Diabetes Screening and Health Promotion -

Evaluation of a Pharmacy Based Campaign

and of Related Activities

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Dekan

To my parents

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Abbreviations

2-h PG	2-h postload glucose
ADA	American Diabetes Association
ATP III	Adult Treatment Panel III
BP	blood pressure
CBG	capillary blood glucose
CHD	coronary heart disease
CVD	cardiovascular disease
DPP	diabetes prevention program
FPG	fasting plasma glucose
GDM	gestational diabetes mellitus
HDL	high density lipoprotein
IFG	impaired fasting glucose
IGT	impaired glucose tolerance
LDL	low density lipoprotein
OGTT	oral glucose tolerance test
PAI-1	plasminogen activator inhibitor-1
TC	total cholesterol
TLC	therapeutic lifestyle change
TTM	transtheoretical model
WCE	white coat effect
WCH	white coat hypertension
WHO	World Health Organization

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Summary

This thesis is based on the evaluation of pharmacy-based screening concepts for cardiovascular risk factors (particularly for type 2 diabetes and dyslipidaemia) and of related health promoting activities.

Type 2 diabetes mellitus and the metabolic syndrome including hypertension and dyslipidaemia are major public health concerns, and projections of future effects are alarming. These metabolic disorders are linked to an increased risk of cardiovascular disease. Type 2 diabetes is one of the most costly and burdensome diseases of our time and is a condition that is increasing in epidemic proportions throughout the world. Early detection and treatment of type 2 diabetes and metabolic syndrome can reduce the burden of complications. In addition, there is large evidence that weight loss and lifestyle changes in nutrition habits and physical activity have positive effects on the prevention of diabetes and cardiovascular disease.

Community pharmacies are regarded as a suitable setting to promote awareness, screen high-risk patients, and to deliver health promoting counselling to persons at risk for diabetes and cardiovascular disease. However, triage guidelines for diabetes and lipid screening in community pharmacies and appropriate cut-off points for measurements in capillary blood are missing. In addition, measurements used in pharmacy-based screenings for diabetes or cardiovascular risk (such as blood pressure and blood glucose) are not validated.

It was ***the goal of this thesis*** to develop and evaluate screening concepts for type 2 diabetes and dyslipidaemia including appropriate triage guidelines and cut-off points for community pharmacy practice as well as to investigate the influence on lifestyle behaviour of different types of counselling. The thesis consists of five projects:

Project A investigated whether a white coat effect in blood pressure measurements (as known from physicians' measurements) can be observed and quantified in community pharmacy practice. Up to date no such findings have been published. It was the aim of this study to validate blood pressure measurement in community pharmacy practice as hypertension is a major risk factor for cardiovascular disease and an important part of screening concepts. For this purpose blood pressure was measured in four different settings: pharmacy, outpatient clinic (measurement by a nurse), self-measurement at home and daytime ambulatory blood pressure

monitoring. Pharmacy blood pressure was statistically significantly higher compared with daytime ambulatory blood pressure monitoring in both systolic and diastolic values. In contrast, only diastolic values of outpatient clinic blood pressure were statistically significantly higher compared with daytime ambulatory blood pressure monitoring. In addition, a total of 16% of the participants showed a white coat hypertension, defined as elevated pharmacy blood pressure (≥140/90 mmHg) and normal daytime ambulatory blood pressure (<135/85 mmHg). Thus, the results of this study have shown that white coat effect and white coat hypertension exist in community pharmacy practice and are at least similar to the effects in an outpatient clinic.

In **Project B**, a sequential screening concept for type 2 diabetes to be used in community pharmacy practice was evaluated. Triage guidelines and appropriate cut-off points for capillary blood glucose have been elaborated in an interdisciplinary and multi-institutional collaboration. A large pharmacy-based national diabetes screening campaign called “Stopp Zucker – Jetzt testen!” provided the possibility to evaluate the sequential screening concept. Community pharmacies participating in this campaign offered a free of charge diabetes risk assessment with consecutive capillary blood glucose measurement. Readiness for lifestyle change has been assessed based on the transtheoretical model (Prochaska) of behaviour change. During five weeks of spring 2002, a total of 94124 persons were screened for previously undiagnosed type 2 diabetes in 530 pharmacies of the German speaking part of Switzerland. The campaign attracted a large number of Swiss German speaking adults (2.4% of the total population) and the sequential screening concept could successfully be implemented into pharmacy practice. Of the generally elderly population screened, a total of 6.9% were suspected to have type 2 diabetes showing abnormal blood glucose values in the screening. A large proportion (71.5%) of the screened population had at least two risk factors but showed normoglycaemia. This provided an opportunity to provide targeted counselling towards health promoting lifestyle change.

In the context of a pilot study, **project C** developed triage guidelines and cut-off points for dyslipidaemia which were evaluated in a regional screening campaign for metabolic syndrome in 30 community pharmacies. The results suggested that screening for the coincidence of ≥2 values of lipid profile above normal with ≥2 other risk factors for cardiovascular disease is the more promising approach than is

exclusive screening for ≥1 or even ≥2 abnormal lipid values without coincidence with other cardiovascular risk factors as this would lead to large referral rates to physicians. On the other hand, if a single value of the lipid profile is elevated on the level requiring drug treatment, even without coincidence with other risk factors, referral is required.

In **project D**, the changes in lifestyle behaviour and body weight after counselling in community pharmacies during the national diabetes screening campaign were investigated. Three different counselling intensities were compared: Standard (non-specific recommendations towards lifestyle change), intensive (additional specific advice to reduce body weight), and standard plus referral to physician for persons at high risk for type 2 diabetes. Three months after screening a stratified sample of 3800 randomly chosen overweight individuals at risk for type 2 diabetes were addressed with written questionnaires to assess changes in body weight and lifestyle. Half a year and one year later the assessment was repeated. All counselling groups showed a significant weight loss three months after screening (0.6-1.9 kg; $p<0.001$). One year later a further significant weight reduction was observed. This reversed the general trend in the common population. Lifestyle changes in physical activity and/or nutrition habits were reported by 72.5% of all persons. Reported lifestyle changes as well as weight loss were most pronounced in the population at high risk for type 2 diabetes. The findings of this study showed that the immediate and targeted counselling after screening for type 2 diabetes in community pharmacies can result in significant and sustainable lifestyle changes and weight loss in overweight individuals. However the uncontrolled design of this project did not allow for stringent conclusions.

Therefore, **project E** investigated the effect of a telephone-based counselling on body weight and lifestyle of overweight persons in a randomised controlled trial. Subjects for this study were recruited out of individuals who participated in the national diabetes screening campaign and provided informed consent for further investigations. After baseline assessment with a written questionnaire, subjects were randomly selected for intervention and control group. Within three months three telephone-based counselling sessions of 15 minutes were provided to the intervention group. Changes in lifestyle and body weight were assessed three months after counselling and another half year later with two evaluation questionnaires. Three months after telephone-based counselling the intervention

group showed a significantly higher weight loss than the control group (-0.37% vs. +0.09%; $p<0.05$). Half a year later differences in weight loss were not significant anymore. However, a greater proportion of subjects in the intervention group progressed at least to the next higher stage of change in the transtheoretical model regarding physical activity (27.0% vs. 21.3%; $p<0.05$) and reported lifestyle changes in nutrition habits and/or physical activity (80.5% vs. 62.9%; $p<0.001$). Thus, the results of this study have shown that a three times 15 minutes telephone-based counselling is able to result in measurable weight loss and significant lifestyle changes in overweight individuals. Best modalities and, because of seasonal interference, the best point in time of a telephone-based counselling need further investigation.

In conclusion this thesis showed that:

- Screening for cardiovascular risk in community pharmacies benefits from a sequential procedure: First an assessment of all risk factors including blood pressure, second capillary blood glucose measurements with retest in case of borderline results and with measurement of lipid profile if possible and finally counselling of persons at risk to initiate lifestyle change.
- The elaborated and evaluated triage guidelines with the cut-off points for diabetes and for lipid screening appear to be appropriate and can be recommended for community pharmacy practice.
- A total of 6.9% of the population screened in the national diabetes screening campaign were suspected to have type 2 diabetes showing abnormal blood glucose values. This rate is representative for the population screened but due to selection effects not for the general Swiss population.
- Blood pressure measurements in community pharmacies are as reliable as those of other health professionals. They are subject to a white coat effect, also known from measurements by physicians and nurses.
- After screening for cardiovascular risk pharmacists should offer targeted counselling to persons at risk according to the readiness to change their lifestyle.
- Health promoting activities provided in community pharmacies or by nurses through telephone-based counselling can have positive effects on lifestyle behaviour and therewith on public health.

1 General introduction

1.1 Pathophysiology and diagnosis of type 2 diabetes mellitus and its correlation to metabolic syndrome and cardiovascular disease

Diabetes is a metabolic disorder characterized by resistance to the action of insulin, insufficient insulin secretion, or both. The major clinical manifestation of the diabetic state is hyperglycaemia. However, insulin deficiency and insulin resistance also are associated with disturbances in lipid and protein metabolism. The chronic hyperglycaemia of diabetes is associated with long-term damage, dysfunction, and failure of various organs, especially the eyes, kidneys, nerves, heart, and blood vessels. Several pathogenic processes are involved in the development of diabetes. These range from autoimmune destruction of the β-cells of the pancreas with consequent insulin deficiency to abnormalities that result in resistance to insulin action. The basis of the abnormalities in carbohydrate, fat, and protein metabolism in diabetes is deficient action of insulin on target tissues. Deficient insulin action results from inadequate insulin secretion or diminished tissue responses to insulin at one or more points in the complex pathways of hormone action. Impairment of insulin secretion and defects in insulin action frequently coexist in the same patient, and it is often unclear which abnormality, if either alone, is the primary cause of the hyperglycaemia [1-3].

Symptoms of marked hyperglycaemia include polyuria, polydipsia, weight loss, sometimes with polyphagia, and blurred vision. Impairment of growth (in children) and susceptibility to certain infections may also accompany chronic hyperglycaemia. Acute, life-threatening consequences of uncontrolled diabetes are hyperglycaemia with ketoacidosis or the nonketotic hyperosmolar syndrome. Long-term complications of diabetes include retinopathy with potential loss of vision; nephropathy leading to renal failure; peripheral neuropathy with risk of foot ulcers, amputations and Charcot joints; and autonomic neuropathy causing gastrointestinal, genitourinary and cardiovascular symptoms as well as sexual dysfunction. Patients with diabetes have an increased incidence of atherosclerotic cardiovascular, peripheral arterial, and cerebrovascular disease. Hypertension and abnormalities of lipoprotein metabolism are often found in people with diabetes [3].

The vast majority of diabetic patients are classified into one of two broad etiopathogenetic categories. In one category, type 1 diabetes, the cause is an absolute deficiency of insulin secretion which results from autoimmune destruction of the pancreatic b-cells [4, 5]. Individuals at increased risk of developing this type of diabetes can often be identified by serological evidence of an autoimmune pathologic process occurring in the pancreatic islets and by genetic markers. While this form of diabetes usually occurs in children and adolescents, it can occur at any age. Younger individuals typically have a rapid rate of β-cell destruction and present with ketoacidosis, while adults often maintain sufficient insulin secretion to prevent ketoacidosis for many years [6]. The more indolent adult-onset variety has been referred to as latent autoimmune diabetes in adults. Eventually, all type 1 diabetic patients will require insulin therapy to maintain normoglycaemia. In the other, much more prevalent category, type 2 diabetes, the cause is a combination of resistance to insulin action and an inadequate compensatory insulin secretory response. In the latter category, a degree of hyperglycaemia sufficient to cause pathologic and functional changes in various target tissues, but without clinical symptoms, may be present for a long period of time before diabetes is detected. During this asymptomatic period, it is possible to demonstrate an abnormality in carbohydrate metabolism by measurement of plasma glucose in the fasting state or after a challenge with an oral glucose load. Besides these two broad categories, women who develop diabetes during their pregnancy, are classified as having gestational diabetes. Finally, there are a variety of uncommon and diverse types of diabetes which are caused by infections, drugs, endocrinopathies, pancreatic destruction, and genetic defects [1-3].

The degree of hyperglycaemia (if any) may change over time, depending on the extent of the underlying disease process (see Figure 1). A disease process may be present but may not have progressed far enough to cause hyperglycaemia. The same disease process can cause impaired fasting glucose (IFG) and/or impaired glucose tolerance (IGT) without fulfilling the criteria for the diagnosis of diabetes. In some individuals with diabetes, adequate glycemic control can be achieved with weight reduction, exercise, and/or oral glucose-lowering agents. These individuals therefore do not require insulin. Other individuals who have some residual insulin secretion but require exogenous insulin for adequate glycemic control can survive without it. Individuals with extensive β-cell destruction and therefore no residual

insulin secretion require insulin for survival. The severity of the metabolic abnormality can progress, regress, or stay the same. Thus, the degree of hyperglycaemia reflects the severity of the underlying metabolic process and its treatment more than the nature of the process itself [3].

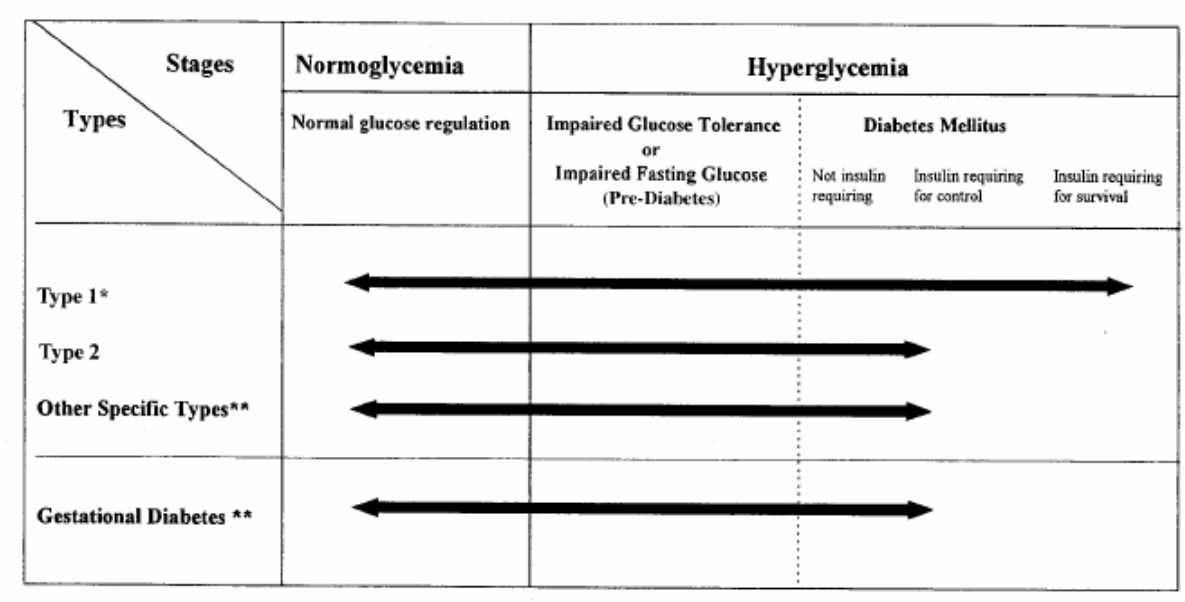

Figure 1: Disorders of glycaemia: etiologic types and stages.

*Even after presenting in ketoacidosis, these patients can briefly return to normoglycaemia without requiring continuous therapy (i.e., “honeymoon” remission); **in rare instances, patients in these categories (e.g., Vacor toxicity, type 1 diabetes presenting in pregnancy) may require insulin for survival.

1.1.1 Pathophysiology of type 2 diabetes

Type 2 diabetes, previously referred to as non-insulin-dependent diabetes or adult-onset diabetes, is a term used for individuals who have insulin resistance and usually have relative (rather than absolute) insulin deficiency [7-10]. This form of diabetes is ranging from predominantly insulin resistance with relative insulin deficiency to predominantly an insulin secretory defect with insulin resistance. In absolute terms, the plasma insulin concentration (both fasting and meal-stimulated) usually is increased, although "relative" to the severity of insulin resistance, the plasma insulin concentration is insufficient to maintain normal glucose homeostasis [11, 12]. But at least initially, and often throughout their lifetime, these individuals do not need insulin treatment to survive.

There are probably many different causes of this form of diabetes. Although the specific etiologies are not known, autoimmune destruction of β-cells does not occur [2]. Most patients with this form of diabetes are obese, and obesity itself causes some degree of insulin resistance [13, 14]. Patients who are not obese by traditional

weight criteria may have an increased percentage of body fat distributed predominantly in the abdominal region [15]. Ketoacidosis seldom occurs spontaneously in this type of diabetes; when seen, it usually arises in association with the stress of another illness such as infection [16-18]. This form of diabetes frequently goes undiagnosed for many years because the hyperglycaemia develops gradually and at earlier stages is often not severe enough for the patient to notice any of the classic symptoms of diabetes [19-21]. Nevertheless, such patients are at increased risk of developing macrovascular and microvascular complications [21-25]. Whereas patients with this form of diabetes may have insulin levels that appear normal or elevated, the higher blood glucose levels in these diabetic patients would be expected to result in even higher insulin values had their β-cell function been normal [26]. Thus, insulin secretion is defective in these patients and insufficient to compensate for the insulin resistance. Insulin resistance may improve with weight reduction and/or pharmacological treatment of hyperglycaemia but is seldom restored to normal [27-31]. The risk of developing this form of diabetes increases with age, obesity, and lack of physical activity [3, 20]. It occurs more frequently in women with prior gestational diabetes mellitus (GDM) and in individuals with hypertension or dyslipidaemia, and its frequency varies in different racial/ethnic subgroups [3, 20, 21]. Type 2 diabetes is often associated with a strong genetic predisposition, more so than is the autoimmune form of type 1 diabetes [32, 33]. It is more common in minority ethnic groups, i.e. Mexican-Americans, Latinos, American Indians, Pacific Islanders, than in individuals of European ancestry. However, the genetics of this form of diabetes are complex and not clearly defined [2, 34].

1.1.2 Diagnosis of type 2 diabetes

The diagnostic criteria for diabetes mellitus have been modified in 2003 by the Expert Committee on the Diagnosis and Classification of Diabetes Mellitus [2] from those previously recommended by the National Diabetes Data Group [35] or WHO [36]. The revised criteria for the diagnosis of diabetes are shown in Table 1. Three ways to diagnose diabetes are possible, and each must be confirmed, on a subsequent day, by any one of the three methods given in Table 1. For example, one instance of symptoms with casual plasma glucose ≥200 mg/dl (11.1 mmol/l), confirmed on a subsequent day by 1) fasting plasma glucose (FPG) ≥126 mg/dl (7.0 mmol/l), 2) an oral glucose tolerance test (OGTT) with the 2-h postload value ≥200 mg/dl (11.1

mmol/l), or 3) symptoms with a casual plasma glucose ≥200 mg/dl (11.1 mmol/l), warrants the diagnosis of diabetes [2].

For epidemiological studies, estimates of diabetes prevalence and incidence should be based on an FPG ≥126 mg/dl (7.0 mmol/l). This recommendation is made in the interest of standardization and also to facilitate field work, particularly where the OGTT may be difficult to perform and where the cost and demands on participants' time may be excessive. This approach will lead to slightly lower estimates of prevalence than would be obtained from the combined use of the FPG and OGTT [2].

Table 1: Criteria for the diagnosis of diabetes mellitus

1. Symptoms of diabetes plus casual plasma glucose concentration ≥200 mg/dl (11.1 mmol/l). Casual is defined as any time of day without regard to time since last meal. The classic symptoms of diabetes include polyuria, polydipsia, and unexplained weight loss.
or
2. FPG ≥126 mg/dl (7.0 mmol/l). Fasting is defined as no caloric intake for at least 8 h.
or
3. 2-h postload glucose ≥200 mg/dl (11.1 mmol/l) during an OGTT. The test should be performed as described by WHO, using a glucose load containing the equivalent of 75 g anhydrous glucose dissolved in water.

In the absence of unequivocal hyperglycaemia, these criteria should be confirmed by repeat testing on a different day. The third measure (OGTT) is not recommended for routine clinical use.

The Expert Committee [2] recognizes an intermediate group of subjects whose glucose levels, although not meeting criteria for diabetes, are nevertheless too high to be considered altogether normal. This group is defined as having FPG levels ≥100 mg/dl (5.6 mmol/l) but <126 mg/dl (7.0 mmol/l) *or* 2-h values in the OGTT of ≥140 mg/dl (7.8 mmol/l) but <200 mg/dl (11.1 mmol/l). The lower cut point defining IFG was recommended to be reduced from 110 mg/dl (6.1 mmol/l) to 100 mg/dl (5.6 mmol/l) by the Expert Committee on the Diagnosis and Classification of Diabetes Mellitus in 2003 [37]. Thus, "normol" was now defined as a FPG < 100 mg/dl instead of < 110 mg/dl. The criteria to diagnose diabetes were redommended to remain as previously defined. Therefore, the categories of FPG values are as follows [3, 37]:

- FPG <100 mg/dl (5.6 mmol/l) = normal fasting glucose
- FPG 100 – 125 mg/dl (5.6 - 7.0 mmol/l) = impaired fasting glucose (IFG)

- FPG ≥126 mg/dl (7.0 mmol/l) = provisional diagnosis of diabetes (the diagnosis must be confirmed, as described above).

The corresponding categories when the OGTT is used are the following:

- 2-h postload glucose (2-h PG) <140 mg/dl (7.8 mmol/l) = normal glucose tolerance
- 2-h PG ≥140 (7.8 mmol/l) and <200 mg/dl (11.1 mmol/l) = impaired glucose tolerance (IGT)
- 2-h PG ≥200 mg/dl (11.1 mmol/l) = provisional diagnosis of diabetes (the diagnosis must be confirmed, as described above).

The terms impaired glucose tolerance (IGT) and impaired fasting glucose (IFG) refer to a metabolic stage intermediate between normal glucose homeostasis and diabetes, now referred to as pre-diabetes. This stage of impaired glucose homeostasis includes individuals who have IGT and individuals with fasting glucose levels ≥110 mg/dl (6.1 mmol/l) but <126 mg/dl (7.0 mmol/l) (IFG). The term IFG was coined by Charles et al. [38] to refer to a fasting plasma glucose (FPG) level ≥110 mg/dl (6.1 mmol/l) but <140 mg/dl (7.8 mmol/l). The Expert Committee [2] is using a similar definition, but with the upper end lowered to correspond to the new diagnostic criteria for diabetes. A fasting glucose concentration of 109 mg/dl (6.1 mmol/l) has been chosen as the upper limit of “normal.” Although it is recognized that this choice is somewhat arbitrary, it is near the level above which acute phase insulin secretion is lost in response to intravenous administration of glucose [39] and is associated with a progressively greater risk of developing micro- and macrovascular complications [40-44]. It must be noted that many individuals with IGT are euglycemic in their daily lives [45] and may have normal or near normal glycated hemoglobin levels [46]. Individuals with IGT often manifest hyperglycaemia only when challenged with the oral glucose load used in the standardized OGTT [2].

1.1.3 Insulin resistance, the metabolic syndrome and cardiovascular risk

Obesity, particularly abdominal (visceral) obesity, is associated with resistance to the effects of insulin on peripheral glucose and fatty acid utilization, often leading to type 2 diabetes mellitus. Insulin resistance, the associated hyperinsulinemia and

hyperglycaemia, and adipocyte cytokines (adipokines) may also lead to vascular endothelial dysfunction, an abnormal lipid profile, hypertension, and vascular inflammation, all of which promote the development of atherosclerotic cardiovascular disease (CVD) [14, 47-49]. A similar profile can be seen in individuals with abdominal obesity who do not have an excess of total body weight [50, 51].
The co-occurrence of metabolic risk factors for both type 2 diabetes and CVD - abdominal obesity, hyperglycaemia / insulin resistance, dyslipidaemia of the high-triglyceride and/or low-HDL type and hypertension— suggested the existence of a "metabolic syndrome" [47, 48, 52, 53]. Other names applied to this constellation of findings have included syndrome X, the insulin resistance syndrome, the deadly quartet, or the obesity dyslipidaemia syndrome [54]. Genetic predisposition, lack of exercise, and body fat distribution all affect the likelihood that a given obese subject will become overtly diabetic or develop CVD.

The metabolic syndrome should not be confused with another disorder called syndrome X in which angina pectoris occurs in patients with normal coronary arteries. Because metabolic syndrome traits co-occur, patients with just a few traits are likely to have many other traits as well as insulin resistance [55]. Whether it is valuable to assess insulin resistance in addition to more readily measured traits of the syndrome is currently uncertain. Guidelines from the 2001 National Cholesterol Education Program (Adult Treatment Panel [ATP] III) suggest that the clinical identification of the metabolic syndrome should be based upon the presence of *any three* of the following traits [56]:

- Abdominal obesity, defined as a waist circumference in men >102 cm (40 in) and in women >88 cm (35 in). ATP III recognized that some men develop multiple metabolic risk factors when waist circumference is only marginally increased (94 to 102 cm [37 to 39 in]); such patients may have a genetic contribution to insulin resistance.
- Serum triglycerides ≥150 mg/dL (1.7 mmol/L).
- Serum HDL cholesterol <40 mg/dL (1 mmol/L) in men and <50 mg/dL (1.3 mmol/L) in women.
- Blood pressure ≥130/85 mmHg.

- Fasting plasma glucose (FPG) ≥110 mg/dL (6.1 mmol/L). However, a 2004 report from the National Heart, Lung, and Blood Institute and the American Heart Association recommended that the FPG threshold be lowered to ≥100 mg/dL (5.6 mmol/L) [54]. This is in accordance with a 2003 recommendation from the American Diabetes Association redefining impaired FPG as ≥100 mg/dL (5.6 mmol/L) [37].

The complications resulting from metabolic syndrome and type 2 diabetes are a significant cause of morbidity and mortality. The chronic hyperglycaemia is associated with long-term dysfunction, damage, and failure of various organs, especially the eyes, kidneys, nerves, heart, and blood vessels. Individuals with type 2 diabetes are also at a significantly higher risk for coronary heart disease, peripheral vascular disease, and stroke, and they have a greater likelihood of having dyslipidaemia, hypertension, and obesity [47, 48, 57-61]. Thus, other traits of the metabolic syndrome besides hyperglycaemia often are present in patients with type 2 diabetes. Because of these abnormalities, patients with type 2 diabetes have a further increased risk of developing macrovascular complications (myocardial infarction and stroke) [49].
The treatment of diabetes has become increasingly sophisticated, with over a dozen pharmacological agents available to lower blood glucose, a multitude of ancillary supplies and equipment available, and a clear recognition by health care professionals and patients that diabetes is a serious disease. Nevertheless the normalization of blood glucose for any appreciable period of time is seldom achieved [62]. In addition, in well-controlled so called “intensively” treated patients, serious complications still occur [63-66], and the economic and personal burden of diabetes remains. Furthermore, microvascular disease is already present in many individuals with undiagnosed or newly diagnosed type 2 diabetes [67-70].

There is growing evidence that at glucose levels above normal but below the diabetes threshold diagnostic now referred to as pre-diabetes (impaired glucose homeostasis; IFG / IGT), there is a substantially increased risk of cardiovascular disease (CVD) and death [61, 71-74]. In the absence of pregnancy, IFG and IGT are therefore not clinical entities in their own right but rather risk factors for future diabetes and cardiovascular disease [40]. IFG and IGT are associated with the

metabolic syndrome [47] and appear as risk factors for type 2 diabetes at least in part because of their correlation with insulin resistance, which is directly involved in the pathogenesis of this type of diabetes [2]. In contrast, the explanation for why IFG and IGT are also risk factors for cardiovascular disease is less clear. The metabolic syndrome includes well-recognized cardiovascular risk factors such as low HDL levels and hypertension. In addition, it includes hypertriglyceridaemia, which is highly correlated with small dense LDL and increased plasminogen activator inhibitor-1 (PAI-1) levels. The former is thought to have enhanced atherogenicity, perhaps as a result of its greater vulnerability to oxidation than normal LDL. PAI-1 is a cardiovascular risk factor probably because it inhibits fibrinoloysis. Thus, the insulin resistance syndrome contains many features that increase cardiovascular risk. IFG and IGT may not in themselves be directly involved in the pathogenesis of cardiovascular disease, but rather may serve as statistical risk factors by association because they correlate with those elements of the insulin resistance syndrome that are cardiovascular risk factors [2]. But the fact that CVD risk factors are more prevalent in individuals with impaired glucose homeostasis [61, 67, 71, 73, 75-78], which of course further increases the cardiovascular risk, is possibly not sufficient to totally explain the increased risk for cardiovascular disease and death of those individuals [79].

In contrast to the clear benefit of glucose lowering to prevent or retard the progression of microvascular complications associated with diabetes [63-66], it is less clear whether the high rate of CVD in people with impaired glucose homeostasis, i.e., those with impaired fasting glucose (IFG), impaired glucose tolerance (IGT), or diabetes, is caused by elevated blood glucose levels or will respond to treatments that lower blood glucose. Epidemiological studies have shown a clear relationship [22, 80], whereas intervention trials in people with diabetes suggest, but have not demonstrated, a clear benefit of glycemic control [63, 64, 66]. Additionally, there are no studies that have investigated a benefit of glucose lowering on macrovascular disease in subjects with only pre-diabetes (IFG or IGT) but not diabetes.

1.2 Screening for type 2 diabetes and cardiovascular risk factors

1.2.1 Risk factors for type 2 diabetes

Type 2 diabetes is often asymptomatic in its early stages and can remain undiagnosed for many years [81]. Because early detection and prompt treatment may reduce the burden of diabetes and its complications, screening for diabetes may be appropriate under certain circumstances [81].

There are certain risk factors that either directly cause type 2 diabetes or are associated with it. The correlation of a risk factor(s) with development of diabetes is never 100%. However, the greater the number of risk factors present in an individual, the greater is the chance of this individual developing or having diabetes. Conversely, the chance of an asymptomatic individual without any risk factors having or developing diabetes is relatively low [81, 82].

The risk of developing type 2 diabetes increases with age, obesity, and lack of physical activity (see Table 2 [82]). Type 2 diabetes is more common in individuals with a family history of the disease and in members of certain racial/ethnic groups. It occurs more frequently in women with prior GDM or polycystic ovary syndrome and in individuals with hypertension, dyslipidaemia, impaired glucose tolerance, or impaired fasting glucose [82].

Table 2: Risk factors for type 2 diabetes

Age ≥45 years
Overweight (BMI ≥25 kg/m^2*)
Family history of diabetes (i.e., parents or siblings with diabetes)
Habitual physical inactivity
Race/ethnicity (e.g., African-Americans, Hispanic-Americans, Native Americans, Asian-Americans, and Pacific Islanders)
Previously identified IFG or IGT
History of GDM or delivery of a baby weighing >9 lbs
Hypertension (≥140/90 mmHg in adults)
HDL cholesterol ≤35 mg/dl (0.90 mmol/l) and/or a triglyceride level ≥250 mg/dl (2.82 mmol/l)
Polycystic ovary syndrome
History of vascular disease

*May not be correct for all ethnic groups.

1.2.2 Principles to assess the value of screening for type 2 diabetes

There is a major distinction between diagnostic testing and screening. When an individual exhibits symptoms or signs of the disease, diagnostic tests are performed, and such tests do not represent screening. The purpose of screening is to identify asymptomatic individuals who are likely to have diabetes. Separate diagnostic tests using standard criteria are required after positive screening tests to establish a definitive diagnosis [81].
Generally, screening in asymptomatic populations is appropriate when seven conditions are met [81]:

1) The disease represents an important health problem that imposes a significant burden on the population.
2) The natural history of the disease is understood.
3) There is a recognizable preclinical (asymptomatic) stage during which the disease can be diagnosed.
4) Tests are available that can detect the preclinical stage of the disease, and the tests are acceptable and reliable.
5) Treatment after early detection yields benefits superior to those obtained when treatment is delayed.
6) The costs of case finding and treatment are reasonable and are balanced in relation to health expenditures as a whole, and facilities and resources are available to treat newly diagnosed cases.
7) Screening will be a systematic ongoing process and not merely an isolated one-time effort.

For type 2 diabetes, conditions 1–4 are met. Conditions 5–7 have not been met entirely because there are no randomized clinical trials documenting the effectiveness of screening programs in decreasing mortality and morbidity from diabetes, and some controversy exists regarding the cost-effectiveness of screening and whether screening as currently carried out is a systematic and ongoing process.
Randomized clinical trials would be the best means to evaluate the benefits and risks of diabetes screening and early treatment. However, rigorous studies that apply currently available treatments to a screened group but not to a control group have not been done and are unlikely to be performed soon because of feasibility, ethical

concerns, and costs. Thus, while it is well established that treating diabetes diagnosed through standard clinical practice is effective in reducing diabetic microvascular complications [63], it is unknown whether the additional years of treatment that might be received by individuals diagnosed through screening would result in clinically important improvements in diabetes-related outcomes. A large clinical trial, the Diabetes Prevention Program (DPP), was performed in the U.S [83]. It has been designed to answer the question of whether treatment with lifestyle interventions or metformin for patients with IGT or IFG detected through a screening program will reduce the incidence of type 2 diabetes. As the DPP has demonstrated a reduction in the incidence of type 2 diabetes as a result of the lifestyle interventions, more widespread screening for these conditions, which would incidentally detect many cases of asymptomatic diabetes, possibly may be justified [82].

The effectiveness of screening may also depend on the setting in which it is performed. In general, community screening outside a health care setting may be less effective because of the failure of people with a positive screening test to seek and obtain appropriate follow-up testing and care or, conversely, to ensure appropriate repeat testing for individuals who screen negative. That is, screening outside of clinical settings may yield abnormal tests that are never discussed with a primary care provider, low compliance with treatment recommendations, and a very uncertain impact on long-term health. Community screening may also be poorly targeted, i.e., it may fail to reach the groups most at risk and inappropriately test those at low risk (the worried well) or even those already diagnosed [82].

1.2.3 General recommendations of the ADA for screening of type 2 diabetes

Based on the lack of data from prospective studies on the benefits of screening and the relatively low cost-effectiveness of screening suggested by existing studies, the American Diabetes Association (ADA) recommends in the clinical practice recommendations [82] that the decision to test for diabetes should ultimately be based on clinical judgment and patient preference.

On the basis of expert opinion [82], screening should be considered by health care providers at 3-year intervals beginning at age 45, particularly in those with BMI ≥25 kg/m^2. The rationale for this interval is that false negatives will be repeated before substantial time elapses, and there is little likelihood of an individual

developing any of the complications of diabetes to a significant degree within 3 years of a negative screening test result.

Testing should be considered at a younger age or be carried out more frequently in individuals who are overweight and have one or more of the other risk factors shown in Table 2. Moreover testing may be considered in other high-risk patients who display any of the following characteristics:

- Have a family history of type 2 diabetes in first- and second-degree relatives;
- Belong to a certain race/ethnic group (Native Americans, African-Americans, Hispanic Americans, Asians/South Pacific Islanders);
- Have signs of insulin resistance or conditions associated with insulin resistance (acanthosis nigricans, hypertension, dyslipidaemia, polycystic ovary syndrome).

Although there is ample scientific evidence showing that certain risk factors predispose individuals to development of diabetes (Table 1), there is insufficient evidence to conclude that community screening is a cost-effective approach to reduce the morbidity and mortality associated with diabetes in presumably healthy individuals. While community screening programs may provide a means to enhance public awareness of the seriousness of diabetes and its complications, other less costly approaches may be more appropriate, particularly because the potential risks are poorly defined. Thus, based on the lack of scientific evidence, community screening for diabetes, even in high-risk populations, is not recommended. The ADA concludes that although the burden of diabetes is well known, the natural history is well characterized, and there is good evidence for benefit from treating cases diagnosed through usual clinical care, there are no randomized trials demonstrating the benefits of early diagnosis through screening of asymptomatic individuals. Considering the methodological difficulties it is not surprising that such trials are missing. Nevertheless, according to the ADA recommendations, there is sufficient indirect evidence to justify opportunistic screening in a clinical setting of individuals at high risk. Also, clinicians should be vigilant in evaluating clinical presentations suggestive of diabetes [82].

1.2.4 Recommended tests in screening for type 2 diabetes

The best screening test for diabetes recommended by the ADA [82], the fasting plasma glucose (FPG), is also a component of diagnostic testing (see Table 1). The FPG test and the 75-g oral glucose tolerance test (OGTT) are both suitable tests for diabetes; however, the FPG test is preferred in clinical settings because it is easier and faster to perform, more convenient and acceptable to patients, and less expensive [3]. An FPG ≥126 mg/dl (7.0 mmol/l) is an indication for retesting, which should be repeated on a different day to confirm a diagnosis. If the FPG is <126 mg/dl (7.0 mmol/l) and there is a high suspicion for diabetes, an OGTT should be performed. A 2-h postload value in the OGTT ≥200 mg/dl (11.1 mmol/l) is a positive test for diabetes and should be confirmed on an alternate day [3, 37, 82].

Nondiabetic individuals with an FPG ≥100 mg/dl (5.6 mmol/l) but <126 mg/dl (7.0 mmol/l) are considered to have IFG, and those with 2-h values in the OGTT ≥140 mg/dl (7.8 mmol/l) but <200 mg/dl (11.1 mmol/l) are defined as having IGT. Patients with IFG and/or IGT are now referred to as having “pre-diabetes,” indicating the relatively high risk for development of diabetes in these patients. Normoglycaemia is defined as plasma glucose levels <100 mg/dl (5.6 mmol/l) in the FPG test and a 2-h postload value <140 mg/dl (7.8 mmol/l) in the OGTT [3, 37].

If necessary, plasma glucose testing may be performed on individuals who have taken food or drink shortly before testing. Such tests are referred to as *casual plasma glucose measurements* and are given without regard to time of last meal. A casual plasma glucose level ≥200 mg/dl (11.1 mmol/l) with symptoms of diabetes is considered diagnostic of diabetes. A confirmatory FPG test or OGTT should be completed on a different day if the clinical condition of the patient permits [82].

Laboratory measurement of plasma glucose concentration is performed on venous samples with enzymatic assay techniques, and the above-mentioned values are based on the use of such methods. The HbA_{1c} test values remain a valuable tool for monitoring glycaemia, but it is not currently recommended for the screening or diagnosis of diabetes. Pencil and paper tests, such as the American Diabetes Association’s risk test, may be useful for educational purposes but do not perform well as stand-alone tests. Capillary blood glucose testing using a reflectance blood glucose meter has also been used, but because of the imprecision of this method, it is better used for self-monitoring rather than as a screening tool [82]. In a report of the WHO and International Diabetes Federation in 2003 [84], fasting capillary blood

glucose is regarded as a possible approach in screening for type 2 diabetes but not yet well investigated concerning appropriate cut-off points. It is very important that screening tests are evaluated regarding sensitivity and speciticity [84]. The *sensitivity* of a screening test is the proportion of people with the disorder who test positive on the screening test (a highly sensitive screening test is unlikely to miss a subject with diabetes). The *specificity* of a screening test is the proportion of people who do not have the disorder who test negative on the screening test (a highly specific test is unlikely to misclassify someone who does not have diabetes as having diabetes.) Although it is desirable to have a test that is both highly sensitive and highly specific, this is usually not possible. In choosing a cut-off point a trade-off needs to be made between sensitivity and specificity, since increasing one reduces the other. The receiver operator characteristic (ROC) curve expresses this relationship. The true positive rate (sensitivity) is plotted on the y axis against the false positive rate (1-specificity) over a range of cut-off values. Tests that discriminate well crowd toward the upper left corner of the ROC curve. In ideal cases, as sensitivity increases, there is little decrease in specificity, until very high levels of sensitivity are reached [84].

1.3 Health promotion and lifestyle change in the prevention of type 2 diabetes and cardiovascular disease

Diabetes is one of the most costly and burdensome chronic diseases of our time and is a condition that is increasing in epidemic proportions in the U.S. and throughout the world [85, 86]. It is estimated that in 2025 about 300 millions of persons worldwide will be affected by type 2 diabetes (see Figure 2). For Switzerland in particular it is estimated that in 2030 about 340’000 persons will be affected by type 2 diabetes [87].

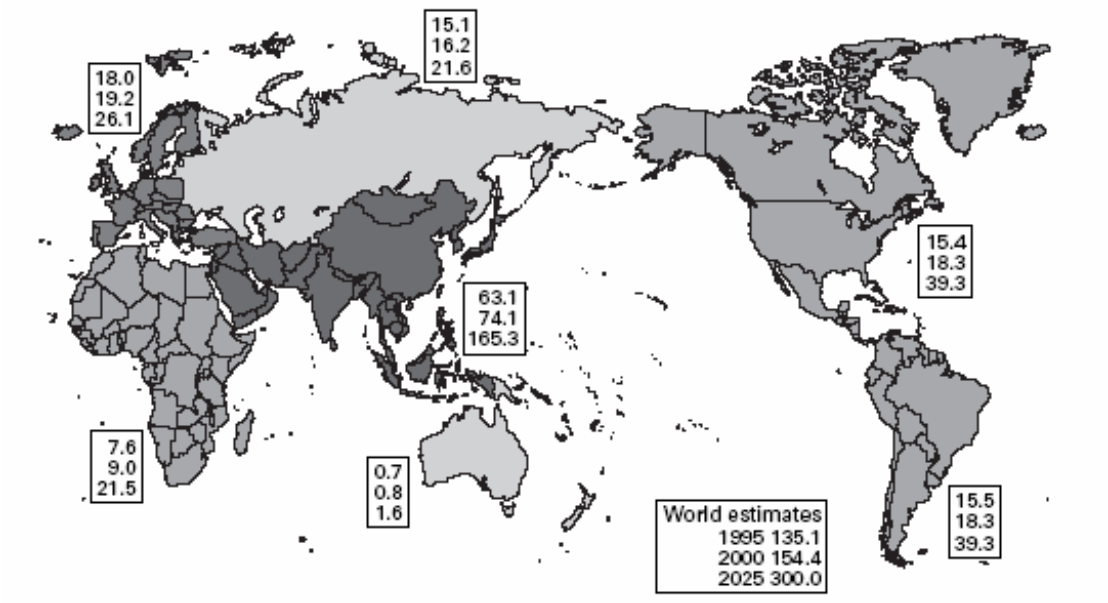

Figure 2: Regional estimates of people with diabetes mellitus (in millions) for 1995, 2000, and 2025.

Given these facts, it is not surprising that studies have been initiated in the last decade to determine the feasibility and benefit of various strategies to prevent or delay the onset of type 2 diabetes. Two early reports [88, 89] suggested that changes in lifestyle can prevent diabetes, but weaknesses in study design limited their general relevance. Recently, however, four well-designed randomized controlled trials have been reported [83, 90-93].

In the Finnish study [90], 522 middleaged (mean age 55 years) obese (mean BMI 31 kg/m2) subjects with IGT were randomized to receive either brief diet and exercise counseling (control group) or intensive individualized instruction on weight reduction, food intake, and guidance on increasing physical activity (intervention group). After an average follow-up of 3.2 years, there was a 58% relative reduction in the incidence of diabetes in the intervention group compared with the control subjects. A strong correlation was also seen between the ability to stop the progression to diabetes and the degree to which subjects were able to achieve one or more of the following: lose weight (goal of 5.0% weight reduction), reduce fat intake (goal of <30% of calories), reduce saturated fat intake (goal of <10% of calories), increase fiber intake (goal of ≥15 g/1,000 kcal), and exercise (goal of >150 min/week). No untoward effects of the lifestyle interventions were observed.

In the Diabetes Prevention Program (DPP) [83, 91, 92], the 3,234 enrolled subjects were slightly younger (mean age 51 years) and more obese (mean BMI 34 kg/m2)

but had nearly identical glucose intolerance compared with subjects in the Finnish study. About 45% of the participants were from minority groups (e.g, African-American, Hispanic), and 20% were ≥60 years of age. Subjects were randomized to one of three intervention groups, which included the intensive nutrition and exercise counseling ("lifestyle") group or either of two masked medication treatment groups: the biguanide metformin group or the placebo group. The latter interventions were combined with standard diet and exercise recommendations. After an average follow-up of 2.8 years (range 1.8–4.6 years), a 58% relative reduction in the progression to diabetes was observed in the lifestyle group (absolute incidence 4.8%), and a 31% relative reduction in the progression of diabetes was observed in the metformin group (absolute incidence 7.8%) compared with control subjects (absolute incidence 11.0%). On average, 50% of the lifestyle group achieved the goal of ≥7%weight reduction, and 74% maintained at least 150 min/week of moderately intense activity. No serious side effects were seen in any group.

Two other studies, each using a different class of glucose-lowering agent, have shown a reduction in progression to diabetes with pharmacological intervention. In the Troglitazone in Prevention of Diabetes (TRIPOD) study [93], 235 Hispanic women with previous gestational diabetes were randomized to receive either placebo or troglitazone (a drug now withdrawn from commercial sale in the U.S. but belonging to the thiazolidinedione class, of which two related drugs are currently available). The mechanism of action of the thiazolidinedione drugs is based upon a reduction of insulin resistance ("insulin sensitizers"). After a median follow-up of 30 months, the annual incidence of type 2 diabetes in the two groups was 12.3 and 5.4%, respectively. Thus, troglitazone treatment was associated with a 56% relative reduction in progression to diabetes.

In the STOP-NIDDM trial [94, 95], 1,429 participants with IGT were randomized in a double-blind fashion to receive either the α-glucosidase inhibitor acarbose or a placebo. The subjects had a mean age of 55 years and a mean BMI of 31 kg/m2. After a mean follow-up of 3.3 years, a 25% relative risk reduction in progression to diabetes, based on one OGTT, was observed in the acarbose-treated group compared with the placebo group. If this diagnosis was confirmed by a second OGTT, a 36% relative risk reduction was observed in the acarbose group compared with the placebo group. The absolute risk reduction in the acarbose-treated group

was 9%. The effect of acarbose was consistent among all age groups, BMI values and between both sexes.

The ADA and the National Institute of Diabetes and Digestive and Kidney Diseases concluded from these findings that there is now substantial evidence that type 2 diabetes can be prevented or delayed. Individuals at high risk of developing diabetes (those with pre-diabetes) can be identified easily. It is not yet known whether the successful interventions will cost-effectively reduce the morbidity and mortality associated with diabetes. Diabetes prevention policies that focus on lifestyle modification, specifically modest weight loss and increased physical activity, are also very likely to have additional health benefits. Public health messages, health care professionals, and health care systems should all encourage behaviour changes to achieve a healthy lifestyle. Further research is necessary to understand better how to facilitate effective and efficient programs for the primary prevention of type 2 diabetes [79].

To reduce the risk for coronary heart disease (CHD) the Third Report of the National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III; ATP III) [96] recommends a multifactorial lifestyle approach. This approach is referred to as *therapeutic lifestyle change* (TLC) and includes the following components: reduced intake of saturated fats and cholesterol, therapeutic dietary options for enhancing LDL (low density lipoprotein) lowering, weight reduction and increased regular physical activity. According to the ATP III, at all stages of dietary therapy, physicians are encouraged to refer patients to registered dieticians or other qualified nutritionists. A high proportion of patients with the metabolic syndrome are overweight or obese and sedentary; for them, weight reduction therapy and physical activity guidance is required to obtain further CHD risk reduction beyond that achieved by LDL lowering through dietary alterations.

1.4 Community pharmacies – a suitable setting for screening and health promoting activities

Community pharmacists are well placed to assist in the provision of preventive care because pharmacies are highly accessible and often the first point of entry into the health care system [97-99]. Pharmacies are regarded to be a suitable place to promote awareness, screen high-risk patients, and to counsel patients on

intervention strategies to delay the onset of diabetes and CVD [82, 100, 101]. Moreover, community pharmacists are in an excellent position to collaborate with other health professionals in screening, monitoring and educating patients with diabetes and cardiovascular risk to prevent long-term complications.

Investigations on implementation of screening programs in community pharmacy practice have already been performed. A lipid screening program in a large chain pharmacy with 159 participants was evaluated [102]. The investigators concluded that the screening program was successfully implemented in community pharmacy practice, but nevertheless more efforts need to be devoted to marketing this service to create value for the customer and to establish it as a viable component of pharmacy business. Another study investigated the implementation of a pharmacist-delivered screening service for cardiovascular risk factors. The authors concluded that community pharmacies are a feasible site for health promotion and screening services for cardiovascular risk factors [103]. Another study demonstrated that, through ongoing screening programs, community pharmacists are in an ideal position to screen patients at risk for cardiovascular and cerebrovascular disease and refer patients to their physicians for further evaluation [104]. For early detection of type 2 diabetes, a combination of risk factor assessment and blood glucose measurement performed in community pharmacies is regarded to be a promising approach and an opportunity for health promotion [82]. However, triage guidelines for diabetes screening in community pharmacies and appropriate cut-off points for capillary blood glucose are largely missing.

Intervention studies in community pharmacies have been performed and they have been shown to have positive effects on cardiovascular risk factors, for example by improving outcomes in hypertension or cholesterol management [105-107]. There is growing evidence that incorporating a pharmacist or some services typically provided by traditional pharmacists into physician practices can improve blood pressure control [108]. A randomized controlled trial has shown that successful weight management can be achieved in a pharmacy setting, where patients have been consulted by the pharmacist every 3 weeks for a time period of 5 months [109]. Moreover, a community pharmacy diabetes care program has shown a clear relationship between pharmaceutical care services and improved HbA_{1c}, improved patient satisfaction with pharmacy services, and decreased all-diagnosis costs. The

authors concluded that pharmacists can act as appropriate diabetes educators to help patients with diabetes improve clinical outcomes [110].

There is enough evidence that community pharmacies are a suitable setting to promote awareness, screen high-risk patients, and to deliver health promoting counselling to persons at risk for diabetes and cardiovascular disease. Unfortunately, triage guidelines for diabetes and/or lipid screening in community pharmacies and appropriate cut-off points for measurements in capillary blood are missing. In addition, measurements used in pharmacy-based screenings for diabetes or cardiovascular risk (such as blood pressure and blood glucose) are not validated.

1.5 Swiss national diabetes screening campaign

With the background described above, the Swiss federation of pharmacists has organised in spring 2002 a national “Self Care” diabetes screening campaign in Switzerland called “Stopp Zucker – Jetzt testen!”. The goal of this campaign was to detect individuals with previously undiagnosed type 2 diabetes and to provide information and advice towards lifestyle change for persons at risk. The campaign has been prepared in an interdisciplinary and multi-institutional collaboration with physicians, experts in the field of diabetes, health promotion or public health and representatives of patient organisations and health insurances. The pharmaceutical care research group at the Institute of Clinical Pharmacy, University of Basel, was assigned to evaluate the screening activities of the campaign. This presupposed the development of a screening concept with triage guidelines and cut-off points for capillary blood glucose measurement. The campaign attracted a large number of persons and resulted in a huge amount of data. For this reason, the evaluation was limited on the data records obtained in the German speaking part of Switzerland. The campaign was later enlarged with a 3 step follow-up study aiming to investigate the impact of a community pharmacy based screening campaign and to enable additional intervention studies.

As dyslipidaemia is like type 2 diabetes associated with an increased risk for cardiovascular disesase, it makes sense to develop a screening concept for metabolic syndrome including screening for type 2 diabetes and dyslipidaemia. A regional screening campaign in community pharmacies gave the opportunity to evaluate in a pilot study the elaborated pharmacy-based triage guidelines for lipid screening.

1.6 Aim of the thesis

The aim of this thesis was to develop and evaluate screening guidelines for cardiovascular risk factors in community pharmacy practice (in particular for type 2 diabetes and dyslipidaemia) including appropriate cut-off points for triage decisions and to investigate the changes in lifestyle behaviour after a pharmacy-based screening campaign and related activities.

As key elements towards these aims, the following projects were elaborated in this thesis:

Blood pressure measurement in community pharmacy practice

Hypertension is a major risk factor for cardiovascular disease. It is therefore important to include blood pressure measurement in any screening for cardiovascular risk factors. Moreover, blood pressure measurement is offered by most community pharmacies with the aim to screen for undetected hypertension or to monitor treated patients.

Project A: The objective of this project was the validation of blood pressure measurement in community pharmacy practice. Therewith it was the aim to investigate whether a white coat effect and white coat hypertension, as known from blood pressure measurement by physicians, can also be observed in community pharmacy practice.

Screening campaigns in community pharmacies

Community pharmacies are regarded as a suitable setting to promote awareness and screen high-risk persons for diabetes and cardiovascular disease. Unfortunately, triage guidelines for diabetes and lipid screening in community pharmacy practice are missing.

Project B: It was the aim of this project to develop a sequential screening concept for type 2 diabetes in community pharmacy practice. A national diabetes screening campaign (Self Care 2002: “Stopp Zucker – Jetzt testen!)

provided the possibility to evaluate the elaborated triage guidelines and cut-off points for capillary blood glucose measurements.

Project C: The objective of this project was in the context of a pilot study to implement screening for dyslipidaemia in a regional pharmacy-based campaign and to investigate the developed triage guidelines and cut-off points for lipid screening in community pharmacies.

Health promotion and lifestyle change

There is growing evidence that weight loss and lifestyle changes in nutrition habits and physical activity have positive effects on the prevention of diabetes and cardiovascular risk. Therefore health promoting counselling in suitable and cost-effective settings, which is able to induce lifestyle changes and weight loss, would be of great value.

Project D: It was the objective of this project to investigate the changes in lifestyle and body weight after immediate counselling in community pharmacies during a national screening campaign for type 2 diabetes.

Project E: In an additional randomised controlled trial it was the aim to investigate the effect of a telephone-based counselling on lifestyle changes and body weight of persons at risk for type 2 diabetes.

2 Blood pressure measurement in community pharmacies

Project A:

White coat effect and white coat hypertension in community pharmacy practice

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Abstract provided at
http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&dopt=Citation&list_uids=15687869

Abstract

Objective

The aim of the present study was to investigate whether a white coat effect (WCE) can be observed and quantified in community pharmacy practice.

Methods

In five community pharmacies of Basel, Switzerland, clients asking for blood pressure (BP) measurement were recruited to participate in a free of charge study. Blood pressure was measured in four different settings: pharmacy (using mercury sphygmomanometers), outpatient clinic (measurement by a nurse using mercury sphygmomanometers), self-measurement at home (using automated wrist devices) and daytime ambulatory BP (ABP) monitoring (using SpaceLabs 90207 monitors). White coat effect was defined as the difference between pharmacy or outpatient and daytime ABP.

Results

A total of 50 subjects completed all measurements (42% male, mean age 53.7 years ± 14.0). Blood pressure values of the different settings: (means in mmHg ± SD, systolic; diastolic): pharmacy BP 129 ± 19; 82 ± 10, outpatient clinic BP 127 ± 15; 82 ± 10, home BP 119 ± 15; 73 ± 9, daytime ABP 124 ± 10; 79 ± 8. Pharmacy BP was significantly higher ($p=0.03$ systolic; $p=0.02$ diastolic) compared with daytime ABP and differences among subjects with antihypertensive medication (n=22) were even more significant ($p<0.01$). Individual differences were found between pharmacy BP and daytime ABP: +4.6 ± 14.8; +2.9 ± 8.3. Outpatient BP was significantly higher compared with daytime ABP in diastolic ($p=0.04$) but not in systolic values. Individual differences between outpatient BP and daytime ABP were +2.5 ± 13.1; +2.8 ± 9.2. ‘Clinically important WCE’ (>=20 mmHg systolic or >=10 mmHg diastolic) was observed in 24% of all subjects in the pharmacy and in 20% in the outpatient clinic.

Conclusions

Our findings show that white coat effect and white coat hypertension exist in community pharmacy practice and are similar to the effects in an outpatient clinic.

Keywords

blood pressure measurement • white coat effect • white coat hypertension • community pharmacy services • pharmaceutical care

Introduction

Blood pressure measurement is probably the most common medical measurement and also offered by most community pharmacies with the aim to screen for undetected hypertension or to monitor treated patients. Since this contribution of pharmacists to health care and prevention has become normal duty, the reliability of the measurement is of particular importance.

From several studies it is well known that standard measurement of blood pressure in a clinical environment may trigger an alerting reaction resulting in a rise of blood pressure in the patient [1, 2]. This phenomenon is called the 'white coat effect' (WCE) and is generally defined as the difference between clinic blood pressure and daytime ambulatory blood pressure (ABP) [3, 4]. Attention has also focused on 'white coat hypertension' (WCH), which is usually defined as an elevated clinic blood pressure compared to normal daytime ABP. Thus white coat hypertension (also called 'isolated office hypertension') is defined as high blood pressure levels (≥140/90 mmHg) at the clinic or medical office, but normal blood pressure levels on ABP monitoring with daytime mean blood pressure below 135/85 mmHg [5, 6]. The prevalence of WCH is approximately 20%, varying according to the criteria adopted for normotension and hypertension [4, 7]. It is important to mention that white coat hypertension and white coat effect are different entities. The first is a binary (yes/no) definition imposed by stratification of blood pressure and the second a quantitative measure of blood pressure rise resulting from clinic visit.

The clinical significance of white coat hypertension and its effect is currently not well described. Some studies have suggested that the risk of future cardiovascular disease events is less in subjects with WCH (elevated clinic/office blood pressure and normal daytime ABP) than in those with sustained hypertension (elevated clinic/office blood pressure and elevated daytime ABP) [8-10]. On the other hand, studies suggested that subjects with WCH are also at increased risk for target organ damage and cardiovascular events [11, 12].

More recently, a phenomenon opposed to white coat hypertension has drawn attention. Masked hypertension is characterized by persistently normal blood pressure levels at the medical office and hypertension on ABP [13]. The prevalence

of masked hypertension ranges from 14% to 30%. It often occurs in older patients with greater body mass indices [14].

To assess the white coat phenomenon, not only ABP monitoring has been performed but also self-measured home blood pressure (HBP). In fact HBP showed less reliability than ABP in detecting WCE, but is nevertheless regarded as an eligible method [3, 7, 15, 16]. Self-reported blood pressure values have been shown to be largely reliable [17, 18], whereas other studies suggest the contrary [19], [20].

For pharmacy practice it could be expected that comparable white coat effects exist, possibly depending on measurement technique (with mercury sphygmomanometer or with automated devices). However, no findings are published on extent and importance of the white coat phenomenon in community pharmacies. Such investigations would be valuable for pharmacy practice, mainly for decisions in pharmaceutical triage after blood pressure measurement. The aim of the present study was to investigate whether the white coat effect could also be observed in a community pharmacy setting. For this purpose we evaluated the variation in blood pressure of subjects between different settings: a) blood pressure measurement in the pharmacy; b) in a clinical setting (measurement by a nurse); c) at home and d) with ambulatory blood pressure monitoring. We also studied the prevalence of white coat hypertension and masked hypertension in our sample.

Methods

Subjects

Over a period of eight weeks in Spring 2003, clients were recruited to this free of charge study from five community pharmacies in Basel, Switzerland. The study population included 52 subjects who went to the pharmacies with the intention of having their blood pressure measured. The subjects were enrolled into the study if the following criteria were met: at least 18 years old and no serious sickness diagnosed. Out of the 52 subjects, two had to be excluded from the analysis because they abandoned ambulatory blood pressure monitoring. The subjects' ages varied from 27 to 83 years (mean 53.7 ± 14.0 years). The present study was approved by the Ethics Committee of Basel and informed consent was given by all participants.

Blood pressure measurements

Blood pressure was measured in the pharmacy, in the outpatient clinic, at home and with ABP monitoring. Before the study, the pharmacists from the five pharmacies that assisted in the study were carefully briefed on how perform blood pressure measurements properly. The pharmacist measured pharmacy blood pressure in the morning using a standard mercury sphygmomanometer with an appropriate cuff for the arm's circumference. All sphygmomanometers used in this study had been calibrated at most within the last 24 months. After the study participant had rested for five minutes in the sitting position, the measurements were taken on the participant's bare right arm, which was comfortably placed at heart level. The mean of two measurements was used.

In addition to blood pressure values, the following data were obtained in the pharmacy: age, sex, weight, height, smoking and existing antihypertensive treatment. For the self-measurement of blood pressure at home (HBP), the subjects used Omron HEM-637IT (Omron Corp., Tokyo, Japan) digital blood pressure monitors. This automated oscillometric device measures wrist artery pressure and has passed clinical validation according to the Association for the Advancement of Medical Instrumentation (AAMI), but not according to the British Hypertension Society (BHS) and International Protocol criteria [21]. At enrolment, the pharmacist instructed the study participants how to use the Omron recorders and provided written guidelines for their operation at home. The subjects recorded their blood pressure in the morning (between 06:00 h and 10:00 h) and in the evening (between 18:00 h and 22:00 h) for four consecutive days during the week. Each measurement session consisted of two readings after five minutes rest in the sitting position and with one minute in between the two recordings. Self-measured blood pressure values were noted by the study participant and kept in a diary. Additionally data stored in the memory of the devices was used to check the validity of recorded data. The average blood pressure of the measurement of the second to forth day was used for analysis. The cuff size (13.5 to 21.5 cm) of the Omron devices was suitable for all study participants.

At the medical outpatient department of the University Hospital of Basel, a nurse using a standard mercury sphygmomanometer with an appropriate cuff for the arm's

circumference measured blood pressure. The two nurses who assisted in the study were carefully briefed on how to perform blood pressure measurements properly. The measurements in the outpatient clinic were performed at nine o'clock. After the study participant had rested for five minutes in the sitting position, the measurements were taken on the participant's bare right arm, which was comfortably placed at heart level. The mean of two measurements was used as well.

After mercury sphygmomanometer measurement by the nurse, ABP monitoring was performed using oscillometric SpaceLabs 90207 monitors (Space Labs Inc., Redmond, Washington, USA), whose accuracies were checked monthly against a mercury column sphygmomanometer. The recorders were programmed to measure blood pressure every 20 minutes from 06:00 h and 18:00 h and every 30 minutes from 18:00 h to 06:00 h.

The monitoring was always performed on a working day, and the subjects were instructed to maintain their usual activities throughout the day. The appropriate cuff for the arm's circumference was placed on the non-dominant arm and the subjects were instructed to keep their arm stretched out along their body and not to move it during measurement. Recordings considered valid for analysis had a minimum duration of 24 hours and in total 54 valid readings were obtained, corresponding to at least 90% of all measurements. The average blood pressure of the daytime period was used, which was defined as the time interval between 06:00 h and 18:00 h

Analysis of data

Based on blood pressure measurements at the pharmacy and on average daytime ABP measurements, the subjects were divided into the following categories: a) sustained hypertension: systolic blood pressure at the pharmacy ≥140 mmHg or diastolic blood pressure ≥90 mmHg, or both, and mean of systolic or diastolic blood pressure of daytime ABP, respectively ≥135 mmHg or ≥85 mmHg, or both; b) white coat hypertension: systolic blood pressure at the pharmacy ≥140 mmHg or diastolic blood pressure ≥90 mmHg, or both, and mean of systolic and diastolic blood pressure of daytime ABP <135 mmHg and <85 mmHg, respectively; c) normotension: systolic blood pressure at the pharmacy <140 mmHg and diastolic blood pressure <90 mmHg, and mean of systolic and diastolic blood pressure of daytime ABP <135 mmHg and <85 mmHg, respectively; d) white coat normotension: systolic blood pressure at the pharmacy <140 mmHg and diastolic blood pressure

<90 mmHg, and mean of systolic or diastolic blood pressure of daytime ABP, respectively ≥135 mmHg or ≥85 mmHg, or both.

The WCE of each subject was defined as difference between the blood pressure measured in the pharmacy (systolic or diastolic) and the average daytime ABP (systolic or diastolic) as well as the difference between pharmacy blood pressure (systolic or diastolic) and the average HBP (systolic or diastolic). Subjects were also evaluated with regard to 'clinically important white coat effect' [4, 22], which was defined to exist if the difference between the pharmacy blood pressure measurement and the mean blood pressure values form the daytime ABP was ≥20 mmHg for systolic blood pressure and ≥10 mmgHg for diastolic blood pressure, respectively. Furthermore, subjects were identified as exhibiting a white coat response if they showed white coat hypertension (blood pressure at the pharmacy ≥140 mmHg and/or ≥90 mmHg and daytime ABP <135 mmHg and <85 mmHg) or a clinically important white coat effect.

Statistical analysis

The SPSS statistical package (SPSS, Inc, Chicago, Illinois, USA) was used to store and analyse the data. Values are expressed as mean ± standard deviation (SD) including 95% confidence intervals (CI). Blood pressure values were analysed using repeated analysis of variance (Generalized linear model: GLM) with linear contrasts to detect pair-wise differences using the measured values in the pharmacy as reference group. In particular differences between pharmacy and the other blood pressure measurements were assessed by paired t-tests, values of $p<0.05$ being considered statistically significant. All p-values were calculated two-sided.

Results

Characteristics of patients

The study group included 50 subjects of whom 21 (42.0%) were male, six (12.0%) were smokers and 22 (44.0%) were under antihypertensive medication. Among those under antihypertensive medication, 11 (50.0%) were receiving one class of antihypertensive drug, 7 (31.8%) were receiving two and 4 (18.1%) were receiving three or more different antihypertensive drugs. The subject's mean age was 53.7 years ± 14.0 (SD) and their average BMI was 25.2 kg/m^2 ± 3.7 (SD).

Blood pressure measurements at different settings

The means of blood pressure values of the different settings are given in Table 1. The level of blood pressure as measured in the pharmacy was significantly higher ($p=0.032$ for systolic blood pressure and $p=0.018$ for diastolic blood pressure, respectively) than that of ABP monitoring. However, there were considerable inter-individual variations. The level of pharmacy blood pressure was particularly significantly elevated compared to that of HBP ($p<0.001$ for both systolic and diastolic blood pressure). Outpatient clinic blood pressure was significantly higher compared with daytime ABP only in diastolic values ($p=0.037$) but not in systolic values. However there was no significant difference in the levels of pharmacy blood pressure versus outpatient clinic blood pressure measurements.

The means of blood pressure values of the subjects with antihypertensive medication ($n=22$) as well as of the subjects without antihypertensive medication ($n=28$) are given in Table 1. In the population with antihypertensive medication the level of blood pressure as measured in the pharmacy was higher than that of ABP monitoring with increased statistical significance compared with the whole population ($p=0.001$ for both systolic and diastolic blood pressure).

White coat effect

The mean of the white coat effects (individual differences between the blood pressure measured in pharmacy and the average daytime ABP) as well as the means of the differences between the blood pressure measured in the pharmacy and HBP of all subjects and of the populations with or without antihypertensive medication are given in Table 2. Analysing the white coat effect of all subjects, individual differences between pharmacy blood pressure and daytime ABP were +4.6 ± 14.8 mmHg for systolic blood pressure and +2.9 ± 8.3 mmHg for diastolic blood pressure. White coat effect in the outpatient clinic was +2.5 ± 13.1 mmHg for systolic blood pressure and +2.8 ± 9.2 mmHg for diastolic blood pressure and thus smaller than WCE measured in the pharmacy, even though not statistically significant. In the population with antihypertensive medication WCE was more expressed with individual differences between pharmacy blood pressure and daytime ABP being

+12.8 ± 15.3 mmHg for systolic blood pressure and +6.8 ± 8.5 mmHg for diastolic blood pressure.

In the pharmacy clinically important white coat effect (difference between pharmacy blood pressure and daytime ABP ≥20 mmHg for systolic blood pressure and/or ≥10 mmHg for diastolic blood pressure) was observed in 12 subjects (24.0%) from the whole study population and in 10 subjects (45.5%) of those persons with antihypertensive medication (n = 22). In the outpatient clinic clinically important white coat effect (difference between outpatient clinic blood pressure and daytime ABP ≥20 mmHg for systolic blood pressure and/or ≥10 mmHg for diastolic blood pressure) was observed in 10 subjects (20.0%) of the whole study population.

White coat hypertension and masked hypertension

Analysing the whole population as well as the populations with or without antihypertensive medication and considering the pharmacy blood pressure values and the mean value of daytime ABP, the following results were observed (Table 3): 54% of the subjects were normotensive, 18% were hypertensive, 16% showed white coat hypertension and 12% showed masked hypertension. In the population with antihypertensive medication (n=22) an increased number of persons with hypertension and white coat hypertension were observed: 27.3% were hypertensive, 22.7% were white coat hypertensive and only 4.5% showed masked hypertension. In the population without antihypertensive medication (n=28) an increased number of persons with masked hypertension were found (17.9%).

A white coat response (white coat hypertension and/or clinically important white coat effect) was shown by 16 subjects (32%) from the whole study population (n=50) and 12 subjects (54.5%) from the population taking antihypertensive medication (n=22).

Discussion

The results of our study show that white coat effect and white coat hypertension can also be observed in community pharmacy practice. Statistically significant differences were identified between pharmacy blood pressure levels and daytime ABP levels. Individual differences between the pharmacy blood pressure and the average

daytime ABP, which is usually defined as white coat effect, were 4.6 mmHg for systolic blood pressure and 2.9 mmHg for diastolic blood pressure in the whole study population. Furthermore we identified WCH in 16.0% of all subjects and in 22.7% of those subjects with antihypertensive medication, which demonstrates the potential for misclassification of hypertensive status if only pharmacy measurements are used. Another remarkable finding is the higher percentage of masked hypertension in the untreated population (17.9%) than in the population with antihypertensive medication (4.5%) as this topic is of increasing interest [23],[24].

Using HBP instead of ABP as reference for determining white coat effect, differences between the pharmacy blood pressure and HBP were 9.7 mmHg for systolic blood pressure and 9.0 mmHg for diastolic blood pressure. The difference between HBP and daytime ABP found in the present work is therefore quite consistent with data reported in the literature [3, 15, 16]. This difference probably not only reflects the different circumstances of measurement but also differences in measurement devices and in the number of measurements. Hond et al. investigated the white coat effect in a physician's practice in 247 hypertensive patients using both methods of ABP monitoring and HBP measurement [16]. The observed white coat effect using ABP, which was regarded as the reference method, was 7.2 mmHg for systolic blood pressure and 5.0 mmHg for diastolic blood pressure. Using HBP to determine white coat effect, they found 12.3 mmHg for systolic blood pressure and 8.6 mmHg for diastolic blood pressure. The findings of Hond et al. suggested that self-measurement at home cannot replace ambulatory monitoring and that both techniques have supplementary roles in the diagnosis of hypertension [16]. Because home devices are easy to use and relatively cheap the recommendation of home blood pressure measurement by pharmacists would therefore be reasonable, particularly in people with elevated blood pressure.

Several studies showed that the higher the blood pressure values, the more persons show clinically important white coat effect [4, 24]. In fact, the population with antihypertensive medication in the present study shows a more expressed white coat effect and a more frequent white coat hypertension than the untreated subjects. It can be supposed that if only hypertensive patients were included in our study, then the observed white coat effect would have been enhanced. Also the number of subjects exhibiting white coat hypertension would probably have been higher.

A limitation of the present study is the rather small number of study subjects. It would be very useful to perform further investigations using a greater number of patients with preferably comparable antihypertensive treatments. Even though not statistically significant, WCE found in pharmacy measurements were expressed more than in outpatient measures. It is possible that this could be due to an order effect (higher first pressures), since the pharmacy blood pressure measurements were the first step in the protocol.

Both pharmacy and outpatient clinic readings were taken using mercury sphygmomanometers, which is still the most common method for measuring blood pressure in Switzerland. The pharmacist himself always took readings in the pharmacy. Nevertheless, it is possible that the observed WCE would be smaller if automated devices would have been used.

A limitation of all studies investigating the white coat phenomenon is the definition of WCE. It has been criticised on the grounds that the difference between the clinic and ambulatory blood pressures will be influenced by many factors other than the stressor effect of the clinic visit. Clearly, the level of activity during the day will be a major factor and therefore, a patient who has a stressful day at work on the day of the ambulatory recording (and consequently a higher daytime blood pressure) is likely to show a smaller WCE than one who stays at home all day and is physically inactive. Another limitation of these studies is that the clinic (in our case pharmacy) and the ambulatory pressures are recorded on different days. This will tend to reduce reliability of the measure. In fact, it can be stated that because WCE is, by definition, a difference score, its reliability is likely to be relatively low [3].

In conclusion the white coat phenomenon also exists in community pharmacy practice. The results of the present study further suggest that WCE and WCH are even more likely to occur in the pharmacy than in an outpatient clinic, where a nurse measures blood pressure. This should be considered in screening for undetected hypertension as well as in monitoring of treated hypertensive patients. Therefore pharmacists as well as physicians should be aware of the existing white coat phenomenon in community pharmacy practice in order to give appropriate advice to patients. However, the white coat effect generated in community pharmacy practice seems to be smaller than that triggered by physicians. Thus blood pressure

measurements in community pharmacies seem to be at least as reliable as those of other health professionals.

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References

1. Mancia G, Bertinieri G, Grassi G, et al. Effects of blood-pressure measurement by the doctor on patient's blood pressure and heart rate. Lancet 1983; 2:695-8.

2. Mancia G, Parati G, Pomidossi G, Grassi G, Casadei R, Zanchetti A. Alerting reaction and rise in blood pressure during measurement by physician and nurse. Hypertension 1987; 9:209-15.

3. Pickering TG, Gerin W, Schwartz AR. What is the white-coat effect and how should it be measured? Blood Press Monit 2002; 7:293-300.

4. Verdecchia P, Schillaci G, Borgioni C, et al. White coat hypertension and white coat effect. Similarities and differences. Am J Hypertens 1995; 8:790-8.

5. Chobanian AV, Bakris GL, Black HR, et al. The Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure: the JNC 7 report. Jama 2003; 289:2560-72.

6. Verdecchia P, Staessen JA, White WB, Imai Y, O'Brien ET. Properly defining white coat hypertension. Eur Heart J 2002; 23:106-9.

7. Estlinbaum T, Martina B, Battegay E. White coat hypertension. Schweiz Med Forum 2002:360-5.

8. Verdecchia P, Porcellati C, Schillaci G, et al. Ambulatory blood pressure. An independent predictor of prognosis in essential hypertension. Hypertension 1994; 24:793-801.

9. Khattar RS, Senior R, Lahiri A. Cardiovascular outcome in white-coat versus sustained mild hypertension: a 10-year follow-up study. Circulation 1998; 98:1892-7.

10. Fagard RH, Staessen JA, Thijs L, et al. Response to antihypertensive therapy in older patients with sustained and nonsustained systolic hypertension. Systolic Hypertension in Europe (Syst-Eur) Trial Investigators. Circulation 2000; 102:1139-44.

11. Palatini P, Penzo M, Canali C, Dorigatti F, Pessina AC. Interactive action of the white-coat effect and the blood pressure levels on cardiovascular complications in hypertension. Am J Med 1997; 103:208-16.

12. Owens PE, Lyons SP, Rodriguez SA, O'Brien ET. Is elevation of clinic blood pressure in patients with white coat hypertension who have normal ambulatory blood pressure associated with target organ changes? J Hum Hypertens 1998; 12:743-8.

13. Selenta C, Hogan BE, Linden W. How often do office blood pressure measurements fail to identify true hypertension? An exploration of white-coat normotension. Arch Fam Med 2000; 9:533-40.

14. Liu JE, Roman MJ, Pini R, Schwartz JE, Pickering TG, Devereux RB. Cardiac and arterial target organ damage in adults with elevated ambulatory and normal office blood pressure. Ann Intern Med 1999; 131:564-72.

15. Stergiou GS, Zourbaki AS, Skeva II, Mountokalakis TD. White coat effect detected using self-monitoring of blood pressure at home: comparison with ambulatory blood pressure. Am J Hypertens 1998; 11:820-7.

16. Hond ED, Celis H, Fagard R, et al. Self-measured versus ambulatory blood pressure in the diagnosis of hypertension. J Hypertens 2003; 21:717-22.

17. Nordmann A, Frach B, Walker T, Martina B, Battegay E. Comparison of self-reported home blood pressure measurements with automatically stored values and ambulatory blood pressure. Blood Press 2000; 9:200-5.

18. Johnson KA, Partsch DJ, Rippole LL, McVey DM. Reliability of self-reported blood pressure measurements. Arch Intern Med 1999; 159:2689-93.

19. Bachmann LM, Steurer J, Holm D, Vetter W. To what extent can we trust home blood pressure measurement? A randomized, controlled trial. J Clin Hypertens (Greenwich) 2002; 4:405-7.

20. Mengden T, Hernandez Medina RM, Beltran B, Alvarez E, Kraft K, Vetter H. Reliability of reporting self-measured blood pressure values by hypertensive patients. Am J Hypertens 1998; 11:1413-7.

21. Altunkan S, Iliman N, Altunkan E. Accuracy of the new wrist blood pressure monitor (Omron 637 IT), for blood pressure measurement. J Hypertens 2003; 21 (suppl 4):S22 (abstract).

22. Myers MG, Oh PI, Reeves RA, Joyner CD. Prevalence of white coat effect in treated hypertensive patients in the community. Am J Hypertens 1995; 8:591-7.

23. Pickering TG, Davidson K, Gerin W, Schwartz JE. Masked hypertension. Hypertension 2002; 40:795-6.

24. Segre CA, Ueno RK, Warde KR, et al. White-coat hypertension and normotension in the League of Hypertension of the Hospital das Clinicas, FMUSP: prevalence, clinical and demographic characteristics. Arq Bras Cardiol 2003; 80:117-26.

Tables

Table 1: Blood pressure values of all subjects and of subjects with or without antihypertensive medication

	All subjects (n=50) Mean (95% CI) ± SD (mmHg)	Subjects with anti-hypertensive medication (n=22) Mean (95% CI) ± SD (mmHg)	Subjects without anti-hypertensive medication (n=28) Mean (95% CI) ± SD (mmHg)
Pharmacy BP			
systolic (mmHg)	129 (124 to 134) ± 19	138 (129 to 147) ± 20	122 (117 to 127) ± 14
diastolic (mmHg)	82 (79 to 85) ± 10	84 (80 to 88) ± 10	80 (76 to 84) ± 10
Outpatient clinic BP			
systolic (mmHg)	127 (123 to 131) ± 15	134 (126 to 142) ± 18	121 (117 to 126) ± 11
diastolic (mmg Hg)	82 (79 to 85) ± 10	84 (79 to 89) ± 11	80 (77 to 83) ± 8
Daytime ABP			
systolic (mmHg)	124 (121 to 127) ± 10	125 (119 to 131) ± 13	124 (121 to 127) ± 7
diastolic (mmHg)	79 (77 to 81) ± 8	77 (74 to 81) ± 8	80 (78 to 83) ± 7
Home blood pressure (HBP)			
systolic (mmHg)	119 (115 to 124) ± 15	126 (119 to 134) ± 17	114 (110 to 118) ± 11
diastolic (mmHg)	73 (70 to 75) ± 9	76 (71 to 80) ± 10	71 (67 to 74) ± 8

BP, blood pressure; ABP, ambulatory blood pressure

Table 2: Means of differences between the different blood pressure (BP) measurements

	All subjects (n=50) Mean (95% CI) ± SD (mmHg)	Subjects with anti-hypertensive medication (n=22) Mean (95% CI) ± SD (mmHg)	Subjects without anti-hypertensive medication (n=28) Mean (95% CI) ± SD (mmHg)
Pharmacy BP – Daytime ABP (=WCE)			
systolic	4.6 (0.4 to 8.9) ± 14.8	12.8 (6.0 to 19.6) ± 15.3	-1.8 (-6.0 to 2.5) ± 11.0
diastolic	2.9 (0.5 to 5.2) ± 8.3	6.8 (3.0 to 10.5) ± 8.5	-0.2 (-2.9 to 2.5) ± 6.9
Pharmacy BP – HBP			
systolic	9.7 (6.5 to 12.8) ± 11.1	11.5 (6.1 to 17.0) ± 12.3	8.2 (4.3 to 12.1) ± 10.1
diastolic	9.0 (6.6 to 11.4) ± 8.4	8.4 (4.5 to 12.3) ± 8.8	9.5 (6.3 to 12.7) ± 8.2
Outpatient clinic BP – Daytime ABP			
systolic	2.5 (-1.2 to 6.3) ± 13.1	8.8 (1.9 to 15.7) ± 15.6	-2.4 (-5.6 to 0.7) ± 8.1
diastolic	2.8 (0.2 to 5.4) ± 9.2	6.8 (2.1 to 11.5) ± 10.6	-0.4 (-2.9 to 2.1) ± 6.4
Outpatient clinic BP – HBP			
systolic	7.6 (4.4 to 10.8) ± 11.3	7.5 (1.3 to 13.8) ± 14.0	7.6 (4.2 to 11.0) ± 8.9
diastolic	8.9 (6.4 to 11.4) ± 8.8	8.4 (3.3 to 13.5) ± 11.5	9.4 (6.9 to 11.8) ± 6.3
Pharmacy BP – Outpatient clinic BP			
systolic	4.0 (-2.5 to 10.5) ± 14.6	0.6 (-3.9 to 5.1) ± 11.7	2.1 (-1.6 to 5.8) ± 13.0
diastolic	0.0 (-4.7 to 4.7) ± 10.7	0.2 (-3.1 to 3.4) ± 8.5	0.1 (-2.6 to 2.8) ± 9.4

BP, blood pressure; ABP, ambulatory blood pressure; HBP, Home blood pressure; WCE, White coat effect

Table 3: Diagnosis of arterial hypertension according to the criteria of blood pressure normality on ABP and at the pharmacy

	Pharmacy BP (mmHg)	ABP (mmg Hg)	Number and % of all subjects (n=50)	Number and % of subjects with antihypertensive medication (n=22)	Number and % of subjects without antihypertensive medication (n=28)
Normotension	<140 and <90	<135 and <85	27 (54%)	10 (45.5%)	17 (60.7%)
Hypertension	≥140 or ≥90	≥135 or ≥85	9 (18%)	6 (27.3%)	3 (10.7%)
White coat hypertension	≥140 or ≥90	<135 and <85	8 (16%)	5 (22.7%)	3 (10.7%)
Masked hypertension	<140 and <90	≥135 or ≥85	6 (12%)	1 (4.5%)	5 (17.9%)

3 Screening campaigns in community pharmacies

3.1 Project B:

Sequential screening for diabetes risk in Swiss community pharmacies – evaluation of a national campaign

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Abstract

Background

For early detection of persons at risk for type 2 diabetes, a combination of risk factor assessment and glucose measurement could be a promising approach and an opportunity for health promotion. A sequential screening concept was developed and used in a national pharmacy based screening campaign.

Methods

Community pharmacies of the German speaking part of Switzerland participating in the national Self Care campaign “Stop diabetes-test now” offered a free of charge diabetes risk assessment with consecutive capillary blood glucose measurement. Motivation for lifestyle change was assessed based on the Transtheoretical Model (TTM) of behaviour change. A 35 items data sheet served as a structured screening protocol and enabled quick and reliable documentation of all relevant data. Outcomes measures were: Age, sex, cigarette smoking, total score of the ADA diabetes risk-factor questionnaire, family history of diabetes, body mass index, lack of physical activity, blood pressure, capillary blood glucose, motivation for lifestyle change, counselling activities and triage decisions of the pharmacy team.

Results

During the 5 weeks of spring 2002, 530 pharmacies screened a total of 94124 persons (33.1% male, mean age 60.9 years $\pm$ 14.1 (SD)). Risk profile: family history of diabetes 26.4%; BMI $\geq$25kg/m2 49.3%; low physical activity 27.2%; elevated blood pressure 45.7%; less than 2 risk factors and normoglycaemia (fasting glucose (FG) or non fasting (NFG) <5.3mmol/l) 21.6%; $\geq$2 risk factors but normoglycaemia 71.5%, borderline glycaemia (FG 5.3-6.1mmol/l, confirmed in a second measurement) 2.5% and hyperglycaemia (FG $\geq$6.1mmol/l or NFG $\geq$11.1mmol/l) 4.4%.

Of all persons screened 6.4% were referred to a physician. More than 69000 participants (73.6%) got targeted advice with respect to physical activity and/or nutrition based on their specific risk profile.

Conclusions

The screening campaign attracted an important part of Swiss German speaking adults (2.4%). The sequential screening could successfully be implemented into pharmacy practice. Only 6.9% of the generally elderly persons screened were detected with suspicion for diabetes type 2. However, 71.5% had at least two risk factors. This provided an opportunity to initiate targeted counselling regarding therapeutic lifestyle change.

Background

Type 2 diabetes is a serious disease with growing prevalence throughout the world. It often remains undetected and its complications causes a heavy burden of suffering [1, 2]. A number of risk factors are associated with prevalent undiagnosed diabetes (age, sex, family history, body mass index, insufficient physical activity). It has been estimated that onset of type 2 diabetes occurs at least 4-7 years before clinical diagnosis [3]. In individuals with type 2 diabetes, cardiovascular disease (CVD) is the leading cause of death. The risk for CVD starts to increase as much as 15 years before diabetes diagnosis [4]. Earlier detection and management of diabetes and related metabolic abnormalities can be beneficial and there is substantial evidence that type 2 diabetes can be prevented or delayed [5].

Different concepts and recommendations for screening have been proposed and evaluated [6-12]. It is important to distinguish between screening and diagnostic testing. The purpose of screening is to identify asymptomatic individuals who are likely to have diabetes, or are at increased risk for development of diabetes. Additional clinical examination and tests are required to establish a definitive diagnosis.

The U.S. Preventive Services Task Force (USPSTF) found good evidence that available screening tests can accurately detect type 2 diabetes during an early, asymptomatic phase. But evidence from prospective studies is still insufficient to recommend for or against routine screening [13]. The American Diabetes Association (ADA) acknowledged that data were insufficient to determine the benefits of diabetes screening and thus concluded that the decision to test for diabetes should be based on clinical judgment and patient preference [14]. In 2003 the World Health Organisation (WHO) in collaboration with the International Diabetes Federation published similar recommendations in a report on different issues specific to screening of asymptomatic individuals [15].

For community pharmacists, uniquely positioned as the easiest accessible health care providers in the community, screening is an important opportunity through which they can help achieve public health goals [16]. However, for diabetes screening in pharmacies no specific guidelines, triage algorithms or validated procedures with specific cut-off points are known. Assessment of risk factors, blood pressure measurements and capillary blood glucose measurements with devices approved for

home use are normal duty in many pharmacies or are easy to implement. On regional level different initiatives have been organised in Switzerland to identify at-risk patients for diabetes or metabolic syndrome through community pharmacy based diabetes screening [17].

Through therapeutic lifestyle change, especially focused on physical activity and healthy nutrition onset of type 2 diabetes can be prevented or delayed [11, 18]. Individually tailored interventions are needed to achieve behaviour change. Using the Transtheoretical Model (TTM) of behaviour change the traditional action-oriented interventions could be tailored to motivational readiness to change [19].
In Switzerland the TTM was introduced into pharmacy practice for counselling on nicotine reduction [20]. Furthermore screening for undetected diabetes proved to be feasible. This offers the opportunity to design a screening concept that is not only aimed to detect pre-diabetic persons but also to deliver individually targeted counselling on therapeutic lifestyle change for persons at risk.

With this background the Swiss federation of pharmacists started in 2002 a national campaign “Stop diabetes – test now”. It was prepared in an interdisciplinary and multi-institutional collaboration with physicians, experts in the field of diabetes, health promotion or public health and representatives of patient organisations and health insurances. The goal of the campaign was to detect previously unidentified persons with or at high risk for diabetes and to deliver information and advice on lifestyle change.
A study group was charged with the evaluation of the campaign.

Research questions were:

- Which population groups used the community pharmacy based free of charge screening?
- What was their risk profile?
- What were the activities of the pharmacy teams including triage decisions and counselling activities?
- What was the feedback of patients and physicians after referral and who were accepted by the medical profession for further treatment?

Later the study was enlarged with a 3 step follow-up to investigate the impact of a community pharmacy based screening campaign on lifestyle change and health promotion and to open the possibility for additional intervention studies.

This paper describes the screening concept and the results gathered during the campaign. A second paper [21] presents the 3-step follow up study with results on the impact and the sustainability of induced lifestyle change 3, 9 and 15 months after a community pharmacy based diabetes screening.

Methods

Sequential screening concept

For community pharmacy practice a specific screening concept was developed and triage guidelines were established. The screening procedure was structured into different sequences (Figure 1):

a) ADA risk assessment questionnaire: The questionnaire according to ADA [22] with 7 items was filled in by the individuals themselves before pharmacy screening to sensitise for diabetes risk assessment. Individuals were informed that a score above 10 (maximum = 27) indicated the appropriateness for a pharmacy diabetes screening, but no person interested in the pharmacy screening was excluded based on a low ADA score.
b) Pharmacy risk assessment: Based on a questionnaire of Herman WH [23] to identify people at increased risk for undiagnosed diabetes, a set of risk factors was defined with the aim to select people for a following blood glucose measurement. The pharmacy risk assessment was performed by the pharmacy team.
c) Blood glucose measurement: With people at risk for undiagnosed diabetes subsequent capillary blood glucose (CBG) was measured by a pharmacist.

Definitions of risk factors and the cut-off points for triage are either based on ADA recommendations for community screening using capillary whole blood glucose [22], adjusted to European cut-off points for BMI (≥25 kg/m2) or adopted from the classification of intensity of health enhancing physical activity used in a Swiss physical activity survey [24, 25].

Blood pressure measurement was included in the pharmacy risk assessment because pilot studies had shown that through a diabetes screening in community pharmacies unknown blood pressure was very frequently detected [17]. Cut-off points were based on WHO criteria with direct referral to a physician when measuring RR ≥160/100 mmHg or identifying as a risk factor when measuring RR ≥ 140/90 mmHg.

Screening in community pharmacies is generally performed with blood glucose monitoring meters using capillary whole blood (finger-stick glucose); the cut-off points used are adapted to this. Fasting was defined as no consumption of food or beverage other than water for at least 8 h before testing. To adapt to the situation in daily pharmacy practice besides the preferred measurement of fasting blood glucose also non fasting blood glucose was used. But the non fasting blood glucose results were only considered as normal, when normal values for fasting (<5.3 mmol/l) were achieved. For higher non fasting blood glucose levels an additional test in the fasting state was recommended. The sequential screening with the triage guidelines and cut-off points is summarised in a flowchart in Figure 2.

The screening campaign

Swiss pharmacies were used to participate in the so called “Self Care-campaigns”, which are annually organised by the Swiss federation of pharmacists. The whole screening and evaluation procedure for this campaign were tested 9 months before in a pilot campaign with a sample of 30 pharmacies. The pilot produced 300 screenings and proved to be feasible and no relevant changes were necessary.

The pharmacies taking part in the campaign had to subscribe and pay a fee (300 EUR) in advance to get all promotional material (flyers, posters), blood glucose meters and free access to all continuing education activities. In an obligatory evening course, pharmacy teams were trained in blood glucose measurement and received oral and written information on triage and counselling guidelines.

CBG measurements were performed in all pharmacies using the same new instruments (GlucometerDex®, Bayer Diagnostics). Pharmacies automatically received refills for their blood glucose meters, when they had delivered 25 completed datasheets.

During the campaign a hotline was installed to answer questions with respect to the evaluation and to the triage guidelines.
Multi-institutional collaboration was used to create awareness in print media and television before and during the campaign. Persons interested could choose a pharmacy and participate free of charge during the 30 working days from 8th April to 10th May 2002. Persons under treatment for diabetes and/or cardiovascular disease could be included, but the aim was to reach persons outside of actual medical care.

Evaluation

A 35 item data sheet was developed to serve as a structured screening protocol and to enable quick and reliable documentation of all relevant data. It was manufactured as an anonymous 3-side carbonless copy paper. The front page served as study record, the first copy was for the patient or his physician and the second copy for pharmacy documentation. Additionally, each patient was asked for an Informed Consent to enable follow up. This consent was linked by an individual numeric code to all study records and later with the questionnaires in the follow up studies.
Persons referred to the physician received a short physician-questionnaire to be handed out to the physician for his feedback.
The study was approved in Dec. 2001 by the ethic committee in Basel and later submitted to regional committees as demanded by Swiss Medical authorities.

All datasheets were designed and automatically processed using Teleform® version 7.0 from Cardiff Software, CA, USA. The records were collected at the study site, processed and stored in order to guarantee confidentiality. After scanning each datasheet was verified on screen and the data were transferred directly to an Access® database. A supervisor retested validity every 300-500 case records. This in-process control showed a rate of miss readings of 0.11% for numeric variables and of 0.18% for multiple choice fields. Distinct plausibility ranges were defined for each numeric variable and data were deleted when out of this range.

The evaluation was based on the following outcome measures:
General measures: year of birth, sex, smoker, total score from the self completed ADA questionnaire, medical treatment in the last 12 months either for a cardiovascular disease and/or for diabetes.

Measures in the pharmacy risk assessment: body mass index, lack of physical activity, age, family history of diabetes, history of delivering a baby weighing > 9 lbs and blood pressure values.
Measures when performing blood glucose measurement: hours since last meal, blood glucose readings, if repeated measurement was recommended with the value from the eventual second visit and an interpretation if blood glucose was elevated.
Assessment of the readiness to change for 3 domains: physical activity, daily consumption of 5 portions of fruit and/or vegetables and restricted consumption of fat. For each domain according to the Transtheoretical Model of behaviour change (TTM) 5 specific questions were asked by the pharmacy team resulting in 3 TTM-scores for the readiness to change (1 = pre-contemplation, 2 = contemplation, 3 = preparation, 4 = action, 5 = maintenance)
Counselling activities assessed with 3 items: recommendation of weight reduction, scheduling an additional counselling session in the pharmacy and other recommendations to specify in an open field (e.g. smoking cessation).
Triage decisions assessed with 3 predefined options: Referral to physician, years until next follow up control in the pharmacy or recommendation to follow treatment plan if individual was already under medical treatment.

Data was processed and analysed using Microsoft Access®, Excel® and SPSS® (SPSS, Inc, Chicago, Illinois, USA). Unpaired Student's t-tests and one-way analyses of variance (ANOVA) with Tukey's correction for multiple comparison were run to compare different samples for dependent variables such as mean age and BMI. All p-values were calculated two-sided, values of $p<0.05$ being considered statistically significant. Further, Pearson's chi-square tests were performed to detect differences in relative frequencies of outcome variables, whereupon p-levels were adjusted for multiplicity of testing using Fisher's exact test, if necessary.

Results

Out of the German speaking part of Switzerland 530 pharmacies (64.4% of n=823 pharmacies) documented during 5 weeks of campaign a total of 96'692 screenings.
A total of 1459 (1.5%) persons reported being treated for diabetes and were excluded. Finally only those individuals (n= 94124) who explicitly stated not to be in medical care for diabetes were included for further analysis. A further 866 (0.93 %)

case records with missing data on sex and/or age were excluded. Thus the eligible study sample included 93258 patients, of which 23279 (24.96%) gave Informed Consent.

Characteristics of study population (Table 1)

The mean age of participants was 60.9 ± 14.1 (SD) years (men 61.34; women 60.69) and 66.9 % were women.

Total score of self completed ADA-questionnaire was noted in the screening record. ADA scores from 78828 (84.5%) individuals were available. Of these, 5092 (6.5%) persons were documented with a score of 0, 1 or 2; 29141(37.0%) persons with a score of 3 to 9 and 44595 (56.6%) persons with a score of 10 or higher.

In the pharmacy risk assessment the prevalence of risk factors were age over 45 years (85.3%), elevated body mass index (49.2%), elevated blood pressure (45.4%), lack of physical activity (27.0%), family history of diabetes (26.3%) and history of delivering a baby weighing > 9 lbs (13.1% of women). Hypertonic blood pressure (RR ≥ 160/100 mmHg) was observed in 16.3%. Thus a total of 25155 (81.5%) men and 47362 (75.9%) women were assessed with 2 or more risk factors according to the triage guidelines.

Capillary blood glucose (CBG) measurements

A CBG measurement was performed in 91’082 (97.7%) persons. Of them 42609 (46.6%) were in the fasting state. The fasting and non fasting CBG values were grouped into 6 categories of glycaemia. We used the cut-off points from our triage flowchart (5.3 / 6.1 / 11.1 mmol/L), cut-off point 7.8 mmol/l based on the ADA 2000 recommendations for non fasting CBG and with respect to the recent recommendation to lower the cut-off point for normal CBG we also used 4.8 mmol/l [22]; [26]; [27].

Table 2 shows prevalence within these blood glucose categories stratified by sex and fasting state. Over all categories, men showed significant higher prevalence of dysglycaemic blood glucose values.

Cut-off point for normoglycaemia for fasting measurement was 5.3 mmol/l. If CBG value in the fasting state was ≥ 6.1 mmol (n = 3889) or in the non fasting state ≥ 11.1 mmol/l (n=203) suspicion for diabetes was identified and these persons (n= 4029; 4.4% of whole study population) were referred. Borderline values (fasting: 5.3 – 6.0

mmol/l; non fasting: 5.3 – 11.0 mmol/l) were observed in 11137 (12.3%) persons. In these cases the triage guidelines recommended a repeated measurement some days later in the fasting state. This was observed with a total of 8514 (76.5%) persons. Out of them additional 2304 persons were detected with suspicion of diabetes based on a second measurement showing CBG values ≥ 5.3 mmol/l. Thus a total of 6396 (6.9%) persons were detected in the pharmacy screening who warranted clinical evaluation by a physician.
Figure 3 compares borderline CBG values (fasting and non fasting) at first measurement with CBG at second measurement which always was performed in the fasting state. The second measurement in the fasting state confirmed dysglycaemia in 1774 (33.2%) of 5330 individuals with low borderline values (5.3 - 7.8 mmol/L) from first non fasting CBG measurement. The second measurement after first borderline CBG in the fasting state confirmed dysglycaemia for 47.4%.

Stratification of the eligible study population into risk groups is shown in Table 3. Thus with respect to the triage guidelines, a total of n=19677 (21.1 %) persons of the study population with either raised blood glucose or blood pressure warranted referral for clinical evaluation and final diagnosis.

Counselling and triage activities

After diabetes risk assessment the pharmacy teams could assess the readiness to change for all three domains in 68691 (73.7%) persons. This assessment directly induced counselling on lifestyle change and specific action plans could be used. The TTM-scores in Table 4 show that women are much more motivated to follow recommendations for healthy nutrition. But for physical activity, significance between the sexes is smaller. Additional recommendation for weight reduction was given for 23.9% of men and 20.1% of women, other recommendations (e.g. smoking cessation) were given to 9.2%. In 1.1% additional counselling was scheduled.

The triage decision was the last item to document and in 22.6% this was omitted. Of all persons screened 5983 (6.4%) were referred to a physician and 2462 (2.6%) persons got the recommendation to return to their treating physician because they already were in medical care. Total referral rate was 9.0%. A majority (55.2%) of them based on more than 2 risk factors with additional abnormal blood glucose, but a

remarkable 17.4% was referred because of high blood pressure with normal blood glucose values and the remaining 27.4% because of multiple risks and measurements near the cut-off points. Again men were much more frequently referred.

Physician feedback

Only persons who declared at screening not to be in medical care for diabetes were included. Off all persons referred only 767 (12.8%) physician questionnaires were returned. In 81.9% of the feedback physicians confirmed dysglycaemic blood glucose and reported for 74.9% scheduling of a second session. With respect to the low return rate we renounced to present in depth these results and the characteristics of non respondents.

Comparison of screening approaches

As the screening service was offered for free we collected from most individuals data from CBG measurement. This allowed for analysis of the pharmacy risk assessment and to depict differences in sensitivity and specificity in comparison with the ADA risk score. We constructed ROC curves including all individuals (n= 78’828) with complete data files concerning ADA-Score, pharmacy risk assessment and CBG measurement. We used abnormal CBG values according to our triage guidelines as reference (fasting blood glucose ≥6.1 mmol/l, non fasting blood glucose ≥11.1 mmol/l or borderline values if confirmed to be abnormal in a second fasting measurement). The resulting receiver operating curves (ROC) are shown in Figure 4. The ROC curves suggest that the ADA diabetes risk score of 10 is less sensitive (76 vs. 92 %) but more specific (45 vs. 23 %) than the cut-off point of 2 risk factors used in the pharmacy risk assessment. Both curves perform somewhat better (larger areas under the curves) for women than for men (not shown in the figure).

Discussion

The campaign attracted a remarkable number of pharmacies although they had to pay for participation as well as a significant part (2.4%) of the Swiss German speaking adult population. Experiences from similar campaigns suggest that this high

public interest is due to a good coverage in the mass media including TV and the attractiveness of the free of charge service.

Demographics

Distribution of age and sex reflect the respective distribution in pharmacy clients seen in other studies. But it must be clearly noted that the eligible study population is not representative of the Swiss population but only for individuals attracted by the campaign.

The design of the campaign and all promotional activities attracted an older population (average age of 60.9 years vs. 48.1 years in the Swiss German adult population [28]). The ADA score and the prevalence of the different risk scores suggest that the campaign selected a higher risk study population. This assumption is supported by the higher prevalence of BMI ≥ 25.0 kg/m2 in the study population compared with the Swiss adult population (59.8 vs. 45.4% for men and 44.1 vs. 29.3% for women) [28].

Prevalence of risk factors

The most prevalent risks found were overweight and insufficient physical activity. For physical activity the dichotomous yes/no assessment was too simple. In the future this should be assessed exactly in number of days a week with moderate and/or high activity level. This would facilitate more targeted counselling and monitoring of induced lifestyle change.

In the study sample 54% showed elevated and 16.3% hypertonic blood pressure. A significant part, 1.6% of all screened individuals, was referred based on a high blood pressure while blood glucose showed normal values. In a recent study, blood pressure measurement in community pharmacies showed to be at least as reliable as those of other health professionals and similar white coat effects were observed [29]. It is therefore important to introduce blood pressure measurement in the pharmacy screening setting.

Men showed higher prevalence of overweight and elevated or high blood pressure. They show this in younger age while insufficient physical activity is equal and a family

history of diabetes is much less prevalent than in women. At the age of 31 to 45 years, 50% of men and 37.4% of women showed ≥ 2 risk factors for diabetes.

Blood glucose measurement

Most persons, even without risk factors, were interested to get this free of charge examination. They were informed that they had to come to the pharmacy preferably in the fasting state. Half of all screened persons followed this recommendation. Additionally, a very high part (87%) of those individuals with borderline results was willing to return for a second measurement. The results from second CBG after first borderline result (Figure 3) indicate that the often used cut-off point 7.8 mmol/L for non fasting CBG is too high. For non fasting individuals only values below 5.3 mmol/l should be interpreted as normal. Our findings strongly support the recommendation in the triage guidelines to repeat measurement in all cases of borderline values.

The prevalence within different CBG categories for fasting and non fasting blood glucose in Table 2 reveals that the triage concept and the cut-off points are well adapted for community pharmacy based screening. Lowering of the threshold for normal fasting CBG from 5.3 mmol/L to 4.9 mmol/L, according to the newly recommended cut-off point of the ADA (5.6 mmol/L for plasma glucose respectively 4.9 mmol/L for capillary whole blood), would for our study population increase prevalence of impaired fasting glucose by 79%. Among women we would observe even a 87% increase of prevalence. In good agreement with other studies we observed that men are much more likely to be at risk and show this in younger age [30]. Further research is required to stimulate a discussion on lowering the cut-off point only for women.

Until now no valid epidemiological data for diabetes prevalence are available for Switzerland. The stratification of the study population into risk groups shows a prevalence of only 6.9% with suspicion for previously unidentified diabetes. Hereby it must be remembered that in our study sample we have excluded 1.5% with already treated diabetes. In the NHANES survey 1999-2000 [31] prevalence of diabetes and impaired fasting glucose was 14.9% and the Inter99 study reported a prevalence of impaired fasting glucose of 1.4 – 16.3% in the Danish population aged 30-60 years [32].

A limitation to apply our results from blood glucose screening is that capillary blood glucose was measured with devices designed for self monitoring without special validation of pharmacists' measurements.

Counselling activities

Immediately after screening (for 72.6 % of all persons) the 3 TTM-scores for the readiness to change lifestyle could be assessed. Overall 30.6% received recommendations for weight reduction or other recommendations. These counselling activities were prompted due to the predefined items in the study protocol and the simple assessment of the TTM scores. This confirms the feasibility of the combination of a screening with subsequent counselling on lifestyle change in community pharmacy practice.

Triage decisions

Here we observed the highest rate of missing data (22.6%). Some can be explained by the fact that individuals with borderline blood glucose results had to return for a second measurement before final triage decision was possible, but 12% didn't follow this. And perhaps the predefined options could not cover all situations and a further item "other decision" was missed. Therefore we calculated the total referral rate of 9% with respect to the total eligible sample. This referral rate is lower than expected and than reported from other community pharmacy screening campaigns [33].

Comparison of screening approaches

The low return rate of physician feedback impeded this important part of validation of our triage concept. This remains an uncovered issue. But using CBG measurement as reference, the cumulative risk assessment of 6 different risk factors with 2 risks as a cut-off could be analysed and compared with the ADA score. ROC analysis in Fig 3 shows that the pharmacy risk assessment setting was more sensitive, but less specific than the ADA score. As in the sequential approach this risk assessment is followed by blood glucose measurement, the low specificity is irrelevant, but good sensitivity is important. Dallo and Weller compared different criteria for testing for diabetes and showed that when any two risk factors are present, diabetes is detected with 98% sensitivity and 53% specificity [34]. Our results are also in agreement with

Rolka et al. who investigated the performance of different screening tests and reported >70% sensitivity of CBG > 6.8 mmol/l for the WHO diabetes criterion at 90 % specificity, but the combination with the ADA-Score was less sensitive[9].

In our sequential screening we used fasting CBG as final criterion for referral to a physician. A limitation of measurement of the fasting glucose is its low sensitivity to detect post challenge hyperglycaemia. Pharmacists must consider this. But our approach is in good agreement with results from the evaluation of different screening strategies based on fasting glucose reported by Schmidt et al. [35].

Thus we can recommend our pharmacy risk assessment for adults older than 30 years as pre-test to select individuals for a subsequent blood glucose measurement. As long as in community pharmacy practice no diagnosis is performed but the screening is aimed to refer persons at risk to a physician for further clinical evaluation the subsequent CBG measurement of fasting glucose is a rational testing. This serial combination of tests can improve performance of screening as is discussed in the report of WHO [15].
Early detection of persons at risk with referral to clinicians offer a variety of interventions during the preclinical phase, including lifestyle change, tight glycaemic control or targeted choice of antihypertensive or lipid lowering treatment or therapy with aspirin. A recent review showed that screening for diabetes with all these interventions during preclinical phase is mainly focused to reduce not only risk of diabetes development, but particularly the risk for cardiovascular disease [36]. Additional validation of the sequential screening concept, presented here, with diagnostic criteria is an important outstanding issue.

Conclusions

The evaluation of this large screening campaign show that for community pharmacy practice a sequential procedure can be recommended: First an assessment of all risk factors including blood pressure, second capillary blood glucose measurement with a cut-off point of 5.3 mmol/l and retest in case of borderline results and finally counselling the persons at risk for diabetes according to the readiness to change their lifestyle.

Despite the age of our study population only 6.9% of screened persons were suspected to have type 2 diabetes. However, 71.5% had at least two risk factors. Men were much more likely to be at risk and showed this at a younger age.
Thus, counselling the many persons at risk regarding lifestyle change is an essential element in every meaningful diabetes screening.

Competing interests

None of the authors have any competing interests to declare.

Authors' contributions

KH contributed substantially to the study's design and interpretation of data, he coordinated the whole project, drafted the paper and wrote the final version.
AB collected all data, contributed substantially to the analysis of data and performed the statistical analysis, assisted with the writing of the manuscript and gave final approval of the version to be published.
MM assisted in the development of the campaign and the screening concept and gave final approval of the version to be published.
RB supervised the whole project and contributed substantially to the study design and interpretation of data and gave final approval of the version to be published.

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References

1. Boyle JP, Honeycutt AA, Narayan KM, et al. Projection of diabetes burden through 2050: impact of changing demography and disease prevalence in the U.S. Diabetes Care 2001; 24:1936-40.

2. Harris M, Flegal K, Cowie C, et al. Prevalence of diabetes, impaired fasting glucose, and impaired glucose tolerance in U.S. adults. The Third National Health and Nutrition Examination Survey, 1988-1994. Diabetes Care 1998; 21:518-524.

3. Harris MI. Undiagnosed NIDDM: clinical and public health issues. Diabetes Care 1993; 16:642-52.

4. Hu FB, Stampfer MJ, Haffner SM, Solomon CG, Willett WC, Manson JE. Elevated risk of cardiovascular disease prior to clinical diagnosis of type 2 diabetes. Diabetes Care 2002; 25:1129-34.

5. American Diabetes Association. The prevention or delay of type 2 diabetes. Diabetes Care 2002; 25:742-9.

6. American Diabetes Association. Screening for diabetes. Diabetes Care 2001; 24 Suppl 1:S21-4.

7. Engelgau MM, Narayan KM, Herman WH. Screening for type 2 diabetes. Diabetes Care 2000; 23:1563-80.

8. Park PJ, Griffin SJ, Sargeant L, Wareham NJ. The Performance of a Risk Score in Predicting Undiagnosed Hyperglycemia Diabetes Care 2002; 25:984-988.

9. Rolka DB, Narayan KM, Thompson TJ, et al. Performance of recommended screening tests for undiagnosed diabetes and dysglycemia. Diabetes Care 2001; 24:1899-903.

10. Wareham NJ, Griffin SJ. Should we screen for type 2 diabetes? Evaluation against National Screening Committee criteria. BMJ 2001; 322:986-988.

11. American Diabetes Association. Screening for diabetes. Diabetes Care 2002; 25 Suppl 1:S21-24.

12. Tabaei BP, Herman WH. A Multivariate Logistic Regression Equation to Screen for Diabetes : Development and validation Diabetes Care 2002; 25:1999-2003.

13. Screening for type 2 diabetes mellitus in adults: recommendations and rationale. Ann Intern Med 2003; 138:212-4.

14. Report of the expert committee on the diagnosis and classification of diabetes mellitus. Diabetes Care 2003; 26 Suppl 1:S5-20.

15. Screening for Type 2 Diabetes - Report of a World Health Organization and International Diabetes Federation meeting. Geneva: World Health Organisation, 2003:54.

16. Babb VJ, Babb J. Pharmacist involvement in Healthy People 2010. J Am Pharm Assoc (Wash) 2003; 43:56-60.

17. Hersberger K, Schnyder A, Tobler A, Zehnder S, Bruppacher R. Screening for diabetes in community pharmacies. Poster Presentation: ESCP 30th European Symposium on Clinical Pharmacy, Oct. 10-13 2001, Antwerp, Belgium 2001:abstract 059.

18. Knowler WC, Barrett-Connor E, Fowler SE, et al. Reduction in the incidence of type 2 diabetes with lifestyle intervention or metformin. N Engl J Med 2002; 346:393-403.

19. Vallis M, Ruggiero L, Greene G, et al. Stages of change for healthy eating in diabetes: relation to demographic, eating-related, health care utilization, and psychosocial factors. Diabetes Care 2003; 26:1468-74.

20. Gschwend P, Steffen T, Hersberger K, Ackermann-Liebrich U. [Smoking cessation in pharmacies--evaluation of the smoking cessation campaign "Tobacco adieu!" among pharmacists in Basel]. Soz Praventivmed 1999; 44:14-21.

21. Botomino A, Bruppacher R, Krähenbühl S, K.E. H. Change of body weight and lifestyle after counselling of persons at risk for type 2 diabetes: follow-up study of a screening campaign in Swiss community pharmacies. BMC Public Health, submitted.

22. American Diabetes Association. Screening for type 2 diabetes. Diabetes Care 2000; 23 Suppl 1:S20-3.

23. Herman WH, Smith PJ, Thompson TJ, Engelgau MM, Aubert RE. A new and simple questionnaire to identify people at increased risk for undiagnosed diabetes. Diabetes Care 1995; 18:382-7.

24. Martin BW. Physical activity related attitudes, knowledge and behaviour in the Swiss population: comparison of the HEPA Surveys 2001 and 1999. Schweiz Z Sportmed Sporttraumatol 2002; 50.

25. Martin BW, Jimmy G, Marti B. [Promotion of exercise among the physically inactive: a challenge also in Switzerland]. Ther Umsch 2001; 58:196-201.

26. Genuth S, Alberti KG, Bennett P, et al. Follow-up report on the diagnosis of diabetes mellitus. Diabetes Care 2003; 26:3160-7.

27. American Diabetes Association. Screening for type 2 diabetes. Diabetes Care 2004; 27 Suppl 1:S11-4.

28. Swiss Federal Statistical Office (SFSO). [Standardtabellen der Schweizerischen Gesundheitsbefragung 2002]; Swiss Health Survey 2002. 2004.

29. Botomino A, Martina B, Ruf D, Bruppacher R, Hersberger K. White coat effect and white coat hypertension in community pharmacy practice. Blood pressure monitoring, in press.

30. Glumer C, Carstensen B, Sandbaek A, Lauritzen T, Jorgensen T, Borch-Johnsen K. A Danish Diabetes Risk Score for Targeted Screening: The Inter99 study Diabetes Care 2004; 27:727-733.

31. Cowie CC ea. Prevalence of diabetes and impaired fasting glucose in adults – United States 1999–2000. MMWR Morb Mortal Wkly Rep 2003; 52:833–7.

32. Glumer C, Jorgensen T, Borch-Johnsen K. Prevalences of diabetes and impaired glucose regulation in a Danish population: the Inter99 study. Diabetes Care 2003; 26:2335-40.

33. Hourihan F, Krass I, Chen T. Rural community pharmacy: a feasible site for a health promotion and screening service for cardiovascular risk factors. Aust J Rural Health 2003; 11:28-35.

34. Dallo FJ, Weller SC. Effectiveness of diabetes mellitus screening recommendations. PNAS 2003; 100:10574-10579.

35. Schmidt MI, Duncan BB, Vigo A, et al. Detection of undiagnosed diabetes and other hyperglycemia states: the Atherosclerosis Risk in Communities Study. Diabetes Care 2003; 26:1338-43.

36. Harris R, Donahue K, Rathore SS, Frame P, Woolf SH, Lohr KN. Screening adults for type 2 diabetes: a review of the evidence for the U.S. Preventive Services Task Force. Ann Intern Med 2003; 138:215-29.

Figures

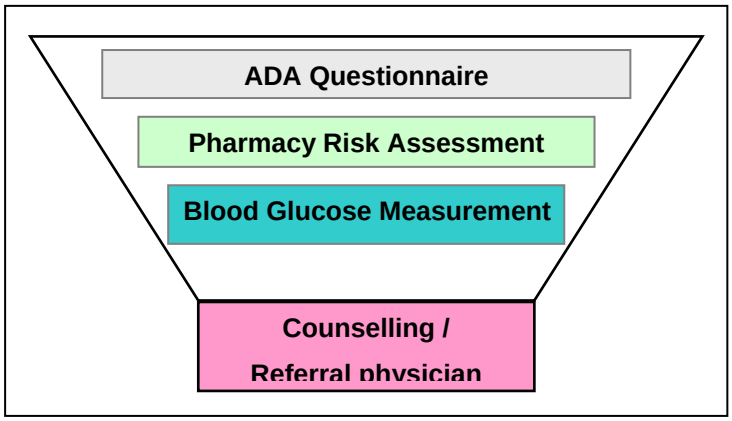

Figure 1: Sequential screening concept

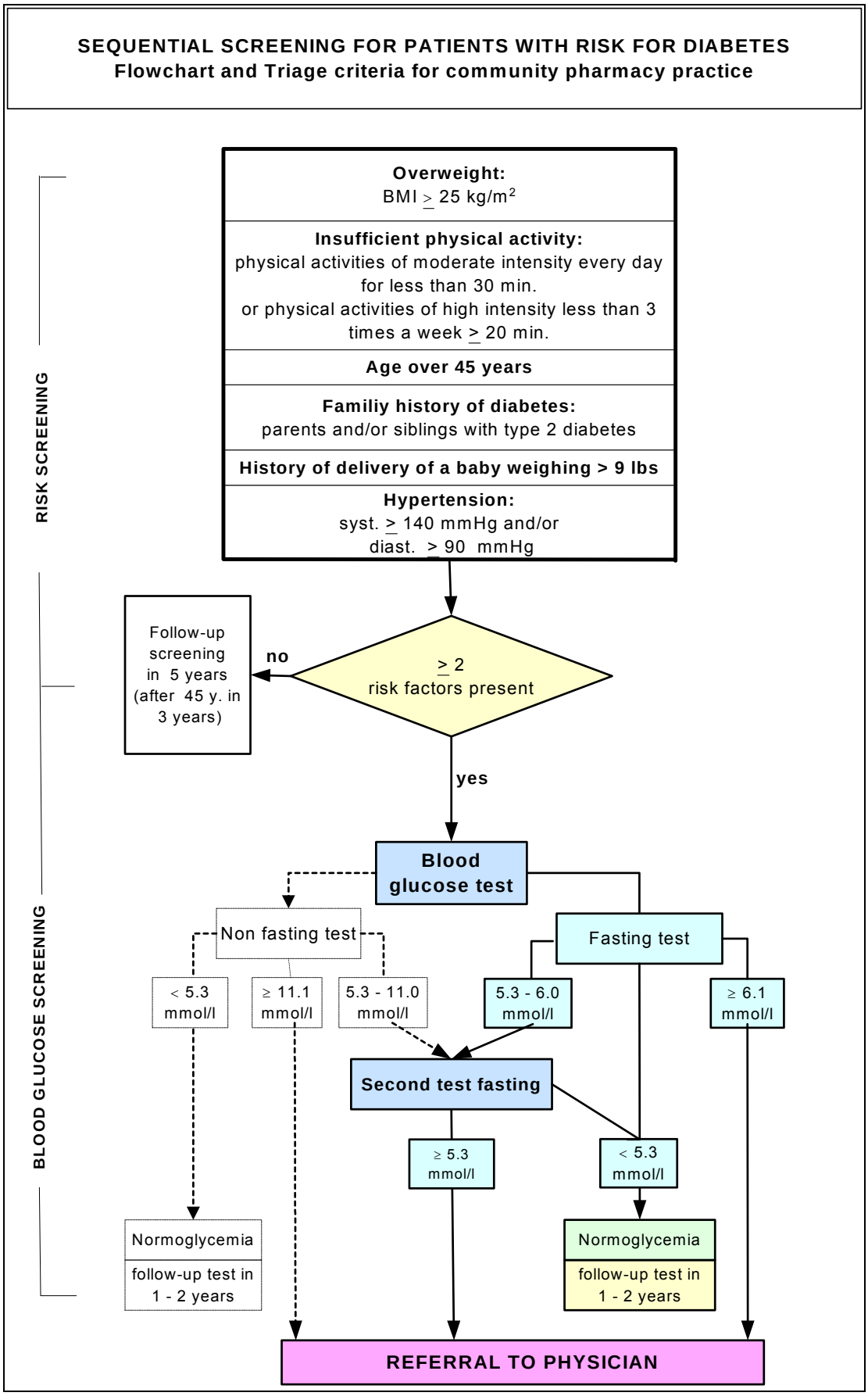

Figure 2: Flowchart and triage criteria for sequential screening in pharmacies for patients with risk for diabetes

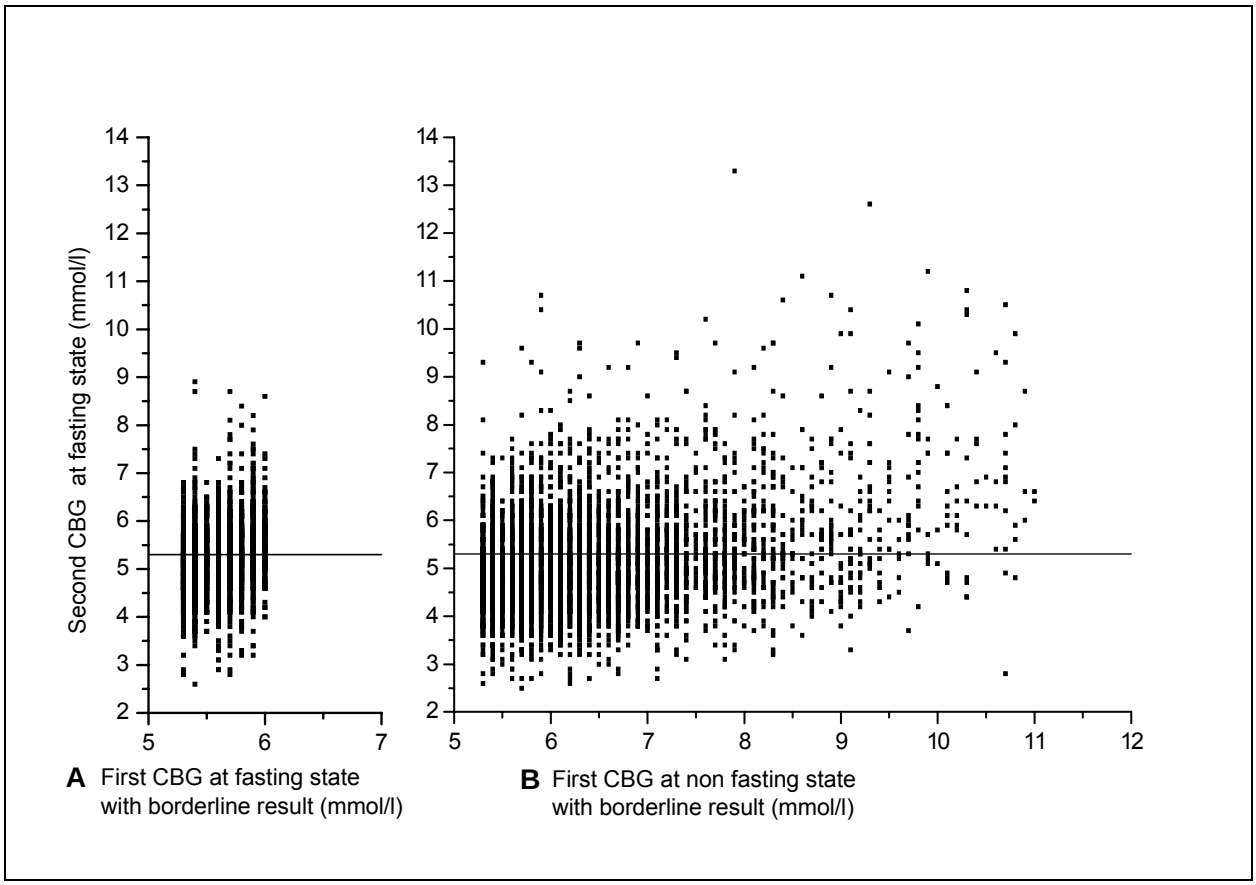

Figure 3: Comparison of borderline CBG values at first measurement with fasting CBG values at second measurement

A) Subjects at fasting state at first measurement (5.3-6.0 mmol/l; n=2555)
B) Subjects at non fasting state at first measurement (5.3-11.0 mmol/l; n=5959)

Cut-off point for normoglycaemia for fasting measurement is 5.3 mmol/l

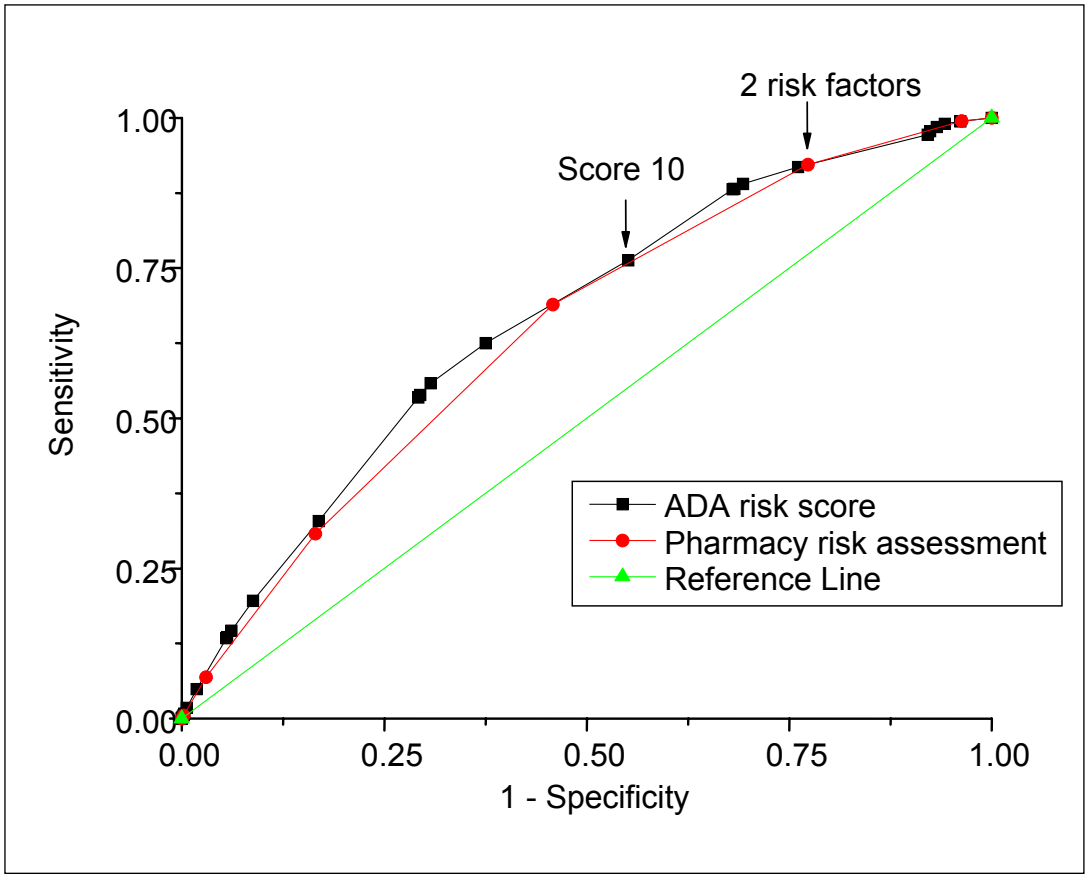

Figure 4: Empirical receiver-operating characteristic (ROC) curves

Sensitivity vs. 1-specificity is plotted over the ranges of ADA risk scores and of risk factors of pharmacy risk assessment for abnormal blood glucose values detected in the pharmacy.

Usual cut-off point for recommendation of blood glucose measurement is a score of ≥ 10 for ADA risk assessment. In the present pharmacy based risk assessment cut-off point ≥ 2 risk factors was used.

Tables

Table 1: Baseline characteristics and results from diabetes screening

	male / female					Total male	Total female	Overall
Age group [years]	≤ 30	31-45	46-60	61-75	> 75			
n	751 / 1677	3744 / 7498	8719 / 19638	12878 / 24390	4786 / 9177	30878	62380	93258
% of whole study population	0.8 / 1.8	4.0 / 8.0	9.3 / 21.1	13.8 / 26.2	5.1 / 9.8	33.1	66.9	100.0
Current smoker [%]	28.3 / 16.5	22.3 / 14.6	24.3 / 8.4	19.5 / 10.1	20.5 / 4.2	17.1	12.0	13.7
Score from ADA diabetes risk test	3.9 / 3.6	5.5 / 4.6	9.5 / 8.7	11.7 / 11.6	12.5 / 12.5	10.3 ± 4.6	9.8 ± 4.8	10.0 ± 4.8
BMI [kg/m2]	24.1 / 22.8	26.0 / 24.3	26.2 / 24.8	26.3 / 25.6	25.7 / 24.9	26.1 ± 3.3	25.0 ± 4.2	25.4 ± 4.0
Risk factor body weight [%]	34.8 / 22.5	56.6 / 34.6	60.8 / 41.1	63.2 / 50.7	55.3 / 44.6	59.8	44.1	49.24
Insufficient physical activity [%]	33.5 / 34.9	38.6 / 34.3	32.2 / 28.2	20.4 / 23.2	24.8 / 29.5	27.0	27.4	27.05
Family history of diabetes [%]	16.4 / 18.0	26.3 / 29.1	26.3 / 31.4	21.8 / 28.9	15.1 / 21.8	22.5	21.8	26.29
History of delivering a baby weighing > 9 lbs (only females) [%]	3.4	13.3	12.3	14.8	11.5		13.	
Systolic blood pressure [mm Hg]	128.2 / 116.7	130.2 / 119.7	135.4 / 128.6	143.3 / 139.7	148.0 / 148.1	139.8 ±19.1	134.5 ±20.4	136.2 ±20.1
Diastolic blood pressure [mm Hg]	78.3 / 74.8	83.3 / 77.9	86.4 / 81.7	85.6 / 82.9	82.6 / 82.3	84.9	81.6 ±11.0	82.7 ±11.2
Risk factor blood pressure [%]	24.7 / 8.7	34.2 / 15.5	46.7 / 31.4	59.6 / 51.9	66.7 / 66.4	53.2	42.0	45.4
≥ 2 risk factors for diabetes [%]	31.2 / 21.5	50.2 / 37.4	85.5 / 78.1	88.2 / 82.1	88.5 / 88.3	81.5	75.9	77.7
Fasting capillary blood glucose [mmol/l]	4.4 / 4.1	4.6 / 4.3	4.9 / 4.5	5.0 / 4.7	5.1 / 4.98	4.9 ±1.1	4.6 ±1.0	4.7 ±1.0
Non fasting capillary blood glucose [mmol/l]	4.8 / 4.5	4.8 / 4.5	5.0 / 4.7	5.3 / 4.9	5.4 / 5.2	5.1 ±1.4	4.8 ±1.2	4.9 ±1.3
Recommendation of second visit for repeated measurement [%]	7.3 / 5.7	9.9 / 6.3	12.6 / 8.3	17.0 / 12.2	20.1 / 15.3	15.1	10.6	12.1
Interpretation as elevated blood glucose by pharmacists [%]	3.8 / 1.3	4.0 / 1.7	8.2 / 3.5	13.7 / 7.6	16.0 / 10.2	11.1	5.9	6.7

Frequencies are given as % in sex and age group. Numeric variables are given as means, means ± SD for totals.
Each baseline variable had < 0.6% missing data.

Table 2: Prevalence within blood glucose categories stratified by sex and fasting state

Blood glucose category	Fasting CBG (n=42’609)			Non fasting CBG (n=48473)		
	Male (%)	Female (%)	Overall (%)	Male (%)	Female (%)	Overall (%)
<4.9 mmol/l	49.8	66.3	60.7	47.6	59.7	55.8
4.9-5.2 mmol/l	20.4	15.7	17.3	16.9	14.4	15.2
5.3-6.0 mmol/l	20.4	12.9	15.4	19.2	15.2	16.5
6.1-7.7 mmol/l	7.9	4.3	5.5	12.6	8.9	10.1
7.8-11.0 mmol/l	1.3	0.6	0.8	2.9	1.5	2.0
>=11.1 mmol/l	0.3	0.2	0.2	0.7	0.3	0.4

Pearson's chi-square tests between sex groups for fasting and non fasting CBG showed highly significant ($p < 0.0001$) differences in relative frequencies.

Table 3: Stratification of the screened population into risk groups

Persons without risk:		20168 (21.6 %)
Persons at risk (≥ 2 risk factors, but normoglycaemia):		66694 (71.5 %)
Subgroup with blood pressure RR ≥160/100mmHg:	13281 (14.2 %)	
Persons suspected to have type 2 diabetes:		6396 (6.9 %)
Subgroup with borderline glycaemia (FG 5.3-6.0mmol/l or NFG 5.3-11.0mmol/l, confirmed in a second measurement at fasting state):	2304 (2.5%)	
Subgroup with hyperglycaemia:		
Fasting CBG ≥6.1mmol/l	3889 (4.2%)	
Non fasting CBG ≥11.1mmol/l	203 (0.2%)	

Table 4: Counselling and triage activities after diabetes screening

N= 93258	Total male (%)	Total female (%)	p-value	Overall (%)
Readiness to change lifestyle:				
Physical activity [#]	61.7	60.5	*	60.9
Five a day [#]	36.5	44.7	***	42.0
Restricted fat consumption [#]	41.3	53.3	***	49.4
Recommendation of weight reduction	23.9	20.1	***	21.4
Scheduling an additional counselling session	1.3	1.0	***	1.1
Other recommendation	10.1	8.7	***	9.2
Triage decision				
• Referral to physician	9.3	5.0		6.4
• Follow up control in the pharmacy	64.8	70.1		68.3
• Follow treatment plan if yet in medical care	2.9	2.5		2.6
• No decision	23.0	22.4	***	22.6

[#] % in “action” or “maintenance” (TTM-score 4 or 5)

Pearson's chi-square tests showed statistically significant differences between sex groups (* = $p < 0.01$; *** = $p < 0.0001$).

3.2 Project C:

Evaluation of cut-off points for the screening for metabolic syndrome in community pharmacies

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A short report of the evaluation of a pharmacy based campaign
(Poster presentation at the 31th Annual Symposium of the
European Society of Clinical Pharmacy, Florence, Italy, October 2002)

Introduction

The risk of suffering from a coronary heart disease (CHD) is increased when factors like obesity, hypertension, dyslipidaemia, diabetes mellitus coincide and worsens with additional family history of premature CHD. The coincidence of two or more risk factors is called the *metabolic syndrome*.

Blood glucose and cholesterol measurements are offered by many community pharmacies. With compact analysers, community pharmacies are able to afford the screening for the risk factors using capillary blood. A previous study showed that if correctly attended, they are appropriate for an efficient screening in community pharmacies leading to accurate values [1].

However, the values gathered in a screening must be judged and reasonable decisions must be made for an individual situation. For community pharmacies, a specific setting leading to rational triage decisions is important.

Objectives

Design of a specific screening setting for community pharmacy practice with specific triage criteria and evaluation of the concept using data from a community pharmacy based screening campaign.

Methods

30 community pharmacies of the Swiss pharmacy chain TopPharm in the German speaking part of Switzerland offered the additional possibility of assessing the lipid profile during a diabetes screening campaign.

The pharmacy teams followed a specific training program and received the guidelines for screening and triage as written information. Based on a multiple risk approach a sequential screening was designed for community pharmacy practice (Figure 1).

Main outcome measures were capillary blood values for glucose, total cholesterol (TC), HDL-Cholesterol (HDL-C), LDL-cholesterol (LDL-C), Triglycerides (TRG), ratio TC/HDL-C, blood pressure values, body mass index, family history of diabetes or of premature cardiovascular disease, cigarette smoking, lack of physical activity and the triage decisions of the pharmacy teams. Results were documented by the pharmacy

teams with uniform datasheets, which were processed automatically with the Cardiff TELEform® Software.

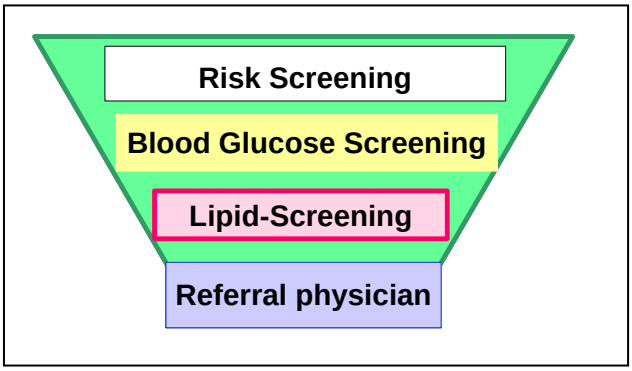

Figure 1: Sequential screening

The levels for the risk factors and the cut-off points were adopted from the recommendations of the Swiss society for cardiology and the ATP III panel recommendations 2001 (Figure 2) [2], [3].

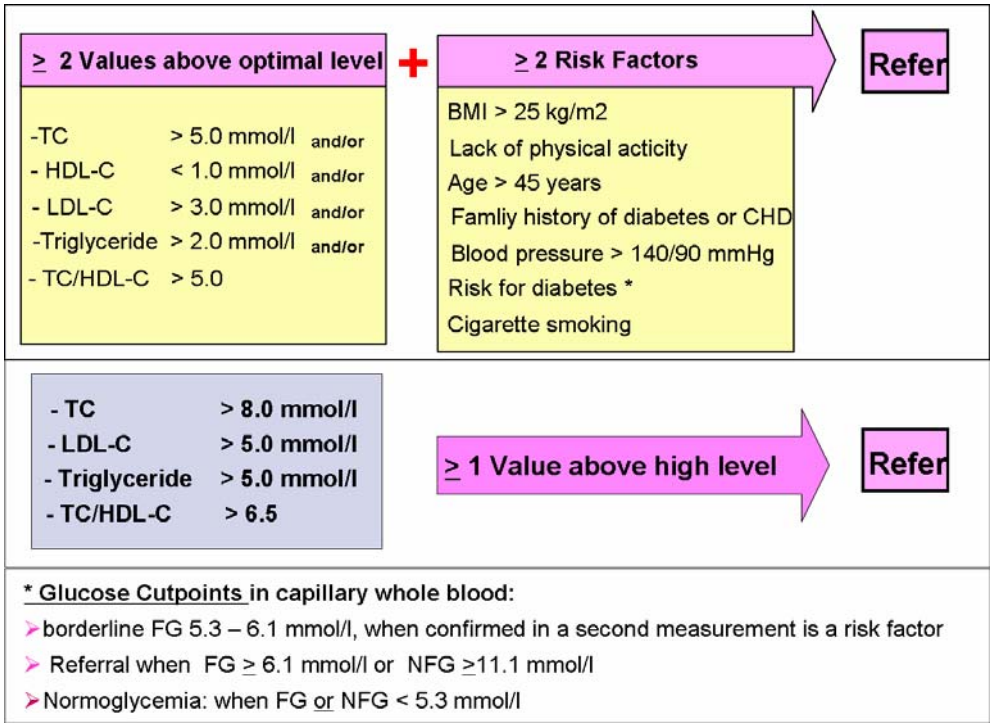

Figure 2: Criterions for referral to physician

Results

During four weeks of campaign (September 2001) 30 pharmacies completed a total of 757 protocols, 528 protocols with lipid profile (62% female) (age = 59.5 years ± 14.2 (SD)). 395 persons declared not to know their risk profile and not to be in medical care for cardiovascular disease or diabetes (Figure 3).

Table 1 shows the results of the multiple risk assessment (metabolic syndrome). If ≥2 values of the lipid profile above normal would be considered as a reason to refer persons to a physician, 68% of screened persons would have been referred. The present triage guidelines refer persons with coincidence of ≥2 values of the lipid profile above normal and ≥2 risk factors for CHD. Referral rate is therefore reduced to a total of 43%. The results of the assessment of single risks which require referral to a physician if present are shown in Table 2.

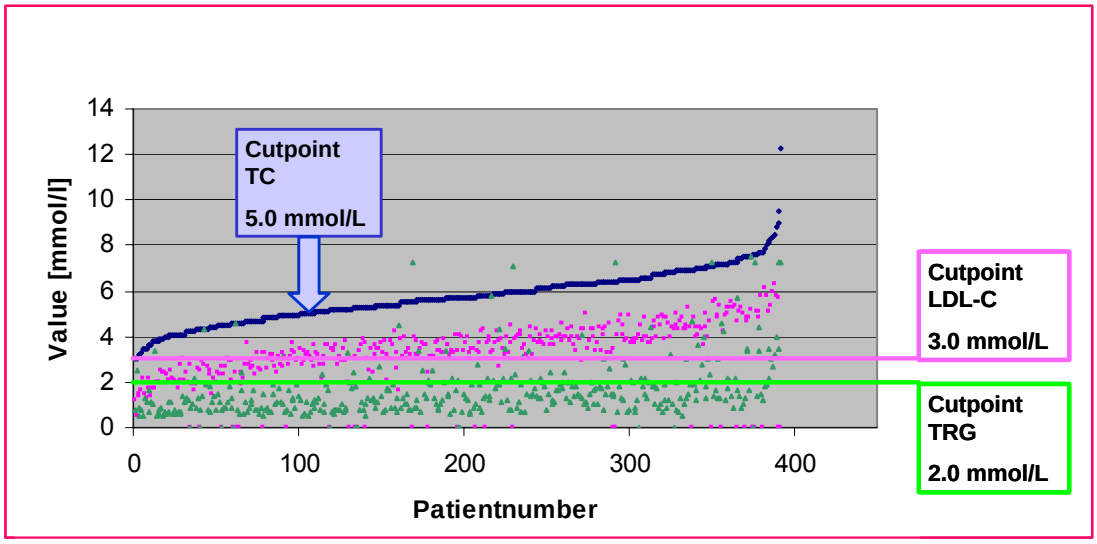

Figure 3: Plot of total cholesterol (TC), LDL-cholesterol (LDL-C) and triglycerides (TRG) with cut-off points for single normal values (n=392 persons not in medical care)

Table 1: Multiple Risk Assessment (Metabolic syndrome)

Lipoprotein profile (TC, LDL-C, HDL-C, Triglycerides, Ratio TC/HDL-C)
312 (79%) with ≥ 1 value elevated, above normal
Of them 196 (49%) with ≥ 2 additional risk factors for CHD
267 (68%) with ≥ 2 values elevated, above normal
Of them 171 (43%) with ≥ 2 additional risk factors for CHD
Blood Pressure, Body Mass Index, Fasting Glucose
143 (36%) overweight (BMI > 25 kg/m2)
117 (30%) with elevated Blood Pressure (>140/90 mmHg)
92 (23%) with elevated Fasting Glucose (≥ 5.3 mmol/l;capillary whole blood)

Table 2: Single Risk Assessment (Cut-off point to consider drug treatment)

57 (14%) with 1 high lipoprotein level (TC>8.0 mmol/l, LDL-C > 5.0mmol/l, TC/HDL-C > 6.5 or Triyglycerides > 5.0 mmol/l)
50 (12%) with High Blood pressure (≥ 160 or 100 mmHg)
26 (6.5%) with BMI > 30 kg/m2
11 (3%) with Fasting Glucose ≥ 6.1 mmol/l (capillary whole blood)

Conclusions

Screening for persons with risk factors for CHD should be done in a multiple risk assessment. In a sequential approach first step is to assess person's risk status and only if necessary in the next steps blood measurements. Using the desirable values for each risk factor as cut-off point for pharmacy practice a reasonable definition of coincidence is important. Single cut-off points for dyslipidaemia would be too strong leading to high rates for referral. When in the lipoprotein screening coincidence of ≥2 values of the lipid profile above normal with ≥2 risk factors for CHD are considered referral rate is significantly reduced.

The revised triage concept consists of screening for the coincidence of 2 values of lipid profile above normal with 2 other risk factors for CHD. When a single risk is high on the level for drug treatment (Table 2), even without coincidence with other risk factors, referral is required.

References

1. Hersberger K, Schnyder A, Tobler A, Zehnder S, Bruppacher R. Screening for diabetes in community pharmacies. Poster Presentation: 30th Annual Symposium, European Society of Clinical Pharmacy, October 2001, Antwerp, Belgium 2001: abstract 059.
2. Third Report of the National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III) final report. Circulation 2002; 106:3143-421.
3. Battegay E, Bertel O, Darioli R, et al. Empfehlungen 1999 zur Behandlungsindikation des Risikofaktors Cholesterin. Schweiz Arzteztg 1999; 80:549-52.

4 Health promotion and lifestyle change

4.1 Project D:

Effect of counselling in community pharmacies on body weight and lifestyle of persons at risk for type 2 diabetes

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Pharm World Sci; submitted

Abstract

Background

During a screening campaign for type 2 diabetes in community pharmacies, immediate counselling on lifestyle behaviour was provided to persons found to be at risk. The aim of this study was to investigate the effects of pharmacy based counselling on changes in lifestyle and body weight.

Methods

Three different counselling intensities were compared: Standard counselling (SC) with non-specific recommendations towards lifestyle change, intensive counselling (IC) with additional specific advice to reduce body weight, and counselling for persons at high risk for type 2 diabetes (HRC) with recommendation to contact a physician. Three months after screening a stratified sample of 3800 randomly chosen overweight persons were addressed with written questionnaires to assess body weight and lifestyle changes. Half year and one year later the assessment was repeated.

Results

The eligible study population included 1370 subjects, 557 in the SC group, 568 in the IC group and 245 in the HR group. All counselling groups showed significant weight loss three months after screening (0.6-1.9 kg; $p<0.001$). At the half-year follow-up, a slight weight gain was observed (seasonal interference), which was not statistically significant in the whole study population. A further weight reduction was observed at one year follow up (1.1-2.4 kg; $p<0.001$). The HRC group showed a higher percentage of weight loss than the IC and SC group three months after screening (-2.25% vs. -1.20% and -0.67%; $p<0.001$) and at one year follow-up (-2.74% vs. -1.54% and -1.29%; $p<0.01$). Three months after screening, 18.0% of the subjects in the HRC group, 11.6% in the IC group and 7.9% in the SC group lost ≥5% of initial body weight ($p<0.001$). At one year follow-up, 24.5% in the HRC group, 17.6% in the IC group and 16.7% in the SC group showed this success ($p<0.05$). Lifestyle changes in physical activity and/or nutrition were reported by 81.2% in the HRC group, 74.1% in the IC group and 67.0% in the SC group ($p<0.001$).

Conclusions

Our findings show that immediate counselling in community pharmacies after screening for type 2 diabetes can result in significant and sustainable lifestyle changes and weight loss in overweight individuals.

Background

Type 2 diabetes mellitus is a public health concern, and projections of its future effects are alarming. The number of patients affected by type 2 diabetes is expected to increase in the future due to population growth, aging, urbanization, and increasing prevalence of obesity and physical inactivity [1, 2]. Type 2 diabetes is often asymptomatic in the early stages and can remain undiagnosed for many years. The risk of developing type 2 diabetes increases with age, obesity and lack of physical activity [3]. Early detection and treatment of type 2 diabetes can reduce the burden of its complications. The American Diabetes Association recommends screening for type 2 diabetes in persons who are 45 years or older and those with a body mass index (BMI) of 25 kg/m^2 or greater [3]. There is substantial evidence that type 2 diabetes can be prevented or delayed by changes in lifestyle [4, 5]. Two well-designed randomised controlled trials have shown that intensive lifestyle modifications through alterations in diet and improvement in exercise regime can delay or prevent progression from impaired glucose tolerance to type 2 diabetes [6, 7]. Lifestyle changes such as more exercise have shown positive effects, even without weight loss [8]. It is thought that the mechanisms by which lifestyle modifications reduce the progression to type 2 diabetes may be through alterations in insulin sensitivity [5].

Overweight, usually defined as BMI ≥25 kg/m^2, and obesity, usually defined as BMI ≥30 kg/m^2, are a growing public health concern globally. Excess weight increases not only the risk for type 2 diabetes but also for cardiovascular disease, hypertension, stroke, and other chronic diseases [9]. Most approaches and products recommended to reduce weight are subjects to criticism due to high relapse rates and subsequent return to the original or even higher body weight. For most individuals, maintenance of weight loss is the most difficult part of any weight management program. Hence, programs which demonstrate long-term weight loss stability would be of great value [10].

Community pharmacists are well placed to assist in the provision of preventive care because pharmacies are highly accessible and often the first point of entry into the health care system [11, 12]. Pharmacies are regarded to be a suitable place to promote awareness, screen high-risk patients, and to counsel patients on intervention strategies to delay the onset of diabetes [3, 5]. For early detection, a combination of risk factor assessment and blood glucose measurement performed in

community pharmacies is regarded to be a promising approach and an opportunity for health promotion [3, 4]. Furthermore, intervention studies in community pharmacies were shown to have positive effects on cardiovascular risk factors, for example by improving outcomes in hypertension or cholesterol management [13-15]. A randomized controlled trial has shown that successful weight management can be achieved in a pharmacy setting, where patients have been consulted by the pharmacist every 3 weeks for a time period of 5 months [16].

With this background, the Swiss federation of pharmacists organised in spring 2002 a national screening campaign in Switzerland called “Stop sugar – test now”, with the aim to detect previously undiagnosed individuals with type 2 diabetes and provide counselling towards lifestyle modifications for persons at risk. The evaluation of the campaign is described in a previous paper [17]. The campaign was extended with a 3 step follow-up study aiming to investigate the impact of a community pharmacy based screening campaign and to enable additional intervention studies.
The pharmacy teams which participated in the screening campaign received a specific training program and written guidelines for screening and triage. After individual risk assessment, a measurement of capillary blood glucose level was recommended to all persons with $\geq$2 risk factors. The risk factors considered were: age >45 years, overweight (BMI ≥25kg/m^2), low physical activity, family history of diabetes, delivery of a baby >9 lbs, and hypertension. The five week campaign took place in 530 pharmacies within the German speaking part of Switzerland. A total of 93’258 persons were screened for undiagnosed type 2 diabetes. Of all the persons screened, 71.5% had $\geq$2 risk factors but showed normoglycaemia. A further 6.9% of the screened population showed abnormal blood glucose values and were therefore suspected to have type 2 diabetes, of them 4.4% with hyperglycaemia (fasting blood glucose ≥6.1 mmol/l or non fasting blood glucose ≥11.1 mmol/l) and 2.5% with borderline glycaemia (fasting blood glucose 5.3-6.0 mmol/l or non fasting blood glucose 5.3–11.0 mmol/l, confirmed by a second fasting measurement) [17]. After screening, the readiness for behaviour change in physical activity and nutrition habits were assessed according to the transtheoretical model (Prochaska) [18]. This enabled targeted counselling concerning therapeutic lifestyle change especially for persons at risk for type 2 diabetes. Pharmacists could freely choose whether they provide an additional intensive counselling concerning weight loss to the overweight

persons at moderate risk for type 2 diabetes (≥2 risk factors). Persons with abnormal blood glucose values (high risk for type 2 diabetes) were referred to a physician for further diagnosis and treatment.

The objective of the present study was to investigate the impact of immediate counselling after screening for type 2 diabetes on body weight and lifestyle change and to compare the effects of the three different types of counselling in community pharmacies (standard versus intensive counselling of persons at moderate risk and referring persons at high risk to a physician). For this purpose we evaluated the changes in body weight and lifestyle in a randomly chosen sample of overweight persons at risk for type 2 diabetes three months after screening, as well as half year and one year after this first assessment. In particular we measured the differences in average BMI and weight as well as the percentage of weight loss between baseline (screening campaign) and follow-up questionnaires. Furthermore we evaluated (as secondary outcome measures) self-reported lifestyle changes in physical activity and nutrition.

Methods

Subjects

Of 93'258 persons who have been screened for undiagnosed type 2 diabetes during the screening campaign (mean age 60.9 years ± 14.1 (SD), 33.1% male), 23'279 persons have provided informed consent for further follow-up. An overview of subject's recruitment is shown in Figure 1. The subjects were enrolled into the follow-up study if the following criteria were met: at least 18 years old and BMI of ≥25.0 kg/m^2. Three months after screening, in August 2002, a stratified sample of 3800 randomly chosen persons (who had provided informed consent and met criteria) were contacted with the first of three written questionnaires, of them 1400 persons at moderate risk for type 2 diabetes (≥2 risk factors but normoglycaemia) and with standard counselling in the pharmacy (SC group), 1500 persons at moderate risk for type 2 diabetes and with intensive counselling (IC group) and 900 at high risk for type 2 diabetes (HRC group: ≥2 risk factors and abnormal blood glucose values defined as fasting blood glucose ≥6.1 mmol/l, non fasting blood glucose ≥11.1 mmol/l or borderline values of fasting blood glucose 5.3-6.0 mmol/l or non fasting blood

glucose 5.3-11.0 mmol/l, if confirmed by a second fasting measurement). In February 2003 the study participants who returned the first questionnaire were contacted with the second questionnaire (half year follow-up). In a final step the last of the three questionnaires was sent in August 2003 to all subjects who returned the second one (one year follow-up). Out of 1436 subjects having returned all three questionnaires, 14 subjects had to be excluded from analysis because of wrong linkage of their datasheets and another 52 subjects had to be excluded because of missing self-reported weight data. The subjects' ages varied from 19 to 90 years (mean 59.9 ± 11.0 years). The present study was approved by the Ethics Committee of Basel. Subjects received no financial compensation for participating in this study except the free of charge blood glucose measurement in the pharmacy during the screening campaign.

Counselling concerning therapeutic lifestyle change in the pharmacy

The pharmacists who assisted in the screening campaign received a specific training program in the form of two obligatory evening courses, where oral and written information on screening and counselling guidelines were provided. Specific action plans, using the transtheoretical model (Prochaska) [18], were taught for counselling on the influence able risk factors, such as physical activity and overweight. During the campaign, immediately after screening, the stages of change for three domains according to the transtheoretical model were individually assessed. The three domains were health enhancing physical activity (half an hour of physical activity daily), reduced fat intake and consumption of 5 servings of fruits and/or vegetables per day ("5-a-day"). Using this information as a starting point, pharmacists were able to perform targeted counselling concerning weight reduction and lifestyle modifications. Pharmacists were free to provide either standard or intensive counselling to subjects at moderate risk (≥2 risk factors). The standard counselling included recommendations towards lifestyle modifications such as physical activity and nutrition. Concerning physical activity, persons were instructed to set a goal of half an hour physical activity daily with at least moderate intensity or three times twenty minutes weekly with vigorous intensity. In respect to nutrition habits persons received advice on reduced fat intake and "5-a-day" recommendations. The intensive counselling included an additional targeted counselling on weight reduction with further precise advices on lifestyle changes. Booklets with information on health

promoting lifestyle were handed out by the pharmacy teams to persons in both intensive and standard counselling groups. Pharmacists provided standard counselling to persons at high risk for type 2 diabetes (abnormal blood glucose values) and additionally recommended to call on a physician for further check up. The interventions for the three counselling groups are summarised in Table 1.

Data collection

During the screening campaign, demographics (age, sex and smoking habits) as well as results of individual risk assessments and measured values were recorded by the pharmacy teams on 35 item datasheets [17]. The individual assessment of the stages of change, which provided a basis for counselling, was documented on these datasheets.

At three, nine and fifteen months after screening the follow-up questionnaires, to be completed anonymously, were sent to the study participants, each along with a reply-paid envelope. The three questionnaires were developed by the investigators and included 42 pilot-tested questions including 138 items on demographics, satisfaction of care provided by the pharmacist, potential consultation of a physician for further check up, as well as the outcome measures of changes in weight and achieved lifestyle changes regarding physical activity and nutrition habits. Weight was recorded in kg without decimal places and height in cm. Lifestyle changes were reported in physical activity including everyday physical activities as well as sports activities and in nutrition habits including reduction of fat intake, increase in consumption of fruits and vegetables as well as unspecific reduction of food consumption.

All datasheets and questionnaires were processed automatically with Teleform® version 7.0 from Cardiff Software, CA, USA. The use of automated forms processing (AFP) software were validated by Jorgensen et al. [19], who showed that AFP reduced processing time. For choice fields the error rate for AFP was very low and comparable to double manual data entry, while for numeric recognition the error rate was higher than for both single and double manual data entry. For this reason all numeric recognitions in the forms used were verified visually on screen. Furthermore, distinct ranges for each variable were defined to test plausibility and data were deleted when out of this range. All data files of the forms were imported into

Microsoft® Access databases. The datasheets from the screening campaign and the three questionnaires were linked to each other with a numerical code of 5 numbers, which identified the documents of each study participant. Thus, anonymity was always warranted. The correct linkage of data files was verified with individual data for sex and age, which were recorded on every protocol. If manual correction based on the original protocol was not possible, the data file of the relevant study participant was excluded from analysis.

Data analysis

Primary outcome measures, calculated from the three questionnaires, were the differences in average BMI and weight as well as percentage of weight loss between baseline and the assessment at 3 months after screening and further follow-up assessments. Further, we analysed percentage of subjects able to lose greater or equal than 5% of their initial body weight. All analyses were performed stratifying the study population in different samples of risk and counselling intensity, which resulted in the three different counselling groups: SC group, IC group and HRC group (Table 1). The HRC group was also analysed for potential impact on weight control from physician's consultation. For this purpose we compared percent change of body weight between subjects who have contacted a physician versus those who didn't. Subjects were also evaluated with regard to self-reported lifestyle changes (as a secondary outcome). Prevalence of reported lifestyle changes were analysed in areas of physical activity including everyday physical activities as well as sports activities and in nutrition habits including reduction of fat intake, increase in consumption of fruits and vegetables as well as unspecific reduction of food consumption. Physical activity areas and nutrition areas were pooled to auxiliary variables of "any positive change in physical activity" and "any positive change in nutrition habits". In a final step all areas were pooled to an auxiliary variable of "any positive lifestyle change". Lifestyle changes were additionally analysed by comparing the different samples of counselling intensity.

Statistical analysis was performed using SPSS 11.5 for Windows (SPSS, Inc, Chicago, Illinois, USA). Values are expressed as mean ± standard deviation (SD) or standard error (SE). Change in body mass index and weight over time was analysed using repeated analysis of variance (Generalized linear model: GLM) with linear

contrasts to detect pair wise differences and with counselling groups as covariates. All p-values were calculated two-sided, values of $p<0.05$ being considered statistically significant. In case of significant difference in repeated analysis of variance for the covariates (i.e. counselling intensities), subsequent pair wise comparisons were performed by Tukey's-HSD multicomparison test. Comparison of the different samples and counselling groups at baseline were performed by one-way analyses of variance (ANOVA) with Tukey correction for multiple comparisons. In addition, differences in prevalence of demographic and outcome variables were assessed using Pearson's two-sided chi-square- or Fisher's exact test as appropriate.

Results

Recruitment and characteristics of study population

Out of the 3800 persons addressed for follow-up, 2177 returned the first questionnaire and 1520 returned the second one. A total of 1436 subjects (37.8%) answered all three questionnaires (Figure 1). Out of them, 66 subjects had to be excluded from analysis due to wrong linkage of datasheets or because of missing self-reported weight data.

Consequently the eligible study population included 1370 subjects, of them 557 (40.7%) in the SC group (subjects at moderate risk who received standard counselling), 568 (41.5%) in the IC group (subjects at moderate risk who received intensive counselling) and 245 (17.9%) in the HRC group (subjects at high risk who were referred to a physician). The mean age of the study population was 59.9 years ± 11.0 (SD), 598 persons (43.6%) were male and 167 subjects (12.2%) declared to be smokers. Table 2 shows further demographic information of the study population and of all non-responders. Significant differences between the study population and non-responders were observed in age and BMI, which both were lower in the study population as well as height which was higher in the study population. Furthermore, subjects at high risk for type 2 diabetes showed a statistically significant higher drop out rate than those at moderate risk.

Table 3 shows the comparison of the three counselling groups (SC, IC and HRC group) regarding their baseline characteristics. There were significant differences

between the HRC group and the two other groups. The HRC group's mean age, weight, BMI and systolic blood pressure were greater than both the other groups' and the HRC group's average height was slightly greater than the other groups' ($p<0.04$). Between the SC group and IC group significant differences were observed only in weight and BMI, both which were higher in the IC group than in the SC group ($p<0.001$). Further differences in gender were statistically significant between all groups and there were less smokers in the IC group than in the other two groups.

Change in body weight and BMI over the four time-points of assessment

In all three counselling groups a statistically significant weight loss over the four time-points of assessment was observed. In Table 4 the progression of weight and BMI is analysed by stratifying the study population into the three counselling groups of subjects at moderate risk with standard counselling (SC group; n=557), subjects at moderate risk with intensive counselling (IC group; n=568) and subjects with high risk counselling (HRC group; n=245). Subjects in all counselling groups showed a significantly lower body weight three months after screening ($p<0.001$). This weight loss was highest in the HRC group. At half year follow-up, a slight weight gain was observed, which was not statistically significant in the study population as a whole. A further significant weight reduction ($p<0.001$) was observed in all counselling groups at one year follow-up. Therefore a seasonal interference on weight control is assumed, with weight loss in the warmer season and weight stability in the colder season. Subjects in the HRC group reached a higher percentage of weight loss than subjects in the IC and SC group three months after screening (-2.25% vs. -1.20% and -0.67%; $p <0.001$) as well as at half year follow-up (-1.99% vs. -0.88% and -0.51%; $p <0.01$) and at one year follow-up (-2.74% vs. -1.54% and -1.29%; $p <0.01$). Furthermore subjects in the IC group reached a higher percentage of weight change than subjects in the SC group three months after screening (-1.20% vs. -0.67%; $p<0.05$), but not at half year and at one year follow-up.

Analysing the HRC group for the impact of physician's consultation on weight loss, a trend towards higher weight loss was observed three months after screening in those subjects who have contacted a physician (n=198; 80.8%) with a weight loss of 2.40% vs. 1.67% in those subjects without consultation (n=47). However, this difference was not statistically significant and there was no significant difference in weight loss over

the four time-points of assessment between subjects who called on a physician and those who did not.

Analysing the whole study population, 154 subjects (11.2%) lost more or equal than 5% of their initial body weight three months after screening. Considering counselling intensity, 7.9% of the subjects in the SC group were able to loose ≥5% of initial body weight, 11.6% in the IC group and 18.0% in the HRC group ($p<0.001$; significant differences between all counselling groups). At one year follow-up, 253 subjects (18.5%) in the whole study population lost ≥5% of their initial body weight. Considering counselling intensity, 16.7% of the subjects in the SC group, 17.6% in the IC group and 24.5% in the HRC group showed ≥5% weight loss ($p<0.05$; significant difference between HRC and IC and SC groups, but not between IC and SC groups).

Self-reported changes in lifestyle

Three months after screening 72.5% of the subjects in the whole study population (n=1370) reported to have changed their lifestyle (physical activity and/or nutrition habits). An influence of pharmacist's counselling intensity was observed in self-reported lifestyle changes (Figure 2) with 67.0% in the SC group declaring to have changed their lifestyle, 74.1% in the IC group and 81.2% in the HRC group ($p<0.001$). The influence of pharmacist's counselling intensity was statistically significant in all areas ($p<0.001$) with the exception of an increase in sports activity. In each of the areas of lifestyle change, a similar pattern emerged. Throughout there were more subjects with self-reported improvements in the HRC group than in the IC group, with statistically significant differences in all areas measured. More persons were found with self-reported improvements in the IC group than in the SC group, with significant differences in four of the eight areas measured (any positive lifestyle change, increase in everyday physical activity, any positive change in nutrition, and reduction of fat intake). The greatest impact of counselling intensity was found on the reduction of fat intake.

Discussion

The results of our study show that in overweight individuals at risk for type 2 diabetes immediate counselling after screening for type 2 diabetes can initiate significant lifestyle changes and weight loss. These effects were shown to be sustainable. We observed a significant decrease in weight and BMI three months after screening as well as at one year follow-up. There was also an impact of pharmacist's counselling intensity on weight loss. Subjects in the HRC group reached a higher percentage of weight change than subjects in the IC and SC group three months after screening (2.25% vs. 1.20% and 0.67%; $p < 0.001$) as well as at one year follow-up (2.74% vs. 1.54% and 1.29%; $p < 0.01$). In total, 11.2% of all subjects lost ≥5% of their initial body weight three months after screening.

In two randomised controlled trials which investigated the effect of either sibutramine or orlistat on weight reduction [20, 21], the placebo groups showed an average weight loss of 4.6% to 6.1% after 24 or 12 months, respectively. In comparison, the 1.3% to 2.7% average weight loss observed in our study thus appears to be modest, but attendance must be paid to the fact that the patients in the two randomised controlled trials were much more obese (average BMI of 36.1 and 36.7 kg/m^2, respectively) than the subjects in the present study. Moreover, dietetic help with medical attendance was provided to the placebo groups in those two trials, whereas the weight loss in our study was achieved with only one intervention and in less obese individuals. With this background the observed weight loss represents a notable result which could still be associated with a significant health improvement. A weight loss of 5-10% can successfully reduce the consequences of co-morbid conditions associated with obesity such as dyslipidaemia, hypertension and diabetes [22, 23].

Furthermore 72.5% of all subjects in the follow-up study population declared to have changed their lifestyle in any measured area three months after screening. Subjects at high risk for type 2 diabetes (HRC group) as well as those who got intensive counselling in the pharmacy after screening for type 2 diabetes (IC group) were more likely to change their lifestyle than subjects in the standard counselling group (SC group). These differences were significant in all areas of self-reported lifestyle change for the HRC group vs. IC group and in four of eight areas for the IC group vs. SC group. Of further interest is the much smaller number of subjects declaring to have increased sports activities as compared to their increase in everyday physical

activity. It seems that especially for overweight persons there is a rather big barrier to increase sportive activities or even more to start with them.

Because subjects at high risk for type 2 diabetes showed more pronounced weight loss as well as self-reported lifestyle changes than subjects at moderate risk with intensive counselling, it is probable that the blood glucose measurement in the pharmacy (and the measured glucose value itself) has initiated a stronger readiness for lifestyle change. No significant influence of a physician's consultation was observed in the HRC group, even though 80.8% of subjects followed the pharmacist's recommendation to call on a physician for further check up. The stronger effects on weight loss in the HRC group were therefore most likely not caused by consulting a physician but rather by the psychological effect of the abnormal blood glucose value detected in the pharmacy.

It is possible that the weight reduction achieved in our study could be enhanced by repeating this singular pharmacy counselling after 3 months. This could reduce the impact of the colder season on weight control. Several studies have shown that the BMI of overweight as well as of normal weight individuals were higher in winter than in summer seasons [24, 25]. With this seasonal effect in mind, Visscher and Seidell suggested waist circumference to be a more sensitive indicator of variations in lifestyle and body composition than body mass index [25].

The Third Report of the National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III; ATP III) [26] recommends a multifactorial lifestyle approach to reducing risk for coronary heart disease (CHD). This approach is referred to as therapeutic lifestyle change (TLC) and includes the following components: reduced intake of saturated fats and cholesterol, therapeutic dietary options for enhancing LDL (low density lipoprotein) lowering, weight reduction and increased regular physical activity. According to the ATP III, at all stages of dietary therapy, physicians are encouraged to refer patients to registered dieticians or other qualified nutritionists. A high proportion of patients with the metabolic syndrome are overweight or obese and sedentary; for them, weight reduction therapy and physical activity guidance is required to obtain further CHD risk reduction beyond that achieved by LDL lowering through dietary alterations. Considering the design and the results of the present study, we would suggest that initiating TLC in community pharmacies could be a promising approach to reduce the risk for diabetes and

coronary heart disease. Especially if the screening is enlarged and dyslipidaemia is observed, subsequent counselling on TLC should be mandatory.

The results of our study are limited by the fact that there was quite a high dropout rate over the three follow-up assessments. Such dropout rates have been observed to a slightly lesser extent also in other weight loss studies, but in those studies personal contact were maintained to health professionals during follow-up [16, 22]. The dropout rates in our study were different between the two risk samples. There was a higher dropout rate in the sample of subjects at high risk for type 2 diabetes than in the sample at moderate risk. Further, the mean age as well as the average BMI was greater in non-responders than in the study population. This suggests that subjects at lower risk for type 2 diabetes are more willing to answer three complex questionnaires and show concern in their lifestyle and health. It is also probable that the subjects who answered all three questionnaires were more inclined to change their lifestyle. Unfortunately the reasons why subjects dropped out and what happened with their weight and lifestyle after having dropped out of the study could not be assessed and are therefore not known.

Interpretation of results is further limited by the design of the study itself which does not include a control group. It would be of special interest to include subjects who did not participate in screening for type 2 diabetes and received no counselling regarding therapeutic lifestyle change. Furthermore there was no randomisation of the participants into the two groups of intensive and standard counselling in the pharmacy. Pharmacists themselves were allowed to decide whether they provided intensive or standard counselling. As could be expected, the average BMI of the intensive counselling group was significantly higher compared to the standard counselling group, as pharmacists have provided intensive counselling more often to subjects with a higher body weight. It is further likely that time availability has influenced the pharmacists' decision of providing either intensive or standard counselling.

Data such as weight and height in the present study were acquired using written questionnaires and results therefore are based on self-reported data. There is substantial evidence that self-reported height and weight can result in subsequent misclassification of overweight status particularly in older adults, whereas other studies have shown self-reported data to be largely reliable [27-29].

Conclusions

The results of this study show that immediate counselling of persons screened for type 2 diabetes in community pharmacies can result in significant lifestyle changes. A measurable, significant weight loss was achieved, and further changes in important lifestyle areas such as physical activity and nutrition habits were reported. These effects were more accentuated in persons at high risk for type 2 diabetes, who showed abnormal blood glucose values during the screening. Counselling effects were likewise more pronounced in the group which received intensive counselling in the pharmacy than in the group with standard counselling.

Combining screening for type 2 diabetes, including blood glucose measurement, with consecutive counselling activities in community pharmacies represents a promising opportunity to initiate therapeutic lifestyle change. Screening for type 2 diabetes in community pharmacies should be followed immediately by targeted counselling with the aim to initiate therapeutic lifestyle change in persons at risk. As we demonstrated, pharmacists can play an important role in helping individuals to control their weight and to change their lifestyle.

Competing interests

None of the authors have any competing interests to declare.

Authors' contributions

AB collected all data, performed the analysis and drafted the manuscript. RB contributed substantially to the study design and to the analysis of data. SK assisted considerably in interpretation of data and provided valuable notions to the drafted manuscript. KH supervised the whole project, contributed substantially to the study’s design and interpretation of data and helped drafting the article. All authors read the manuscript and gave final approval of the version to be published.

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References

1. Wild S, Roglic G, Green A, Sicree R, King H. Global prevalence of diabetes: estimates for the year 2000 and projections for 2030. Diabetes Care 2004; 27:1047-53.

2. King H, Aubert RE, Herman WH. Global burden of diabetes, 1995-2025: prevalence, numerical estimates, and projections. Diabetes Care 1998; 21:1414-31.

3. American Diabetes Association. Screening for type 2 diabetes. Diabetes Care 2004; 27 Suppl 1:S11-4.

4. American Diabetes Association: The prevention or delay of type 2 diabetes. Diabetes Care 2002; 25:742-9.

5. Irons BK, Mazzolini TA, Greene RS. Delaying the onset of type 2 diabetes mellitus in patients with prediabetes. Pharmacotherapy 2004; 24:362-71.

6. Tuomilehto J, Lindstrom J, Eriksson JG, et al. Prevention of type 2 diabetes mellitus by changes in lifestyle among subjects with impaired glucose tolerance. N Engl J Med 2001; 344:1343-50.

7. Knowler WC, Barrett-Connor E, Fowler SE, et al. Reduction in the incidence of type 2 diabetes with lifestyle intervention or metformin. N Engl J Med 2002; 346:393-403.

8. Duncan GE, Perri MG, Theriaque DW, Hutson AD, Eckel RH, Stacpoole PW. Exercise training, without weight loss, increases insulin sensitivity and postheparin plasma lipase activity in previously sedentary adults. Diabetes Care 2003; 26:557-62.

9. Obesity: preventing and managing the global epidemic. Report of a WHO consultation. World Health Organ Tech Rep Ser 2000; 894:i-xii, 1-253.

10. Clinical Guidelines on the Identification, Evaluation, and Treatment of Overweight and Obesity in Adults--The Evidence Report. National Institutes of Health. Obes Res 1998; 6 Suppl 2:51S-209S.

11. Tsuyuki RT, Johnson JA, Teo KK, et al. Study of Cardiovascular Risk Intervention by Pharmacists (SCRIP): a randomized trial design of the effect of a community pharmacist intervention program on serum cholesterol risk. Ann Pharmacother 1999; 33:910-9.

12. Ford S, Jones K. Integrating pharmacy fully into the primary care team. BMJ 1995; 310:1620-1.

13. Tsuyuki RT, Johnson JA, Teo KK, et al. A randomized trial of the effect of community pharmacist intervention on cholesterol risk management: the Study of Cardiovascular Risk Intervention by Pharmacists (SCRIP). Arch Intern Med 2002; 162:1149-55.

14. Chabot I, Moisan J, Gregoire JP, Milot A. Pharmacist intervention program for control of hypertension. Ann Pharmacother 2003; 37:1186-93.

15. Peterson GM, Fitzmaurice KD, Naunton M, Vial JH, Stewart K, Krum H. Impact of pharmacist-conducted home visits on the outcomes of lipid-lowering drug therapy. J Clin Pharm Ther 2004; 29:23-30.

16. Ahrens RA, Hower M, Best AM. Effects of weight reduction interventions by community pharmacists. J Am Pharm Assoc (Wash DC) 2003; 43:583-9.

17. Hersberger K, Botomino A, Mancini M, Bruppacher R. Sequential screening for diabetes risk in Swiss community pharmacies - evaluation of a national campaign. BMC Public Health, submitted.

18. Prochaska JO, Velicer WF. The transtheoretical model of health behavior change. Am J Health Promot 1997; 12:38-48.

19. Jorgensen CK, Karlsmose B. Validation of automated forms processing. A comparison of Teleform with manual data entry. Comput Biol Med 1998; 28:659-67.

20. James WP, Astrup A, Finer N, et al. Effect of sibutramine on weight maintenance after weight loss: a randomised trial. STORM Study Group. Sibutramine Trial of Obesity Reduction and Maintenance. Lancet 2000; 356:2119-25.

21. Sjostrom L, Rissanen A, Andersen T, et al. Randomised placebo-controlled trial of orlistat for weight loss and prevention of weight regain in obese patients. European Multicentre Orlistat Study Group. Lancet 1998; 352:167-72.

22. Munsch S, Biedert E, Keller U. Evaluation of a lifestyle change programme for the treatment of obesity in general practice. Swiss Med Wkly 2003; 133:148-54.

23. Wing RR, Hill JO. Successful weight loss maintenance. Annu Rev Nutr 2001; 21:323-41.

24. Dzien A, Dzien-Bischinger C, Lechleitner M. Seasonal fluctuation in body mass index. Clin Nutr 2003; 22:425-6.

25. Visscher TL, Seidell JC. Time trends (1993-1997) and seasonal variation in body mass index and waist circumference in the Netherlands. Int J Obes Relat Metab Disord 2004.

26. Third Report of the National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III) final report. Circulation 2002; 106:3143-421.

27. Kuczmarski MF, Kuczmarski RJ, Najjar M. Effects of age on validity of self-reported height, weight, and body mass index: findings from the Third National Health and Nutrition Examination Survey, 1988-1994. J Am Diet Assoc 2001; 101:28-34; quiz 35-6.

28. Strauss RS. Comparison of measured and self-reported weight and height in a cross-sectional sample of young adolescents. Int J Obes Relat Metab Disord 1999; 23:904-8.

29. Engstrom JL, Paterson SA, Doherty A, Trabulsi M, Speer KL. Accuracy of self-reported height and weight in women: an integrative review of the literature. J Midwifery Womens Health 2003; 48:338-45.

Figures

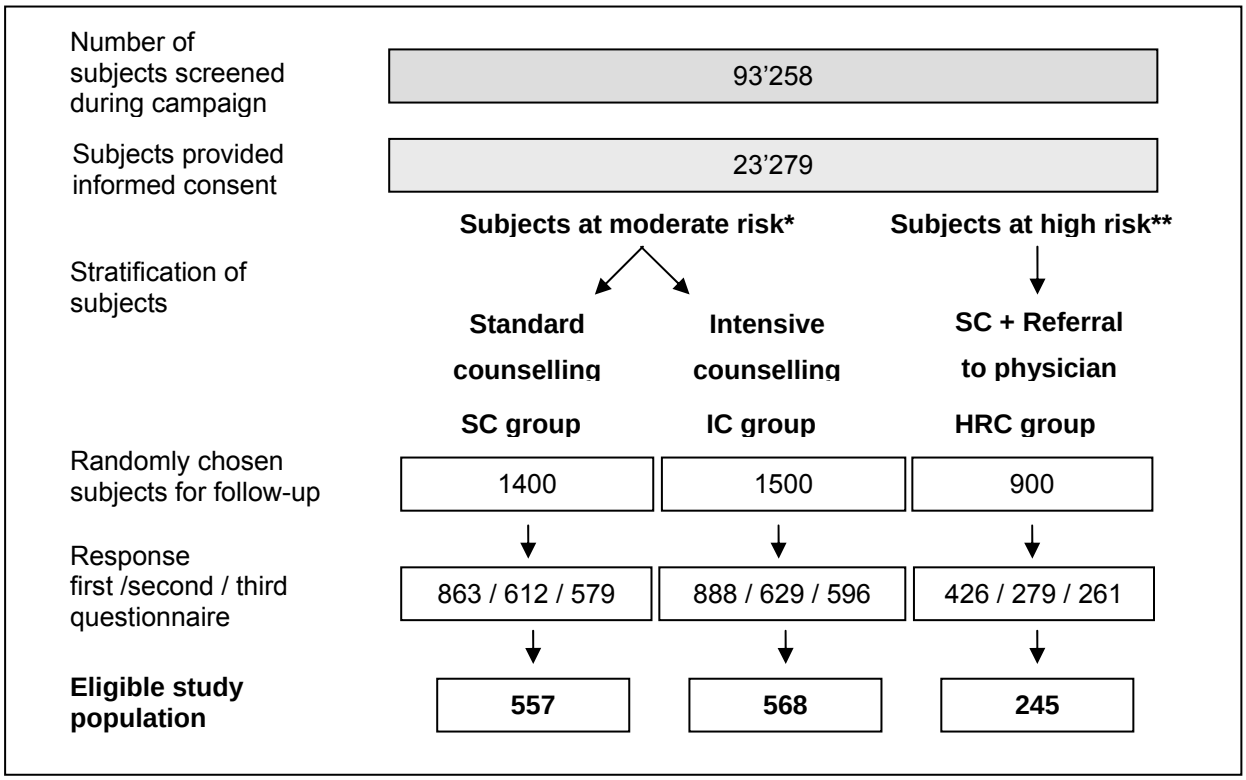

Figure 1: Recruitment of the study population

* moderate risk: ≥2 risk factors (out of 6) but normoglycaemia
** high risk: ≥2 risk factors (out of 6) and abnormal blood glucose (fasting blood glucose ≥6.1 mmol/l, non fasting blood glucose ≥11.1 mmol/l or borderline values of fasting blood glucose 5.3-6.0 mmol/l or non fasting blood glucose 5.3-11.0 mmol/l, confirmed by a second measurement in the fasting state)
SC: standard counselling
IC: intensive counselling
HRC: high risk counselling

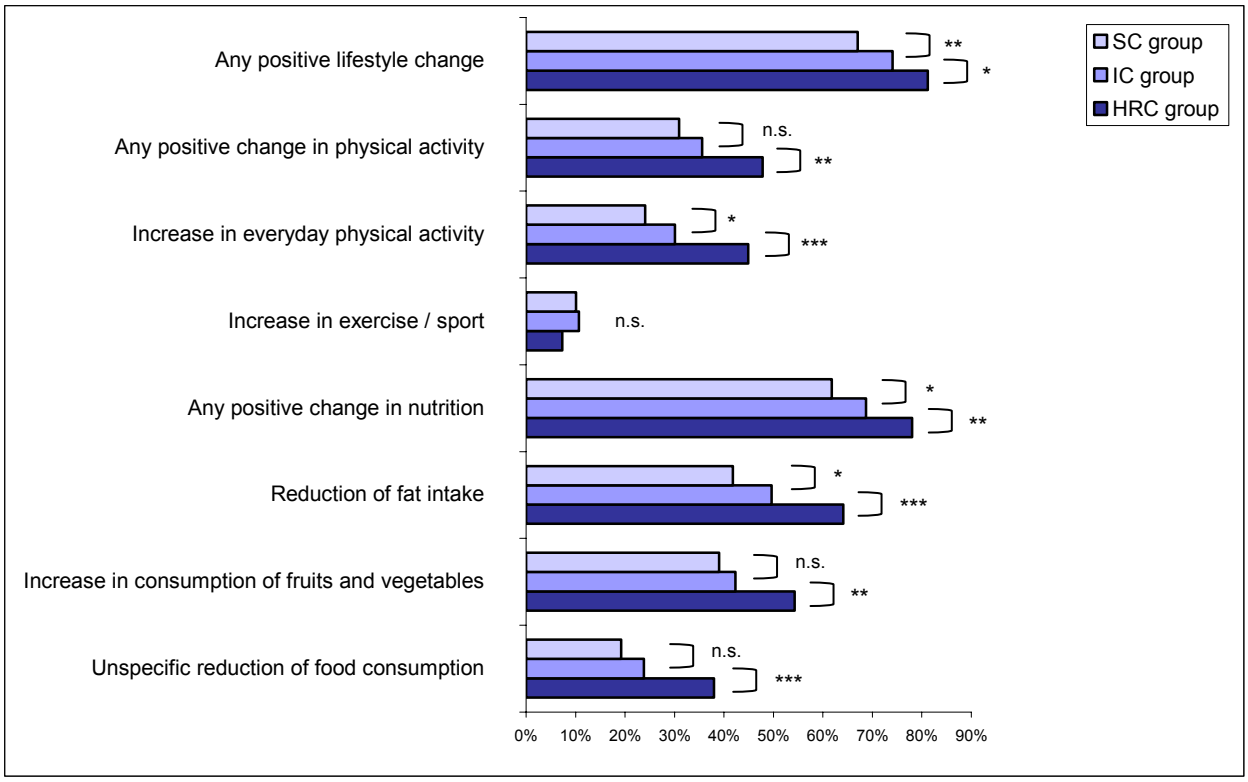

Figure 2: Self-reported positive changes in lifestyle three months after screening

SC: standard counselling
IC: intensive counselling
HRC: high risk counselling
Statistically significant differences are indicated (*p<0.05; ** p<0.01; *** p<0.001)

Tables

Table 1: Interventions for the three different counselling groups

Counselling group	Risk constellation	Intervention			
		Assessment of three stages of change according to the trans-theoretical model (adequate physical activity, low fat intake, 5-a-day)	Unspecific recommendations concerning physical activity and nutrition	Explicit advice to reduce body weight including targeted counselling on weight reduction and additional precise advice towards lifestyle change	Referral to a physician for further check up
Standard counselling (SC group)	Moderate risk (≥2 risk factors, but normal blood glucose values)	+	+		
Intensive counselling (IC group)	Moderate risk (≥2 risk factors, but normal blood glucose values)	+	+	+	
High risk counselling (HRC group)	High risk (≥2 risk factors **and** abnormal blood glucose values)	+	+		+

Table 2: Comparison of baseline characteristics between study population and non-responders

	Study population (n = 1370) Mean ± SD	Non-responders (n = 2364) Mean ± SD	p-value
Age [years]	59.9 ± 11.0	60.8 ± 11.3	0.03
Gender			
male	43.6%	41.0%	
female	56.4%	59.0%	0.12
Smoking habits			
Current smoker	12.4%	13.1%	
Not current smoker	87.6%	86.9%	0.58
Risk intensity for type 2 diabetes			
moderate risk	82.1%	73.3%	
high risk	17.9%	26.7%	<0.001
Height [cm]	168.8 ± 8.5	167.6 ± 8.2	0.003
Weight [kg]	80.5 ± 11.2	80.8 ± 11.6	0.35
Body mass index [kg/m^2]	28.3 ± 3.1	28.8 ± 3.3	<0.001
Systolic blood pressure [mmHg]	139.5 ± 18.2	140.1 ± 19.4	0.35
Diastolic blood pressure [mmHg]	86.2 ± 11.2	85.6 ± 11.5	0.14

Table 3: Baseline characteristics of the three different counselling groups

	SC group (n = 557) Mean ± SD	IC group (n = 568) Mean ± SD	HRC group (n = 245) Mean ± SD	p-value
Age [years]	59.4 ± 10.8	58.3 ± 11.6	64.9 ± 8.6	<0.001 ♣
Gender				
male	45.1%	36.6%	56.7%	
female	54.9%	63.4%	43.3%	<0.001 *
Smoking habits				
Current smoker	14.4%	9.7%	14.3%	
Not current smoker	85.6%	90.3%	85.7%	0.035 +
Height [cm]	168.9 ± 8.6	168.2 ± 8.4	169.8± 8.4	0.045 ♦
Weight [kg]	77.9 ± 10.4	81.7 ± 11.2	83.6 ± 11.5	<0.001 ‡
Body mass index [kg/m^2]	27.3 ± 2.6	28.8 ± 3.2‡	29.0 ± 3.3	<0.001 ‡
Systolic blood pressure [mmHg]	137.3 ± 18.1	139.0 ± 17.5	145.9 ± 18.8	<0.001 ♣
Diastolic blood pressure [mmHg]	85.5 ± 11.3	86.6 ± 10.9	86.8 ± 11.4	0.16

SC: standard counselling
IC: intensive counselling
HRC: high risk counselling
♣ Significant differences only between HRC vs. IC group and between HRC vs. SC group
* Significant differences between all groups
+ Significant differences only between IC vs. SC group
♦ Significant differences only between HRC vs. IC group
‡ Significant differences only between HRC vs. SC group and IC vs. SC group

Table 4: Change of BMI, body weight and percent change of body weight in the different counselling groups

Variable	Screening campaign (T1)	3 months after screening (T2)		½ year Follow-up (T3)			1 year Follow-up (T4)			
			p-value T1/T2		p-value T2/T3	p-value T1/T3		p-value T3/T4	p-value T2/T4	p-value T1/T4
BMI [kg/m^2]										
SC	27.3 ± 2.6	27.1 ± 2.7	***	27.1 ± 2.7	n.s.	**	26.9 ± 2.7	***	**	***
IC	28.8 ± 3.2	28.5 ± 3.3	***	28.6 ± 3.5	*	***	28.4 ± 3.4	***	*	***
HRC	29.0 ± 3.3	28.3 ± 3.3	***	28.4 ± 3.3	n.s.	***	28.2 ± 3.3	***	*	***
Weight [kg]										
SC	77.9 ± 10.4	77.3 ± 10.6	***	77.4 ± 10.4	n.s.	**	76.8 ± 10.6	***	***	***
IC	81.7 ± 11.2	80.7 ± 11.4	***	80.9 ± 11.7	*	***	80.4 ± 11.6	***	n.s.	***
HRC	83.6 ± 11.5	81.7 ± 11.4	***	81.9 ± 11.5	n.s.	***	81.2 ± 11.5	***	*	***
Percent change of body weight										
SC		-0.67%		-0.51%			-1.29%			
IC		-1.20%		-0.88%			-1.54%			
HRC		-2.25%		-1.99%			-2.74%			

SC: standard counselling
IC: intensive counselling
HRC: high risk counselling
Values are given as mean ± SD
The p-values refer to linear contrasts of repeated analysis of variance (* p<0.05 ** p<0.01; *** p<0.001; n.s.; not significant)

4.2 Project E:

Effect of a telephone-based intervention on body weight and lifestyle of persons at risk for type 2 diabetes

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Swiss Med Wkly; submitted

Abstract

Objective

The objective of the present study was to investigate the effect of a telephone-based counselling intervention on body weight and lifestyle of overweight persons at risk for type 2 diabetes.

Methods

Subjects were recruited among participants in a pharmacy based diabetes screening campaign and randomly selected for intervention and control group. Eligibility criteria were: age 18-75 years, BMI≥25kg/m2 and no medical care for cardiovascular disease. Within three months three telephone-based counselling sessions with a mean duration of 8 minutes were provided to the intervention group. Body weight and lifestyle were assessed before intervention, three months after and another half year later with written questionnaires.

Results

Three months after the intervention mean percent change of body weight was -0.37% in the intervention group (n=385) and +0.09% in the control group (n=778) ($p<0.05$). The proportion for loss of ≥3% of initial body weight was 15.1% in the intervention vs. 10.4% in the control group ($p<0.05$). Half a year later differences were not significant anymore. The proportion of subjects who newly achieved targeted goals of either moderate or vigorous physical activity showed no differences. However, a greater proportion of subjects in the intervention group progressed at least to the next higher stage of change in the transtheoretical model (27.0% vs. 21.3%; $p<0.05$). Lifestyle changes in physical activity and/or nutrition were reported by 80.5% vs. 62.9% ($p<0.001$).

Conclusions

With three telephone-based counselling interventions with a mean duration of 8 minutes a measurable weight loss and significant lifestyle changes could be achieved.

Keywords

telephone-based counselling • type 2 diabetes • overweight • body mass index • physical activity • nutrition habits • lifestyle change • stages of change • transtheoretical model

Introduction

Type 2 diabetes mellitus is a public health concern, and projections of its future effect are alarming. The number of persons affected by type 2 diabetes is expected to increase in the future due to population growth, aging, urbanization, and increasing prevalence of obesity and physical inactivity [1], [2]. Type 2 diabetes is often asymptomatic in its early stages and can remain undiagnosed for many years. The risk increases with age, obesity and lack of physical activity [3].

World wide overweight (body mass index [BMI] 25–30 kg/m2) and obesity (BMI ≥30 kg/m2) are a growing public health problem. Excess weight increases not only risk for type 2 diabetes but also for cardiovascular disease, hypertension, stroke, and other chronic diseases [4]. There is substantial evidence that type 2 diabetes can be prevented or at least delayed by changes in lifestyle [5], [6]. Two randomised controlled trials have shown that intensive lifestyle modifications through alterations in diet and improvement in exercise can delay or prevent progression of impaired glucose tolerance to type 2 diabetes [7, 8]. The 3-year follow-up of the Finnish Diabetes Prevention Study has even shown sustainability of reduced diabetes risk in the intervention group [9]. Lindstrom et al. concluded from these results that initiating lifestyle change by intervention programs is a feasible option to prevent type 2 diabetes. Lifestyle changes such as physical exercising have been shown to have positive effects even without weight loss [10]. The mechanisms by which lifestyle modifications reduce the progression may be through alterations in insulin sensitivity [6].

Telephone-based counselling is an alternative to face-to-face interventions which are expensive due to high personnel costs. Telephone contact lacks some of the features that may make personal contact effective, but it is conceptually superior to mail-based approaches because it provides greater certainty that participants will receive regular reminders of their weight control objectives. However, studies on telephone-assisted interventions on weight control and lifestyle change are still relatively rare and show controversial results. Some studies have shown beneficial effects on weight control, physical activity and nutrition habits [11] while others did not show statistically significant effects on physical activity and nutrition habits [12], [13]. A randomised controlled trial with 64 participants showed no significant difference in weight loss between telephone-based intervention and control group [14]. Nevertheless, Hellerstedt

and Jefferey [14] concluded that this type of investigations should be continued as it is possible to identify a more effective design of such interventions.

The objective of the present study was to investigate whether three telephone-based counselling sessions with a mean duration of 8 minutes have a beneficial influence on body weight and lifestyle of overweight persons at risk for type 2 diabetes. Subjects for this study were recruited from participants of a national diabetes screening campaign in Switzerland [15] and randomly assigned to either the intervention or control group. To assess the short term as well as the long term efficacy of the telephone-based counselling the differences in average weight, BMI and percentage of weight loss as well as in stage of change for physical activity according to the transtheoretical model (Prochaska) [16] were determined three and nine month after the counselling respectively. In addition, self-reported lifestyle changes in physical activity and nutrition habits were evaluated.

Methods

Recruitment of subjects

Of 93'258 persons who have been screened during the diabetes screening campaign, 23'279 persons provided informed consent for further follow-up studies. A total of 4700 overweight subjects at risk for type 2 diabetes were selected for the present study. The participants had to meet the following criteria: 18 to 75 years old, BMI ≥25.0 kg/m2 and no medical care for cardiovascular disease. For baseline assessment the subjects were addressed with a written questionnaire three month after the screening campaign (August 2002). Out of 2597 persons having answered the first questionnaire, 1160 persons were randomly assigned to the telephone-based counselling (intervention group) and 1437 subjects to the control group. The intervention group got three telephone-based counselling calls from October to December 2002. In February 2003, the subjects were addressed with the second questionnaire to evaluate the effect of the telephone-based counselling. A third questionnaire was sent in August 2003 to all subjects who returned the second questionnaire (half year follow-up). Subjects received no financial compensation for participating. The project was approved by the Ethics Committee of Basel.

Telephone-based counselling

The counselling calls were conducted by health counsellors of the Medvantis medical call center in Switzerland. All counsellors were nurses or physician assistants who had experience with this type of counselling and were supervised weekly by physicians. Prior to the telephone calls, in a half-day course, the counsellors were trained in behavioural counselling technique. Each subject of the intervention group received three counselling calls with intervals of at least 3 weeks and at most 4 weeks between two calls. The counsellors addressed both physical activity and nutrition with the aim to reduce body weight. Subjects were informed about the recommendation of at least half an hour physical activity of moderate intensity (e.g. walking, gardening) a day or three times twenty minutes weekly of activities with vigorous intensity (e.g. jogging, fast cycling). They got advice regarding low fat intake and increased consumption of fruits and vegetables, in particular consumption of 5 servings of fruits and/or vegetables per day ("5-a-day behaviour"). Furthermore, counsellors provided tips towards physical activity and nutrition habits which could easily be implemented into everyday life. In each call the counsellors asked whether the participants reached their goals and they counselled about strategies to overcoming possible barriers. The counsellor focused the call based on a standardized script on the target behaviour the participant found most difficult. If the participants easily met their goals, they were encouraged to either increase these goals or select new ones. Mean duration of the counselling calls was 8 minutes with a range of 5 to 20 minutes.

Data collection

The three questionnaires were to be completed anonymously and were sent to the study participants each along with a reply-paid envelope. They were developed by the investigators and were pre-tested with 20 individuals, but no adaptations were necessary. The basic questionnaire included 24 questions with 52 items on demographics and on outcome measures of body weight and achieved lifestyle changes in physical activity and nutrition habits. The second questionnaire contained 26 questions with 56 items on demographics and outcome measures as well as towards quality of the telephone-based counselling. The third questionnaire included 15 questions with 35 items on demographics and outcome measures. Weight was recorded in kg without decimal places and height in cm. Physical activity was assessed with the items from the Swiss HEPA (health enhancing physical activity) Survey 2001

[17]. Two sets of questions were used to assess activities of both moderate and vigorous level in a two-step-procedure (days per week; average duration). The intention to become more physically active within the next six months and within the next month as well as the duration since the introduction of the current activity behaviour were also assessed. To report changes in physical activity questions like new participation in sport courses, new workout in fitness centres, increase in sportive activities and increase in everyday physical activity were included. Changes in nutrition habits could be reported in reduction of fat intake, increase in consumption of fruits and vegetables, improvement in “5-a-day behaviour” and unspecific reduction of food consumption.
All questionnaires were processed automatically using Teleform® version 7.0 from Cardiff Software, CA, USA. This software has been validated by Jorgensen et al. [18]. For choice fields the error rate was very low and comparable to double manual data entry, while for numeric recognition the error rate was higher than for both single and double manual data entry. Therefore in the present study all numeric recognitions have been verified visually on screen. The three questionnaires were linked to each other with a numerical code of 5 numbers and anonymity was always guaranteed. The link of data files was verified with individual data for sex and age. If manual correction based on the hard copy was not possible the according data file was excluded from analysis.

Analysis of data

Primary outcome measures were: differences in average BMI and weight, percent change of body weight and percentage of patients loosing more or equal than 3% of their initial body weight. Physical activity was assessed with the stages of change of the transtheoretical model (Prochaska) [19]. Half an hour physical activity daily (≥5 days per week) with at least moderate intensity and/or three times twenty minutes weekly of activities with vigorous intensity was used as respective target behaviours. The stages of change were calculated using an algorithm on the basis of the two sets of questions for both moderate and vigorous activity. They included: (1) pre-contemplation: inactive and no intention to become active; (2) contemplation: inactive with intention to become active within the next 6 months; (3) preparation: inactive with intention to become active within the next month; (4) action: meeting the moderate intensity or vigorous intensity recommendations since up to half a year; (5) maintenance: meeting the recommendations since at least half a year.

As secondary outcome measures prevalence rates of self-reported lifestyle changes in physical activity and in nutrition habits were evaluated. They were pooled to auxiliary variables of “any positive change in physical activity” as well as “any positive change in nutrition habits” and in a final step to “any positive lifestyle change”.

Statistical analysis was performed using SPSS 11.5 for Windows (SPSS, Inc, Chicago, Illinois, USA). Values are expressed as mean ± standard deviation (SD) or standard error (SE). Change in BMI and body weight over time was analysed using repeated analysis of variance (Generalized linear model: GLM) with intervention and control group as covariates. Linear contrasts were applied to detect pairwise differences. All p-values were calculated two-sided, values of $p<0.05$ being considered statistically significant. Unpaired student's t-tests were used to compare numeric variables of baseline characteristics and outcome measures. In addition, differences in prevalences of demographic and outcome variables were assessed using Pearson's two-sided chi-square- or Fisher’s exact test as appropriate.

Results

Recruitment and characteristics of study population

Of 1160 persons randomly chosen for telephone-based intervention 611 (52.7%) participated in the three counselling calls. Subjects who refused to participate in the intervention (non-participants) were compared with participants regarding their baseline characteristics and results are given in Tables

Table 3. Statistically significant differences were found in sex with a greater prevalence of women in the group of participants. Further, non-participants showed a healthier risk constellation with a lower BMI than participants ($p=0.02$) and a slightly higher mean stage of change for physical activity ($p=0.04$).

Response rates three months after the intervention were 72.2% in the intervention group vs. 70.9% in the control group and 94.6% vs. 94.9% at half year follow-up, respectively. Out of 1384 subjects having returned all questionnaires 23 subjects had to be excluded from analysis because of wrong linkage of their data records. Another 198 subjects had to be excluded because of missing data in primary outcome measures. Thus, the eligible study population consisted of 1163 subjects, 385 of them belonging to the intervention group and 778 to the control group. The mean age of the study

population was 57.8 years ± 10.7 (SD), 484 (41.6%) were male and 134 (11.5%) declared to be smokers. Statistically significant differences between study population and non-responders were observed only in BMI (higher in non-responders) and in height (smaller in non-responders). The comparison of the baseline characteristics of intervention and control group (Tables
Table 3) showed no statistically significant differences between intervention and control group except for physical activity: mean stage of change was higher in the control group than in the intervention group ($p<0.01$).

Changes in body weight and BMI

The changes in body weight and BMI are shown in Table 4. Subjects in the intervention group showed a statistically significant weight loss three months after counselling whereupon in the control group a slight, but statistically not significant weight gain was observed. At half year follow-up (August 2003) there was a significant weight reduction in both intervention and control group. Three months after the telephone-based counselling the intervention group has reached a higher percent change of body weight than the control group (-0.37% vs. +0.09%; $p=0.02$). At half year follow-up subjects in the intervention group showed also a higher percent change of body weight (-0.85% vs. -0.71%); however this difference was not statistically significant anymore.
Three months after intervention, a greater part of subjects in the intervention group lost 3 or more percent of their initial body weight (58 subjects [15.1%] in the intervention group vs. 81 subjects [10.4%] in the control group [$p<0.05$]). At half year follow-up, 84 subjects (21.8%) in the intervention group lost ≥3% of the initial body weight vs. 156 subjects (20.1%) in the control group (difference not significant).

Changes in physical activity

Three months after the telephone-based counselling as well as at half year follow-up chi-square analysis revealed no significant differences between intervention and control group for either moderate or vigorous physical activity in the proportion of subjects who newly achieved targeted goals (30 min. ≥5 times per week for vigorous activity and 20 min ≥3 times per week for moderate physical activity). However, a significant difference between intervention and control group was observed regarding mean differences in stage of change three months after the intervention (-0.02 vs. -0.31; $p=0.01$). However, at half year follow-up this difference was not significant anymore (+0.10 vs. -0.03; n.s.).

Figure 3 shows the proportion of subjects who progressed at least to the next higher stage of change, stayed in the same stage, or regressed to a previous stage three months after counselling. Subjects in the intervention group were more likely to progress at least to the next higher stage of change ($p=0.033$). At half year follow-up 26.5% of subjects in the intervention group vs. 22.5% in the control group progressed at least for one stage of change. However, this difference was not statistically significant anymore.

Regarding development of mean stage of change, the intervention group showed no statistically significant differences neither after three months nor at half year follow-up. In contrast, subjects in the control group showed a significant decrease in mean stage of change three months after screening ($p<0.001$). At half year follow-up, the control group's mean stage of change increased to its status at baseline.

Self-reported changes in lifestyle

A significant effect of the telephone-based counselling was observed in self-reported lifestyle changes (Figure 4). In the intervention group, 80.5% of subjects declared to have changed their lifestyle in any of the eight topics and in the control group 62.9%, respectively ($p<0.001$). In all domains a similar pattern emerged. In the intervention group there was a greater part of subjects with self-reported improvements than in the control group with statistically significant differences in all areas except for increase in sportive physical activities. Overall, a greater proportion of subjects reported improvements in everyday physical activity than in sportive activities. Furthermore, improvements were more often reported in nutrition habits than in physical activity domains with the exception of "5-a-day behaviour": 44.4% in the intervention group and 32.1% in the control group ($p<0.001$) reported to have generally increased their consumption in fruits and vegetables whereas only 9.9% vs. 7.7% (n.s.) declared to have improved their "5-a-day behaviour".

Discussion

The results of the present study show that 3 telephone-based counselling interventions with a mean duration of 8 minutes can initiate significant lifestyle changes and measurable weight loss in overweight persons at risk for type 2 diabetes. Subjects in the intervention group showed a statistically significant weight loss three months after telephone-based counselling whereas the control group showed a slight, statistically not significant weight gain. At half year follow-up in both groups a considerable weight loss was observed. Thus, a seasonal interference on weight control was observed in the control group with weight stability in the colder season and weight loss in the warmer season.

Three months after counselling there was a significant difference between intervention and control group regarding percent change of body weight (-0.37% vs. +0.09%; $p<0.05$). In two randomised controlled trials which investigated the effect of either sibutramine or orlistat on weight reduction [20, 21], the placebo groups showed an average weight loss of 4.6% to 6.1% after 24 or 12 months, respectively. In comparison, the 0.9% average weight loss observed in our study appears to be modest, but attention must be paid to the fact that the patients in the two trials were much more obese (average BMI of 36.1 and 36.7 kg/m2, respectively) than the subjects in the present study. Moreover, dietetic help with medical attendance was provided to the placebo groups in those two trials, whereas the weight loss in the present study was achieved with only three telephone-based counsels of a mean duration of 8 minutes. With this background the observed weight loss represents a notable result which could still be associated with a certain health improvement.

The effect on physical activity was less pronounced in the present study. No significant differences were detected between intervention and control group for either moderate or vigorous physical activity in the proportion of subjects who newly achieved targeted goals. Nevertheless, there was a statistically significant difference between intervention and control group regarding persons who progressed at least for one stage of change three months after the telephone-based counselling. It must be noticed that the identification of changes from stage 4 to stage 5 was impeded by the tight 6 months time frame. However the modest effect on physical activity suggests that it was easier to change nutrition habits than to enhance physical activity, especially as the intervention was carried out in the colder season.

Another significant effect was found in self-reported lifestyle changes. 80.5% of subjects in the intervention group vs. 62.9% in the control group declared to have changed their lifestyle in any of the eight areas ($p<0.001$). Moreover in 6 of the 8 domains a statistically significant greater proportion of subjects in the intervention group declared to have improved their health related behaviours. Another interesting finding is the much smaller proportion of subjects declaring to have enhanced sportive activities than everyday life physical activity. It seems that especially for overweight individuals there is a rather big barrier to increase sportive activities or even to start with.

Overall, a significant effect of the telephone-based counselling on weight control and physical activity was observed three months after counselling but not at half year follow-up. However, a seasonal interference on weight control was observed in the control group with weight stability in the colder season and weight loss in the warmer season. Several studies have shown that BMI levels of overweight as well as of normal weight individuals were higher in winter than in summer [22], [23]. Referring to this result, Visscher and Seidell [23] suggested waist circumference to be a more sensitive indicator of variations in lifestyle and body consumption than is body mass index. As the telephone-based counselling has been performed in the colder season, the intervention's effect seems to be negatively influenced by this time constellation. It is most likely that the effect would be more pronounced if the intervention would have been carried out in spring instead of autumn. Further on, it might be possible that the effects observed in the present study could have been enhanced by repeating the counselling after 3 or 6 months. Continuing this type of counselling could have had benefited from the general positive effect of the warmer season on weight control.

As participants were recruited out of individuals who participated in a diabetes screening campaign, they were already influenced by counselling provided in community pharmacies. A follow-up study of the campaign has shown that this counselling in the pharmacy has resulted in considerable weight loss and lifestyle changes [24].Thus, the telephone-based counselling in the present study represented an additional intervention to persons already sensitised on the same topics. It is likely that the exposure of participants to previous counselling in the pharmacy is another reason for the rather modest impact on primary outcome measures.

There was a relatively high dropout rate over the three time-points of assessment. This is not uncommon and has been observed to similar extents in other weight loss studies

[25], [26]. Certainly there was a selection of willing subjects in the present study, which limits the generalisability of our findings. The average BMI of the non-responders was significantly higher than the responder's. This suggests that subjects with less overweight and therefore minor health risk are more willing to answer three complex questionnaires and to confront themselves with their lifestyle or health situation.

In addition, there was a further selection through telephone-based counselling by only 52.7% of subjects randomised into the intervention group willing to participate. Women were more willing to participate than men. Altogether, subjects taking part in the intervention had a higher body mass index and a worse physical activity level and were therefore at higher risk for type 2 diabetes. It was probably easier to convince individuals with higher health risk to participate in a health promoting intervention study. Moreover, it is most likely that subjects who were willing to participate in the telephone-based counselling as well as those who answered all three questionnaires are more disposed to change their lifestyle. Certainly this circumstance has influenced the results.

In the present study data such as weight and height were collected using written questionnaires (self-reported data). There is substantial evidence that self-reported height and weight can result in subsequent misclassification of overweight status particularly in older adults [27], [28]. Other studies have shown self-reported data to be largely reliable [29], [30].

Conclusion

The effects induced by the three telephone-based intervention sessions of a mean duration of 8 minutes on primary outcome measures were not drastic but clearly measurable and of public health relevance. They possibly would have been enhanced by a repeated telephone-based encouragement 3 or 6 months later. Average weight loss following the present intervention is less than weight loss achieved in high-contact programs. On the other hand such a telephone-based counselling can reach a large and diverse population at modest costs. Based on the findings of this study there appears to be an audience predestined for such programs. Best modalities and best time of intervention still need further exploration. However, the results of the present study show that a telephone-based counselling is able to induce significant lifestyle changes and a measurable weight loss of overweight individuals.

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References

1. Wild S, Roglic G, Green A, Sicree R, King H. Global prevalence of diabetes: estimates for the year 2000 and projections for 2030. Diabetes Care 2004; 27:1047-53.

2. King H, Aubert RE, Herman WH. Global burden of diabetes, 1995-2025: prevalence, numerical estimates, and projections. Diabetes Care 1998; 21:1414-31.

3. American Diabetes Association. Screening for type 2 diabetes. Diabetes Care 2004; 27 Suppl 1:S11-4.

4. Obesity: preventing and managing the global epidemic. Report of a WHO consultation. World Health Organ Tech Rep Ser 2000; 894:i-xii, 1-253.

5. American Diabetes Association: The prevention or delay of type 2 diabetes. Diabetes Care 2002; 25:742-9.

6. Irons BK, Mazzolini TA, Greene RS. Delaying the onset of type 2 diabetes mellitus in patients with prediabetes. Pharmacotherapy 2004; 24:362-71.

7. Tuomilehto J, Lindstrom J, Eriksson JG, Valle TT, Hamalainen H, Ilanne-Parikka P, et al. Prevention of type 2 diabetes mellitus by changes in lifestyle among subjects with impaired glucose tolerance. N Engl J Med 2001; 344:1343-50.

8. Knowler WC, Barrett-Connor E, Fowler SE, Hamman RF, Lachin JM, Walker EA, et al. Reduction in the incidence of type 2 diabetes with lifestyle intervention or metformin. N Engl J Med 2002; 346:393-403.

9. Lindstrom J, Louheranta A, Mannelin M, Rastas M, Salminen V, Eriksson J, et al. The Finnish Diabetes Prevention Study (DPS): Lifestyle intervention and 3-year results on diet and physical activity. Diabetes Care 2003; 26:3230-6.

10. Duncan GE, Perri MG, Theriaque DW, Hutson AD, Eckel RH, Stacpoole PW. Exercise training, without weight loss, increases insulin sensitivity and postheparin plasma lipase activity in previously sedentary adults. Diabetes Care 2003; 26:557-62.

11. Gold DB, Anderson DR, Serxner SA. Impact of a telephone-based intervention on the reduction of health risks. Am J Health Promot 2000; 15:97-106.

12. Calfas KJ, Sallis JF, Zabinski MF, Wilfley DE, Rupp J, Prochaska JJ, et al. Preliminary evaluation of a multicomponent program for nutrition and physical activity change in primary care: PACE+ for adults. Prev Med 2002; 34:153-61.

13. Castro CM, King AC, Brassington GS. Telephone versus mail interventions for maintenance of physical activity in older adults. Health Psychol 2001; 20:438-44.

14. Hellerstedt WL, Jeffery RW. The effects of a telephone-based intervention on weight loss. Am J Health Promot 1997; 11:177-82.

15. Hersberger K, Botomino A, Mancini M, Bruppacher R. Sequential screening for diabetes risk in Swiss community pharmacies - evaluation of a national campaign. BMC Public Health submitted.

16. Prochaska JO, Velicer WF. The transtheoretical model of health behavior change. Am J Health Promot 1997; 12:38-48.

17. Martin BW. Physical activity related attitudes, knowledge and behaviour in the Swiss population: comparison of the HEPA Surveys 2001 and 1999. Schweiz Z Sportmed Sporttraumatol 2002; 50.

18. Jorgensen CK, Karlsmose B. Validation of automated forms processing. A comparison of Teleform with manual data entry. Comput Biol Med 1998; 28:659-67.

19. Marcus BH, Selby VC, Niaura RS, Rossi JS. Self-efficacy and the stages of exercise behavior change. Res Q Exerc Sport 1992; 63:60-6.

20. James WP, Astrup A, Finer N, Hilsted J, Kopelman P, Rossner S, et al. Effect of sibutramine on weight maintenance after weight loss: a randomised trial. STORM Study Group. Sibutramine Trial of Obesity Reduction and Maintenance. Lancet 2000; 356:2119-25.

21. Sjostrom L, Rissanen A, Andersen T, Boldrin M, Golay A, Koppeschaar HP, et al. Randomised placebo-controlled trial of orlistat for weight loss and prevention of weight regain in obese patients. European Multicentre Orlistat Study Group. Lancet 1998; 352:167-72.

22. Dzien A, Dzien-Bischinger C, Lechleitner M. Seasonal fluctuation in body mass index. Clin Nutr 2003; 22:425-6.

23. Visscher TL, Seidell JC. Time trends (1993-1997) and seasonal variation in body mass index and waist circumference in the Netherlands. Int J Obes Relat Metab Disord 2004.

24. Botomino A, Bruppacher R, Krähenbühl S, K.E. H. Change of body weight and lifestyle after counselling of persons at risk for type 2 diabetes: follow-up study of a screening campaign in Swiss community pharmacies. BMC Public Health submitted.

25. Ahrens RA, Hower M, Best AM. Effects of weight reduction interventions by community pharmacists. J Am Pharm Assoc (Wash DC) 2003; 43:583-9.

26. Munsch S, Biedert E, Keller U. Evaluation of a lifestyle change programme for the treatment of obesity in general practice. Swiss Med Wkly 2003; 133:148-54.

27. Kuczmarski MF, Kuczmarski RJ, Najjar M. Effects of age on validity of self-reported height, weight, and body mass index: findings from the Third National Health and Nutrition Examination Survey, 1988-1994. J Am Diet Assoc 2001; 101:28-34; quiz 35-6.

28. Engstrom JL, Paterson SA, Doherty A, Trabulsi M, Speer KL. Accuracy of self-reported height and weight in women: an integrative review of the literature. J Midwifery Womens Health 2003; 48:338-45.

29. Strauss RS. Comparison of measured and self-reported weight and height in a cross-sectional sample of young adolescents. Int J Obes Relat Metab Disord 1999; 23:904-8.

30. Calfas KJ, Zabinski MF, Rupp J. Practical nutrition assessment in primary care settings: a review. Am J Prev Med 2000; 18:289-99.

Figures

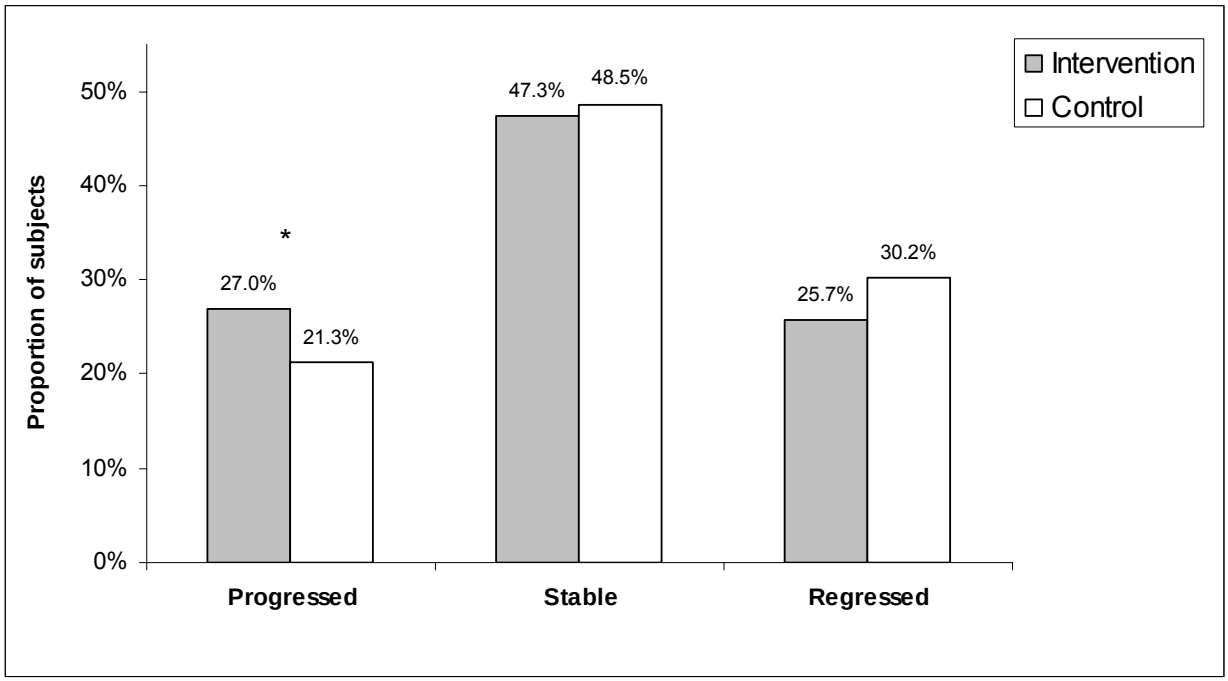

Figure 3: Proportion of subjects moving along the stages of change in physical activity three months after telephone-based counselling

Intervention (n=385) and control group (n=778); statistically significant differences are indicated (*p<0.05).

“Progressed” / “regressed”: at least for one stage of change

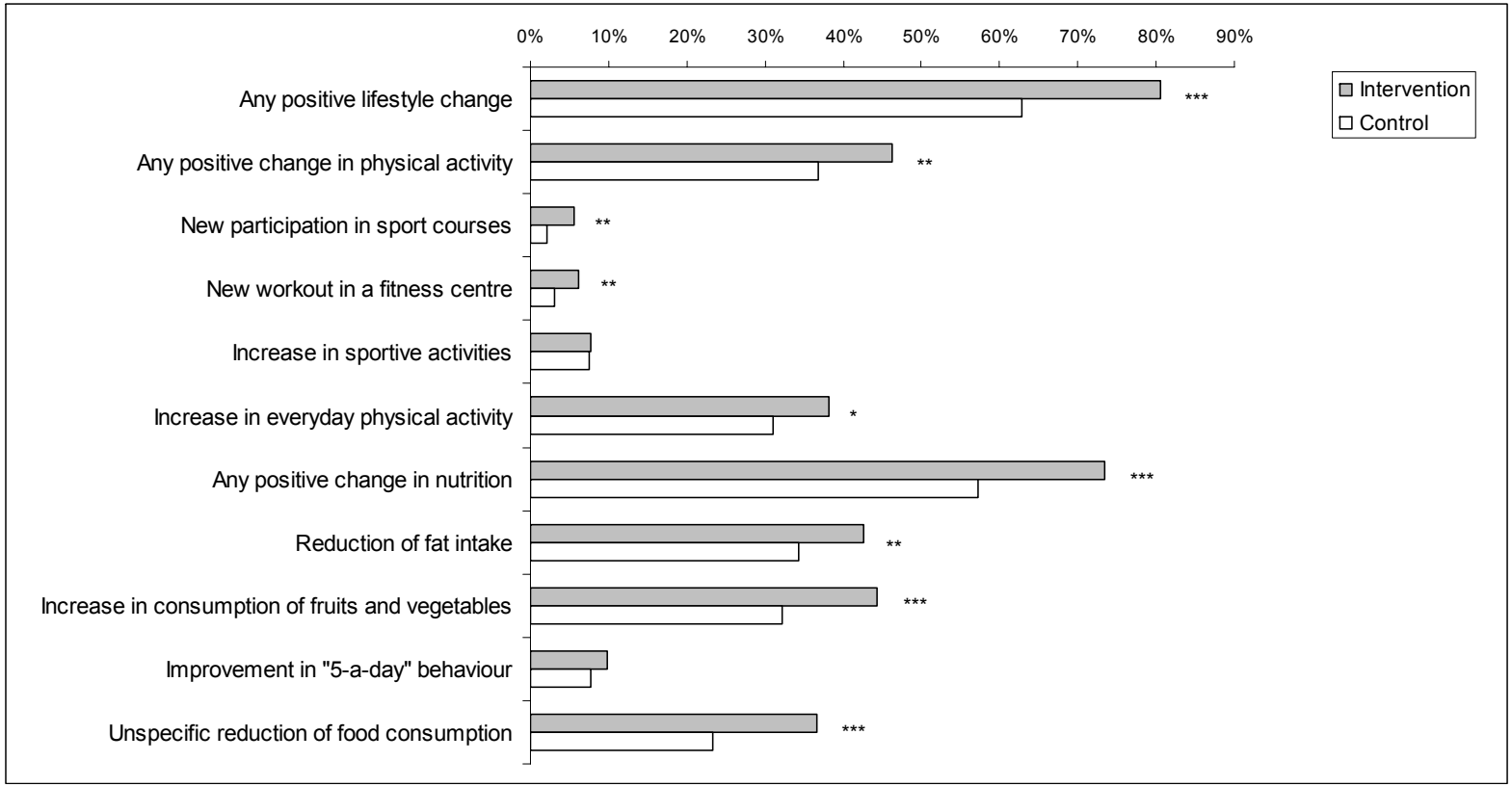

Figure 4: Proportion of study subjects with self reported positive changes in lifestyle three months after the telephone-based intervention

Statistically significant differences are indicated (*p<0.05; **p<0.01; ***p<0.001)

Tables

Table 3: Baseline characteristics of participants vs. non-participants and of intervention vs. control group

	Participants (n = 611)	Non-participants (n = 549)		Intervention group (n = 385)	Control group (n = 778)	
	Mean ± SD	Mean ± SD		Mean ± SD	Mean ± SD	
Age [years]	57.3 ± 10.7	57.7 ± 11.2		57.4 ± 10.3	58.0 ± 10.9	
Gender						
male	39.3%	49.0%		41.6%	41.6%	
female	60.7%	51.0%	**	58.4%	58.4%	
Smoking habits						
Current smoker	12.7%	13.8%		11.7%	11.5%	
Not current smoker	87.3%	86.2%		88.3%	88.5%	
Height [cm]	168.7 ± 8.4	169.5 ± 8.7	*	169.1 ± 8.2	168.8 ± 8.6	
Weight [kg]	81.4 ± 11.0	81.1 ± 11.0		81.3 ± 10.9	80.8 ± 11.3	
BMI [kg/m^2]	28.6 ± 3.0	28.2 ± 2.8	*	28.4 ± 2.8	28.3 ± 3.0	
Mean stage of change for physical activity	3.0 ± 1.7	3.2 ± 1.7	*	2.9 ± 1.7	3.2 ± 1.7	**
Stages of change for physical activity						
Stage 1	27.2%	27.4%		28.3%	26.9%	
Stage 2	24.9%	16.5%		25.7%	17.5%	
Stage 3	9.3%	11.1%		9.6%	9.0%	
Stage 4	3.5%	4.1%		2.9%	4.6%	
Stage 5	35.2%	41.0%	**	33.5%	42.0%	**

Statistically significant differences are indicated (*p<0.05; **p<0.01), others p≥0.05

Table 4: BMI, body weight and percent change of body weight

Variable	Before intervention (T1)	After intervention (T2)		Half year follow-up (T3)		
			p-value [1] T1/T2		p-value [1] T2/T3	p-value [1] T1/T3
BMI [kg/m^2]						
Intervention	28.37 ± 0.14	28.26 ± 0.14	*	28.12 ± 0.15	**	***
Control	28.30 ± 0.11	28.32 ± 0.11	n.s.	28.09 ± 0.11	***	***
Weight [kg]						
Intervention	81.30 ± 0.55	80.98 ± 0.56	*	80.56 ± 0.56	**	***
Control	80.79 ± 0.41	80.85 ± 0.41	n.s.	80.19 ± 0.41	***	***
			p-value [2] Intervention vs. Control		p-value [2] Intervention vs. Control	
Change in body weight [kg]						
Intervention		-0.32	*	-0.74	n.s.	
Control		+0.06		-0.60		
Percent change of body weight						
Intervention		-0.37%	*	-0.85%	n.s.	
Control		+0.09%		-0.71%		

Values are given as mean ± SE

[1] The p-values refer to linear contrasts of repeated analysis of variance (GLM) (* p<0.05 ** p<0.01; *** p<0.001; n.s.; not significant)

[2] The p-values refer to unpaired t-test within groups (* p<0.05; n.s.; not significant)

5 General discussion and conclusions

In this thesis screening concepts for cardiovascular risk factors (particularly for type 2 diabetes and dyslipidaemia) and related health promoting activities were evaluated.

With the aim to validate blood pressure measurement in community pharmacies, **project A** revealed that white coat effect and white coat hypertension exist in community pharmacy practice and are at least similar to the effects in an outpatient clinic, where a nurse measures blood pressure. The results of this study were limited by the rather small number of 50 included subjects. As several studies have shown more expressed white coat effect in subjects with stronger hypertension, it can be supposed that if only hypertensive patients were included in this study, then the observed white coat effect would have been enhanced. No studies on extent and importance of the white coat phenomenon in pharmacies could be retrieved to compare our findings. However, the white coat effect generated in community pharmacy practice seems to be smaller than that triggered by physicians as reported in the literature. This indicates that blood pressure measurements in community pharmacies are at least as reliable as those of other health professionals.

In **project B**, a national diabetes screening campaign in community pharmacies called “Stopp Zucker – Jetzt testen!” provided the possibility to evaluate a sequential screening concept for type 2 diabetes to be used in community pharmacy practice. Triage guidelines and appropriate cut-off points for blood glucose measurement in capillary blood were elaborated. A total of 94124 persons were screened for previously undiagnosed type 2 diabetes. The screening campaign therefore attracted a large number of Swiss German speaking adults (2.4% of the total population) and the screening concept has successfully been implemented into pharmacy practice. Despite the advanced age of the screened population, only 6.9% were suspected to have type 2 diabetes using the developed triage guidelines. Hereby it must be noted that 1.5% of the screened persons with already treated diabetes were excluded from analysis. Epidemiologic studies revealed prevalence rates of diabetes and impaired fasting glucose of 1.4 – 16.3%. This wide range illustrates the difficulties of assessing diabetes prevalence rates in the population. Risk factor assessment of the screened persons suggested that the campaign has selected a higher risk population which

further impedes the assessment of prevalence rates. Individuals suspected to have type 2 diabetes were referred to a physician for further check-up. Due to the low physicians' response rate it was not possible to assess the outcome of these consultations after referral by the pharmacists. Another 71.5% of the screened persons had at least two risk factors. This provided the opportunity to deliver targeted counselling towards lifestyle change to a large population group. As community pharmacies are highly accessible health promoting counselling in community pharmacies could easily be implemented into daily practice. This would represent a significant contribution to preventive and health promoting care in community health.
The evaluation of this large screening campaign showed that for community pharmacy practice the elaborated sequential screening procedure can be recommended: First an assessment of all risk factors should be performed including blood pressure with cut off point ≥2 risk factors to select individuals for blood glucose measurement. This pre-screening showed higher sensitivity but lower specificity than the ADA questionnaire. As the risk assessment is followed by blood glucose measurement, the low specificity is irrelevant, but high sensitivity is important. For the subsequent capillary blood glucose measurement cut-off point, 5.3 mmol/l was used. Lowering of this threshold for normal fasting capillary blood glucose from 5.3 mmol/l to 4.9 mmol/l, according to the new recommendation by the ADA (5.6 mmol/l for plasma glucose respectively 4.9 mmol/l for capillary whole blood), would increase the prevalence of impaired fasting glucose by 79% in this study population. Thus for community pharmacy practice a cut-off point of 5.3 mmol/l is a rational threshold, but in case of borderline results retest is required.

In **project C,** a pharmacy-based screening concept for metabolic syndrome including a multiple risk assessment for coronary heart disease was evaluated during a campaign in 30 community pharmacies. The triage guidelines and cut-off points for dyslipidaemia were elaborated based on the ATP III guidelines. The results of this pilot study suggested that screening for the coincidence of ≥2 values of lipid profile above normal with ≥2 other risk factors for coronary heart disease is a reasonable approach. Exclusive screening for ≥1 or even ≥2 abnormal lipid values without coincidence with other cardiovascular risk factors would produce large rates for referral to physicians. On the other hand, if a single value is elevated at a level at which drug therapy is considered, even without coincidence with other risk factors,

referral to a physician is required. The results of this pilot study are based on a rather small number of individuals. Therefore further comprehensive investigations including validation of the triage guidelines by evaluating outcomes resulting from physicians' consultations after referral by the pharmacists would be of particular interest.

Project D showed that immediate counselling after screening for cardiovascular risk in community pharmacies can result in significant and sustainable lifestyle changes and weight loss in overweight individuals. Subjects with abnormal blood glucose values measured in the diabetes screening (see project B) showed stronger effects than those with normal values. It is therefore most likely that the measured blood glucose value itself has initiated a stronger readiness for lifestyle change. Moreover, an abnormal value probably provided a basis to the pharmacist in counselling towards health promoting lifestyle. The drop out rate over the three assessments possibly lead to a selection of subjects being more inclined to change their lifestyle. In addition, the uncontrolled design of the study did not allow for stringent conclusions. Nevertheless, the results of this study suggest that community pharmacies are a promising setting to initiate lifestyle change. Pharmacists could therefore play an important role in helping individuals to control their weight and to change their lifestyle. The opportunity to initiate therapeutic lifestyle change and to provide targeted counselling to persons at risk after screening for type 2 diabetes should not be missed.

A randomised controlled trial **(project E)** showed that a three times 15 minutes telephone-based counselling is able to result in significant lifestyle changes and measurable weight loss. It has to be considered, however, that subjects for this randomised controlled trial were recruited out of individuals who participated in the national diabetes screening campaign (see project B). Therefore they were already influenced by counselling provided in community pharmacies. This may have lead to a higher level of awareness also in the control group and may have reduced possible differences. The quite high drop out rate over the three time-points of assessment is not uncommon when compared to literature but certainly has lead to a selection of more willing subjects. Due to the controlled design this affects the results of this study not in the same manner as those in project D. However, there was also a selection through the telephone-based counselling as not all individuals were willing

to participate. It is most likely that subjects who were willing to participate in the telephone-based counselling were more inclined to change their lifestyle. The effects of this telephone-based counselling were not drastic and smaller than those achieved in high-contact programs as reported in literature. Nevertheless, they are of particular relevance as this sort of counselling can be delivered easily and can reach a large and diverse population at modest costs. Best modalities and, because of seasonal interference, the best point in time of a telephone-based counselling need further exploration.

In conclusion this thesis shows that:

- Screening for cardiovascular risk in community pharmacies benefits from a sequential procedure: First an assessment of all risk factors including blood pressure, second capillary blood glucose measurements with retest in case of borderline results and with measurement of lipid profile if possible and finally counselling of persons at risk to initiate lifestyle change.

- The elaborated and evaluated triage guidelines with the cut-off points for diabetes and for lipid screening (project B and C) appear to be appropriate and can be recommended for community pharmacy practice.

- A total of 6.9% of the population screened in the national diabetes screening campaign were suspected to have type 2 diabetes showing abnormal blood glucose values. This rate is representative for the population screened but due to selection effects not for the general Swiss population.

- Blood pressure measurements in community pharmacies are as reliable as those of other health professionals. They are subject to a white coat effect as reported also for measurements by physicians and nurses. The validation of community pharmacists' measurements of blood glucose and lipid profile in capillary blood as well as the outcome after referral to a physician remain outstanding issues.

- Health promoting activities provided in community pharmacies or by nurses through telephone-based counselling can have positive effects on lifestyle behaviour and therewith on public health.

- After screening for cardiovascular risk pharmacists should offer targeted counselling to persons at risk according to the readiness to change their lifestyle. They can also consider expanding this lifestyle counselling with repeated interventions using telephone-based counselling and continuous monitoring. This could add to effectiveness and sustainability.

6 References to general introduction and discussion[1]

1. The Expert Committee on the Diagnosis and Classification of Diabetes Mellitus. Report of the Expert Committee on the Diagnosis and Classification of Diabetes Mellitus. Diabetes Care 1997; 20:1183-97.

2. The Expert Committee on the Diagnosis and Classification of Diabetes Mellitus. Report of the Expert Committee on the Diagnosis and Classification of Diabetes Mellitus. Diabetes Care 2003; 26 Suppl 1:S5-20.

3. American Diabetes Association. Diagnosis and classification of diabetes mellitus. Diabetes Care 2004; 27 Suppl 1:S5-S10.

4. Kukreja A, Maclaren NK. Autoimmunity and diabetes. J Clin Endocrinol Metab 1999; 84:4371-8.

5. Atkinson MA, Eisenbarth GS. Type 1 diabetes: new perspectives on disease pathogenesis and treatment. Lancet 2001; 358:221-9.

6. Zimmet PZ, Tuomi T, Mackay IR, et al. Latent autoimmune diabetes mellitus in adults (LADA): the role of antibodies to glutamic acid decarboxylase in diagnosis and prediction of insulin dependency. Diabet Med 1994; 11:299-303.

7. Reaven GM, Bernstein R, Davis B, Olefsky JM. Nonketotic diabetes mellitus: insulin deficiency or insulin resistance? Am J Med 1976; 60:80-8.

8. Olefsky JM, Kolterman OG, Scarlett JA. Insulin action and resistance in obesity and noninsulin-dependent type II diabetes mellitus. Am J Physiol 1982; 243:E15-30.

9. DeFronzo R, Deibert D, Hendler R, Felig P, Soman V. Insulin sensitivity and insulin binding to monocytes in maturity-onset diabetes. J Clin Invest 1979; 63:939-46.

10. Turner RC, Holman RR, Matthews D, Hockaday TD, Peto J. Insulin deficiency and insulin resistance interaction in diabetes: estimation of their relative contribution by feedback analysis from basal plasma insulin and glucose concentrations. Metabolism 1979; 28:1086-96.

11. DeFronzo RA. Lilly lecture 1987. The triumvirate: beta-cell, muscle, liver. A collusion responsible for NIDDM. Diabetes 1988; 37:667-87.

12. DeFronzo RA. Pathogenesis of type 2 (non-insulin dependent) diabetes mellitus: a balanced overview. Diabetologia 1992; 35:389-97.

13. Kolterman OG, Gray RS, Griffin J, et al. Receptor and postreceptor defects contribute to the insulin resistance in noninsulin-dependent diabetes mellitus. J Clin Invest 1981; 68:957-69.

14. Bogardus C, Lillioja S, Mott DM, Hollenbeck C, Reaven G. Relationship between degree of obesity and in vivo insulin action in man. Am J Physiol 1985; 248:E286-91.

15. Kissebah AH, Vydelingum N, Murray R, et al. Relation of body fat distribution to metabolic complications of obesity. J Clin Endocrinol Metab 1982; 54:254-60.

[1] References for the individual projects are contained in the manuscripts of the publications.

16. Butkiewicz EK, Leibson CL, O'Brien PC, Palumbo PJ, Rizza RA. Insulin therapy for diabetic ketoacidosis. Bolus insulin injection versus continuous insulin infusion. Diabetes Care 1995; 18:1187-90.

17. Banerji MA, Chaiken RL, Huey H, et al. GAD antibody negative NIDDM in adult black subjects with diabetic ketoacidosis and increased frequency of human leukocyte antigen DR3 and DR4. Flatbush diabetes. Diabetes 1994; 43:741-5.

18. Umpierrez GE, Casals MM, Gebhart SP, Mixon PS, Clark WS, Phillips LS. Diabetic ketoacidosis in obese African-Americans. Diabetes 1995; 44:790-5.

19. Harris MI. Impaired glucose tolerance in the U.S. population. Diabetes Care 1989; 12:464-74.

20. Zimmet PZ. Kelly West Lecture 1991. Challenges in diabetes epidemiology--from West to the rest. Diabetes Care 1992; 15:232-52.

21. Fujimoto WY, Leonetti DL, Kinyoun JL, Shuman WP, Stolov WC, Wahl PW. Prevalence of complications among second-generation Japanese-American men with diabetes, impaired glucose tolerance, or normal glucose tolerance. Diabetes 1987; 36:730-9.

22. Moss SE, Klein R, Klein BE, Meuer SM. The association of glycemia and cause-specific mortality in a diabetic population. Arch Intern Med 1994; 154:2473-9.

23. Kuusisto J, Mykkanen L, Pyorala K, Laakso M. NIDDM and its metabolic control predict coronary heart disease in elderly subjects. Diabetes 1994; 43:960-7.

24. Andersson DK, Svardsudd K. Long-term glycemic control relates to mortality in type II diabetes. Diabetes Care 1995; 18:1534-43.

25. Uusitupa MI, Niskanen LK, Siitonen O, Voutilainen E, Pyorala K. Ten-year cardiovascular mortality in relation to risk factors and abnormalities in lipoprotein composition in type 2 (non-insulin-dependent) diabetic and non-diabetic subjects. Diabetologia 1993; 36:1175-84.

26. Polonsky KS, Sturis J, Bell GI. Seminars in Medicine of the Beth Israel Hospital, Boston. Non-insulin-dependent diabetes mellitus - a genetically programmed failure of the beta cell to compensate for insulin resistance. N Engl J Med 1996; 334:777-83.

27. Scarlett JA, Gray RS, Griffin J, Olefsky JM, Kolterman OG. Insulin treatment reverses the insulin resistance of type II diabetes mellitus. Diabetes Care 1982; 5:353-63.

28. Firth RG, Bell PM, Rizza RA. Effects of tolazamide and exogenous insulin on insulin action in patients with non-insulin-dependent diabetes mellitus. N Engl J Med 1986; 314:1280-6.

29. Simonson DC, Ferrannini E, Bevilacqua S, et al. Mechanism of improvement in glucose metabolism after chronic glyburide therapy. Diabetes 1984; 33:838-45.

30. Henry RR, Wallace P, Olefsky JM. Effects of weight loss on mechanisms of hyperglycemia in obese non-insulin-dependent diabetes mellitus. Diabetes 1986; 35:990-8.

31. Wing RR, Blair EH, Bononi P, Marcus MD, Watanabe R, Bergman RN. Caloric restriction per se is a significant factor in improvements in glycemic control and insulin sensitivity during weight loss in obese NIDDM patients. Diabetes Care 1994; 17:30-6.

32. Newman B, Selby JV, King MC, Slemenda C, Fabsitz R, Friedman GD. Concordance for type 2 (non-insulin-dependent) diabetes mellitus in male twins. Diabetologia 1987; 30:763-8.

33. Barnett AH, Eff C, Leslie RD, Pyke DA. Diabetes in identical twins. A study of 200 pairs. Diabetologia 1981; 20:87-93.

34. van Tilburg J, van Haeften TW, Pearson P, Wijmenga C. Defining the genetic contribution of type 2 diabetes mellitus. J Med Genet 2001; 38:569-78.

35. National Diabetes Data Group. Classification and diagnosis of diabetes mellitus and other categories of glucose intolerance. National Diabetes Data Group. Diabetes 1979; 28:1039-57.

36. World Health Organisation. Diabetes mellitus. Report of a WHO Study Group. World Health Organ Tech Rep Ser 1985; 727:1-113.

37. The Expert Committee on the Diagnosis and Classification of Diabetes Mellitus. Follow-up report on the diagnosis of diabetes mellitus. Diabetes Care 2003; 26:3160-7.

38. Charles MA, Fontbonne A, Thibult N, Warnet JM, Rosselin GE, Eschwege E. Risk factors for NIDDM in white population. Paris prospective study. Diabetes 1991; 40:796-9.

39. Brunzell JD, Robertson RP, Lerner RL, et al. Relationships between fasting plasma glucose levels and insulin secretion during intravenous glucose tolerance tests. J Clin Endocrinol Metab 1976; 42:222-9.

40. Fuller JH, Shipley MJ, Rose G, Jarrett RJ, Keen H. Coronary-heart-disease risk and impaired glucose tolerance. The Whitehall study. Lancet 1980; 1:1373-6.

41. Charles MA, Balkau B, Vauzelle-Kervroedan F, Thibult N, Eschwege E. Revision of diagnostic criteria for diabetes. Lancet 1996; 348:1657-8.

42. Jarrett RJ, Keen H. Hyperglycaemia and diabetes mellitus. Lancet 1976; 2:1009-12.

43. Klein R, Barrett-Connor EL, Blunt BA, Wingard DL. Visual impairment and retinopathy in people with normal glucose tolerance, impaired glucose tolerance, and newly diagnosed NIDDM. Diabetes Care 1991; 14:914-8.

44. McCartney P, Keen H, Jarrett RJ. The Bedford Survey: observations on retina and lens of subjects with impaired glucose tolerance and in controls with normal glucose tolerance. Diabete Metab 1983; 9:303-5.

45. Reaven GM, Olefsky J, Farquhar JW. Does hyperglycaemia or hyperinsulinaemia characterise the patient with chemical diabetes? Lancet 1972; 1:1247-9.

46. Little RR, England JD, Wiedmeyer HM, et al. Relationship of glycosylated hemoglobin to oral glucose tolerance. Implications for diabetes screening. Diabetes 1988; 37:60-4.

47. Reaven GM. Banting lecture 1988. Role of insulin resistance in human disease. Diabetes 1988; 37:1595-607.

48. DeFronzo RA, Ferrannini E. Insulin resistance. A multifaceted syndrome responsible for NIDDM, obesity, hypertension, dyslipidemia, and atherosclerotic cardiovascular disease. Diabetes Care 1991; 14:173-94.

49. Lindsay RS, Howard BV. Cardiovascular risk associated with the metabolic syndrome. Curr Diab Rep 2004; 4:63-8.

50. Richelsen B, Pedersen SB. Associations between different anthropometric measurements of fatness and metabolic risk parameters in non-obese, healthy, middle-aged men. Int J Obes Relat Metab Disord 1995; 19:169-74.

51. Ruderman N, Chisholm D, Pi-Sunyer X, Schneider S. The metabolically obese, normal-weight individual revisited. Diabetes 1998; 47:699-713.

52. Ferrannini E, Haffner SM, Mitchell BD, Stern MP. Hyperinsulinaemia: the key feature of a cardiovascular and metabolic syndrome. Diabetologia 1991; 34:416-22.

53. Haffner SM, Valdez RA, Hazuda HP, Mitchell BD, Morales PA, Stern MP. Prospective analysis of the insulin-resistance syndrome (syndrome X). Diabetes 1992; 41:715-22.

54. Grundy SM, Brewer HB, Jr., Cleeman JI, Smith SC, Jr., Lenfant C. Definition of metabolic syndrome: Report of the National Heart, Lung, and Blood Institute/American Heart Association conference on scientific issues related to definition. Circulation 2004; 109:433-8.

55. Meigs JB. Invited commentary: insulin resistance syndrome? Syndrome X? Multiple metabolic syndrome? A syndrome at all? Factor analysis reveals patterns in the fabric of correlated metabolic risk factors. Am J Epidemiol 2000; 152:908-11; discussion 912.

56. Executive Summary of The Third Report of The National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation, And Treatment of High Blood Cholesterol In Adults (Adult Treatment Panel III). Jama 2001; 285:2486-97.

57. Adler AI, Neil HA, Manley SE, Holman RR, Turner RC. Hyperglycemia and hyperinsulinemia at diagnosis of diabetes and their association with subsequent cardiovascular disease in the United Kingdom prospective diabetes study (UKPDS 47). Am Heart J 1999; 138:S353-9.

58. Adler AI, Stratton IM, Neil HA, et al. Association of systolic blood pressure with macrovascular and microvascular complications of type 2 diabetes (UKPDS 36): prospective observational study. Bmj 2000; 321:412-9.

59. Stratton IM, Adler AI, Neil HA, et al. Association of glycaemia with macrovascular and microvascular complications of type 2 diabetes (UKPDS 35): prospective observational study. Bmj 2000; 321:405-12.

60. Turner RC, Millns H, Neil HA, et al. Risk factors for coronary artery disease in non-insulin dependent diabetes mellitus: United Kingdom Prospective Diabetes Study (UKPDS: 23). Bmj 1998; 316:823-8.

61. The DECODE Study Group. Glucose tolerance and cardiovascular mortality: comparison of fasting and 2-hour diagnostic criteria. Arch Intern Med 2001; 161:397-405.

62. Turner RC, Cull CA, Frighi V, Holman RR. Glycemic control with diet, sulfonylurea, metformin, or insulin in patients with type 2 diabetes mellitus: progressive requirement for multiple therapies (UKPDS 49). UK Prospective Diabetes Study (UKPDS) Group. Jama 1999; 281:2005-12.

63. UK Prospective Diabetes Study (UKPDS) Group. Intensive blood-glucose control with sulphonylureas or insulin compared with conventional treatment and risk of complications in patients with type 2 diabetes (UKPDS 33). Lancet 1998; 352:837-53.

64. UK Prospective Diabetes Study (UKPDS) Group. Effect of intensive blood-glucose control with metformin on complications in overweight patients with type 2 diabetes (UKPDS 34). Lancet 1998; 352:854-65.

65. Reichard P, Nilsson BY, Rosenqvist U. The effect of long-term intensified insulin treatment on the development of microvascular complications of diabetes mellitus. N Engl J Med 1993; 329:304-9.

66. The Diabetes Control and Complications Trial Research Group. The effect of intensive treatment of diabetes on the development and progression of long-term complications in insulin-dependent diabetes mellitus. N Engl J Med 1993; 329:977-86.

67. Harris MI. Undiagnosed NIDDM: clinical and public health issues. Diabetes Care 1993; 16:642-52.

68. Rajala U, Laakso M, Qiao Q, Keinanen-Kiukaanniemi S. Prevalence of retinopathy in people with diabetes, impaired glucose tolerance, and normal glucose tolerance. Diabetes Care 1998; 21:1664-9.

69. Kohner EM, Aldington SJ, Stratton IM, et al. United Kingdom Prospective Diabetes Study, 30: diabetic retinopathy at diagnosis of non-insulin-dependent diabetes mellitus and associated risk factors. Arch Ophthalmol 1998; 116:297-303.

70. Turner R, Cull C, Holman R. United Kingdom Prospective Diabetes Study 17: a 9-year update of a randomized, controlled trial on the effect of improved metabolic control on complications in non-insulin-dependent diabetes mellitus. Ann Intern Med 1996; 124:136-45.

71. Saydah SH, Loria CM, Eberhardt MS, Brancati FL. Subclinical states of glucose intolerance and risk of death in the U.S. Diabetes Care 2001; 24:447-53.

72. Coutinho M, Gerstein HC, Wang Y, Yusuf S. The relationship between glucose and incident cardiovascular events. A metaregression analysis of published data from 20 studies of 95,783 individuals followed for 12.4 years. Diabetes Care 1999; 22:233-40.

73. Balkau B, Shipley M, Jarrett RJ, et al. High blood glucose concentration is a risk factor for mortality in middle-aged nondiabetic men. 20-year follow-up in the Whitehall Study, the Paris Prospective Study, and the Helsinki Policemen Study. Diabetes Care 1998; 21:360-7.

74. Bjornholt JV, Erikssen G, Aaser E, et al. Fasting blood glucose: an underestimated risk factor for cardiovascular death. Results from a 22-year follow-up of healthy nondiabetic men. Diabetes Care 1999; 22:45-9.

75. Eastman RC, Cowie CC, Harris MI. Undiagnosed diabetes or impaired glucose tolerance and cardiovascular risk. Diabetes Care 1997; 20:127-8.

76. Wei M, Gaskill SP, Haffner SM, Stern MP. Effects of diabetes and level of glycemia on all-cause and cardiovascular mortality. The San Antonio Heart Study. Diabetes Care 1998; 21:1167-72.

77. Isomaa B, Almgren P, Tuomi T, et al. Cardiovascular morbidity and mortality associated with the metabolic syndrome. Diabetes Care 2001; 24:683-9.

78. Fuller JH, Shipley MJ, Rose G, Jarrett RJ, Keen H. Mortality from coronary heart disease and stroke in relation to degree of glycaemia: the Whitehall study. Br Med J (Clin Res Ed) 1983; 287:867-70.

79. Prevention or Delay of Type 2 Diabetes. Diabetes Care 2004; 27:47S-54S.

80. Khaw KT, Wareham N, Luben R, et al. Glycated haemoglobin, diabetes, and mortality in men in Norfolk cohort of european prospective investigation of cancer and nutrition (EPIC-Norfolk). Bmj 2001; 322:15-8.

81. Engelgau MM, Narayan KM, Herman WH. Screening for type 2 diabetes. Diabetes Care 2000; 23:1563-80.

82. American Diabetes Association. Screening for type 2 diabetes. Diabetes Care 2004; 27 Suppl 1:S11-4.

83. Knowler WC, Barrett-Connor E, Fowler SE, et al. Reduction in the incidence of type 2 diabetes with lifestyle intervention or metformin. N Engl J Med 2002; 346:393-403.

84. Screening for Type 2 Diabetes - Report of a World Health Organization and International Diabetes Federation meeting. Geneva: World Health Organisation, 2003:54.

85. King H, Aubert RE, Herman WH. Global burden of diabetes, 1995-2025: prevalence, numerical estimates, and projections. Diabetes Care 1998; 21:1414-31.

86. Wild S, Roglic G, Green A, Sicree R, King H. Global prevalence of diabetes: estimates for the year 2000 and projections for 2030. Diabetes Care 2004; 27:1047-53.

87. World Health Organisation. The Diabetes Programme 2004. Assessed September 2004, at http://www.who.int/diabetes/en/.

88. Eriksson KF, Lindgarde F. Prevention of type 2 (non-insulin-dependent) diabetes mellitus by diet and physical exercise. The 6-year Malmo feasibility study. Diabetologia 1991; 34:891-8.

89. Pan XR, Li GW, Hu YH, et al. Effects of diet and exercise in preventing NIDDM in people with impaired glucose tolerance. The Da Qing IGT and Diabetes Study. Diabetes Care 1997; 20:537-44.

90. Tuomilehto J, Lindstrom J, Eriksson JG, et al. Prevention of type 2 diabetes mellitus by changes in lifestyle among subjects with impaired glucose tolerance. N Engl J Med 2001; 344:1343-50.

91. The Diabetes Prevention Program. Design and methods for a clinical trial in the prevention of type 2 diabetes. Diabetes Care 1999; 22:623-34.

92. The Diabetes Prevention Program Research Group. The Diabetes Prevention Program: baseline characteristics of the randomized cohort. Diabetes Care 2000; 23:1619-29.

93. Buchanan TA, Xiang AH, Peters RK, et al. Preservation of pancreatic beta-cell function and prevention of type 2 diabetes by pharmacological treatment of insulin resistance in high-risk hispanic women. Diabetes 2002; 51:2796-803.

94. Chiasson JL, Gomis R, Hanefeld M, Josse RG, Karasik A, Laakso M. The STOP-NIDDM Trial: an international study on the efficacy of an alpha-glucosidase inhibitor to prevent type 2 diabetes in a population with impaired glucose tolerance: rationale, design, and preliminary screening data. Study to Prevent Non-Insulin-Dependent Diabetes Mellitus. Diabetes Care 1998; 21:1720-5.

95. Chiasson JL, Josse RG, Gomis R, Hanefeld M, Karasik A, Laakso M. Acarbose for prevention of type 2 diabetes mellitus: the STOP-NIDDM randomised trial. Lancet 2002; 359:2072-7.

96. Third Report of the National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III) final report. Circulation 2002; 106:3143-421.

97. Tsuyuki RT, Johnson JA, Teo KK, et al. Study of Cardiovascular Risk Intervention by Pharmacists (SCRIP): a randomized trial design of the effect of a community pharmacist intervention program on serum cholesterol risk. Ann Pharmacother 1999; 33:910-9.

98. Ford S, Jones K. Integrating pharmacy fully into the primary care team. BMJ 1995; 310:1620-1.

99. Babb VJ, Babb J. Pharmacist involvement in Healthy People 2010. J Am Pharm Assoc (Wash) 2003; 43:56-60.

100. Irons BK, Mazzolini TA, Greene RS. Delaying the onset of type 2 diabetes mellitus in patients with prediabetes. Pharmacotherapy 2004; 24:362-71.

101. Hawkins D, Bradberry JC, Cziraky MJ, Talbert RL, Bartels DW, Cerveny JD. National Pharmacy Cardiovascular Council treatment guidelines for the management of type 2 diabetes mellitus: toward better patient outcomes and new roles for pharmacists. Pharmacotherapy 2002; 22:436-44.

102. Tice B, Phillips CR. Implementation and evaluation of a lipid screening program in a large chain pharmacy. J Am Pharm Assoc (Wash) 2002; 42:413-9.

103. Hourihan F, Krass I, Chen T. Rural community pharmacy: a feasible site for a health promotion and screening service for cardiovascular risk factors. Aust J Rural Health 2003; 11:28-35.

104. Mangum SA, Kraenow KR, Narducci WA. Identifying at-risk patients through community pharmacy-based hypertension and stroke prevention screening projects. J Am Pharm Assoc (Wash) 2003; 43:50-5.

105. Tsuyuki RT, Johnson JA, Teo KK, et al. A randomized trial of the effect of community pharmacist intervention on cholesterol risk management: the Study of Cardiovascular Risk Intervention by Pharmacists (SCRIP). Arch Intern Med 2002; 162:1149-55.

106. Chabot I, Moisan J, Gregoire JP, Milot A. Pharmacist intervention program for control of hypertension. Ann Pharmacother 2003; 37:1186-93.

107. Peterson GM, Fitzmaurice KD, Naunton M, Vial JH, Stewart K, Krum H. Impact of pharmacist-conducted home visits on the outcomes of lipid-lowering drug therapy. J Clin Pharm Ther 2004; 29:23-30.

108. Carter BL, Zillich AJ, Elliott WJ. How pharmacists can assist physicians with controlling blood pressure. J Clin Hypertens (Greenwich) 2003; 5:31-7.

109. Ahrens RA, Hower M, Best AM. Effects of weight reduction interventions by community pharmacists. J Am Pharm Assoc (Wash DC) 2003; 43:583-9.

110. Cranor CW, Christensen DB. The Asheville Project: short-term outcomes of a community pharmacy diabetes care program. J Am Pharm Assoc (Wash) 2003; 43:149-59.

7 Appendix

Project A:

Project B:

Project C:

Project D and E:

7.1 Informed consent

INSTITUT FÜR KLINISCHE PHARMAZIE
Departement Pharmazie der Universität Basel
Pharmaceutical Care Research Group
Klingelbergstr. 50 / 4056 Basel

Teilnahme an der Untersuchung des „Weisskittel-Effektes“ in der Apotheke

Informed Consent (Schriftliche Einverständniserklärung des Patienten)

Sehr geehrte Dame / Sehr geehrter Herr

Bluthochdruck ist eine weit verbreitete ernst zunehmende Erkrankung, die mit Medikamenten gut behandelt werden kann. Es kommt vor, dass Patienten nur beim Arzt einen zu hohen Blutdruck aufweisen, dies wird auch „Weisskittel-Effekt“ genannt. Im Rahmen einer Diplomarbeit (Pharmazie, Universität Basel), unter der Leitung von Herrn Dr. Kurt Hersberger und Herrn PD Dr. med., Benedict Martina, möchten wir untersuchen, ob ein „Weisskittel-Effekt“ auch in den Apotheken beobachtet wird.

Im Rahmen dieser Studie werden folgende Messungen durchgeführt:

- Blutdruckmessung in der Apotheke: 2 Messungen
- Blutdruckmessung zu Hause: während 4 Tagen, jeweils am Morgen und am Abend je 2 Messungen
- Blutdruckmessung im Kantonsspital Basel: 2 Messungen auf der Medizinischen Universitätspoliklinik
- Blutdruckmessung während 24 Stunden: Anlegen und Initialisierung des Gerätes im Kantonsspital Basel. Während 24 Stunden normalen, täglichen Tätigkeiten nachgehen. Am Tag wird der Blutdruck automatisch alle 20 Minuten gemessen und während der Nacht alle 40 Minuten.

Wir ersuchen Sie um Ihr Einverständnis bei der Teilnahme dieser Studie.
Ihr Nutzen besteht in einer umfassenden, kostenlosen Kontrolle Ihres Blutdruckes inklusive 24-Stunden Messung. Des weiteren helfen Sie mit, wertvolle Erkenntnisse zum „Weisskittel-Effekt“ zu gewinnen. Die Teilnahme an dieser Studie ist freiwillig und kostenlos. Sie können sich jeder Zeit und ohne Angabe von Gründen zurückziehen; dies hat für Sie keinerlei Nachteile.

Alle an der Studie teilnehmenden Personen sind über die Apothekenhaftpflichtversicherung oder während der 24-Stunden-Messung durch die Probandenversicherung des Kantonsspital Basel versichert.

Nur die Studienleitung hat Zugang zu den persönlichen Daten und nach Abschluss der Studie werden sie gelöscht. Die Auswertung der erhobenen Daten erfolgt strikt anonym.

Ich bin mit der Teilnahme an der Studie einverstanden:

Geburtsdatum: ☐☐.☐☐.☐☐☐☐

Name/Vorname: _____ _____

Adresse: _____

PLZ/Ort: ☐☐☐☐ _____

Datum: ☐☐.☐☐. 2003 Unterschrift: _____

7.2 Instruction for the blood pressure measurement in the pharmacy

UNI BASEL

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Departement Pharmazie der Universität Basel
Pharmaceutical Care Research Group
Klingelbergstr. 50 / 4056 Basel
Tel. 061 267 14 27, Fax 061 267 14 28

Merkblatt zur Blutdruckmessung in der Apotheke

Allgemeine Bemerkungen:

- Der Patient sollte mindestens 30 Minuten vor der Blutdruckmessung auf Rauchen und Koffeineinnahme verzichten.
- Vor der Messung mindestens 5 Minuten ruhig und entspannt sitzen.
- Die Messung muss sitzend und immer am gleichen Handgelenk/Arm durchgeführt werden.
- Messen Sie den Blutdruck zuerst nach der Riva-Rocci-Methode.
- Messen Sie den Blutdruck mit dem Handgelenkmessgerät 2 Mal (dazwischen 1 Minute Pause).
- ***Tragen Sie die Werte in das vorgegebene Protokoll ein!***

Ablauf der Handgelenkblutdruckmessung:

1) Vergewissern Sie sich, dass das Handgelenk frei ist und die Kleidung den Durchfluss des Blutes nicht stört.
2) Vergewissern Sie sich, dass das Handgelenk, an dem gemessen werden soll, mit der Voreinstellung im Menü übereinstimmt. Das Gerät ist für die Messung am ***linken Handgelenk*** **(LEFT WRIST)** eingestellt.
3) Legen Sie die Manschette um das Handgelenk, ca. 1 - 1,5 cm unterhalb des Handballens. Der Daumen zeigt nach oben.
4) Die richtige Höhe finden (WICHTIG: das Gerät muss auf *Herzhöhe* sein). Der Patient soll den Ellbogen aufstützen (um Bewegungen zu vermeiden) und dann den Zeigefinger auf das Schlüsselbein legen. Ist die Höhe korrekt ertönt ein *Piepton* und die Messung beginnt.
5) Der Patient darf sich nicht bewegen, bevor das Messergebnis angezeigt wird.
6) **Wenn das Messergebnis angezeigt wird, tragen Sie diesen Wert ins Protokoll ein!**
7) Ist der Messvorgang beendet und die Luft aus der Manschette raus, **schalten Sie das Gerät ab** und drücken Sie die **Taste M** (somit wird der Messwert zusätzlich gespeichert)!!!
8) Ist mindestens 1 Minute vergangen, schalten Sie das Gerät erneut ein und messen Sie gleich wie zuvor (Punkt 1 bis und mit Punkt 7).

7.3 Instruction for the home blood pressure measurement

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Merkblatt zur Blutdruckmessung zu Hause

Allgemeine Bemerkungen:

- Mindestens 30 Minuten vor der Blutdruckmessung sollten Sie auf Rauchen und Koffeineinnahme verzichten
- Vor der Messung mindestens 5 Minuten ruhig und entspannt sitzen
- Führen Sie die Messung sitzend und immer am gleichen Handgelenk durch
- Messen Sie Ihren Blutdruck vor Einnahme blutdrucksenkender Medikamente
- **Tragen Sie Ihre Werte in das vorgegebene Protokoll ein!**
- Tragen Sie im Protokoll unter Bemerkungen folgende Ereignisse ein:
  - wenn der gemessene Wert aussergewöhnlich hoch oder tief ist (tragen Sie diesen Wert unter Bemerkungen ein und wiederholen Sie die Messung und tragen diesen neuen Wert ins Protokoll ein)
  - Unwohlsein auftritt (Übelkeit, Schwindel, Schlafstörungen, Atemnot, Schmerzen, Herzklopfen usw.)
  - aussergewöhnliche Ereignisse auftreten

Ablauf der Handgelenk-Blutdruckmessung:

1) Vergewissern Sie sich, dass Ihr Handgelenk frei ist und Ihre Kleidung den Durchfluss des Blutes nicht stört.

2) Vergewissern Sie sich, dass das Handgelenk, an dem gemessen werden soll, mit der Voreinstellung im Menü übereinstimmt. Das Gerät ist für die Messung am ***linken Handgelenk*** **(LEFT WRIST)** eingestellt.

3) Legen Sie die Manschette um Ihr Handgelenk, ca. 1-1,5 cm unterhalb des Handballens. Ihr Daumen zeigt nach oben (vgl. Abbildung auf der Manschette!).

4) Finden Sie die richtige Höhe (WICHTIG: das Gerät muss auf *Herzhöhe* sein). Stützen Sie Ihren Ellbogen auf den Tisch und legen Sie Ihren Zeigefinger auf Ihr Schlüsselbein. Ist die Höhe korrekt, ertönt ein *Piepton* und die Messung beginnt.

5) Bewegen Sie sich nicht, bevor das Messergebnis angezeigt wird.

6) **Wenn das Messergebnis angezeigt wird, tragen Sie diesen Wert ins Protokoll ein!**

7) Ist der Messvorgang beendet und die Luft aus der Manschette raus, **schalten Sie das Gerät ab** und drücken Sie die **Taste M** (damit wird Ihr Messwert im Gerät gespeichert).

8) Ist 1 Minute vergangen, schalten Sie das Gerät erneut ein und messen Sie gleich wie zuvor (Punkt 1 bis und mit Punkt 7).

7.4 Data sheet of the diabetes screening campaign

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INSTITUT FÜR KLINISCHE PHARMAZIE
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Erfassungsblatt Apotheke

IC-Nummer
Etikette **hier** aufkleben

Bitte lassen Sie den 'Informed Consent' vom Patienten unterzeichnen!

Initialen: ☐☐

Datum der Messung: Tag 0 0 / Monat 0 0 / Jahr 2002

Jahrgang: ☐☐☐☐

Punktetotal aus Diabetesrisiko-Fragebogen: ☐☐

Geschlecht: ☐ männlich ☐ weiblich

In ärztl. Behandlung wegen Herz-Kreislauferkrankung: ☐ ja ☐ nein

Raucher: ☐ ja ☐ nein

In ärztl. Behandlung wegen Diabetes: ☐ ja ☐ nein

Übergewicht: BMI > 25 kg/m2 ☐ **ja** ☐ **nein**

Körpergewicht: ☐☐☐ kg Grösse: ☐,☐☐ m BMI: ☐☐,☐ kg/m2

(Angaben des Patienten) (BMI = Körpergewicht [kg] / Grösse [m] / Grösse [m])

Bewegungsmangel: ☐ **ja** ☐ **nein**

- Patient macht zur Zeit nie oder weniger als 30 Min. täglich körperliche Aktivitäten von mittlerer Intensität
- oder Patient macht an weniger als 3 Tagen pro Woche während mind. 20 Min. körperliche Aktivitäten von hoher Intensität

Alter über 45 Jahre: ☐ **ja** ☐ **nein**

Familiäres Diabetes-Risiko: ☐ **ja** ☐ **nein**
Erstgrad-Verwandte (Eltern, Geschwister) mit Diabetes Typ 2

Geburt eines Babys mit Geburtsgewicht über 4000 g (nur bei Frauen)**:** ☐ **ja** ☐ **nein**

Blutdruck erhöht: syst. ≥ 140 und/oder diast. ≥ 90 mmHg ☐ **ja** ☐ **nein**

Messwert: syst. ☐☐☐ mmHg diast. ☐☐☐ mmHg

Wenn mindestens **2 Risikofaktoren** vorhanden sind --> Blutzuckermessung

BLUTGLUCOSE - SCREENING

Letzte Mahlzeit vor: ☐☐ h

Patient nüchtern? ☐ **ja** ☐ **nein**
letzte Nahrung vor ≥ 8h

Messwert Glucose: ☐☐,☐ mmol/l
kapilläres Vollblut

Falls Messwert grenzwertig:

Vorläufiger Entscheid:

☐ Wiederholungsmessung empfohlen

Wiederholungsmessung nüchtern: ☐☐,☐ mmol/l

Beurteilung Apotheke:

Blutglucose erhöht? ☐ **ja** ☐ **nein**

nüchtern ≥ 6.1 mmol/l
oder nicht nüchtern ≥ 11.1 mmol/l
oder Wiederholungsmessung ≥ 5.3 mmol/l

BERATUNGSPROTOKOLL

Abklärung Motivationsstufe (1 - 5):

☐ Bewegung
☐ Früchte & Gemüse
☐ Fettarme Ernährung

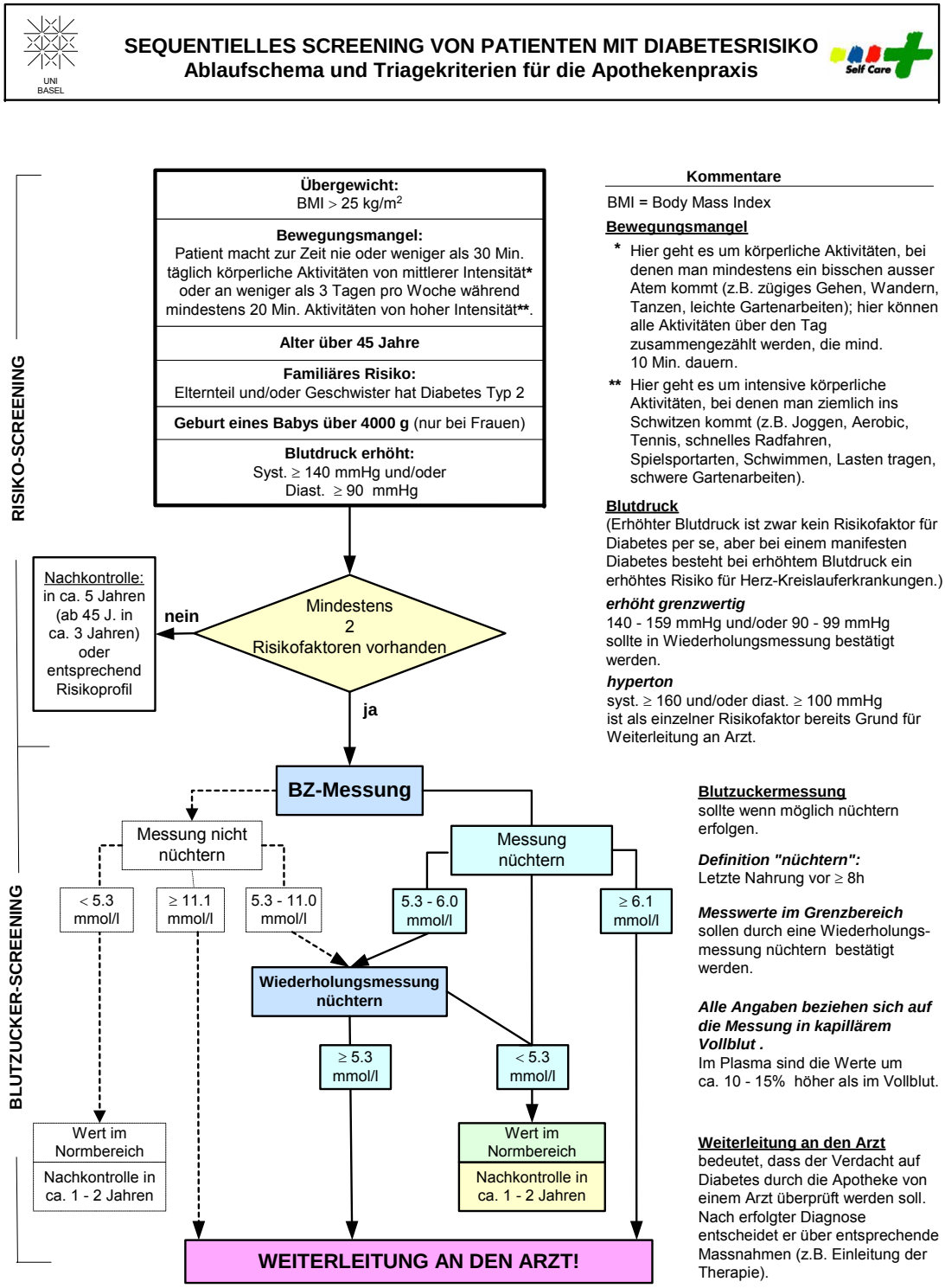
☐ Empfehlung Gewichtsreduktion
☐ Weiterer Beratungstermin vereinbart
☐ andere Empfehlungen:

ENTSCHEID nach Screening Apotheke (nur 1 Antwort)

☐ Weiterleitung an Arzt (zur Diagnosestellung)
☐ Nachkontrolle in ☐ Jahr(en)
☐ Fortsetzung der ärztlichen Behandlung

Visum: .....

7.5 Flow chart and triage criteria of the diabetes screening campaign



Kommentare

BMI = Body Mass Index

Bewegungsmangel

* Hier geht es um körperliche Aktivitäten, bei denen man mindestens ein bisschen ausser Atem kommt (z.B. zügiges Gehen, Wandern, Tanzen, leichte Gartenarbeiten); hier können alle Aktivitäten über den Tag zusammengezählt werden, die mind. 10 Min. dauern.

** Hier geht es um intensive körperliche Aktivitäten, bei denen man ziemlich ins Schwitzen kommt (z.B. Joggen, Aerobic, Tennis, schnelles Radfahren, Spielsportarten, Schwimmen, Lasten tragen, schwere Gartenarbeiten).

Blutdruck

(Erhöhter Blutdruck ist zwar kein Risikofaktor für Diabetes per se, aber bei einem manifesten Diabetes besteht bei erhöhtem Blutdruck ein erhöhtes Risiko für Herz-Kreislauferkrankungen.)

erhöht grenzwertig

140 - 159 mmHg und/oder 90 - 99 mmHg sollte in Wiederholungsmessung bestätigt werden.

hyperton

syst. ≥ 160 und/oder diast. ≥ 100 mmHg ist als einzelner Risikofaktor bereits Grund für Weiterleitung an Arzt.

Blutzuckermessung

sollte wenn möglich nüchtern erfolgen.

Definition "nüchtern":

Letzte Nahrung vor ≥ 8h

Messwerte im Grenzbereich

sollen durch eine Wiederholungs-messung nüchtern bestätigt werden.

Alle Angaben beziehen sich auf die Messung in kapillärem Vollblut .

Im Plasma sind die Werte um ca. 10 - 15% höher als im Vollblut.

Weiterleitung an den Arzt

bedeutet, dass der Verdacht auf Diabetes durch die Apotheke von einem Arzt überprüft werden soll. Nach erfolgter Diagnose entscheidet er über entsprechende Massnahmen (z.B. Einleitung der Therapie).

Self Care "Unerkannter Diabetes" 2002 / K. Hersberger, UNI BS

7.6 Informed Consent for the follow-up

47690

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Teilnahme an der Nachbefragung: Self Care "Unerkannter Diabetes"

Informed Consent (Schriftliche Einverständniserklärung des Patienten)

Sehr geehrte Dame / Sehr geehrter Herr

Der Nutzen von Früherfassungskampagnen und die beste Art ihrer Durchführung sind noch nicht ausreichend dokumentiert. Am wichtigsten ist dabei die Erfahrung der Teilnehmerinnen und Teilnehmer. Deshalb ist im Anschluss an die Früherkennungskampagne "Unerkannter Diabetes" eine schriftliche Nachbefragung geplant, welche von einer Arbeitsgruppe an der Universität Basel unter der Leitung von Dr. Kurt Hersberger durchgeführt wird. Ca. 10% der in dieser Kampagne erfassten Personen werden nach dem Zufallsprinzip für diese Nachbefragung ausgewählt. Diese Personen werden den ersten Fragebogen in ca. 4 Monaten erhalten. Weitere Befragungen sind geplant.
Wir ersuchen Sie um Ihr ausdrückliches Einverständnis für die Nachbefragung, damit wir auch Ihre Erfahrung einbeziehen können. Für Sie entsteht zwar aus der Nachbefragung kein direkter persönlicher Nutzen, aber Sie helfen mit, die Qualität künftiger Kampagnen zu verbesseren. Die Teilnahme an dieser Nachbefragung ist freiwillig. Sie können sich jederzeit und ohne Angabe von Gründen zurückziehen; dies hat für Sie keinerlei Nachteile.
Nur die Studienleitung wird Zugang zu den persönlichen Angaben haben. Diese dienen ausschliesslich der Kontaktnahme und werden nach Abschluss der Nachbefragung wieder gelöscht. Ausserhalb der Nachbefragung erfolgt die Auswertung der erhobenen Daten strikt anonym.

Ich bin mit der Teilnahme an der Nachbefragung einverstanden:

Geburtsdatum: | | | | | | | | |

Name / Vorname:

Adresse:

PLZ / Ort:

Datum: | | | | | | | | Unterschrift: _____

IC-Nummer	Für Erfassungsblatt Apotheke	Für Patientenkarte	Für Arztbericht

7.7 Patient's report sheet of the diabetes screening campaign

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Sehr geehrte Dame, sehr geehrter Herr

Sie haben Ihr persönliches Risiko für eine Zuckerkrankheit in der Apotheke überprüfen lassen. Die ermittelten Werte sollten von einem Arzt abgeklärt werden. Ihr Apothekenteam hat Ihnen deshalb einen Arztbesuch empfohlen und Ihnen Unterlagen für den Arzt mitgegeben. Die Aktion zur Früherkennung der Zuckerkrankheit wird in einer wissenschaftlichen Studie untersucht. **Wir bitten Sie deshalb freundlich, uns diese vorfrankierte Postkarte nach Ihrem Arztbesuch ausgefüllt zurückzusenden.** Das Formular wird elektronisch verarbeitet; verzichten Sie deshalb auf zusätzliche Angaben wie Name und Adresse. Dank eines Codes können Ihre anonymisierten Angaben mit den in der Apotheke und vom Arzt ermittelten Daten verglichen werden.

Wir danken Ihnen für Ihre Mithilfe.

Dr. Kurt Hersberger Prof. Dr. Rudolf Bruppacher Andrea Botomino

Ihre Erfahrungen sind wichtig
Patientenbericht nach Arztbesuch

IC-Nummer-Etikette in der Apotheke **immer** hier anbringen

Arztbesuch am: Tag ☐☐ Monat ☐☐ Jahr 2002

Ihr letzter Arztbesuch erfolgte im Jahre: ☐☐☐☐ ☐ in der gleichen Praxis ☐ in einer anderen Praxis

Fragen zu Ihrem Apothekenbesuch:

Zu welchen Themen wurden Sie in der Apotheke beraten?

Empfehlung zu mehr Bewegung	☐ ja	☐ nein
Empfehlung zur Umstellung der Ernährung	☐ ja	☐ nein
Empfehlung zur Gewichtsreduktion	☐ ja	☐ nein

Wie beurteilen Sie die Risikoabklärung in der Apotheke?

Risikoabklärung und Beratung waren gut und kompetent ausgeführt	☐ ja	☐ nein
Die Überweisung an den Arzt durch die Apotheke war aus Ihrer Sicht berechtigt	☐ ja	☐ nein
Sie begrüssen diese Zusammenarbeit zwischen Apothekern und Ärzten zur Risikofrühabklärung	☐ ja	☐ nein

Fragen zu Ihrem Arztbesuch:

Welche Untersuchungen oder Messungen wurden in der Arztpraxis durchgeführt oder sind für später geplant?

Blutzucker	☐ ja	☐ nein
Cholesterin/Blutfette	☐ ja	☐ nein
Kontrolle Herz (EKG)	☐ ja	☐ nein
Kontrolle der Augen	☐ ja	☐ nein
Kontrolle der Füsse	☐ ja	☐ nein

Welche Ratschläge hat Ihnen der Arzt betreffend Diabetesrisiko erteilt?

- ☐ Vermehrte körperliche Aktivität oder Sport
- ☐ Umstellung der Ernährung
- ☐ Besuch einer Diabetesberatung
- ☐ Empfehlung Gewichtsreduktion
- ☐ Beginn einer medikamentösen Therapie
- ☐ Keine Therapie und keine Massnahmen erforderlich betreffend Diabetesrisiko

Haben Sie einen weiteren Arzttermin vereinbart? ☐ ja ☐ nein
(gleicher oder anderer Arzt)

7.8 Physician's report sheet of the diabetes screening campaign

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45221
Pharmaceutical Care Research Group
Klingelbergstr. 50/4056 Basel e-mail: diabetes-pharma@unibas.ch

Sehr geehrte Frau Doktor, sehr geehrter Herr Doktor

Im Rahmen der Self Care Kampagne "Unerkannter Diabetes" wird eine Screening-Aktion zur Früherfassung von Risikopatienten für Diabetes Typ 2 durchgeführt. In einer Apotheke wurde ein Risikoprofil ermittelt, welches eine ärztliche Abklärung rechtfertigt.

Die Kampagne wird begleitet von einer Studie, in welcher sämtliche Aktivitäten der Apothekenteams evaluiert werden. Den Triageentscheid der Apotheke im vorliegenden Fall können Sie durch Ihre Untersuchung validieren.

Sofern der Patient Ihnen das Einverständnis gibt, ersuchen wir Sie, uns als Studienzentrale nach der Erstkonsultation nachstehende Angaben zu übermitteln. Verzichten Sie dabei auf Angaben zu Ihrer Praxis und zum überwiesenen Patienten. Das untenstehende Formular wird elektronisch verarbeitet. Dank eines Codes können Ihre anonymisierten Angaben mit den in der Apotheke ermittelten Daten verglichen werden.

Wir danken Ihnen für Ihre Mitarbeit.

Dr. Kurt Hersberger Prof. Dr. Rudolf Bruppacher Andrea Botomino

Arztbericht nach Weiterleitung durch Apotheke

IC-Nummer-Etikette in der Apotheke **immer** hier anbringen

Datum der Konsultation: Tag ☐☐ Monat ☐☐ Jahr 2002

War der Patient/die Patientin erstmals bei Ihnen in der Praxis? ☐ ja ☐ nein

wenn nein: betrifft/betraf die Behandlung ☐ Herz-Kreislauferkrankung ☐ Diabetes ☐ Andere
in welchem Jahr war die letzte Konsultation? ☐☐☐☐

Blutglucosekontrolle: Messung: ☐ durchgeführt ☐ geplant ☐ nicht nötig

Messwert Glucose: ☐☐,☐ mmol/l ☐ Messwert liegt noch nicht vor

Patient nüchtern? *letzte Nahrung vor ≥ 8 Std.*	☐ ja	☐ nein
Messung im Plasma? *)	☐ ja	☐ nein
Wurde dieser Befund in Ihrer Praxis erstmals erfasst?	☐ ja	☐ nein

**) Messung in Apotheke erfolgte in kapillärem Vollblut, im Plasma sind Werte um ca. 10 - 15% höher*

Weitere Untersuchungen, welche durchgeführt wurden oder geplant sind:

- ☐ Fusskontrolle
- ☐ Augenhintergrundkontrolle
- ☐ Kontrolle Morgenurin (Mikroalbuminurie)
- ☐ EKG
- ☐ Andere Untersuchungen:

_____

_____

Weitere Planung:

- ☐ keine Therapie erforderlich
- ☐ Ernährungsberatung
- ☐ Tabakentwöhnung
- ☐ Ueberweisung an Augenarzt
- ☐ Ueberweisung an Diabetologe
- ☐ Therapie mit "Aspirin"
- ☐ Medikamentöse Therapie bei:
  - ☐ Hypertonie ☐ Dyslipidämie
  - ☐ Diabetes ☐ andere

Wurde ein weiterer Arzttermin vereinbart ? ☐ **ja** ☐ **nein** Visum: .....

7.9 Data sheet of the pharmacy based screening for metabolic syndrome

25641 toppharm

Auf dem Kopieblatt für Patient und für Ablage in der Apotheke hier je eine Adressetikette anbringen

Das Deckblatt bleibt anonym!

Erfassungsblatt Metabolisches Syndrom

Initialen: ☐☐ **Jahrgang:** 1 9 ☐☐

Geschlecht: ☐ männlich ☐ weiblich

Datum der Messung: Tag ☐☐ Monat ☐☐ Jahr 2 0 0 ☐

in ärztl. Behandlung wegen Herz-Kreislauferkrankung ☐ ja ☐ nein

in ärztl. Behandlung wegen Diabetes ☐ ja ☐ nein

Notizen (z.B. Medikamenten-Anamnese)

Anlass für die Messung ☐ unbekannte Werte ☐ Überprüfung bekannter Werte

Messmöglichkeit bekannt durch: ☐ TopMail ☐ Presse ☐ Lokal-TV ☐ Apotheke selbst

Familiäres Risiko: ☐ **ja** ☐ **nein**
Patient hat Erstgrad-Verwandte (Eltern, Geschwister) mit Typ-2 Diabetes oder Erstgrad-Verwandte mit Hirnschlag, Herzinfarkt oder Angina pectoris vor dem 55. Lebensjahr (Männer) oder vor dem 65. Lebensjahr (Frauen)

Bewegungsmangel: ☐ **ja** ☐ **nein**
Patient macht zur Zeit nie oder weniger als 30 Min. täglich körperliche Aktivitäten von mittlerer Intensität oder
Patient macht an weniger als 3 Tagen pro Woche während mind. 20 Min. körperliche Aktivitäten von hoher Intensität

Alter über 45 Jahre: ☐ **ja** ☐ **nein**

Rauchen: ☐ **ja** ☐ **nein**

Geburt eines Babys mit Geburtsgewicht über 4100 g (nur bei Frauen)**:** ☐ **ja** ☐ **nein**

Übergewicht: *BMI > 25 kg/m2* ☐ **ja** ☐ **nein**
Grösse: ☐ m ☐☐ cm Körpergewicht: ☐☐☐ kg BMI: ☐☐.☐ kg/m2

Blutdruck erhöht: *≥ 140 und/oder ≥ 90 mmHg* ☐ **ja** ☐ **nein**
Messwert: syst. ☐☐☐ mmHg diast. ☐☐☐ mmHg

Blutglucosemessung
Patient nüchtern? ☐ ja ☐ nein
letzte Nahrung vor > 8 Std.
Messwert Glucose: ☐☐.☐ mmol/l
Vollblut kapillär
Wiederholungsmessung ☐☐.☐ mmol/l
nüchtern, Vollblut kapillär

Blutglucose erhöht? ☐ **ja** ☐ **nein**
≥ 5.3 mmol/l
Wurde ein normaler/erhöhter Wert heute erstmals erfasst? ☐ **ja** ☐ **nein**

Erfassung Lipidprofil *(im Vollblut kapillär)*

Gesamtcholesterin TC *Grenzwert > 5.0 mmol/l*	☐☐.☐ mmol/l
HDL-Cholesterin *Grenzwert: < 1.0 mmol/l*	☐☐.☐ mmol/l
LDL-Cholesterin *Grenzwert: > 3.0 mmol/l*	☐☐.☐ mmol/l
Triglyzeride *Grenzwert: > 2.0 mmol/l*	☐☐.☐ mmol/l
TC / HDL-Cholesterin *Grenzwert: > 5.0*	☐.☐

Risiko Dyslipidämie *≥ 1 Grenzwert überschritten?* ☐ **ja** ☐ **nein**

Wurde mind. 1 erhöhter Wert heute erstmals erfasst? ☐ **ja** ☐ **nein**

Beratung zur Verhaltensänderung bezüglich:
☐ fettarme Ernährung ☐ Bewegung
☐ Früchte & Gemüse ☐ Entrauchen

☐ **Empfehlung Gewichtsreduktion**
☐ **andere Empfehlungen:**

ENTSCHEID
☐ Weiterleitung an Arzt
☐ Nachkontrolle in 1 - 2 Jahren
☐ Nachkontrolle in ca. 3 Jahren (ab 45 J.)
☐ Nachkontrolle in ca. 5 Jahren (vor 45 J.)

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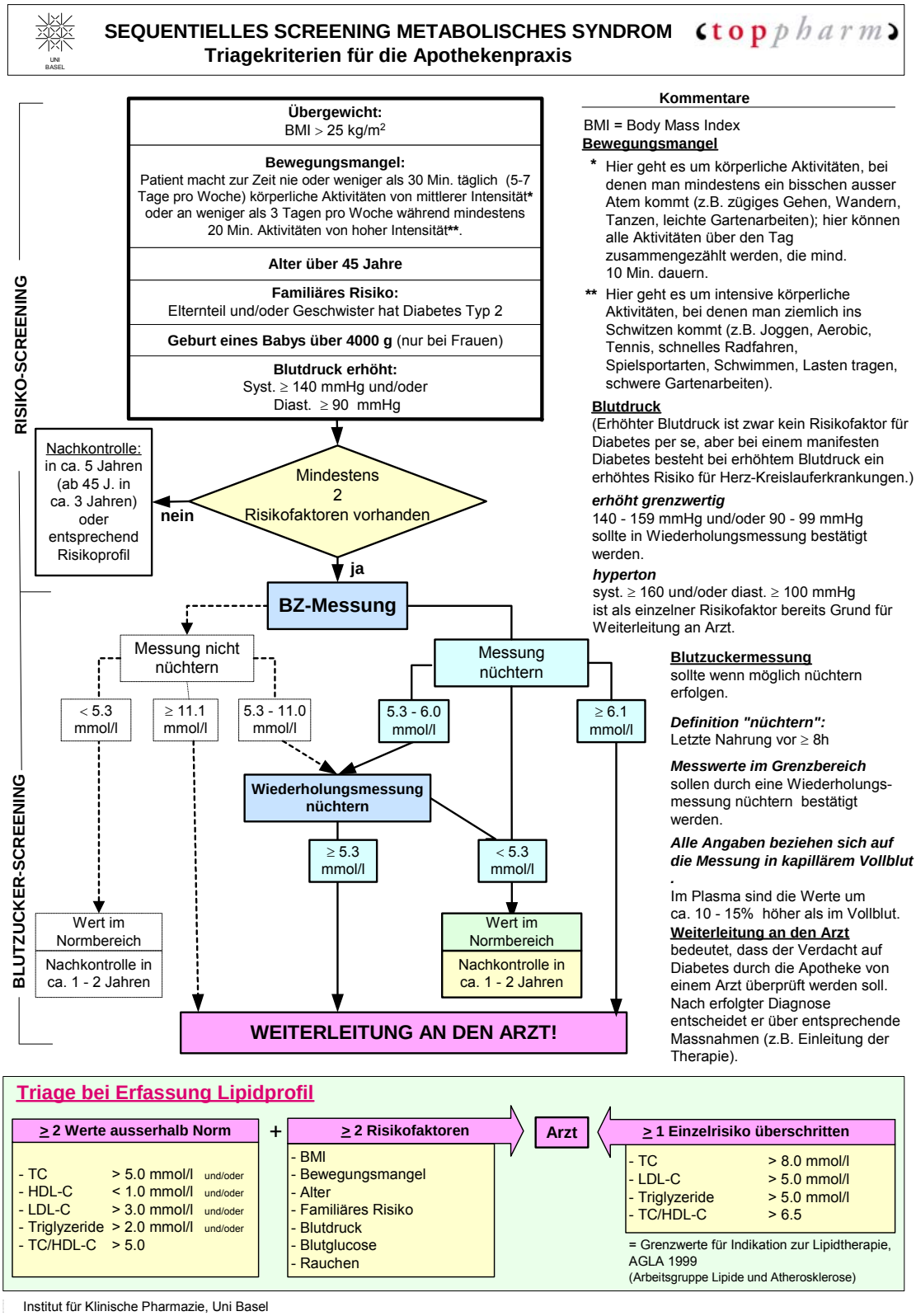
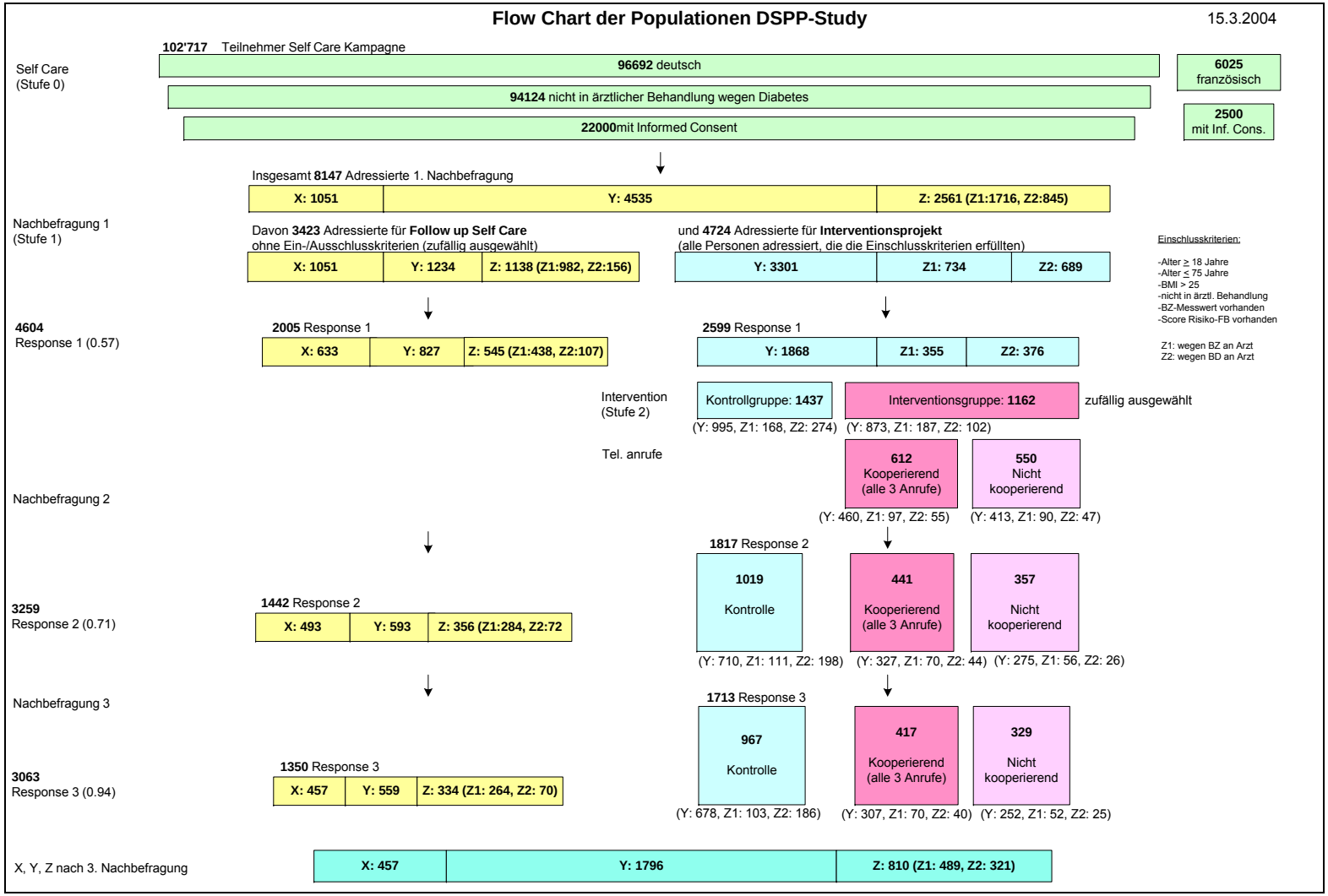
7.10 Flow chart and triage criteria of the pharmacy based screening for metabolic syndrome



7.11 Flow chart follow-up diabetes screening campaign and telephone-based intervention



7.12 First questionnaire of follow-up

52686 IC-Nummer

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Nachbefragung im Anschluss an die Aktion "Stopp Zucker - jetzt testen"

Herzlichen Dank, dass Sie sich die Zeit nehmen, diesen Fragebogen auszufüllen!

Vorab einige Hinweise zum Ausfüllen dieses Fragebogens:

- "Diabetes Typ 2" ist der Fachausdruck für Zuckerkrankheit. Man spricht auch von "Alterszucker" oder "Altersdiabetes", obwohl heute immer öfter auch junge Personen betroffen sind.
- Bitte verwenden Sie zum Ausfüllen einen dunklen Kugelschreiber oder Filzstift
- Bitte setzen Sie die Kreuze so exakt wie möglich in die Kästchen: Richtig ☒ Falsch ☒

1 Risikoabklärung und Beratung in der Apotheke

1.1 Wie wurden Sie auf die Aktion "Stopp Zucker - jetzt testen" aufmerksam?
(Mehrere Antworten sind möglich)

☐ Apotheke (Schaufenster)
☐ Apotheke (Postkarte/Zirkular)
☐ Apotheke (Information durch das Personal)
☐ Apothekenmagazin zB. "astrea", "optima"
☐ Krankenkasse (Mitgliedermagazin)
☐ Artikel in der Tageszeitung
☐ Artikel in der Zeitschrift "Schweizer Familie"
☐ TV-Sendung PULS (SF DRS)
☐ TV-Spot "Stopp Zucker - jetzt testen"
☐ Hinweis von Verwandten / Bekannten
☐ auf andere Art:
— — — — — — — — — — — — — — — — — — — —

1.2 Was war der Grund für Sie, vom Angebot "Stopp Zucker - jetzt testen" Gebrauch zu machen?
(Mehrere Antworten sind möglich)

☐ ich wollte wissen, wie hoch mein Diabetesrisiko ist
☐ ich wollte wissen, wie hoch mein Blutzuckerwert ist
☐ ich hatte im Diabetesrisikofragebogen eine hohe Punktzahl
☐ ich kenne meine Blutzuckerwerte, wollte sie aber in der Apotheke überprüfen lassen
☐ ich habe die Dienstleistung genutzt, weil sie gratis war
☐ andere Gründe

1.3 Haben Sie in der Apotheke schriftliche Unterlagen erhalten?
(Mehrere Antworten sind möglich)

☐ ja...

☐	☐	☐
○ Risikofragebogen mit 7 Fragen	○ Leitfaden "Werden Sie aktiv"	○ Broschüre action-d "Tun Sie etwas für Ihre Gesundheit"

☐ nein, ich habe keine dieser Unterlagen erhalten
☐ weiss nicht

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1.4 Zu welchen Themen wurden Sie in der Apotheke beraten?
(Mehrere Antworten sind möglich)

☐ vermehrt Früchte und Gemüse in der Ernährung
☐ weniger Fett in der Ernährung
☐ mehr Bewegung
☐ Gewichtsreduktion / Gewicht halten
☐ ich wurde in der Apotheke zu keinem der Themen beraten
☐ weiss nicht

1.5 Wurde Ihnen in der Apotheke empfohlen, einen Arzt aufzusuchen, um Ihr Diabetesrisiko überprüfen zu lassen?

☐ ja
☐ nein
☐ weiss nicht

1.6 Haben Sie seit Mai 2002 nach der Aktion "Stopp Zucker - jetzt testen" einen Arzt aufgesucht?

☐ ja, um mein Diabetesrisiko beim Arzt überprüfen zu lassen...
  ○ aufgrund der schriftlichen Unterlagen (Risikofragebogen, Leitfaden, Broschüre action d)
  ○ aufgrund der Empfehlung in der Apotheke
  ○ anderes

☐ ja, aber nicht wegen meinem Diabetesrisiko
☐ nein

1.7 Falls Ihnen in der Apotheke empfohlen wurde, einen Arzt aufzusuchen, Sie aber bis jetzt keinen Arzt aufgesucht haben, was war der Grund dafür?

☐ Ich habe bis jetzt keinen Arzt aufgesucht...
  ○ weil ich das Risiko für Diabetes Typ 2 nicht als bedrohlich einschätze
  ○ weil ich mich damit nicht auseinandersetzen möchte
  ○ weil ich keine Zeit hatte
  ○ weil ich nicht weiss, an wen ich mich wenden soll (habe keinen Hausarzt)
  ○ anderer Grund: _____

☐ Ein Arztbesuch ist in den nächsten 6 Monaten geplant

1.8 Wie beurteilen Sie die Aktion "Stopp Zucker - jetzt testen" in der Apotheke?

	schlecht	akzeptabel	gut	sehr gut	weiss nicht
Risikofragebogen mit 7 Fragen	○	○	○	○	○
Broschüre action-d "Tun Sie etwas für Ihre Gesundheit"	○	○	○	○	○
Leitfaden "Werden Sie aktiv"	○	○	○	○	○
Blutzuckermessung in der Apotheke	○	○	○	○	○
Beratung in der Apotheke	○	○	○	○	○
Aktion "Stopp Zucker - jetzt testen" insgesamt	○	○	○	○	○

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2 Beratung und Untersuchungen beim Arzt/bei der Ärztin

(Nur beantworten, falls Sie die Frage 1.6 mit "ja, um mein Diabetesrisiko beim Arzt überprüfen zu lassen" beantwortet haben)

2.1 Wurden folgende Untersuchungen in der Arztpraxis durchgeführt?

(Mehrere Antworten sind möglich)

☐ ja...

- ○ Messung des Blutzuckers
- ○ Messung Cholesterin/Blutfette
- ○ Messung des Blutdruckes
- ○ Kontrolle der Füsse
- ○ Kontrolle der Augen

☐ nein, keine dieser Untersuchungen wurden durchgeführt

☐ weiss nicht

2.2 Welche Ratschläge hat Ihnen der Arzt betreffend Diabetesrisiko erteilt?

(Mehrere Antworten sind möglich)

☐ vermehrt Früchte und Gemüse in der Ernährung

☐ weniger Fett in der Ernährung

☐ mehr Bewegung

☐ Gewichtsreduktion / Gewicht halten

☐ Beginn einer medikamentösen Therapie

☐ der Arzt hat mir keine Ratschläge betreffend meines Diabetesrisikos erteilt

☐ weiss nicht

2.3 Wurde bei Ihnen jemals durch einen Arzt ein Diabetes Typ 2 festgestellt?

☐ ja

☐ nein

☐ weiss nicht

Wenn ja, wann? Monat ☐☐ Jahr ☐☐☐☐

3 Diabetes Typ 2 - Risikofaktoren

3.1 Was, denken Sie, kann eine Person tun, um ihr Risiko für Diabetes Typ 2 zu senken?

(Mehrere Antworten sind möglich)

☐ nichts: das Risiko, an Diabetes Typ 2 zu erkranken, ist nicht beeinflussbar

☐ regelmässige Einnahme von Aspirin

☐ gesunde Ernährung

☐ genügend Schlaf

☐ genügend Bewegung

☐ Übergewicht vermeiden

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4 Körpergewicht

4.1 Wieviel beträgt Ihr Körpergewicht zur Zeit?

Gewicht: ☐☐☐ kg

4.2 Denken Sie, dass Sie übergewichtig sind?

☐ ja
☐ nein
☐ weiss nicht

4.3 Welches Ziel verfolgen Sie bezüglich Ihres Körpergewichts?

☐ ich möchte zunehmen
☐ ich möchte mein Gewicht halten
☐ ich möchte abnehmen
☐ ich verfolge keine Ziele bezüglich meines Körpergewichts

4.4 Welches Ziel haben Sie bezüglich Ihres Körpergewichts?

Gewicht: ☐☐☐ kg

5 Ernährung

5.1 Auf was sollte eine Person bei der Ernährung achten, damit ihre Gesundheit positiv beeinflusst wird?

(Mehrere Antworten sind möglich)

☐ weniger Süssigkeiten konsumieren
☐ nur eine Mahlzeit pro Tag einnehmen
☐ viel Früchte und/oder Gemüse konsumieren
☐ Bier als Durstlöscher konsumieren
☐ mehr Fleisch konsumieren
☐ weniger Fett konsumieren

5.2 Wieviele Portionen Früchte oder Gemüse assen Sie in den letzen beiden Monaten durchschnittlich pro Tag?

○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ mehr als 5

6 Bewegung

6.1 Wie oft und wie lange, denken Sie, sollte sich eine Person *im Minimum* bewegen, um gesund zu bleiben? (Nur eine Antwort ist möglich)

☐ täglich zehn Minuten
☐ täglich eine halbe Stunde
☐ täglich dreimal eine halbe Stunde
☐ zweimal pro Woche eine halbe Stunde

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☞ *Bitte beachten Sie: Bei Frage 6.2 und Frage 6.3 fragen wir nach zwei verschiedenen Arten von Bewegung!*

6.2 Hier geht es um körperliche Aktivität, bei der Sie mindestens einen leicht beschleunigten Atem bekommen (zum Beispiel zügiges Gehen, Wandern, Tanzen, leichtere Gartenarbeiten):

a) An wie vielen Tagen pro Woche waren Sie in den letzten beiden Monaten durchschnittlich in dieser Art körperlich aktiv?

○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ 6 ○ 7

b) Wie lange waren Sie durchschnittlich an jedem dieser Tage in dieser Art aktiv?

☐ weniger als 10 Minuten pro Tag
☐ 10 Minuten pro Tag
☐ 20 Minuten pro Tag
☐ eine halbe Stunde pro Tag
☐ mehr als eine halbe Stunde pro Tag

c) Seit wann sind Sie schon auf diese Weise aktiv?

☐ weniger als 1 Monat
☐ weniger als 6 Monate
☐ 6 - 12 Monate
☐ länger als 1 Jahr
☐ länger als 5 Jahre

d) Haben Sie vor, diese körperliche Aktivität zu steigern?

☐ ja...
  ○ im nächsten Monat
  ○ in den nächsten 2-6 Monaten
☐ nein

6.3 Hier geht es um sportliche oder körperliche Aktivitäten, bei denen Sie ziemlich ins Schwitzen kommen (z. B. Joggen, Aerobics, Tennis, schnelles Radfahren, Spielsportarten, Schwimmen, Lasten tragen, Graben, Schaufeln):

a) An wie vielen Tagen pro Woche haben Sie in den letzten beiden Monaten Aktivitäten dieser Art gemacht?

○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ 6 ○ 7

b) Wie lange waren Sie durchschnittlich an jedem dieser Tage in dieser Art aktiv?

☐ weniger als 10 Minuten pro Tag
☐ 10 Minuten pro Tag
☐ 20 Minuten pro Tag
☐ eine halbe Stunde pro Tag
☐ mehr als eine halbe Stunde pro Tag

c) Haben Sie vor, diese körperliche Aktivität zu steigern?

☐ ja...
  ○ im nächsten Monat
  ○ in den nächsten 2-6 Monaten
☐ nein

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7 Änderungen des Lebensstils

7.1 Haben Sie seit Mai 2002 aufgrund der Aktion "Stopp Zucker - jetzt testen" ihren Lebensstil geändert?

(Mehrere Antworten sind möglich)

☐ ja...

- ○ ich nehme neu an einem Bewegungskurs teil
- ○ ich trainiere neu in einem Fitnesscenter
- ○ ich bewege mich mehr im Alltag (z.B. zu Fuss gehen, Velo benutzen)
- ○ ich mache mehr Sport
- ○ ich habe mich für eine Ernährungsberatung angemeldet
- ○ ich achte beim Kauf und bei der Wahl von Lebensmitteln auf ihren Fettgehalt
- ○ ich habe meine Ernährung umgestellt

☐ nein...

- ○ aber ich habe mir einen Termin gesetzt, wann ich meinen Lebensstil ändern werde
- ○ ich will meinen Lebensstil beibehalten
- ○ ich bin zu wenig motiviert, meinen Lebensstil zu ändern
- ○ ich habe meinen Lebensstil aus anderen Gründen nicht geändert

7.2 Hatten Sie mit der Änderung Ihrer Gewohnheiten Erfolg?
(Nur beantworten, falls Sie Frage 7.1 mit "ja" beantwortet haben)

(Mehrere Antworten sind möglich)

☐ ja...

- ○ ich konnte mein Gewicht halten oder in die gewünschte Richtung beeinflussen
- ○ ich fühle mich wohler in meiner Haut

☐ nein...

- ○ ich nehme bis jetzt keine Fortschritte wahr
- ○ ich habe es wieder aufgegeben, meine Gewohnheiten ändern zu wollen

7.3 Haben Sie aufgrund der Aktion "Stopp Zucker - jetzt testen" Ihre Ernährungsgewohnheiten geändert?

(Mehrere Antworten sind möglich)

☐ ja...

- ○ ich achte auf den Fettgehalt in meiner Nahrung
- ○ ich esse generell mehr Früchte und Gemüse
- ○ ich esse häufiger 5 Portionen Früchte oder Gemüse pro Tag
- ○ ich esse generell weniger

☐ nein, aber ich habe vor, meine Essgewohnheiten zu ändern

☐ nein, und ich habe auch nicht vor, meine Essgewohnheiten zu ändern

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7.4 Was ist oder wäre für Sie hilfreich, um Ihren Lebensstil zu ändern?

(**- -** gar nicht hilfreich, **-** mässig hilfreich, **+** ziemlich hilfreich, **++** sehr hilfreich)

	— —	—	+	++
Zusammen mit Gleichgesinnten etwas für meine Gesundheit unternehmen	○	○	○	○
Fitnessangebote in der Nähe (z.B. Fitnesscenter, Vita Parcours)	○	○	○	○
Kennzeichnung gesunder Lebensmittel im Lebensmittelgeschäft	○	○	○	○
Kennzeichnung gesunder Menus im Restaurant	○	○	○	○
Ernährungsberatung	○	○	○	○
Beratung zu gesundheitsförderlicher Bewegung	○	○	○	○
Unterstützung durch die Krankenkasse (Information/Gutscheine)	○	○	○	○
Unterstützung durch den Hausarzt	○	○	○	○
Unterstützung durch die Apotheke	○	○	○	○
Unterstützung durch Personen, die im gleichen Haushalt wohnen	○	○	○	○
Unterstützung durch andere Personen, die mir nahe stehen	○	○	○	○
Anderes: — — — — — — — — — — — — — — — —	○	○	○	○

8 Fragen zu Ihrer Person

8.1 Persönliche Angaben

Jahrgang: ☐☐☐☐

Körpergrösse: ☐☐☐ cm

Geschlecht: ○ männlich
○ weiblich

8.2 Wohnen Sie mit anderen Personen im gleichen Haushalt?

☐ ja...

- ○ mit Partner/-in
- ○ mit Kind(ern)
- ○ mit den Eltern
- ○ mit anderen Verwandten
- ○ mit nicht verwandten Personen

☐ nein

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8.3 Was haben Sie für eine Nationalität?

☐ Schweiz
☐ Andere, nämlich: ____

Falls "Andere": Wie lange leben Sie schon in der Schweiz? ☐☐ Jahre

8.4 Welches ist die höchste Ausbildung, die Sie abgeschlossen haben?

☐ keine Ausbildung
☐ Obligatorische Schule
☐ Berufslehre, Berufsschule
☐ Maturitätsschule, Lehrerseminar; andere allgemein bildende Schule
☐ Höhere Berufsausbildung (Meisterdiplom, Eidg. Fachausweis, höhere Fachschule, HTL, HWV)
☐ Universität, Hochschule

8.5 Wie hoch ist das gesamte monatliche Bruttoeinkommen Ihres Haushaltes?

☐ < Fr. 3000.-
☐ Fr. 3000.- bis 6000.-
☐ Fr. 6000.- bis 9000.-
☐ > Fr. 9000.-

8.6 Rauchen Sie?

☐ ja
☐ nein, ich habe aufgehört zu rauchen...
○ ...in den letzten 12 Monaten
○ ...vor mehr als 12 Monaten
☐ nein, ich habe noch nie geraucht

8.7 Zahlt Ihre Krankenkasse einen Beitrag zur Förderung gesunden Verhaltens (z.B. Fitnessstudio)?

☐ ja
☐ nein
☐ weiss nicht

8.8 Bei welcher Krankenkasse sind Sie versichert?

☐ Helsana
☐ Visana
☐ CSS
☐ ÖKK
☐ Concordia
☐ Andere

---

9 Kommentare, Bemerkungen

- -

- -

Herzlichen Dank für Ihre wertvolle Mitarbeit!

7.13 Second questionnaire of follow-up

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2. Nachbefragung im Anschluss an die Aktion "Stopp Zucker - Jetzt testen"

Herzlichen Dank, dass Sie an unserer ersten schriftlichen Nachbefragung im August 2002 teilgenommen haben. Ihre Mitarbeit ist für uns sehr wertvoll!

Vorab einige Hinweise zum Ausfüllen dieses Fragebogens:

- "Diabetes Typ 2" ist der Fachausdruck für Zuckerkrankheit. Man spricht auch von "Alterszucker" oder "Altersdiabetes", obwohl heute immer öfter auch junge Personen betroffen sind.
- Bitte verwenden Sie zum Ausfüllen einen dunklen Kugelschreiber oder Filzstift
- Bitte setzen Sie die Kreuze so exakt wie möglich in die Kästchen: Richtig ☒ Falsch ☒

1 Fragen zu Ihrer Person

Jahrgang: ☐☐☐☐ Geschlecht: ○ männlich ○ weiblich

Rauchen Sie zur Zeit? ☐ ja
☐ nein

---

2 Beratung und Untersuchungen beim Arzt/bei der Ärztin

2.1 Haben Sie seit unserer ersten schriftlichen Befragung im August 2002 einen Arzt aufgesucht?

☐ **nein** (⇨ weiter mit Frage 3.1!)

☐ ja, um mein Diabetesrisiko beim Arzt abklären zu lassen
- ○ aufgrund der Aktion "Stopp Zucker - Jetzt testen"
- ○ aufgrund der telefonischen Beratung, die ich im Herbst 2002 erhalten habe
- ○ anderes

☐ ja, aber nicht wegen meines Diabetesrisikos

In welchem Monat fand dieser Arztbesuch statt?
- ☐ August 2002
- ☐ September 2002
- ☐ Oktober 2002
- ☐ November 2002
- ☐ Dezember 2002
- ☐ Januar 2003
- ☐ Februar 2003

☐ Ich war vor August 2002 beim Arzt (⇨ weiter mit Frage 3.1!)

2.2 Welche der folgenden Untersuchungen wurden in der Arztpraxis durchgeführt?
(Mehrere Antworten sind möglich)

- ☐ Messung des Blutzuckers
- ☐ Messung Cholesterin/Blutfette
- ☐ Messung des Blutdruckes
- ☐ keine dieser Untersuchungen wurden durchgeführt
- ☐ weiss nicht

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2.3 Welche Ratschläge hat Ihnen der Arzt erteilt?

(Mehrere Antworten sind möglich)

☐ Ratschläge zur Umstellung der Ernährung
☐ Ratschläge zu mehr Bewegung
☐ Ratschläge zur Gewichtskontrolle/Gewichtsreduktion
☐ Beginn einer medikamentösen Therapie
☐ der Arzt hat mir keine Ratschläge betreffend meines Diabetesrisikos erteilt
☐ weiss nicht

2.4 Wurde bei Ihnen seit unserer ersten schriftlichen Befragung im August 2002 durch einen Arzt ein Diabetes Typ 2 festgestellt?

☐ ja
☐ nein
☐ weiss nicht

Wenn ja, wann? Monat ☐☐ Jahr 2 0 0 ☐

3 Körpergewicht und Ernährung

3.1 Wieviel beträgt Ihr Körpergewicht zur Zeit?

Gewicht: ☐☐☐ kg

3.2 Welches Ziel haben Sie bezüglich Ihres Körpergewichts?

☐ ich möchte zunehmen
☐ ich möchte mein Gewicht halten
☐ ich möchte abnehmen
☐ ich verfolge keine Ziele bezüglich meines Körpergewichts

3.3 Welches Körpergewicht möchten Sie erreichen?

Gewicht: ☐☐☐ kg

3.4 Wieviele Portionen Früchte oder Gemüse assen Sie in den letzen beiden Monaten durchschnittlich pro Tag?

○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ mehr als 5

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4 Bewegung

☞ *Bitte beachten Sie: Bei Frage 4.1 und Frage 4.2 fragen wir nach zwei verschiedenen Arten von Bewegung!*

4.1 Hier geht es um körperliche Aktivität, bei der Sie mindestens einen leicht beschleunigten Atem bekommen (zum Beispiel zügiges Gehen, Wandern, Tanzen, leichtere Gartenarbeiten):

a) An wie vielen Tagen pro Woche waren Sie in den letzten beiden Monaten durchschnittlich in dieser Art körperlich aktiv?

○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ 6 ○ 7

b) Wie lange waren Sie durchschnittlich an jedem dieser Tage in dieser Art aktiv?

☐ weniger als 10 Minuten pro Tag
☐ 10 Minuten pro Tag
☐ 20 Minuten pro Tag
☐ eine halbe Stunde pro Tag
☐ mehr als eine halbe Stunde pro Tag

c) Seit wann sind Sie schon auf diese Weise aktiv?

☐ weniger als 1 Monat
☐ weniger als 6 Monate
☐ 6 - 12 Monate
☐ länger als 1 Jahr
☐ länger als 5 Jahre

d) Haben Sie vor, diese körperliche Aktivität zu steigern?

☐ ja...
  ○ im nächsten Monat
  ○ in den nächsten 2-6 Monaten
☐ nein

4.2 Hier geht es um sportliche oder körperliche Aktivitäten, bei denen Sie ziemlich ins Schwitzen kommen (z. B. Joggen, Aerobics, Tennis, schnelles Radfahren, Spielsportarten, Schwimmen, Lasten tragen, Graben, Schaufeln):

a) An wie vielen Tagen pro Woche haben Sie in den letzten beiden Monaten Aktivitäten dieser Art gemacht?

○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ 6 ○ 7

b) Wie lange waren Sie durchschnittlich an jedem dieser Tage in dieser Art aktiv?

☐ weniger als 10 Minuten pro Tag
☐ 10 Minuten pro Tag
☐ 20 Minuten pro Tag
☐ eine halbe Stunde pro Tag
☐ mehr als eine halbe Stunde pro Tag

c) Haben Sie vor, diese körperliche Aktivität zu steigern?

☐ ja...
  ○ im nächsten Monat
  ○ in den nächsten 2-6 Monaten
☐ nein

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5 Änderungen des Lebensstils

5.1 Haben Sie seit unserer ersten schriftlichen Befragung im August 2002 Ihren Lebensstil geändert?

(Mehrere Antworten sind möglich)

☐ ja...

- ○ ich nehme neu an einem Bewegungskurs teil
- ○ ich trainiere neu in einem Fitnesscenter
- ○ ich bewege mich mehr im Alltag (z.B. zu Fuss gehen, Velo benutzen)
- ○ ich mache mehr Sport
- ○ ich habe mich für eine Ernährungsberatung angemeldet
- ○ ich habe meine Ernährung umgestellt:
  - ○ ich achte beim Kauf und bei der Wahl von Lebensmitteln auf ihren Fettgehalt
  - ○ ich habe meinen Fettkonsum reduziert
  - ○ ich esse generell mehr Früchte und Gemüse
  - ○ ich esse häufiger 5 Portionen Früchte oder Gemüse pro Tag
  - ○ ich esse generell weniger

☐ nein...

- ○ aber ich habe vor, meinen Lebensstil ändern:
  - ○ im nächsten Monat
  - ○ in den nächsten 2-6 Monaten
- ○ ich will meinen Lebensstil beibehalten
- ○ ich bin zu wenig motiviert, meinen Lebensstil zu ändern
- ○ ich habe meinen Lebensstil aus anderen Gründen nicht geändert

5.2 Hatten Sie mit der Änderung Ihrer Gewohnheiten Erfolg?

(Nur beantworten, falls Sie Frage 5.1 mit "ja" beantwortet haben)

(Mehrere Antworten sind möglich)

☐ ja...

- ○ ich konnte mein Gewicht halten oder in die gewünschte Richtung beeinflussen
- ○ ich fühle mich in besserer körperlicher Verfassung

☐ nein...

- ○ ich nehme bis jetzt keine Fortschritte wahr
- ○ ich habe es wieder aufgegeben, meine Gewohnheiten zu ändern

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5.3 Wie finden Sie die Idee, bei einer Änderung des Lebensstils (Bewegung und Ernährung) durch eine Fachperson per Telefon unterstützt zu werden?

○ sehr gut ○ gut ○ wenig sinnvoll ○ gar nicht sinnvoll ○ weiss nicht

5.4 Würden Sie persönlich die Gelegenheit nutzen, kostenlos durch eine Fachperson per Telefon bei einer Verhaltensänderung unterstützt zu werden?

○ ja, auf jeden Fall ○ ja, eventuell ○ eher nicht ○ nein, sicher nicht ○ weiss nicht

6 Fragen zur erfolgten telefonischen Beratung

☞ *Folgende Fragen bitte nur beantworten, falls Sie zwischen September 2002 und Januar 2003 die telefonische Beratung durch eine Gesundheitsberaterin von action d erhalten haben!*

6.1 Wie beurteilen Sie die Qualität der telefonischen Beratung, die Sie durch die Gesundheitsberaterin von action d erhalten haben?

	sehr gut	gut	akzeptabel	schlecht	weiss nicht
Fachwissen der Gesundheitsberaterin	○	○	○	○	○
Freundlichkeit der Gesundheitsberaterin	○	○	○	○	○
Hilfsbereitschaft der Gesundheitsberaterin	○	○	○	○	○
Einfühlungsvermögen der Gesundheitsberaterin	○	○	○	○	○
Tipps/Empfehlungen der Gesundheitsberaterin	○	○	○	○	○

6.2 Wie beurteilen Sie die durchschnittliche Dauer der Telefongespräche, die Sie von der Gesundheitsberaterin erhalten haben?

Die Dauer war meiner Meinung nach:

☐ zu kurz
☐ gerade richtig
☐ zu lang
☐ weiss nicht

6.3 Wie beurteilen Sie die Anzahl der Telefongespräche, die Sie von der Gesundheitsberaterin erhalten haben?

Die Anzahl der Anrufe (in der Regel 3 Anrufe) war meiner Meinung nach:

☐ zu wenig
☐ gerade richtig
☐ zu viel
☐ weiss nicht

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6.4 Wie beurteilen Sie den zeitlichen Abstand zwischen den Telefongesprächen, die Sie von der Gesundheitsbeaterin erhalten haben?

Der zeitliche Abstand zwischen den Anrufen (in der Regel 3 Wochen) war meiner Meinung nach:

☐ zu kurz
☐ gerade richtig
☐ zu lang
☐ weiss nicht

6.5 Konnte die telefonische Unterstützung durch die Gesundheitsberaterin Sie zu einer Änderung Ihres Lebensstils anregen?

○ ja, sehr ○ ja ○ wenig ○ nein, gar nicht ○ weiss nicht

6.6 Haben Sie dank der telefonischen Unterstützung durch die Gesundheitsberaterin Ihren Lebensstil tatsächlich verändert?

○ ja, sehr ○ ja ○ teilweise ○ nein, gar nicht ○ weiss nicht

6.7 Würden Sie bei einer solchen Telefonberatung wieder mitmachen?

☐ ja
☐ eventuell
☐ nein
☐ weiss nicht

6.8 Was waren für Sie <u>positive</u> Aspekte der telefonischen Unterstützung?

a) _____
b) _____
c) _____

6.9 Was waren für Sie <u>negative</u> Aspekte der telefonischen Unterstützung?

a) _____
b) _____
c) _____

7 Weitere Kommentare und Bemerkungen

_____
_____

Herzlichen Dank für das Ausfüllen dieses Fragebogens!

7.14 Third questionnaire of follow-up

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3. Nachbefragung im Anschluss an die Aktion "Stopp Zucker - Jetzt testen"

Herzlichen Dank, dass Sie an unseren ersten beiden Nachbefragungen im August 2002 bzw. im Februar 2003 teilgenommen haben. Ihre Mitarbeit ist für uns sehr wertvoll!

Vorab einige Hinweise zum Ausfüllen dieses Fragebogens:

- "Diabetes Typ 2" ist der Fachausdruck für Zuckerkrankheit. Man spricht auch von "Alterszucker" oder "Altersdiabetes", obwohl heute immer öfter auch junge Personen betroffen sind.
- Bitte verwenden Sie zum Ausfüllen einen dunklen Kugelschreiber oder Filzstift
- Bitte setzen Sie die Kreuze so exakt wie möglich in die Kästchen: Richtig ☒ Falsch ☒

1 Fragen zu Ihrer Person

Jahrgang: ☐☐☐☐ Geschlecht: ○ männlich ○ weiblich

Rauchen Sie zur Zeit? ☐ ja
☐ nein

---

2 Beratungen in einer Apotheke

Haben Sie seit der Aktion "Stopp Zucker - Jetzt testen" im Mai 2002 eine der folgenden Dienstleistungen in einer Apotheke beansprucht?

(Mehrere Antworten sind möglich)

☐ ja, ich habe folgende Dienstleistung(en) beansprucht:

- ○ Beratung zur Umstellung der Ernährung
- ○ Beratung zu mehr Bewegung
- ○ Beratung zur Gewichtskontrolle/Gewichtsreduktion
- ○ Beratung zu Rauchstopp
- ○ Messung des Blutzuckers
- ○ Messung Cholesterin/Blutfette
- ○ Messung des Blutdruckes

☐ nein, ich habe keine der oben aufgeführten Dienstleistungen beansprucht

☐ weiss nicht

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3 Beratung und Untersuchungen beim Arzt/bei der Ärztin

3.1 Haben Sie seit unserer zweiten schriftlichen Befragung im Februar 2003 einen Arzt aufgesucht?

☐ **nein** (⇨ weiter mit Frage 3.4!)

☐ ja, um mein Diabetesrisiko beim Arzt abklären zu lassen

- ○ aufgrund der Aktion "Stopp Zucker - Jetzt testen"
- ○ aufgrund der telefonischen Beratung, die ich im Herbst 2002 erhalten habe
- ○ anderes

☐ ja, aber nicht wegen meines Diabetesrisikos

In welchem Monat fand dieser Arztbesuch statt?

☐ Februar 2003	☐ Juni 2003
☐ März 2003	☐ Juli 2003
☐ April 2003	☐ August 2003
☐ Mai 2003	

☐ Ich war vor Februar 2003 beim Arzt (⇨ weiter mit Frage 3.4!)

3.2 Welche der folgenden Untersuchungen wurden in der Arztpraxis durchgeführt?

(Mehrere Antworten sind möglich)

☐ Messung des Blutzuckers
☐ Messung Cholesterin/Blutfette
☐ Messung des Blutdruckes
☐ keine dieser Untersuchungen wurden durchgeführt
☐ weiss nicht

3.3 Welche Ratschläge hat Ihnen der Arzt erteilt?

(Mehrere Antworten sind möglich)

☐ Ratschläge zur Umstellung der Ernährung
☐ Ratschläge zu mehr Bewegung
☐ Ratschläge zur Gewichtskontrolle/Gewichtsreduktion
☐ Beginn einer medikamentösen Therapie
☐ der Arzt hat mir keine Ratschläge betreffend meines Diabetesrisikos erteilt
☐ weiss nicht

3.4 Wurde bei Ihnen jemals ein Diabetes Typ 2 festgestellt?

☐ ja
☐ nein
☐ weiss nicht

Wenn **ja**, wann? Monat ☐☐ Jahr ☐☐☐☐

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4 Diabetes Typ 2 - Risikofaktoren

Was, denken Sie, kann eine Person tun, um ihr Risiko für Diabetes Typ 2 zu senken?

(Mehrere Antworten sind möglich)

☐ nichts: das Risiko, an Diabetes Typ 2 zu erkranken, ist nicht beeinflussbar
☐ regelmässige Einnahme von Aspirin
☐ gesunde Ernährung
☐ genügend Schlaf
☐ genügend Bewegung
☐ Übergewicht vermeiden

5 Körpergewicht und Ernährung

5.1 Wieviel beträgt Ihr Körpergewicht zur Zeit?

Gewicht: ☐☐☐ kg

5.2 Welches Ziel haben Sie bezüglich Ihres Körpergewichts?

☐ ich möchte zunehmen
☐ ich möchte mein Gewicht halten
☐ ich möchte abnehmen
☐ ich verfolge keine Ziele bezüglich meines Körpergewichts

5.3 Welches Körpergewicht möchten Sie erreichen?

Gewicht: ☐☐☐ kg

5.4 Auf was sollte eine Person bei der Ernährung achten, damit ihre Gesundheit positiv beeinflusst wird?

(Mehrere Antworten sind möglich)

☐ weniger Süssigkeiten konsumieren
☐ nur eine Mahlzeit pro Tag einnehmen
☐ viel Früchte und/oder Gemüse konsumieren
☐ Bier als Durstlöscher konsumieren
☐ mehr Fleisch konsumieren
☐ weniger Fett konsumieren

5.5 Wieviele Portionen Früchte oder Gemüse assen Sie in den letzen beiden Monaten durchschnittlich pro Tag?

○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ mehr als 5


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6 Bewegung

6.1 Wie oft und wie lange, denken Sie, sollte sich eine Person im Minimum bewegen, um gesund zu bleiben? (Nur eine Antwort ist möglich)

☐ täglich zehn Minuten
☐ täglich eine halbe Stunde
☐ täglich dreimal eine halbe Stunde
☐ zweimal pro Woche eine halbe Stunde

☞ *Bitte beachten Sie: Bei Frage 6.2 und Frage 6.3 fragen wir nach zwei verschiedenen Arten von Bewegung!*

6.2 Hier geht es um körperliche Aktivität, bei der Sie mindestens einen <u>leicht beschleunigten Atem</u> bekommen (zum Beispiel zügiges Gehen, Wandern, Tanzen, leichtere Gartenarbeiten):

a) An wie vielen Tagen pro Woche waren Sie in den letzten beiden Monaten durchschnittlich in dieser Art körperlich aktiv?

○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ 6 ○ 7

b) Wie lange waren Sie durchschnittlich an jedem dieser Tage in dieser Art aktiv?

☐ weniger als 10 Minuten pro Tag
☐ 10 Minuten pro Tag
☐ 20 Minuten pro Tag
☐ eine halbe Stunde pro Tag
☐ mehr als eine halbe Stunde pro Tag

c) Seit wann sind Sie schon auf diese Weise aktiv?

☐ weniger als 1 Monat
☐ weniger als 6 Monate
☐ 6 - 12 Monate
☐ länger als 1 Jahr
☐ länger als 5 Jahre

d) Haben Sie vor, diese körperliche Aktivität zu steigern?

☐ ja...
  ○ im nächsten Monat
  ○ in den nächsten 2-6 Monaten
☐ nein

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6.3 Hier geht es um sportliche oder körperliche Aktivitäten, bei denen Sie ziemlich ins Schwitzen kommen (z. B. Joggen, Aerobics, Tennis, schnelles Radfahren, Spielsportarten, Schwimmen, Lasten tragen, Graben, Schaufeln):

a) An wie vielen Tagen pro Woche haben Sie in den letzten beiden Monaten Aktivitäten dieser Art gemacht?

○ 0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ 6 ○ 7

b) Wie lange waren Sie durchschnittlich an jedem dieser Tage in dieser Art aktiv?

☐ weniger als 10 Minuten pro Tag
☐ 10 Minuten pro Tag
☐ 20 Minuten pro Tag
☐ eine halbe Stunde pro Tag
☐ mehr als eine halbe Stunde pro Tag

c) Haben Sie vor, diese körperliche Aktivität zu steigern?

☐ ja...
  ○ im nächsten Monat
  ○ in den nächsten 2-6 Monaten
☐ nein

7 Änderungen des Lebensstils

7.1 Haben Sie seit Februar 2003 Ihren Lebensstil geändert?

(Mehrere Antworten sind möglich)

☐ ja...

- ○ ich nehme neu an einem Bewegungskurs teil
- ○ ich trainiere neu in einem Fitnesscenter
- ○ ich bewege mich mehr im Alltag (z.B. zu Fuss gehen, Velo benutzen)
- ○ ich mache mehr Sport
- ○ ich habe mich für eine Ernährungsberatung angemeldet
- ○ ich achte beim Kauf und bei der Wahl von Lebensmitteln auf ihren Fettgehalt
- ○ ich habe meinen Fettkonsum reduziert
- ○ ich esse mehr Früchte und Gemüse
- ○ ich esse generell weniger

☐ nein...

- ○ aber ich habe vor, meinen Lebensstil zu ändern:
  - ○ im nächsten Monat
  - ○ in den nächsten 2-6 Monaten
- ○ ich will meinen Lebensstil beibehalten
- ○ ich bin zu wenig motiviert, meinen Lebensstil zu ändern
- ○ ich habe aus anderen Gründen meinen Lebensstil nicht geändert

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7.2 Hatten Sie mit der Änderung Ihrer Gewohnheiten Erfolg?
(Nur beantworten, falls Sie Frage 7.1 mit "ja" beantwortet haben)

(Mehrere Antworten sind möglich)

☐ ja...
- ○ ich konnte mein Gewicht halten oder in die gewünschte Richtung beeinflussen
- ○ ich fühle mich in besser körperlichen Verfassung

☐ nein...
- ○ ich nehme bis jetzt keine Fortschritte wahr
- ○ ich habe es wieder aufgegeben, meine Gewohnheiten ändern zu wollen

7.3 Was ist oder wäre für Sie hilfreich, um Ihren Lebensstil zu ändern?

(☹☹ gar nicht hilfreich, ☹ mässig hilfreich, ☺ ziemlich hilfreich, ☺☺ sehr hilfreich)

	☹☹	☹	☺	☺☺
Zusammen mit Gleichgesinnten etwas für meine Gesundheit unternehmen	○	○	○	○
Unterstützung durch eine telefonische Beratung	○	○	○	○
Unterstützung durch Personen, die mir nahe stehen	○	○	○	○
Bewegungsangebote am Arbeitsplatz	○	○	○	○
Gesundes Ernährungsangebot am Arbeitsplatz	○	○	○	○
Mehr Freizeit	○	○	○	○
Anderes: ___ ___ ___ ___ ___ ___ ___ ___ ___ ___ ___ ___ ___ ___ ___	○	○	○	○

7.4 Sind Sie daran interessiert, von action d in Zukunft aktuelle schriftliche Informationen über Diabetes Typ 2 zu erhalten?

☐ ja
☐ nein

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8 Neue Medikamente

Wurden Ihnen seit der Aktion "Stopp Zucker - Jetzt testen" im Mai 2002 Medikamente verordnet, die Sie zur Zeit regelmässig einnehmen müssen?

☐ ja
☐ nein
☐ weiss nicht

Wenn ja, welche? (Bitte notieren Sie hier alle regelmässig einzunehmenden Medikamente, die Ihnen seit Mai 2002 **neu** verordnet wurden.)

1) __ __ __ __ __ __ __ __ __ __ __
2) __ __ __ __ __ __ __ __ __ __ __
3) __ __ __ __ __ __ __ __ __ __ __
4) __ __ __ __ __ __ __ __ __ __ __
5) __ __ __ __ __ __ __ __ __ __ __
6) __ __ __ __ __ __ __ __ __ __ __

9 Weitere Kommentare und Bemerkungen

Herzlichen Dank für das Ausfüllen dieses Fragebogens!

Curriculum vitae

Personal data

Name	Andrea Monika Botomino
Date of Birth	Mai 21st 1975
Place of Origin	Bottmingen (BL)

Education and Professional Life

1982 - 1991	Basic education at Therwil, Bottmingen and Binningen
1991 – 1994	High school at Gymnasium Oberwil
December 1994	Matura, main subject science (maturity type C)
1995 – 2000	Studies in pharmacy at the University of Basel
1997 – 1998	Practical year at the pharmacy “Weiherschloss-Apotheke”, Bottmingen
	Diploma thesis „Influence of Apigenin, Biapigenin and Amentoflavon on P-glycoprotein” under the supervision of Prof. Dr. J. Drewe at the University Hospital, Basel
November 2000	Swiss federal diploma in pharmacy
März 2001 – September 2001	Employed as deputy pharmacist at the pharmacy “Weiherschloss-Apotheke”, Bottmingen
Oktober 2001 – February 2005	PhD thesis at the Institute of Clinical Pharmacy, University of Basel under the supervision of Dr. Kurt E. Hersberger and Prof. Dr. S. Krähenbühl. Thesis topic: Diabetes screening and health promotion – evaluation of a pharmacy based campaign and of related activities
	Assistant in university courses of Clinical Pharmacy.
	Author in the framework of i.m@il-Offizin, a drug information service for community pharmacies.

Additional Course

2002	ESCP Congress in Florence, Italy
	"Clinical significance of drug supporting proteins" Symposium, University of Basel
	"Drug safety in hospital: pharmacogenetic / pharmacogenomic", University Hospital Basel
2003	"Pharmacoepidemiology and Drug Safety" Symposium, University of Basel
2004	ESCP Congress in Paris, France
	SGIM Congress in Lausanne, Switzerland
2004 – 2005	Women into Industry (WIN), Mentoring Program at Novartis, Basel

Scientific Publications

Gutmann H, Bruggisser R, Schaffner W, Bogman K, Botomino A, Drewe J. Transport of amentoflavone across the blood-brain barrier in vitro. Planta Med 2002; 68: 804-7.

Botomino A, Martina B, Ruf D, Bruppacher R, Hersberger KE. White coat hypertension and white coat effect in community pharmacy practice. Blood Press Monit 2005; 10: 13-8.

Hersberger KE, Botomino A, Mancini M, Bruppacher R. Sequential screening for diabetes risk in Swiss community pharmacies – evaluation of a national campaign. Pharm World Sci, submitted.

Botomino A, Bruppacher R, Krähenbühl S, Hersberger KE. Change of body weight and lifestyle after counselling of persons at risk for type 2 diabetes: follow-up study of a screening campaign in Swiss community pharmacies. Pharm World Sci, submitted.

Botomino A, Bruppacher R, Guggenbühl B, Reinli K, Hersberger KE. Effect of a telephone-based counselling intervention on body weight and lifestyle of persons at risk for type 2 diabetes. Swiss Med Wkly, submitted.

Poster Presentations

Hersberger KE, Botomino A, Petitjean-Wiesner C, Bruppacher R. Evaluation of cutpoints for the screening for metabolic syndrome in community pharmacies. 31th Annual Symposium, European Society of Clinical Pharmacy, Florence, Italy, October 2002, abstract 192.

Botomino A, Bruppacher R, Krähenbühl S, Mancini M, Ruiz J, Hersberger KE. Evaluation of a national diabetes screening campaign in community pharmacies. 2nd ACCP-ESCP International Congress on Clinical Pharmacy, Paris, France, April 2004, abstract in Pharm World Sci 2004; 26: A6.

Botomino A, Bruppacher R, Keller U, Krähenbühl S, Mancini M, Ruiz J, Hersberger KE. Diabetes Screening and Health Promotion in Community Pharmacies - a first evaluation of the national screening campaign 'Stopp Zucker – Jetzt testen!' (Stop sugar-test now!). 72nd annual assembly of the Swiss Society of Internal Medicine, Lausanne, Switzerland, May 2004, abstract in Schweiz Med Forum 2004; 4 (Suppl 17): S72.

Oral Presentations

Botomino A, Bruppacher R, Krähenbühl S, Mancini M, Ruiz J, Hersberger KE. Evaluation of a national diabetes screening campaign in community pharmacies. 2nd ACCP-ESCP International Congress on Clinical Pharmacy, Paris, France, April 2004, abstract in Pharm World Sci 2004; 26: A6.

Botomino A, Martina B, Ruf D, Bruppacher R, Hersberger KE. White coat hypertension and white coat effect in community pharmacy practice. Oral Presentation, 72nd annual assembly of the Swiss Society of Internal Medicine, Lausanne, Switzerland, May 2004, abstract in Schweiz Med Forum 2004; 4 (Suppl 17): S15

Lectures

During my studies I followed courses of the following lecturers:

Barass JP, Bartels HC, Berger KA, Bienz R, Bruppacher R, Drewe J, Durrer H, Erb P, Ernst B, Folkers G, Guentert T, Hädener A, Haefeli W, Haegeli A, Hersberger KE, Hunziker W, Iberg N, Kraehenbuehl S, Kress A, Leuenberger H, Marbet G, Meier B, Meyer UA, Moroni Ch, Oelhafen P, Schaffner W, Scholer A, Sequin U, Sigel H, Spornitz UM, Weiss P, Zuberbühler A