OBJECTIVE
The aim of this study was to assess the efficacy of a 12-month prevention program conducted in 42 community pharmacies in reducing the risk for diabetes.

RESEARCH DESIGN AND METHODS
In a cluster-randomized controlled trial in 1,092 participants, mean change in the risk for diabetes (indicated by the Finnish Diabetes Risk Score [FINDRISC]) between intervention and control groups was calculated. In the intervention program GLICEMIA, three appointments with individual counseling and five educational group sessions were combined, whereas in the control group, only information about the participants’ health was obtained in three assessments.

RESULTS
After adjusting for cluster structure and differences in baseline characteristics, improvement in FINDRISC in the intervention group was 0.74 (95% CI 0.42–1.04) points above the control group.

CONCLUSIONS
The GLICEMIA program shows the feasibility of a pharmacy-based intervention and leads to a significant modest reduction in diabetes risk score but does not reduce the rate of diabetes progression over 1 year.

The prevalence of type 2 diabetes is increasing worldwide (1). As recently published in a meta-analysis, diabetes prevention in the outpatient setting can be effective (2). Community pharmacies could be a suitable site to establish a conveniently accessible diabetes prevention program (3,4). Therefore, the diabetes prevention program GLICEMIA was developed according to international guidelines and requirements of the German statutory health insurance (5–7). The aim of this study was to evaluate the feasibility and effectiveness of the diabetes prevention program GLICEMIA in community pharmacies.

RESEARCH DESIGN AND METHODS
The trial is a prospective multicenter cluster-randomized controlled intervention study. The 42 participating community pharmacies in Bavaria, South Germany, were randomly assigned one-to-one to the intervention or to the control group. Pharmacists from each center participated in a 1-day training on how to conduct the study. The intervention pharmacies had an additional 0.5-day training on counseling for behavior changes. Thus, the study was not blinded. The trial started in October 2012.
and lasted until January 2014. Ethical approval was obtained from the Freiburg Ethics Commission International.

Eligible study subjects had an increased risk for diabetes according to a German Finnish Diabetes Risk Score (FINDRISC) ≥7 and were at least 35 years old. Exclusion criteria were pregnancy, diabetes, cancer, and participation in a clinical trial 30 days before enrollment. After screening with the FINDRISC, written informed consent was obtained.

The results refer to changes between baseline and the 12-month follow-up measurement. Pharmacists assessed waist and hip circumference, height, weight in a nonfasting state in light clothes, postprandial capillary plasma glucose level, and blood pressure according to standard operating procedures (8–10). The FINDRISC, a self-developed demographic and behavior questionnaire, and the 12-item Short Form Health Survey (SF-12) quality-of-life instrument were completed.

All participants received written information about a healthy diet and physical activity. Control group participants were assessed and informed about their health status but did not receive any further counseling.

The intervention group received three individual counseling sessions and five group-based lectures (program GLICEMIA). In the individual counseling, diet and physical activity were discussed and recorded in an individual prevention journal. At the second and third appointment, goal attainment was monitored by the pharmacists, and new personal objectives were agreed on. The five accompanying group-based lectures lasted 75–90 min and covered the following topics: diabetes and risk factors, healthy diet, physical activity, psychological aspects of behavior change, and maintenance of a healthy lifestyle. All participants were informed that the study aimed to prevent diabetes, but they did not know what the outcome measures were.

**Study Outcomes**

The primary outcome was change in FINDRISC after 12 months. Secondary end points were weight reduction, changes in blood pressure, self-reported physical activity, and quality of life.

**Statistical Analysis**

An intention-to-treat analysis was performed, imputing missing values using the last observation carried forward method. An additional sensitivity analysis was performed on the completer sample. To investigate the efficacy of the intervention on the primary and secondary end points, we applied linear mixed-effects regression, taking into account the cluster structure of the data and differences between groups at baseline. As a response variable, we used the change in outcome between baseline and 12 months. In a fixed-effects model, we included the grouping variable (intervention vs. control) and possible confounders from baseline, whereas the corresponding community pharmacy was included as a random effect. The resulting adjusted effect size for the grouping variable with corresponding 95% CIs are reported for both primary and secondary end points.

**RESULTS**

Of the 42 community pharmacies in this study, 40 completed the trial (Supplementary Data). Two pharmacies in the intervention group dropped out due to illness and insolvency. A total of 1,140 participants were recruited (565 in the intervention group and 575 in the control group). The drop-out rate was 13.0% (n = 148). Participants were excluded from the analysis if they did not fulfill the inclusion criteria or if the pharmacy became insolvent (Supplementary Fig. 1). Thus, 530 participants in the intervention group and 562 in the control group were analyzed, including 115 (10.5%) for whom the missing end points were imputed through the last observation carried forward method due to dropout. In the overall sample, 68.6% of the participants were female (n = 749), and the mean age was 57.5 ± 11.3 years. Comparisons of baseline characteristics between the groups in Supplementary Table 1 show significant differences for age, BMI, FINDRISC, physical activity, and physical quality of life as well as for sex, family status, and employment. The proportion of participants who were overweight at baseline was 84.7% in the intervention group (449 of 530) and 79.3% in the control group (445 of 561).

For the primary end point, we found a significant effect of the intervention. The mean change of the FINDRISC after 1 year was a reduction of −0.55 ± 1.84 points in the intervention group and an increase in the control group of 0.17 ± 1.64 points (Table 1). After adjusting for the cluster structure and differences in baseline characteristics (sex, age, BMI, employment, level of education), improvement in the FINDRISC in the intervention group was 0.74 (95% CI 0.42–1.04) points above the control group.

| Table 1—Change in outcome parameters from baseline to the end of the study period by treatment group (intention-to-treat analysis) |
|---|---|---|
| **Primary outcome** | **Control group**<br>(n = 562) | **Intervention group**<br>(n = 530) | **Adjusted effect size**<br>(95% CI) |
| Change in FINDRISC | 0.17 ± 1.64 | −0.55 ± 1.84 | −0.74 (−1.04 to −0.42) |
| **Secondary outcomes** | | | |
| 1. Mean weight change (kg) (overall sample) | 0.11 ± 3.58 | −1.52 ± 3.84 | −1.57 (−2.23 to −0.90) |
| 2. Change in systolic BP (mmHg) | −3.61 ± 14.62† | −3.32 ± 13.01 | 0.40 (−1.88 to 2.71) |
| 3. Change in diastolic BP (mmHg) | −1.50 ± 9.25† | −0.91 ± 8.42 | 0.42 (−0.93 to 1.77) |
| 4. Change in physical activity (h/week) | −0.23 ± 1.72 | 0.31 ± 1.63 | 0.52 (0.32 to 0.73) |
| 5. Change in SF-12 physical component summary (QOL) | −0.73 ± 7.34† | 1.74 ± 8.05† | 2.39 (1.43 to 3.34) |
| 6. Change in SF-12 mental component summary (QOL) | 0.37 ± 8.62† | 1.29 ± 9.90† | 1.08 (−0.21 to 2.37) |

Data are mean ± SD (follow-up − baseline) unless otherwise indicated. BP, blood pressure; QOL, quality of life. *Adjusted through a linear mixed-effects models for sex, age, BMI at baseline, employment, and level of education (fixed effects) and for corresponding community pharmacy (random effect). †One missing value in the control group. ‡Three missing values in the intervention group and two in the control group.
Overall, a reduction of the FINDRISC was reached by 39.1% of the intervention group and 21.0% of the control group ($\chi^2$ test $P<0.001$).

The analysis of secondary outcomes (Table 1) showed an adjusted effect on weight loss of $-1.57$ kg (95% CI $-2.23$ to $-0.90$) in the intervention group compared with the control group. Physical activity and physical quality of life improved significantly more among participants in the intervention group. No differences were found for blood pressure and mental quality of life. The sensitivity analysis of the completer sample led basically to the same results as the intention-to-treat analysis (Supplementary Table 2).

During the trial, diabetes was diagnosed in seven participants in the intervention group and five in the control group. At the third appointment, three participants in the intervention group and five in the control group had clinically meaningful high plasma glucose levels (fasting $\geq 7.0$ mmol/L, postprandial $\geq 11.1$ mmol/L). All were referred to their primary care physician.

CONCLUSIONS

This randomized controlled trial with a lifestyle intervention program to prevent type 2 diabetes is the first to our knowledge conducted in community pharmacies. It was feasible to carry out the program GLICEMIA in community pharmacies. The adjusted effect size of the FINDRISC change was $-0.74$ (95% CI $-1.04$ to $-0.42$) points. Although this effect was statistically significant, further research is needed to assess the clinical relevance because this is the first study to consider the FINDRISC as a primary end point. Bergmann et al. (11) analyzed the correlation between the FINDRISC and diabetes progression indicated by an oral glucose tolerance test 3 years after an intervention. They found that people with a lower FINDRISC would more likely benefit from intervention. Thus, the reduction by 0.55 points in the intervention group in 1 year might be a step to prevent diabetes, but the duration of the study was not long enough to show a reduction in the rate at which participants developed diabetes.

Acknowledgments. The authors thank the participants and 40 community pharmacies for efforts during the study, the German Diabetes Foundation for expert advice, and the Central Laboratory of German Pharmacists for free participation in quality assurance measurements for plasma glucose level.

Funding. This work was supported by the Dr. August and Dr. Anni Lesmuller-Stiftung Foundation, the Bavarian State Ministry of Public Health and Care Services (through the funding and health promotion initiative GesundLeben. Bayern.), the Bavarian State Corporate Health Insurers, and the funding initiative for prevention (Förderinitiative Prävention e.V.). The blood glucose meters and test strips were made available free of charge to the pharmacies from Roche Diagnostics, Germany.

Duality of Interest. No potential conflicts of interest relevant to this article were reported.

Author Contributions. K.S. contributed to the study concept and design, development of the GLICEMIA program, data acquisition from the pharmacies, data analysis and interpretation, and drafting of the manuscript. A.M. and C.F. contributed to the data analysis and interpretation and critical revision of the manuscript for important intellectual content. H.S. and K.F. contributed to the study concept and design, development of the GLICEMIA program, data interpretation, critical revision of the manuscript for important intellectual content, and final approval of the manuscript. K.S. is the guarantor of this work and, as such, had full access to all the data in the study and takes responsibility of the integrity of the data and the accuracy of the data analysis.

Prior Presentation. Parts of this study were presented in abstract form at the annual meeting of the German Pharmaceutical Society, Freiburg, Germany, 9–11 October 2013; the annual meeting of the German Diabetes Association, Berlin, Germany 8–11 May 2013; the third WIPIG-PZ Prevention Congress, Nuremberg, Germany, 16–18 May 2014; and the annual meeting of the German Diabetes Association, Berlin, Germany, 28–31 May 2014.

References


Acknowledgments. The authors thank the participants and 40 community pharmacies for efforts during the study, the German Diabetes Foundation for expert advice, and the Central Laboratory of German Pharmacists for free participation in quality assurance measurements for plasma glucose level.

Funding. This work was supported by the Dr. August and Dr. Anni Lesmüller-Stiftung Foundation, the Bavarian State Ministry of Public Health and Care Services (through the funding and health promotion initiative GesundLeben. Bayern.), the Bavarian State Corporate Health Insurers, and the funding initiative for prevention (Förderinitiative Prävention e.V.). The blood glucose meters and test strips were made available free of charge to the pharmacies from Roche Diagnostics, Germany.

Duality of Interest. No potential conflicts of interest relevant to this article were reported.

Author Contributions. K.S. contributed to the study concept and design, development of the GLICEMIA program, data acquisition from the pharmacies, data analysis and interpretation, and drafting of the manuscript. A.M. and C.F. contributed to the data analysis and interpretation and critical revision of the manuscript for important intellectual content. H.S. and K.F. contributed to the study concept and design, development of the GLICEMIA program, data interpretation, critical revision of the manuscript for important intellectual content, and final approval of the manuscript. K.S. is the guarantor of this work and, as such, had full access to all the data in the study and takes responsibility of the integrity of the data and the accuracy of the data analysis.

Prior Presentation. Parts of this study were presented in abstract form at the annual meeting of the German Pharmaceutical Society, Freiburg, Germany, 9–11 October 2013; the annual meeting of the German Diabetes Association, Berlin, Germany 8–11 May 2013; the third WIPIG-PZ Prevention Congress, Nuremberg, Germany, 16–18 May 2014; and the annual meeting of the German Diabetes Association, Berlin, Germany, 28–31 May 2014.

References