or purpose of the additional meetings. Some gave information relating to behavior change efforts and others provided group physical activity to avoid participants dropping out. More consistency was found in timing of the additional meetings. They tended to be offered before

the last 6 to 12 months of the intervention. Half of the intervention sites reported implementing further activities to support participants to stay in track, including remainder emails, rescheduling missed appointments and opportunity to enter a prize draw.

Discussion

Not all hypotheses were supported. PREMIT-attendance was found to be associated with weight regain and changes in self-efficacy, chronic stress, and mood over time. Although intervention protocol was adhered to, intervention sites commonly offered additional support and incentives outside the scheduled group meetings to encourage attendance and adherence. While quantifying the influence of additional support was not possible with the available data, results highlighted that implementation contained additional, not intended, support at each site.

Results were only partially in line with the expectations of the program theory, which considered action self-efficacy important during early stages of behavior change.^{29,32,33} Unexpectedly,^{28,31,32} action self-efficacy (diet and PA) remained unchanged during preparation and action stages. This may have reflected already high appraisal of capabilities to act on the new behaviors, leaving limited capacity for improvements (ceiling effect). Further, it was unclear why only diet action self-efficacy decreased as expected during the middle adherence stage, but only for “frequent” and “very frequent attenders.” It could be postulated that “infrequent attenders” may have not been able to utilize on the support to transfer from action to adherence of the behaviors. Secondly, physical activity behaviors may have been acted on more quickly than diet. Thus, action self-efficacy for PA leveled off quicker than expected.

As coping self-efficacy is central for behavioral adherence^{28,33} it was unexpected to observe decline during the early adherence stage. Furthermore, it was unforeseen³³ that at the end of the adherence stage action self-efficacy only for “frequent attenders” was inversely associated with weight regain. As previously,1 explanation could be the ceiling effect. Further, PREMIT attendance may have supported maintaining a high level of coping self-efficacy as neither diet nor PA coping self-efficacy declined for the very frequent attenders. In addition, “very frequent attendance” was inversely associated with weight regain, which suggested that participation was beneficial. Considering the overall weight regain among the participants, the unexpected inverse association between weight regain and action self-efficacy at the end of the intervention may reflect some participants’ ability to re-start healthy diet and PA behaviors after relapses.

Behavior change is a multifactorial concept incorporating both behavioral and affective elements.^{29,36} While higher chronic stress may hinder diet and PA behavior

change,⁴¹ group-based T2D prevention interventions may reduce chronic stress and thus strengthen behavioral outcomes.^{25,26} As expected, chronic stress was observed to be inversely associated with frequency of group session attendance, though only during preparation and action stages. Surprisingly, chronic stress was observed to increase for all participants during the “middle adherence stage,” coinciding with the declining regularity of the group-sessions. Therefore, 1 possible explanation could be the reduction in direct support, when the new behaviors were not yet fully stabilized. The fact that the stress level in the group of participants who rarely attended the group sessions decreased toward the end of the intervention may be related to the point that their expectation of a change in behavior was confirmed, even though these participants attended the group sessions less frequently than those in the other 2 groups. The participants may have realized that they were more likely to prevent weight gain if they were more involved in the intervention. They do not see the development of DT2 as inevitable and this reduces their perception of stress. But this is speculative. No changes in mood were observed.

Part of an evidence-based preventive intervention in primary care includes understanding the theoretical foundations of an intervention program.^{15,16} Despite intervention sites spread globally, good fidelity to intervention processes were reported, implicating applicability to different healthcare settings. However, despite adherence to intervention protocol, many sites felt necessary to offer unscheduled activities or support. Although PREMIT itself was designed to support successful completion,²¹ nearly half of the participants who started the weight-loss maintenance phase dropped out.⁷ Therefore, it was not entirely surprising that intervention sites invested additional resources outside the protocol to encourage adherence and attendance. This, however, has implications for potential transfer to clinical practice in primary care outside research settings.

Should the PREVIEW and PREMIT measures be implemented outside a controlled environment, strategies to encourage regular attendance must be developed and implemented. Strategies to encourage attendance and adherence may be implemented, for example, in a primary care health promotion programs with varying ease. Strategies such as group meeting reminders or extra information evenings may be easier to implement than strategies using hybrid formats with online elements (eg, material) or rewards schemes, which can be more dependent on funding constraints. Furthermore, during the last 12 months of the PREVIEW intervention, group sessions were offered 6-monthly with results indicating very limited changes in behavioral mechanisms. This poses the question whether implementation in a primary healthcare setting should consider shorter timeframe than 36 months.

This study had a number of limitations. Only participants who concluded the 36-months intervention were included. Participants were divided into 3 PREMIT-attendance frequency groups retrospectively, and different methodology for dividing the groups could have influenced the results. The small effect sizes for the pairwise comparisons emphasize the need for cautious interpretation, especially considering difficulties in participant retention. Also, other variables not measured in this study, for example perceived social support for behavior changes, could have influenced the outcomes. Further research should consider interactions in self-efficacy and attendance among participants who dropped out before completion.

Conclusions

The current study indicated that group-based behavior change intervention in weight-loss maintenance can be successful. In this study, program theory with behavior change techniques such as feedback and information were combined with principles of health promotion and education to influence behavioral mechanisms.^{9,10} Although the expected interventions mechanisms were only partially supported by the results, the results indicated that frequency of attendance was inversely associated with weight regain. Furthermore, the PREVIEW- and PREMIT-interventions were successfully applied in different countries all over the world by trained primary care providers, indicating cultural transferability. However, intervention implementation outside experimental conditions in T2D prevention can be challenging. This is likely to require adjustments such as more compact format and strategies to encourage participant retention.

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Author Contributions

The PREVIEW project was designed by Anne Raben, Jennie Brand-Miller, Margriet Westerterp-Plantenga, Mikael Fogelholm, Wolfgang Schlicht, and Edith Feskens. The PREVIEW intervention study (RCT) for the adult participants was designed by Anne Raben, Mikael Fogelholm, and Thomas Meinert Larsen. The PREMIT behavior modification intervention was designed by Wolfgang Schlicht, Daniela Kahlert (University of Stuttgart, Germany), and Annelie Unyi-Reicherz (University of Stuttgart, Germany). Maija Huttunen-Lenz concept of the paper, first complete draft including tables and figures, statistical analyses. All authors contributed to critical revision of the manuscript for important intellectual content. All authors agreed that the accuracy and integrity of the work has been appropriately investigated and resolved, and all approved the final version of the manuscript. The corresponding author had full access to the data and had final responsibility for the decision to submit for publication. The corresponding author (MHL) attests that all listed authors meet authorship criteria, and that no others meeting the criteria have been omitted.

Data Availability Statement

Data not available due to [ethical/legal/commercial] restrictions. Due to the nature of this research, participants of this study did not agree for their data to be shared publicly, so supporting data is not available.

Declaration of Conflicting Interests

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Each study site obtained the ethics approval from the relevant authorities according to national and institutional requirements.

Consent to Participate

Each participant was required to provide written informed consent before participation. This included information how data was used. All information and consent forms were provided in local languages.

Consent for Publication


Not applicable

Trial Registration

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Supplemental Material

Supplemental material for this article is available online.

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