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Efficacy of Dia*Life*, an Education Program for Relatives of Adults with Diabetes – A Cluster Randomized Controlled Trial

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ABSTRACT

Objective: Diabetes affects the lives of patients and their close relatives. Considering the proven benefit of patient education programs, DiaLife was elaborated as the first German education program addressing the needs of relatives. The objective of this study was to investigate its efficacy.
Methods: The evaluation was implemented in the form of a cRCT with longitudinal design and waiting list condition. In total, 179 relatives were recruited. Participants' diabetes-related knowledge was defined as the primary outcome. Diabetes-related strains, family interaction and other psychosocial factors were determined as secondary outcomes.
Results: A generalized estimating equation model showed a persistent increase of diabetes-related knowledge in the intervention group compared to the control group regardless of the type of diabetes. Concerning secondary outcomes, mixed linear models showed an improvement for relatives of people with type 2 diabetes who participated in the Dia*Life* program.
Conclusion: This study provides evidence of Dia*Life*'s efficacy regarding a persistent increase of diabetes-related knowledge and a positive effect on psychosocial outcomes in relatives of people with type 2 but not in type 1 diabetes. Adding (an)other psychosocial module(s) might improve their well-being and psychosocial outcomes.
Practice Implications: Diabetes centers should consider implementing an education program for relatives, such as Dia*Life*, in their curriculum.
Trial registration: The study was registered at the German Clinical Trials Register (DRKS00015157; date of registration: 24.08.2018).

1. Introduction

Diabetes mellitus is a metabolic disease defined by a dysfunctional regulation of blood glucose. People with diabetes are not only affected by the disease itself but are also at higher risk of multiple comorbid physical [1,2] and mental diseases [3].

Apart from people who have been diagnosed with diabetes, it also affects their close relatives on a psychological, financial or emotional level [4]. Even though some interventions for family members exist, they have not been evaluated in German-speaking countries. So far, no tailor-made education program for relatives of adults with diabetes has been developed and evaluated for German-speaking countries. Relatives are sometimes invited as guests into education programs for patients with diabetes, but they are rarely

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addressed specifically as a relevant group in diabetes care, which might be a missed chance. Diabetes-related knowledge must be considered key to a family intervention program and would empower family members [4,5]. Dia*Life*, an education program for relatives, was developed against this background. Objectives and a detailed description of the program are presented in the study protocol published previously [6].

Our main hypothesis stipulated that participation in the DiaLife education program would lead to an increase in diabetes-related knowledge irrespective of the type of diabetes (H1). In terms of exploration regarding secondary outcomes, we also hypothesized that, irrespective of the type of diabetes, participation in the Dia*Life* education program would decrease diabetes-related distress and strains (H2) and improve the mental and physical well-being of relatives would improve (H3).

We conducted a cluster randomized control trial (cRCT) to investigate the efficacy of Dia*Life*, which was assessed by the objective parameter of diabetes-related knowledge (i.e. primary outcome) 12 months after intervention (i.e. primary endpoint). Moreover, we aimed to assess psychosocial factors as secondary outcomes for exploratory purposes.

2. Methods

2.1. Trial design

The efficacy of the Dia*Life* education program was examined in a quantitative longitudinal survey within a cRCT. Seventeen study centers (i.e. practices specialized in diabetes) were recruited that, in turn, invited eligible participants to participate in the study. Data of participants were collected through questionnaires at four points in time: the time of recruitment (baseline), directly after the intervention (follow-up [FUP] I), 6 months after intervention (FUP II) and 12 months after intervention (FUP III). Participants who were assigned to the waiting list group completed the same questionnaire at identical time intervals. All participants were invited by postal mail to visit their respective study center and fill out the questionnaires. Participating relatives received a monetary incentive of 50 Euro after the completion of the last questionnaire (FUP III).

2.2. Randomization

Study centers were randomly assigned at the ratio of 1:1 and stratified by the type of diabetes to either the intervention or control group. Block randomization was conducted by using nQuery 7.0. Study centers and participants were informed about their group allocation after obtaining their written consent to participate. Randomization and analyses were conducted by a blinded biometrician.

2.3. Participants

Relatives of people who have been diagnosed with diabetes were recruited through participating study centers. Accordingly, information material, such as flyers and posters, were displayed in study centers. In addition, practice staff was asked to reach out to relatives and people with diabetes to inform them about this study and invite them to participate. Regarding inclusion criteria, it was determined that only adult relatives of a person with type 1 or 2 diabetes from the same household as the patient could participate in this study. Relatives who have been diagnosed with diabetes themselves, who had a severe cognitive disease or were not able to participate in the intervention on a steady basis were excluded. A detailed description of the recruitment procedure was published previously in the study protocol [6].

We conducted a power calculation to determine the sample size required (α = 5%). Previous studies [7] confirmed the efficacy of diabetes education programs for patients with an effect size of 29%. The latter refers to the proportion of correct answers to questions assessing diabetes-related knowledge between the control and intervention studies. This effect size is derived from other studies in this field, where a difference of 29% was shown. This size is included in the power analysis. Based on these previous models, we also used diabetes-related knowledge as a primary outcome to conduct the power calculation. According to our power calculation, 12 participating relatives of people with diabetes type 1 and 2 were required, respectively, in each group (intervention and control) to reach a sufficient power of 90%. We increased the sample size to n = 14 per group in order to compensate for a presumed dropout rate of 10%. In addition, we assumed data correlation within study centers. Depending on the cluster size and the degree of correlation within clusters, known as the intracluster (or intraclass) correlation coefficient (ρ), the effective sample size decreases. Therefore, we corrected the sample size by using the design effect [18], which increased the sample size to n = 44 per group. A total sample size of 176 participants was determined, distributed in four different groups:

- n = 44 participants who were related to a person with type 1 diabetes/intervention group
- n = 44 participants who were related to a person with type 2 diabetes/intervention group
- n = 44 participants who were related to a person with type 1 diabetes/control group
- n = 44 participants who were related to a person with type 2 diabetes/control group

A more detailed description of the sample size calculation is reported in the study protocol [6].

2.4. Intervention

The Dia*Life* education program was developed in two versions to consider the peculiarities of type 1 and 2 diabetes comprehensively. It consists of mandatory (i.e. basic and psychosocial) and elective modules, which are displayed in Table 1. A detailed description of how the Dia*Life* education program was developed can be obtained in the study protocol [6]. Each study center designated a certified diabetes care and education specialist (CDCES; i.e. a valid certification for Germany), who had been previously qualified to conduct the Dia*Life* education program. Depending on whether their relatives were diagnosed with type 1 or 2 diabetes, participants of the intervention group completed the adequate Dia*Life* education program within the study. Participants of the control group were assigned to the waiting list condition, which means that they were invited to participate in the Dia*Life* education program after the last FUP assessment.

2.5. Outcomes

One of the main objectives of the Dia*Life* program is to increase the diabetes-related knowledge of relatives 12 months after participation in the Dia*Life* program (i.e. the primary endpoint). Hence, diabetes-related knowledge was defined as the primary outcome. We further hypothesized that psychosocial strains would diminish after participating in the Dia*Life* education program. Therefore, diabetes-related distress, family interaction, physical and mental health, life satisfaction, depressive symptoms and quality of life were specified as secondary outcomes.

Table 1
Contents of the DiaLife education program for relatives of people with type 1 and 2 diabetes.

	Diabetes mellitus Type 1	Diabetes mellitus Type 2
Mandatory modules	Basic modules	
	- Fundamental principles of diabetes type 1	- Fundamental principles of diabetes type 2
	- Emergency situations (e.g. hypo and hyperglycemia)	- Emergency situations (e.g. hypo and hyperglycemia)
	- Insulin therapy	- Diet and exercise
	Psychosocial modules	
	- Understanding the impact of diabetes on daily life	- Understanding the impact of diabetes on daily life
	- Strategies of communication	- Strategies of communication
Elective modules	- Understanding dementia and its consequences	- Understanding dementia and its consequences
	- Special situations (e.g. vacation, pregnancy)	- Special situations (e.g. vacation)
	- Diet and exercise	- Insulin therapy
	- Diabetes-associated conditions	

2.6. Instruments

All instruments used to assess different diabetes-related dimensions are described in the following. All data were self-reported by the participating relatives.

2.6.1. Diabetes-related knowledge

In this study, the difference in diabetes-related knowledge was assessed by two questionnaires, which assessed relatives' knowledge about type 1 and 2 diabetes, respectively. We used the validated templates of Kronsbein et al. [8,9] and Mühlhauser et al. [8,9] and adapted them slightly to assess the diabetes-related knowledge of relatives. Each of the questionnaires consists of 16 items in a multiple-choice format. The maximum score of the questionnaire referring to type 1 diabetes amounts to 69 points, and the one referring to type 2 diabetes amounts to 63 points, with higher scores indicating greater diabetes-related knowledge. Participants were asked to answer the respective questionnaire at each time of the survey, whereby the baseline measurement was used as the reference value. Further details of the construction were published in the study protocol [6]. Both questionnaires can be obtained from the authors on reasonable request.

2.6.2. Diabetes-related distress

The diabetes-related distress of relatives was assessed with two instruments. Firstly, we assessed the general diabetes-related distress by using the Problem Areas in Diabetes – DAWN Family Members Diabetes Distress Scale (PAID-5-DFM). The latter consists of 5 items, which rate relatives' perceived distress on a 5-point Likert scale, ranging from 0 (= no problem) to 4 (= major problem).

[10] Secondly, we applied the DAWN Impact of Diabetes Profile – Family Members (DDIP-FM) to assess the diabetes-related distress in detail. Within the DDIP-FM, participating relatives are asked to rate the impact of the diabetes disease on certain areas of life.

The DDIP-FM was divided into two subscales, the first with eight items (DDIP-FM 1) displaying diabetes-related strains on a 7-point rating scale, ranging from 1 (= strongly positive) to 7 (= strongly negative); a higher point value implies a higher burden (max. 56 points). The second subscale with three items (DDIP-FM 2) reports confidence in diabetes self-management on a 5-point rating scale, ranging from 0 (= very bad confidence) to 4 (= high confidence); a higher point value indicates a higher confidence in the diabetes self-management (max. 12 points).

2.6.3. Family Interaction

In addition, we assessed relatives' reactions towards diabetes self-management. Accordingly, we applied the Diabetes Family Behavior Checklist (DFBC), which consists of 16 items assessing social interaction on a 5-point Likert scale ranging from 1 (= never) to 5 (= always). The DFBC can be divided into two subscales for analysis. Higher scores in the DFBC 1 (six questions) display negative family interaction (max. 30 points), whereas higher scores in the DFBC 2 (ten questions) show positive family interactions (max. 50 points).

Moreover, we used the DAWN Family Support Scale – Family Members (DFSS-FM), which rates familial support with ten items on a 5-point rating scale [10]. The subscales of the DFSS-FM display, on the one hand, the support of the person with diabetes (DFSS-FM 1) with a rating scale from 0 (= never) to 4 (= always), and on the other hand, perceived possibilities of supporting the person with diabetes (DFSS-FM 2) with a rating scale from 1 (= never) to 5 (= always). Higher scores display greater support (max. 28 points) or, rather, a better understanding of how people with diabetes can be supported (max. 15 points).

2.6.4. Other psychosocial factors

Participants' quality of life was assessed by using the Short Form Health Questionnaire (SF-12) [11], which consists of 12 items assessing the physical and mental health of participants. We analyzed physical and mental health separately. Higher scores within the SF-12 define a better perceived health status.

We also asked participants to rate their life satisfaction on a 10-point one-item scale (l-1) [12], whereby higher scores indicate a better life satisfaction.

In addition, we assessed depressive symptoms among participants by using the nine-item Patient Health Questionnaire (PHQ-9) [13]. The latter asked participants to rate the frequency of depressive symptoms on a 4-point scale ranging from 0 (= not at all) to 3 (= nearly every day).

2.6.5. Sociodemographic characteristics

In addition to general sociodemographic variables (age, gender, and degree of relationship), we assessed participants' socioeconomic status (SES). The latter was assessed with a validated questionnaire comprising education, highest professional position and household net income, and ranges from a minimum of 3 to a maximum of 21 points [14], whereby higher scores indicate higher socioeconomic status.

2.6.5.1. Data Analysis. All data were analyzed using SPSS 26.0. We investigated relatives of people with type 1 and 2 diabetes separately. In order to compare the primary outcome, we fitted a generalized estimating equation model for clustered data (i.e. study center) with intervention as a factor and baseline value as a covariate to assess whether diabetes-related factors improve over time and differ between the intervention and control group. In order to compare secondary outcomes, in a first step, we conducted mixed linear models with intervention as a fixed factor and study centers as a random factor to assess whether diabetes-related factors improve over time and differ between the intervention and control group. Moreover, unadjusted independent *t*-tests were conducted to determine group differences (intervention vs. control condition), whereas paired *t*-tests were applied to test for differences within

Table 2
Participants' sociodemographic characteristics.

	Type 1 diabetes						Type 2 diabetes					
Baseline Sample size	Total n = 90		IG n = 43		CG n = 47		Total n = 89		IG n = 43		CG n = 46	
Dropout	3	(3.3%)	1	(2.3%)	2	(4.3%)	11	(12.4%)	6	(14.0%)	5	(10.9%)
Sample Size	**Total n = 87**		**IG n = 42**		**CG n = 45**		**n = 78**		**n = 37**		**n = 41**	
Gender												
Male	33	(37.9%)	16	(38.1%)	17	(37.8%)	15	(19.2%)	6	(16.2%)	9	(22.0%)
Female	49	(56.3%)	24	(57.1%)	25	(55.6%)	62	(79.5%)	31	(83.8%)	31	(75.6%)
Prefer not to say	5	(5.7%)	2	(4.8%)	3	(6.7%)	1	(1.3%)	0	(0%)	1	(2.4%)
Degree of relationship												
Spouse	73	(83.9%)	35	(83.3%)	38	(84.4%)	65	(83.3%)	32	(86.5%)	33	(80.5%)
Sibling	1	(1.1%)	0	(0%)	1	(2.2%)	1	(1.3%)	0	(0%)	1	(2.4%)
Parent	0	(0%)	0	(0%)	0	(0%)	3	(3.8%)	2	(5.4%)	1	(2.4%)
Grandparent	0	(0%)	0	(0%)	0	(0%)	1	(1.3%)	0	(0%)	1	(2.4%)
Differently related	4	(4.6%)	2	(4.8%)	2	(4.4%)	1	(1.3%)	1	(2.7%)	0	(0%)
Friend	2	(2.3%)	1	(2.4%)	1	(2.2%)	4	(5.1%)	1	(2.7%)	3	(7.3%)
Prefer not to say	7	(8.0%)	4	(9.5%)	3	(6.6%)	3	(3.8%)	1	(2.7%)	2	(4.9%)
Age; M (SD)	52.6	(16.39)	51.1	(16.42)	54.2	(16.41)	61.3	(14.01)	62.4	(13.79)	60.3	(14.31)
SES; M (SD)	14.1	(4.41)	15.3	(4.33)	12.7	(4.17)	12.6	(4.42)	12.8	(4.48)	12.3	(4.45)

Notes: IG = Intervention Group, CG = Control Group

groups over time. The confirmatory analysis was performed for the primary endpoint at the significance level of 0.05. The analysis was carried out according to the intention-to-treat principle.

3. Results

A total of 179 relatives were recruited, of which 90 participants were related to people with type 1 diabetes and 89 participants to people with type 2 diabetes. Apart from the SES of relatives of people with type 1 diabetes ($t(47) = -2112$, $p = 0.04$), the intervention and control groups did not differ regarding the participants' characteristics at the baseline. The results of the descriptive analysis are displayed in Table 2.

2.7. Primary outcome: diabetes-related knowledge

The two flow charts (Fig. 1) show the numbers of cases assessing the diabetes-related knowledge of relatives of people with type 1 and 2 diabetes at each time of data assessment. The varying numbers of cases between the FUPs can be explained by participants' compliance. Some participants skipped single assessments but returned at a later FUP. These cases are labeled as "lost to FUP." Since we analyzed each FUP separately, we used the respective data basis.

The generalized estimating equation models revealed significant differences between participants of the intervention and control group at almost all time points of data assessments (Table 3). We found significantly better diabetes-related knowledge in participants

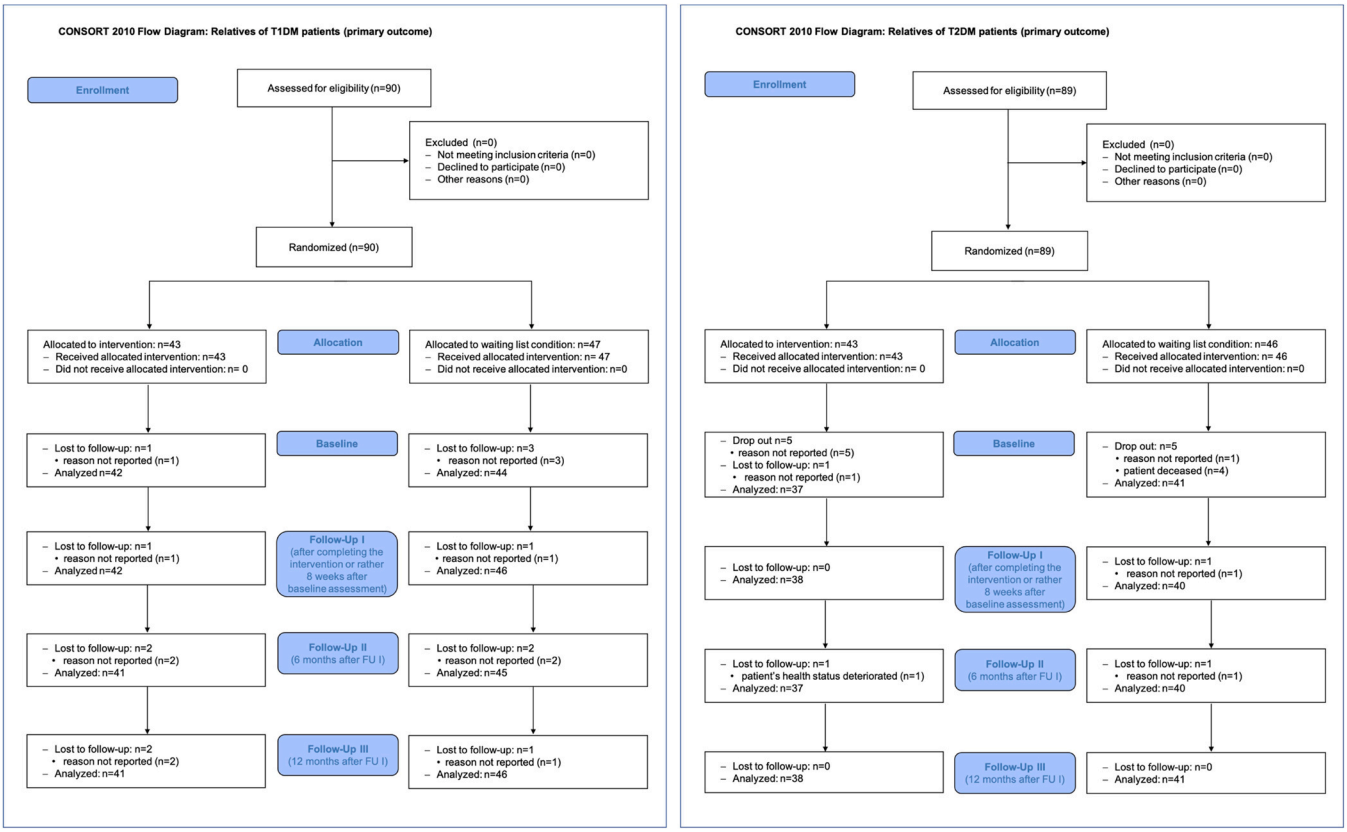

Fig. 1. CONSORT flowchart of participating relatives of people with type 1 and 2 diabetes (data available on the primary outcome).

Table 3
Results of generalized estimating equation models concerning diabetes-related knowledge of participants over time.

		Baseline	Follow up I		Follow up II		Follow up III	
Relatives of people with type 1 diabetes								
Intervention group	M	47.5	57.5		56.9		55.8	
	(95% CI)		(55.94-	59.02)	(55.09-	58.77)	(53.93-	57.60)
Control group	M	51.0	52.0		55.0		52.5	
	(95% CI)		(50.96-	53.03)	(53.71-	56.28)	(51.24-	53.85)
Test statistics	p-value	0.232	< 0.001		0.088		0.003	
Relatives of people with type 2 diabetes								
Intervention group	M	44.4	47.0		48.9		48.0	
	(95% CI)		(45.10-	48.88)	(47.70-	50.11)	(46.22-	49.82)
Control group	M	44.3	44.4		45.2		45.6	
	(95% CI)		(43.52-	45.26)	(43.66-	46.74)	(44.95-	46.21)
Test statistics	p-value	0.958	0.015		< 0.001		0.012	

who were assigned to the intervention group compared to those of the control group. Regarding relatives of people with type 1 diabetes, these differences were significant for the primary outcome at FUP III after 12 months and also at FUP I, whereas these differences were significant at all FUPs (FUP I–III) for relatives of people with type 2 diabetes (Table 3). The significant results confirm our main hypothesis (H1) that there is sustained increased diabetes-related knowledge in the intervention group compared to relatives who were assigned to the control group.

2.8. Secondary outcome: psychosocial factors

Adjusted mixed linear models did not reveal any persistent differences between intervention and control groups in participating relatives of people with type 1 diabetes (Table 4). However, we found that participants of the intervention group showed significantly more diabetes-related strains at FUP III compared to participants of the control group. Furthermore, the mixed linear model showed significantly more support for people with diabetes in the control group at FUP II compared to the intervention group. Moreover, participants of the intervention and the control group differed significantly at the baseline assessment regarding the perceived possibilities of how people with diabetes could be supported. Participants of the intervention group perceived significantly fewer possibilities of supporting their relatives with type 1 diabetes compared to participants of the control group. However, both groups converged after the intervention.

When comparing relatives of people with type 2 diabetes, we found some significant differences (Table 4). The results indicate that participants of the intervention group had better mental health compared to the control group right after and six months after they completed the intervention. We also found a higher level of life satisfaction among participants of the intervention group at FUP I and FUP II compared to the control group. Moreover, we found fewer depressive symptoms (PHQ-9) at the time of FUP I compared to participants of the control group.

We also conducted unadjusted pairwise *t*-tests to assess the differences within groups over time compared to baseline assessments. Regarding relatives of people with type 1 diabetes, we found significant changes within the intervention and control group. The diabetes-related distress decreased within the intervention (DDIP-FM-2: FUP I: $t(40) = -3.12$, $p = 0.003$; FUP II: $t(39) = -3.866$, $p = < 0.001$; FUP III: $t(38) = -2.322$, $p = 0.026$) and control group (DDIP-FM-2: FUP I: $t(44) = -2.609$, $p = 0.012$, FUP II: $t(43) = -3.764$, $p < 0.001$, FUP III: $t(43) = -1.291$, $p = 0.204$), but was more persistent in the intervention group.

Participants of the intervention group showed a significant increase of perceived possibilities of supporting people with diabetes after the intervention (DFSS 2, FUP I: $t(39) = -3.974$, FUP II: $t(39) = -4.308$; FUP III: $t(36) = -3.479$; $p < 0.001$). Participant's family interaction within the intervention group also improved significantly after the intervention but not persistently (DFBC 2: FUP I: $t(40) = -0.484$, $p = 0.015$). We also found that the physical well-being of participants of the intervention group decreased significantly at the time of FUP II and III (SF-12: FUP II: $t(37) = 2.672$, $p = 0.011$; FUP III: $t(36) = 3.713$; $p < 0.001$). We found no differences between participants (relatives of people with type 1 diabetes) within groups over time in the remaining secondary outcomes. In sum, the results indicate that our hypotheses (H2 and H3) do not apply to relatives of people with type 1 diabetes.

By contrast, we found some indications that these hypotheses (H2 and H3) are applicable for relatives of people with type 2 diabetes. Regarding relatives of people with type 2 diabetes, we found that the perceived possibilities of supporting people with diabetes increased significantly in participants of the intervention group after the intervention took place compared to the baseline assessment (DFSS 2, FUP I: $t(32) = -2.380$, $p = 0.023$, FUP III: $t(34) = -2.571$, $p = 0.015$). Participants of the control group showed less support for people with diabetes at the first FUP compared to the baseline assessment (DFSS 1, FUP I: $t(39) = 2.615$, $p = 0.013$).

The unadjusted pairwise *t*-test also showed that the perceived quality of life increased significantly in the intervention group directly after the intervention (FUP I: $t(33) = -2.06$, $p = 0.047$), whereas it decreased in the control group (FUP I: $t(40) = 2.136$, $p = 0.039$; FUP II: $t(40) = 2.994$, $p = 0.005$). We found no differences between the intervention and control group over time among participating relatives of people with type 2 diabetes for any of the remaining secondary outcomes.

3. Discussion and Conclusion

3.1. Discussion

This cRCT sought to examine the efficacy of Dia*Life*, an education program for relatives of adults with diabetes. Results of generalized estimating equation models revealed significant knowledge-based differences between the intervention and control groups for relatives of people with type 1 and 2 diabetes. These results provide evidence for the efficacy of the Dia*Life* education program regarding the primary endpoint, i.e. better diabetes-related knowledge after 12 months of intervention. In addition, we found a significantly better diabetes-related knowledge (compared to the control group) directly after the intervention (FUP I), regardless of the type of diabetes, and 6 months after the intervention (FUP II) in relatives of people with type 2 diabetes.

Looking at the results regarding the secondary outcomes, mixed linear models did not reveal improved (diabetes-related) psychosocial outcomes of relatives of people with type 1 diabetes of the intervention group compared to those of the control group. In particular, we found significantly higher diabetes-related strains (DDIP-FM 1) in participants of the intervention group compared to those of the control group at FUP III. Moreover, participants of the

Table 4
Results of mixed linear models concerning psychosocial factors in participants over time.

			Baseline		Follow up I		Follow up II		Follow up III	
Relatives of people with type 1 diabetes										
PAID 5	Intervention group	M	7.6		6.5		5.7		5.9	
	Control group	M	5.6		5.3		4.7		5.4	
	Test statistics	p	0.079		0.192		0.308		0.553	
		95% CI	(−4.33	-0.24)	(−3.06	-0.63)	(−3.32	-1.13)	(−2.39	-1.29)
DDIP-FM 1	Intervention group	M	14.9		15.1		13.7		**17.3**	
	Control group	M	11.4		9.9		11.3		**8.7**	
	Test statistics	p-value	0.201		0.147		0.486		**0.001**	
		95% CI	(−8.88	-1.90)	(−12.51	-2.13)	(−9.97	-5.06)	**(−13.71**	**-3.52)**
DDIP-FM 2	Intervention group	M	5.7		6.5		6.8		6.4	
	Control group	M	6.2		6.9		7.0		6.6	
	Test statistics	p-value	0.498		0.549		0.767		0.742	
		95% CI	(−0.98	-1.90)	(−1.08	-1.88)	(−1.09	-1.43)	(−1.06	-1.40)
DFBC 1	Intervention group	M	17.7		17.4		16.7		17.3	
	Control group	M	17.9		17.5		16.5		17.4	
	Test statistics	p-value	0.803		0.915		0.797		0.923	
		95% CI	(−1.90	-2.45)	(−2.12	-2.36)	(−2.41	-1.86)	(−2.21	-2.44)
DFBC 2	Intervention group	M	35.1		34.7		36.0		35.5	
	Control group	M	32.8		35.5		34.5		33.8	
	Test statistics	p-value	0.307		0.693		0.338		0.278	
		95% CI	(−2.54	-7.12)	(−5.69	-3.91)	-1.61	-4.63)	(−1.42	-4.86)
DFSS-FM 1	Intervention group	M	15.4		15.0		**13.7**		14.2	
	Control group	M	17.1		16.1		**15.9**		15.7	
	Test statistics	p-value	0.153		0.324		**0.021**		0.231	
		95% CI	(−0.84	-4.30)	(−1.07	-3.20)	**(0.34**	**-4.12)**	(−1.09	-4.07)
DFSS-FM 2	Intervention group	M	**8.6**		10.0		10.0		10.0	
	Control group	M	**10.0**		10.0		9.7		9.9	
	Test statistics	p-value	**0.010**		0.868		0.489		0.794	
		95% CI	**(0.35**	**-2.46)**	(−1.17	-0.99)	(−1.22	-0.59)	(−1.17	-0.90)
SF-12 physical health	Intervention group	M	51.6		50.7		48.6		46.7	
	Control group	M	48.7		49.3		46.7		48.8	
	Test statistics	p-value	0.065		0.492		0.306		0.335	
		95% CI	(−5.85	-0.18)	(−5.80	-2.94)	(−5.80	-1.85)	(−2.89	-7.19)
SF-12 mental health	Intervention group	M	48.8		49.5		48.3		49.0	
	Control group	M	51.4		49.9		51.6		51.9	
	Test statistics	p-value	0.219		0.885		0.135		0.269	
		95% CI	(−1.57	-6.76)	(−5.30	-6.06)	(−1.23	-7.70)	(−2.49	-8.17)
L1	Intervention group	M	7.2		7.4		7.2		7.1	
	Control group	M	7.4		7.7		7.4		7.4	
	Test statistics	p-value	0.602		0.497		0.699		0.559	
		95% CI	(−0.62	-1.07)	(−0.62	-1.19)	(−0.64	-0.95)	(−0.87	-1.51)
PHQ-9	Intervention group	M	4.9		4.8		5.3		5.6	
	Control group	M	4.7		4.2		3.6		4.0	
	Test statistics	p-value	0.818		0.453		0.097		0.135	
		95% CI	(−1.84	-1.46)	(−2.14	-0.96)	(−3.71	-0.35)	(−3.77	-0.58)
Relatives of people with type 2 diabetes										
PAID 5	Intervention group	M	6.5		4.4		5.1		4.5	
	Control group	M	6.6		5.5		5.3		5.4	
	Test statistics	p-value	0.921		0.238		0.818		0.324	
		95% CI	(−2.21	-2.44)	(−0.75	-2.96)	(−2.19	-2.68)	(−0.92	-2.75)
DDIP-FM 1	Intervention group	M	6.6		10.9		7.6		9.2	
	Control group	M	11.5		10.1		12.2		7.2	
	Test statistics	p-value	0.053		0.856		0.082		0.540	
		95% CI	(−0.07	-9.81)	(−9.53	-8.05)	(−0.60	-9.70)	(−8.97	-5.09)
DDIP-FM 2	Intervention group	M	6.8		7.6		7.4		7.5	
	Control group	M	7.1		7.0		7.5		7.3	
	Test statistics	p-value	0.522		0.158		0.811		0.624	
		95% CI	(−0.57	-1.11)	(−1.43	-0.24)	(−0.88	-1.10)	(−1.05	-0.63)
DFBC 1	Intervention group	M	18.1		18.2		19.4		19.3	
	Control group	M	17.9		19.4		18.0		19.6	
	Test statistics	p-value	0.941		0.340		0.386		0.786	
		95% CI	(−3.69	-3.45)	(−1.41	-3.79)	(−4.67	-1.94)	(−2.14	2.77)
DFBC 2	Intervention group	M	35.4		37.3		37.5		36.9	
	Control group	M	34.9		36.5		35.1		36.2	
	Test statistics	p-value	0.823		0.572		0.191		0.644	
		95% CI	(−4.53	-3.67)	(−3.67	-2.05)	(−5.91	-1.20)	(−4.40	-2.84)
DFSS-FM 1	Intervention group	M	17.2		17.1		17.9		16.1	
	Control group	M	17.6		16.9		15.5		17.2	
	Test statistics	p-value	0.783		0.927		0.071		0.420	
		95% CI	(−2.81	-3.65)	(−3.09	-2.84)	(−4.89	-0.21)	(−1.94	-4.26)
DFSS-FM 2	Intervention group	M	9.8		10.7		10.9		10.8	
	Control group	M	9.5		9.8		10.1		10.2	
	Test statistics	p-value	0.727		0.106		0.056		0.145	
		95% CI	(−1.58	-1.13)	(−2.12	-0.23)	(−1.71	-0.02)	(−1.38	-0.21)

(*continued on next page*)

Table 4 (*continued*)

			Baseline		Follow up I		Follow up II		Follow up III	
SF-12 physical health	Intervention group	M	45.4		46.7		45.4		45.8	
	Control group	M	45.5		44.1		43.5		45.0	
	Test statistics	p-value	0.969		0.313		0.464		0.818	
		95% CI	(−5.25	-5.44)	(−8.45	-3.28)	(−7.59	-3.68)	(−8.52	-6.88)
SF-12 mental health	Intervention group	M	53.0		**52.7**		**52.5**		50.4	
	Control group	M	49.3		**48.1**		**46.8**		48.0	
	Test statistics	p-value	0.122		**0.043**		**0.026**		0.436	
		95% CI	(−8.28	-0.88)	**(−8.99**	**-(−0.14)**	**(−10.60**	**-(−0.68)**	(−9.35	-4.72)
L1	Intervention group	M	7.7		**8.3**		**7.9**		7.9	
	Control group	M	7.6		**6.8**		**6.8**		7.0	
	Test statistics	p-value	0.806		**0.013**		**0.015**		0.230	
		95% CI	(−1.33	-1.07)	**(0.38**	**-2.53)**	**(0.28**	**-2.06)**	(−0.60	-2.11)
PHQ-9	Intervention group	M	4.1		**3.2**		4.4		4.6	
	Control group	M	5.4		**5.8**		5.3		5.9	
	Test statistics	p-value	0.171		**0.026**		0.292		0.229	
		95% CI	(−3.29	-0.66)	**(−4.65**	**-(−0.42)**	(−2.43	-0.74)	(−3.88	-1.05)

control group showed significantly more support for people with type 1 diabetes at FUP II compared to participants of the intervention group (DFSS-FM 1). These findings were unexpected and are rather difficult to explain. Participants might not have been fully aware of the psychosocial consequences that people with diabetes face daily. Participants might have felt overwhelmed by raising the awareness of psychosocial strains. In order to empower relatives, it might be effective to add another psychosocial module to improve their well-being and psychosocial outcomes, such as stress and strains. On the other hand, participants of the control group (waiting list condition) might have rated their possibilities of supporting the patient higher because they would soon attend an education program.

Regarding relatives of people with type 2 diabetes, mixed linear models revealed better mental health, a higher quality of life and fewer symptoms of depression in the intervention group compared to the control group. These results were confirmed by paired *t*-tests that (also) revealed an increased perception of possibilities of supporting people with type 2 diabetes and a higher quality of life. Thus, the Dia*Life* education program had a positive impact on the mental well-being of relatives of people with type 2 diabetes.

The causes for differences regarding the secondary outcomes between relatives of type 1 and 2 diabetes remain unclear. Divergent results between secondary outcomes between relatives of type 1 and 2 diabetes might indicate a moderator effect of the type of diabetes, which needs to be investigated in future research. Another possible explanation might be found in the divergent Dia*Life* curricula for type 1 and 2 diabetes. Based on the crucial role of comorbidities for type 1 diabetes, we implemented an extra module (diabetes-associated conditions) for people with type 1 diabetes. Assuming that (relatives of) people with type 1 diabetes might not have been aware of the severe diabetes-related complications in older age, they might have been triggered by giving this topic such a prominent role within the Dia*Life* education program. On the other hand, for relatives of people with type 2 diabetes, this topic was integrated into the module "fundamental principles of diabetes type 2." Moreover, people with type 2 diabetes and their spouses might perceive diabetes "only" as an additional disease that comes with a more advanced age.

However, it needs to be emphasized that only the confirmatory analysis for the outcome knowledge after 12 months (primary outcome at primary endpoint) achieves robust results. All other results at the remaining time points should be regarded as exploratory and require further investigation.

It is important to bear possible biases in mind. We did not conduct a fidelity check on how Dia*Life* was presented by the CDCES, which is a major limitation. However, a train-the-trainer seminar was determined as an inclusion criterion for the CDCES. In these seminars, the Dia*Life* program and its application were presented. Thus, a correct application of the Dia*Life* education program can be assumed. However, CDCESs might differ regarding their didactic skills. Moreover, the recruitment of study centers and participants were both based on a convenience sample. We must, therefore, consider that participants were biased regarding their motivation and interest in the topic, which becomes evident when considering the already good level of diabetes-related knowledge at the baseline assessment. However, since Dia*Life* is an offer of support rather than an obligation for relatives, it can be assumed that merely interested relatives would partake in this program. A limitation of the study might be caused by the study's design, i.e. a cRCT. Study centers were randomly assigned either to the intervention or control group. Our analysis showed that the participants of the intervention and control group differed regarding their SES at the baseline assessment, which might be caused, for example, by the location of the study centers. Due to practical reasons, it was not possible to stratify the participants into groups based on their SES. All data obtained are based on participants' self-report that might be biased, particularly regarding the self-perception of support for people with diabetes. Even though participants think that they are supporting their relatives with diabetes, this might not necessarily be perceived as supportive by those affected. However, Dia*Life* includes two mandatory psychosocial modules for relatives of people with type 1 and 2 diabetes (understanding the impact of diabetes on a daily basis; strategies of communication), which address helpful and destructive forms of support and how to communicate them. Therefore, Dia*Life* encourages relatives to reflect on their previous form of support and improve it. Relatives of people who have recently been diagnosed with diabetes might be a particular target group that could be empowered by participating in the Dia*Life* education program. However, the baseline assessment of this cRCT showed that the participants of this study already had a good level of diabetes-related knowledge. One reason might be that relatives who are living together with a person with diabetes might already be familiar with basic diabetes-related facts. Unfortunately, we neither assessed the date of diagnosis nor the timespan of how long participants have been living together with the person diagnosed with diabetes. Therefore, future studies could assess these data to provide information to answer the question of when Dia*Life* is most efficient.

3.2. Conclusion

Taken together, the efficacy of Dia*Life* could be proved regarding increasing relatives' diabetes-related knowledge persistently. In terms of improving participant's psychosocial well-being, mixed results were found that indicate better well-being in relatives of people with type 2 diabetes. Moreover, the fact that Dia*Life* could be

implemented successfully as a new clinical teaching program at so many centers underlines its feasibility.

3.3. Practice Implications

The Dia*Life* education program for relatives of people with diabetes is an effective intervention that increases relatives' diabetes-related knowledge. Diabetes centers should, therefore, consider implementing an education program for relatives in their curriculum.

Ethics approval and consent to participate

The study protocol was approved by the Ethical Review Committee of the University of Jena. Moreover, the ethical approvals of the Ethical Review Committees of the following State Chambers of Physicians were obtained: Saxony, Schleswig-Holstein, Baden-Wuerttemberg, Hesse, Saarland, Brandenburg, North Rhine, Westphalia-Lippe and Rhineland-Palatinate. Given that the study had already been approved by the Ethical Review Committee of the University of Jena, no ethical approvals were required in Bavaria and Berlin.

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CRediT authorship contribution statement

MB, NM, LH, GF and CLS outlined and specified the research question. MB wrote the first draft of the manuscript. TL and NM conducted statistical analyses. NM, LH, GF, AH and CLS edited and revised the manuscript critically for important intellectual content. All authors contributed to and have approved the final manuscript.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Not applicable.

Consent to participate

Informed consent was obtained from all individual participants included in the study.

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