Lifestyle intervention in general practice for physical activity, smoking, alcohol consumption and diet in elderly: A randomized controlled trial

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ABSTRACT

The purpose of the study was to compare the effectiveness of programmed and intensified intervention on lifestyle changes, including physical activity, cigarette smoking, alcohol consumption and diet, in patients aged $\geq$65 with the usual care of general practitioners (GP). In this multicenter randomized controlled trial, 738 patients aged $\geq$65 were randomly assigned to receive intensified intervention ($N = 371$) or usual care ($N = 367$) of a GP for lifestyle changes, with 18-month follow-up. The main outcome measures were physical activity, smoking, alcohol consumption and diet. The study was conducted in 59 general practices in Croatia between May 2008 and May 2010. The patients' mean age was 72.3 ± 5.2 years. Significant diet correction was achieved after 18-month follow-up in the intervention group, comparing to controls. More patients followed strictly Mediterranean diet and consumed healthy foods more frequently. There was no significant difference between the groups in physical activity, tobacco smoking and alcohol consumption or diet after the intervention. In conclusion, an 18-month intensified GP's intervention had limited effect on lifestyle habits. GP intervention managed to change dietary habits in elderly population, which is encouraging since elderly population is very resistant regarding lifestyle habit changes.

Clinical trial registration number. ISRCTN31857696.

1. Introduction

Physical inactivity and sedentary lifestyle are the hallmarks of modern human behavior in the developed world, and are now becoming increasingly common in developing countries. It is assumed that 60% of world's population is not physically active enough (Erlichman, Kerbey, & James, 2002; Hu et al., 2005; Katzmarzyk, Janssen, & Ardern, 2003). A well-known Framingham Study has shown the importance of physical activity in lowering of cardiovascular (CV) risk (Boutry & Nivikoff, 1975). The INTERHEART study (Yusuf et al., 2004), conducted in 52 countries, showed a positive correlation between physical inactivity and early myocardial infarction. Urbanization, public transport, as well as using technology at work and at home (TV, computer, Internet) promotes sedentary lifestyle. Negative effects of inactivity are overweight and obesity, insulin resistance, dyslipidemia, hypertension, and increased morbidity of CV disease and diabetes (Blair & Morris, 2009; James, 2008).

In contrast, regular physical activity has a preventive effect against the incidence of CV disease and reduces the risk of heart attack, stroke, and cardiac death, while improving the quality of life. In elderly people aged $\geq$65 years, physical activity can help to preserve good functional and cognitive abilities, and prolong life. According to the guidelines of the World Health Organization (WHO) from 2010, 150 min a week of moderate physical activity is recommended for the elderly, with preliminary assessment of each individual patient, including fitness, comorbidities and state of CV system (WHO, 2010). In 2012, WHO proposed five priority interventions for healthy aging, and has positioned promotion of physical activity on the second place (WHO, 2012).

Smoking is one of the most important risk factors for atherosclerosis, CV disease and many cancers. Smokers live on

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average ten years less than their non-smoking peers do. Quitting smoking reduces the risk for stroke after two years, and after five, it equals the risk of the nonsmoking peers. Quitting smoking at 60, 50 or 40 years of age, gets an average of 6, 9, or 10 extra years of life (Doll, Peto, Boreham, & Sutherland, 2004). Moderate alcohol consumption (equivalent of 20 g ethanol for men of any age and postmenopausal women), carries a lower risk for CV disease and stroke in comparison with the excessive consumption or total "soberness". People that drink alcohol excessively have a significantly higher CV risk, blood pressure and mortality (Tomson & Lip, 2006).

Modern diet is rich in calories, saturated fat and refined carbohydrates. Many studies, including PREDIMED and EUROL-IVE have shown that the diet pattern of inhabitants of Southern Europe (so-called Mediterranean diet), based on olive oil, nuts, fish and white meat (poultry), fresh fruits and vegetables, brown bread and complex carbohydrates has a protective effect on the CV system (Trichopoulou, Costacou, Bamia, & Trichopoulos, 2003).

In Croatia, CV disease is the leading cause of mortality, accounting for almost 50% of all deaths. Regarding the age-standardized ischemic heart disease and stroke mortality rates, Croatia is positioned high on the ninth and sixth place in Europe, respectively (Muller-Nordhorn, Binting, Roll, & Willich, 2008). According to the First Croatian Health Project (Turek et al., 2001) and the Croatian Health Survey (CHS) data, unfavorable health behavior is frequent in population in Croatia: many adults smoke (34% of men and 27% of women), consume alcohol excessively and are not physically active enough (30% men, 44% of women) (Kern, Strnad, Coric, & Vuletic, 2005). According to the WHO data from 2005, the proportion of smoking as a risk factor for total mortality in population of Croatia amounted to 21.3%, alcohol 4.1%, and physical inactivity 6.9% (WHO, 2005). High prevalence of CVD risk factors in Croatia (Bergman Markovic et al., 2011; Vrdoljak et al., 2012) and suboptimal CVD care in Croatian health system (Novak et al., 2010) leave plenty of room for preventive actions.

Longitudinal studies of elderly European populations have shown that the health behavior pattern that includes a healthy diet, non-smoking and moderate physical activity was associated with lower risk of morbidity and overall mortality (Haveman-Nies et al., 2002; Knoops et al., 2004). Changing ingrained human habits is not easy and it presents a challenge in daily work of a general practitioner. However; patients themselves often want to change their lifestyle, but do not know how, and many of them want to get advice precisely from the GP (Klemenc-Ketis, Bulc, & Kersnik, 2011). Due to the frequent contacts with the population in care, a general practitioner is in the ideal position to promote healthy lifestyles as well to provide systematic intervention to change the unhealthy ones. GPs should "prescribe" lifestyle change in the same way they prescribe medication for chronic disease.

It is important to "tailor" the recommended plan of lifestyle changes to an individual patient depending on a patient's background, values and preferences, to empower and include patient in decision making and to encourage long-term monitoring and maintenance of achieved beneficial effects of the changes introduced. A recent project EUROACTION (Wood et al., 2008) showed that a nurse-coordinated multidisciplinary, family-based preventive CV program could successfully change the health behavior of patients in both primary and secondary CV prevention.

The aim of this study was to determine to what extent the intensive intervention directed toward elderly in GPs care could change their lifestyle habits (smoking, alcohol drinking, physical activity) after a period of eighteen months.

2. Methods

2.1. Sample and participants

The participants aged ≥ 65 years were taken from the sample of patients from Cardiovascular Risk Intervention Study in Croatia-family medicine (ISRCTN 31857696), which included participants of both sexes aged ≥ 40 years. The target population for this part of the study included citizens of Croatia aged ≥ 65 years who visited their GP for any reason, in the period from May to August 2008. Participants with communication disability (dysphasia, aphasia), severe dementia or severe mental illness and those with estimated life expectancy of less than six months were excluded from the target population.

The sample was two-stage, disproportionate and mixed-gender. In the first phase, the 4-stage disproportionate stratified random sampling of general practices was created. The sample of general practices was stratified based on 21 Croatian counties and 2 regions (coastal, continental). Coastal region included practices on islands and in villages and towns up to 30 km away from the sea (if there is no natural obstacle between them, such as a hill or a mountain). Further stratification was performed into five strata according to the settlement size (up to 3999 inhabitants, 4000 to 9999, 10,000 to 29,999, 30,000 to 89,999 and 90 000 inhabitants and more, settlements with <4000 inhabitants were defined as village, while those with ≥4000 were defined as a town). Finally, the sample was stratified into three strata based on the number of insured people in a GP's care having a contract with the Croatian Institute for Health insurance (CIHI) in 2007 (≤1399, 1400–1799, ≥1800). Within each stratum, GP offices were randomized and selected by the random number generator, from the list of all contracted CIHI general practices in 2007. The randomization was done by Biometrika Healthcare Research company (central randomization) using random number generator. For each initially contacted physician, a reserve sample of four more GPs was made, according to the fourfold stratum. If a GP declined to participate, a most closely located GP from a reserve sample was invited. All GPs were verbally informed in detail about the study and then signed a consent form to participate in the research. The sample size needed to reach 95% confidence interval and the desired power of statistical tests. Of the 82 GPs invited to participate in this study, 64 of them accepted (78%), of which five declined participation at first follow up, so the total number of GPs in the final sample was 59.

In the second stage, each GP chose a systematic, disproportionate sample of the first 55 patients who visited the practice for any reason from the day the study began, and who met the inclusion criteria and confirmed their consent by signing a written informed consent. All the participating GPs included the same number of patients ($N = 55$), regardless of the total number of insured persons they have contracted with CIHI, and the total number of patients from the target population they examined. This was corrected by post hoc weight factors prior to statistical analysis.

Of 992 patients aged ≥65 years that were assessed for eligibility and invited to participate in the study, 738 patients completed the study at 18-month follow-up, as indicated in the flow chart in Fig. 1.

2.2. Questionnaire

The data were collected with a standardized questionnaire, designed for the purpose of this study, validated through a pilot study on a sample of ten GP offices and 100 participants. During an interview with participants, GPs collected information on socio-demographic, socioeconomic, personal and family history and data on life habits. Adherence to the traditional Mediterranean diet was