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A Collaborative Care Model of Health Risk Assessment and Counselling in Older Persons: A Randomised Clinical Trial

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Abstract

Background: Potentially avoidable risk factors continue to cause unnecessary disability and premature death in older people. Health risk assessment, a method successfully used in working-age populations, is a promising method for cost effective health promotion and prevention in older persons, but long-term effects of this approach are unknown. The objective was to evaluate the effects of an innovative approach of health risk assessment and counselling in older persons on health behaviours, preventive care, and long-term survival.

Methods and Findings: Pragmatic, single-centre randomised controlled clinical trial, in community-dwelling persons aged 65 years or older registered with one of 19 primary care physician practices in a mixed rural and urban area in Switzerland. From November 2000 to January 2002, 874 participants were randomly allocated to the intervention and 1410 to usual care. The intervention consisted of health risk assessment based on self-administered questionnaires and individualised computer-generated feed-back reports, combined with nurse and primary care physician counselling over a 2-year period. Primary outcomes were health behaviours and preventive care use at 2 years, and all-cause mortality at 8 years.

At baseline, participants in the intervention group had a mean (±SD) of 6.9±3.7 risk factors (including unfavourable health behaviours, health and functional impairments, and social risk factors) and 4.3±1.8 deficits in recommended preventive care. At 2 years favourable health behaviours and use of preventive care were more frequent in the intervention than in the control group (based on z-statistics from general estimation equation models). For example, 70% compared to 62% were physically active (odds ratio 1.43, 95% confidence interval [CI] 1.16-1.77, p=0.001), and 66% compared to 59% had influenza vaccinations in the past year (odds ratio 1.35, 95% CI 1.09-1.66, p=0.005). At 8 years, based on an intention-to-treat analysis, the estimated proportion alive was 77.9% in the intervention and 72.8% in the control group, for an absolute mortality difference of 4.9% (95% CI 1.3%-8.5%, p=0.009; based on z-test for risk difference). The hazard ratio of death comparing intervention with control was 0.79 (95% CI

0.66-0.94, *p*=0.009; based on Wald-test from Cox regression model), and the number needed to prevent 1 death was 21 (95% CI 12-79).

The main limitations of the study include: single-site study design, use of a brief self-administered questionnaire for two-year outcome data collection, non-availability of other long-term outcome data (e.g. functional status, nursing home admissions), and availability of long-term follow-up data on mortality for analysis only in 2014.

Conclusions: This is the first trial demonstrating that a collaborative care model of health risk assessment in community-dwelling older people not only results in better health behaviours and increased use of recommended preventive interventions, but also improves survival. The intervention tested in our study may serve as a model of how to implement a relatively low-cost but effective program of prevention and health promotion in older persons.

Trial Registration: International Standard Randomized Controlled Trial Number: ISRCTN 28458424.

Introduction

An increasing number of older persons are affected by multiple risks and morbidities, leading to functional impairment, nursing home admissions, or premature death, with enormous social and economic costs to society [1]. These adverse outcomes might at least in part be avoidable. For example, recent studies demonstrate a continued high prevalence of unhealthy behaviours and preventive care deficits in older persons despite evidence supporting the importance of healthy lifestyles and optimal preventive care in later life [2]. Also, early identification of, and intervention for previously unknown health and functional deficits may contribute to better outcomes in older people [3]. The search for, and the implementation of multimodal programs for cost effective prevention and health promotion has therefore become a top health policy priority worldwide.

It has been shown that multimodal interventions may substantially improve health status and reduce mortality for chronically ill older persons. For example, one randomised controlled trial found that chronically ill older adults who were offered a community-based nurse intervention had a 25% lower risk of death as compared to control group persons with usual care [4]. However, previous studies of multimodal interventions in non-disabled community-living older persons revealed inconsistent findings. A meta-analysis of health check programs for adults in various age groups concluded that these interventions did not have favourable effects on mortality, perhaps since these programs were organized in parallel to, and not aligned with, primary care [5]. On the other hand, some trials found that preventive home visit programs reduce or delay nursing home admissions in older persons [6], but a meta-analysis found no consistent effects on mortality and other outcomes for studies testing these programs [7].

Health risk assessment (HRA) has recently received attention as a method for multidimensional preventive intervention among older persons [8,9]. Originally developed for workforce health promotion, HRA is based on self-reports to guide risk factor interventions with subsequent individualized feed-back to participants on their health status and on how to promote health, maintain function, or prevent disease [10,11]. HRA is a potentially promising approach for

use in older persons, with scientific evidence for favourable effects on intermediate outcomes such as health behaviours and use of preventive care [8,9,12]. However, a 2011 systematic analysis found no controlled study with long-term health outcomes of HRA on mortality or functional status in older persons [9], and to our knowledge, no new study with long-term health outcomes has been published since then.

Multiple earlier randomised controlled studies of HRA in older persons demonstrated that HRA may improve intermediate outcomes, but found that HRA-based interventions are only effective for intermediate outcomes if older persons receive HRA combined with some form of personal reinforcement [8,9]. This was also confirmed by the findings of two recent randomized controlled trials funded by the European Union [13,14]. One trial conducted in London (U.K.) tested the effects of a single health risk assessment, combined with an electronic health record reminder system for use in the primary care practice setting [13]. However it is not known to what extent these reminders were actually used for counselling. At one-year follow-up, this study found no or only minimal intervention effects on health behaviours and preventive care use among older persons, which is consistent with the fact that personal reinforcement was likely minimal [13]. The other trial was conducted in Hamburg (Germany) [14]. It also offered an initial health risk assessment in the primary care setting, and in addition, older persons of the intervention arm participated in a half-day group counselling session, or alternatively received an initial home visit with individual counselling. This trial found mild to moderate intervention effects on health behaviours and use of preventive care among older persons, which is consistent with the fact that this intervention ensured some amount of reinforcement of HRA-based recommendations [14].

Although multiple earlier studies have addressed intermediate outcomes of HRA-based interventions, a 2011 systematic analysis found no controlled study with long-term health outcomes of HRA on mortality or functional status in older persons [9], and to our knowledge, no new study of this type has been published since then. We designed a randomized controlled

study with a system to collect intermediate and long-term follow-up data, using an intention-to-treat approach. The purpose of this study is to confirm whether a HRA-based intervention with a reliable long-term system of reinforcement has favourable effects on health behaviours and preventive care use in community-dwelling older persons, and to evaluate whether this also results in favourable long-term outcomes.

Methods

Ethical Review

The study was approved by the Ethics Committee of the Canton of Solothurn (EKO-0023) and of the Canton of Bern (205/06).

Study Design

The study methods and selected baseline findings of the present trial conducted in Solothurn have been previously published [15,16], and the detailed study protocol and analysis plan are available in the Supplementary Information (S1 Text). The study was conducted at the offices of 19 primary care physicians (PCPs) serving 2 mixed rural and urban primary care catchment areas in the Canton of Solothurn in Switzerland. Recruitment began in November, 2000 and ended in January, 2002. The study received funding from the European Union as part of the PRO-AGE (PRevention in Older people – Assessment in GEneralists' practices) study and regional foundations. The PRO-AGE study consists of three trials of health risk assessment conducted in Solothurn (the present trial), in Hamburg and in London. The two trials conducted in Hamburg and London were designed as short-term trials, and the final results of these trials (including effects on preventive care use and health behaviours at one-year follow-up) have been published (for brief description of these studies, see above in Introduction section this article) [13,14].

Study Participants

The PCPs generated lists of all patients aged 65 years or older they had seen at least once over the past 5 years. Patients with disability (defined as needing human assistance for performing basic activities of daily living) [17], cognitive impairment (equivalent to a Mini Mental Status score of 24 or less) [18], terminal disease, or inability to speak German, were excluded. Remaining patients who gave written informed consent were sequentially listed for enrolment by

the local study centre based in Solothurn, and were randomly allocated to intervention and control groups by the study centre based at the University of Bern using a computer generated allocation sequence. Persons living in the same household were allocated to the same group. Participants allocated to the control group continued to receive usual care by their PCPs.

Interventions

The HRA for older persons (HRA-O) questionnaire was developed based on a systematic literature review [15,19,20] and Expert Panel consensus. Experts selected risk factors for functional status decline based on 4 criteria: potential impact on functional impairment; strength of evidence; potential for risk reduction; and feasibility of assessment. For each risk factor, assessment questions were selected based on reliability, validity, feasibility and previous use in large studies of older persons. The risk factors included unfavourable health behaviours, health and functional impairments, and social risk factors (S1 Table). For health behaviours, questions on participants' intention to change unfavourable behaviours were added [21]. In addition, the expert group also selected 11 preventive recommendations for inclusion in the questionnaire based on the 1996 guidelines of the US Preventive Health Services Task Force [22]. Field tests among community-dwelling older persons in the United States, the United Kingdom, Germany and Switzerland demonstrated the acceptance and feasibility of the HRA-O questionnaire [13,14,15,23]. The U.K. English version was translated and regionally adapted to the German language (for U.K. English and German versions of HRA-O questionnaire, see S3 and S4 Texts). For this trial, an intervention manual prepared for use in U.K. primary care practices was translated, regionally adapted, and modified for use by nurse counsellors and primary care physicians. This manual was used as training material and a reference guide for the PCPs and nurse counsellors involved in the intervention (for U.K. English and German version intervention manual, see S5 and S6 Texts). The role of the health professionals in the intervention is summarised in Table 1.

Table 1. Role of health professionals in the intervention.

Primary care physicians	Sent baseline and one-year follow-up HRA-O questionnaire to participants, and received provider feed-back reports, for use in clinical care.[a]
	Approved/ modified plan with prioritised preventive goals in case discussion with nurse counsellors taking into account participant's priorities.
	Were encouraged to reinforce recommendations related to health behaviour and to implement preventive care measures change during routine office visits, and to refer participants for specialist preventive care.
Nurse counsellors	Received baseline and one-year follow-up HRA-O provider report on participants' problems and risks, and visited participants at home to obtain additional information on problems and risks as needed.
	Prepared a tentative plan for each participant's preventive goals for case discussion with geriatrician and subsequent approval by primary care physician.
	Selected and prioritised preventive goals for each participant based on baseline and yearly case discussions with geriatrician and primary care physician (main criteria: relevance of the risk factor for adverse outcomes, potential for successful risk factor modification, and participant's self-reported readiness to change).
	Made phone calls (three months after baseline, and additionally if needed) and home visits home (at baseline and every six months, and additionally if needed) to discuss the individualised HRA-O participant reports with participants, and motivate participants to adhere with recommendations.
	Supported participants in implementing preventive goals by empowering participants to address risks, reminding them of non-completed recommendations, and facilitating appropriate referrals to health and social care agencies.
	Had weekly training sessions with senior nurse counsellor.
Geriatricians	Trained nurse counsellors with initial and subsequent monthly training sessions, based on intervention manual.[b]
	Offered training to primary care physicians with initial and subsequent three-monthly interactive group sessions, based on intervention manual.[b]
	Were available for specialist advice for primary care physicians.

[a]For HRA-O (Health Risk Appraisal for Older Persons) questionnaire, see S3 and S4 Texts.

[b]For intervention manual, see S5 and S6 Texts.

At baseline and 1-year follow-up PCPs sent a HRA-O questionnaire to patients allocated to the intervention arm. Based on completed HRA-O questionnaires individualized computer-generated participant and provider feedback reports were generated and returned to the PCPs and the older participants. PCPs used the reports to motivate patients to reduce unhealthy behaviours in collaboration with the nurse counsellors, to implement preventive interventions (e.g., influenza vaccination, blood pressure measurement), and to refer patients for specialty-based preventive care (e.g., breast cancer screening, ophthalmology referral). Over the 2-year intervention period nurse counsellors visited participants at home (at baseline and every 6 months, and additionally if needed) and contacted them by phone (at 3 months, and additionally if needed) to evaluate risks and reinforce HRA-O-based recommendations. The nurse counsellors had one initial meeting and then meetings each year over 2 years with the geriatricians to refine recommendations for each participant. The PCPs and nurse counsellors received training and support by project geriatricians.

Study Assessments and Outcomes

Baseline data were obtained from practice registers, a brief pre-randomisation questionnaire including questions to calculate the Pra Score, a previously validated overall risk score identifying older people at high risk for adverse health outcomes [24], and information from the Swiss Population Census 2000 through record linkage with the Swiss National Cohort [25,26]. At one-year follow-up, a long self-administered questionnaire was sent to surviving participants for short-term outcome analysis, but due to a high rate of non-return of these questionnaires, these data could not be used for further analyses (further details in S1 Text). At 2 years, surviving participants were sent a short validated questionnaire to measure 6 health-related behaviours, dependency in basic activities of daily living, and self-perceived health status [27]. Non-responding participants were contacted by trained interviewers blinded to group allocation, and were interviewed face to face if possible. Participants' adherence to the preventive care

recommendations usually performed in the PCP practice were abstracted from PCP records by data extractors blinded to group allocation. Since PCPs only saw patients during routine clinical care and often not at the time of 2-year follow-up, an initial plan to collect 2-year measurement data in the practice setting could not be realised. For logistic reasons, 2-year follow-up data were not available for participants living in nursing homes at the 2-year follow-up. At 2 years participating PCPs were sent a brief questionnaire on their perception of the intervention.

At 2 years, primary outcomes were adherence with six recommended health behaviours (physical activity, fruit/vegetable/fibre intake, fat intake, seat belt use, tobacco consumption, alcohol use) and six preventive care services (blood pressure measurement, cholesterol measurement, glucose measurement, influenza vaccination, pneumococcal vaccination, faecal occult blood testing). An initial plan to use composite variables (e.g., by calculating an overall adherence rate for summarising the information on adherence with each of the six recommended health behaviours) was dropped because the main study hypothesis was to test the effects on individual, and not on combined items. Secondary outcomes were nursing home admissions, dependency in basic activities of daily living, and self-perceived health status. At 8 years the primary end point was all-cause mortality, and the secondary endpoint cause-specific mortality. Vital status at the end of 2008 was ascertained for all study participants, either through probabilistic linkage with the Swiss National Cohort [25] or, if linkage was unsuccessful, from municipal registers. The underlying cause of death was ascertained from the death certificate, based on the International Classification of Diseases Tenth Revision (ICD-10).

Sample Size and Statistical Analysis

The number of participants needed to demonstrate a 1.3 times increase in the prevalence of positive health behaviours or preventive care use with 80% power at a significance level of 0.05 was 1000 persons in each group, assuming a control group prevalence of 20%, and a 20% drop-out rate. For a 1:2 randomisation (intervention to control) ratio, the

required numbers were 732 persons in the intervention and 1464 in the control group. We changed the randomisation ratio from 1:1 to 1:2 in March 2001, when resource constraints mandated a reduction of the size of the intervention group. Enrolment was terminated in January 2002 when the required sample size was reached.

Analyses comparing the prevalence of healthy behaviours and adherence to preventive care at 2 years were based on a modified (i.e., using imputation methods for handling missing data) intention-to-treat analysis based on all surviving participants. We used multiple imputation by chained equations assuming a missing at random situation [28]. Analyses were run on 25 imputation datasets and results combined with Rubin's rule [29]. In sensitivity analyses we used the complete case data, excluding individuals with missing data. Further, we conducted a sensitivity analysis to test the potential impact of attrition bias due to lost-to-follow-up individuals at 2 years [30]. We used inverse-probability-of-attrition weighting to examine the influence of attrition bias on the group allocation and the 2 year outcomes [31]. Standard intention-to-treat analyses were used for mortality analysis. We used generalised estimating equation models with an underlying equicorrelation structure to compare health behaviour and preventive care outcomes [32]. Survival was analysed using Kaplan-Meier life table methods and Cox regression models with the time from the date of randomisation to date of death or 31 December 2008, as the underlying time scale. Maximal individual observational time was restricted to 8 years of follow-up. The proportional-hazard assumption was tested by Schoenfeld's test [33]. All analyses were unadjusted. A p-value of less than 0.05 from 2-sided test statistics was considered to indicate statistical significance. The number needed to treat was calculated from absolute risk differences over the follow-up period [34,35]. Models accounted for the allocation of persons living in the same household to the same group. The effect of the intervention in the pre-specified subgroups at low and high risk (high risk defined as a Pra score ≥ 0.286) was assessed by treatment - subgroup interactions. Analyses were done using Stata 12.1 (Stata

Corp., College Station, TX, USA) or R version 3.0.1 (R Foundation for Statistical Computing, Vienna, Austria) software.

Results

A total of 4115 patients aged 65 years and older were assessed for eligibility, 3493 were eligible, and 2284 were included in the study and underwent randomisation (Fig 1).

Fig 1. PRO-AGE Solothurn CONSORT diagram. Note: The randomisation ratio (intervention to control group) was 1:1 in the first project phase, and 1:2 in the second project phase, resulting in a ratio overall of 1:1.6.

Eight-hundred and seventy-four participants were allocated to the intervention group, and 1410 to the control group. There were no significant (p<0.05; based on z-statistics from general estimation equations models) differences between intervention and control groups in any of the baseline characteristics listed in Table 2.

Table 2. Baseline characteristics of study participants.

Characteristic	Intervention Group, n=874	Control Group, n=1410
Age at randomisation[a]: years	74.5 ±5.8	74.5 ±6.1
Gender: female	497 (56.9)	796 (56.5)
Hospital use in past year[b]: ≥ 1 admissions	174 (19.9)	261 (18.5)
Doctor visits in past year[b]: ≥ 7 visits	210 (24.0)	343 (24.3)
Self-perceived health[b]		
Excellent	22 (2.5)	33 (2.3)
Very good	133 (15.2)	189 (13.4)
Good	545 (62.4)	839 (59.5)
Fair	168 (19.2)	338 (24.0)
Poor	6 (0.7)	11 (0.8)
Self-reported diabetes[b]	91 (10.4)	169 (12.0)
Self-reported coronary heart disease[b]	189 (21.6)	325 (23.0)

Table 2. *(continued)*

Characteristic	Intervention Group, n=874	Control Group, n=1410
No informal caregiver available if needed[bc]	86 (9.8)	163 (11.6)
Pra-score[a,d]	0.29±0.10	0.29±0.11
Highest completed education[e]		
Compulsory education or less (≤ 9 y)	388 (44.4)	606 (43.0)
Tertiary level education (≥ 12 y)	68 (7.8)	126 (8.9)
Secondary level education (10 to 12 y)	399 (45.7)	643 (45.6)
Unknown	19 (2.2)	35 (2.5)
Living arrangement[e]		
Living alone	261 (29.9)	404 (28.7)
Not living alone	600 (68.6)	977 (69.3)
Unknown	13 (1.5)	29 (2.1)
Marital status[e]		
Single	37 (4.2)	73 (5.2)
Married	548 (62.7)	875 (62.1)
Widowed	258 (29.5)	399 (28.3)
Divorced	18 (2.1)	34 (2.4)
Unknown	13 (1.5)	29 (2.1)
Religious affiliation[e]		
Protestant	461 (52.7)	735 (52.1)
Catholic	364 (41.6)	571 (40.5)
No religious affiliation	14 (1.6)	34 (2.4)
Other/unknown	35 (4.0)	70 (5.0)
Socio-economic status[a,f]**:** Swiss neighbourhood index	61.2 ±7.3	60.8 ±7.4

[a]Numbers are mean ± SD or n (%).
[b]Based on self-reported information from pre-randomisation baseline questionnaire.
[c]Said no to the question: “Is there a friend, relative or neighbour who would take care of you for a few days if necessary?”
[d]The Pra score is calculated from the person’s age, gender, information on hospital admissions, doctor visits, health status, diabetes, heart disease, caregiver availability [24].
[e]Based on linkage with data from Swiss Population Census (2000).
[f]Higher scores denoting higher levels of socio-economic status [26].

Uptake of the Intervention

At baseline, 748 (85.6%) of the 874 participants allocated to the intervention group returned the HRA-O questionnaire. It revealed a mean (±SD) of 6.9±3.7 risk factors for functional status decline per participant (Table 3).

Table 3. Prevalence rates of risk factors for functional status decline among study participants in the intervention group at baseline (n=748).

Risk Factor Domain	Definition of Risk Factors	Prevalence, n (%)
Accident prevention	Does not always wear a seat belt	90 (12.0)
Activities of daily living	Difficulty/ need for human assistance in ≥ 2 IADL items	135 (18.0)
	Changed kind of mobility activity (preclinical mobility disability)	366 (48.9)
	Decreased frequency of mobility activity (preclinical mobility disability)	262 (35.0)
Alcohol use	Possible misuse of alcohol	85 (11.4)
Falls	Repeated (≥1) falls in past 12 months	50 (6.7)
	Self-reported limitation of activities due to fear of falling	167 (22.3)
Health status	Self-perceived health status “moderate” or “poor”	116 (15.5)
Hearing	Impaired hearing	178 (23.8)
Incontinence	Urinary incontinence on >5 days in past 12 months	144 (19.3)
Medication use	Use of ≥ 4 medications	200 (26.7)
	Total number of medications used (mean ± SD)	2.6 ± 2.2
	Use of long-acting benzodiazepine or amitriptyline	54 (7.2)
	Self-reported medication side effects	64 (8.6)
	Possible prescribed medication adverse reaction	33 (4.4)
Medical history	Presence of ≥ 3 chronic condition(s)	279 (37.3)
	Number of chronic conditions (mean ± SD)	2.1 ± 1.6
Memory	Memory problems	46 (6.1)
Mood	Depressive mood	105 (14.0)

Table 3. *(continued)*

Risk Factor Domain	Definition of Risk Factors	Prevalence, n (%)
Nutrition	Body mass index <20 kg/m^2	14 (1.9)
	Body mass index ≥ 27 kg/m^2	375 (50.1)
	Body mass index kg/m^2 (mean ± SD)	27.2 ± 4.5
	Loss of weight (≥ 5kg in past 6 months)	35 (4.7)
	Consumption of >2 high fat food items per day	354 (47.3)
	Consumption of <5 fruit/ fibre items per day	489 (65.4)
Oral Health	Oral health problem	188 (25.1)
Pain	Presence of moderate to severe pain	166 (22.2)
Physical activity	Moderate or strenuous physical activity on <5 days/ week	524 (70.1)
Social factors	Low level of emotional support	64 (8.6)
	High risk of social isolation	66 (8.8)
	Marginal family ties	45 (6.0)
	Marginal friendship ties	126 (16.8)
	No participation in social groups or organizations	149 (19.9)
Tobacco use	Current tobacco use	86 (11.5)
Vision	Problem in ≥ 1 vision sub-domains	93 (12.4)

Based on self-report data of 748 participants of the intervention group to the baseline HRA -O (Health Risk Appraisal for Older Persons) questionnaire. Participant nonresponse was categorised as absence of risk (this was for participants who completed some of the questionnaire but missed parts). Participant nonresponse ranged between 17 and 184 for the risk factors listed in the Table). IADL denotes instrumental activities of daily living. For detailed definitions and references of instruments, see S1 Table.

For example, 167 (22.3%) participants reported fear of falling [36], 262 (35.0%) a reduction in physical activity in the past year [37], and 354 (47.3%) high intake of fatty foods. Only a small minority of participants reported an intention to change adverse health behaviour; for example only 6 (1.6%) of the 354 participants reporting high intake of fatty foods reported plans to reduce their fat intake in the near future (S2 Table). In addition, the questionnaire revealed a mean (±SD) of 4.3±1.8 deficits per participant among the 11 recommended preventive care

recommendations, with ≥ 1 deficits in 731 participants (S3 Table). Overall, 586 (80.2%) of the 731 participants with ≥ 1deficits did not realize that they had deficits in preventive care (S4 Table).

Among the 874 participants of the intervention group, 514 (58.8%) received the intervention for the entire 2-year period, with a mean of 5.3 nurse counsellor visits and 2.0 telephone contacts. Ninety-four (10.8%) participants declined nurse counselling, but received the PCP component of the intervention for the 2-year period. The 126 (14.4%) participants who did not return the base-line HRA-O questionnaire did not receive the intervention. The remaining 140 (16.0%) participants received the intervention (including nurse counselling) for less than 2 years due to death (n=21), nursing home admission (n=6), withdrawal of 1 PCP (n=25), or participant request (n=88).

Of the 19 PCPs, 18 participated in the intervention for the entire 2-year time period, and 1 PCP withdrew from the project in the second year for personal reasons. Sixteen PCPs responded to questions on their perception of the preventive intervention at the end of the 2-year follow-up (S5 Table). Most of them did not see relevant resource constraints for offering the recommended preventive care services to their patients. All 16 PCPs considered the evidence for recommending yearly influenza vaccinations to older persons as strong, but some PCPs considered the evidence as weak for recommending other preventive care measures (e.g., 10 of the 16 PCPs considered the evidence for recommending colon cancer screening as weak). PCPs and nurse counsellors did not report any harm resulting from the intervention.

Outcomes at 2-Year Follow-Up

Overall, 827 participants in the intervention group and 1320 among controls survived and were living in the community at the 2-year follow-up and were included in the 2-year follow-up analyses which included imputation of missing data (see Fig 1 and S6 Table for information on missing data). Table 4 summarises primary outcomes at 2-year follow-up.

Table 4. Primary outcomes at 2-year follow-up: health behaviours and adherence with preventive care recommendations.

Health behaviours	Intervention Group, n (%)	Control Group, n (%)	Odds Ratio (95% CI)	*p*-Value
Medium to high level of physical activity (daily average ≥ 30 minutes)	580 (70.1)	820 (62.1)	1.43 (1.16-1.77)	0.001
Medium to high level of fruit/ vegetable/ fibre intake (≥ 2 portions per day)	386 (46.7)	511 (38.7)	1.40 (1.15-1.70)	0.001
Low level of fat intake (< 2 portions of high fat items per day)	249 (30.1)	332 (25.2)	1.35 (1.08-1.68)	0.008
Use of seat belt (always use of seat belt)	734 (88.8)	1117 (84.6)	1.42 (1.06-1.92)	0.02
No tobacco consumption	742 (89.7)	1180 (89.4)	1.03 (0.75-1.42)	0.86
No or little alcohol use (≤ 1 alcoholic drink per day)	773 (93.5)	1186 (89.8)	1.64 (1.15-2.33)	0.006
Preventive care recommendations				
Blood pressure measurement in past y	759 (91.8)	1168 (88.5)	1.45 (1.06-2.00)	0.02
Cholesterol measurement (persons aged <75 y) in past 5 y	435 (90.2)[a]	676 (86.2)[a]	1.48 (1.02-2.13)	0.04
Glucose measurement in past 3 y	670 (81.0)	1014 (76.8)	1.29 (1.03-1.62)	0.03
Influenza vaccination in past y	544 (65.8)	781 (59.2)	1.35 (1.09-1.66)	0.005
Pneumococcal vaccination (ever)	259 (31.3)	266 (20.2)	1.90 (1.52-2.37)	<0.001
Faecal occult blood test in past y (persons aged <80 y)	191 (28.1)[b]	234 (21.5)[b]	1.45 (1.15-1.85)	0.002

Table 4. *(Continued)*

Modified intention-to-treat analysis based on all participants surviving in the community, with multiple imputation for missing values (intervention group, n=827; control group n=1320). Odds ratios and p-values based on z-statistics from general estimation equation models. For analysis with complete case dataset alone (i.e., dataset without imputed data) see S7 Table. Control group is reference group; CI, confidence interval.

[a]Denominator includes persons aged <75 years only: intervention group, n=482; control group, n=784 (persons aged ≥ 75 years were excluded since the recommendation for cholesterol measurement was given to persons aged <75 years only).

[b]Denominator includes persons aged <80 years only: intervention group, n=680; control group, n=1089 (persons aged ≥ 80 years were excluded since the recommendation for faecal occult blood testing was given to persons aged <80 years only).

Health behaviour related to physical activity, diet, seat belt use, and alcohol consumption in the intervention group was better than in the control group (Table 4). For example, in the intervention group 70.1% of individuals reported to be physically active on average at least 30 minutes per day compared to 62.1% in the control group. Adherence with the preventive care recommendations was also greater in the intervention group as compared to control (Table 4). Complete case analyses yielded similar results (S7 Table). Also, the sensitivity analyses with Inverse Probability of Attrition Weighting for investigating attrition bias were similar to complete case and multiple imputation results (S7 Text).

There were no statistically significant differences between intervention and control groups for self-reported dependency in basic activities of daily living (S8 Table), and nursing home admissions (S9 Table) at the 2-year follow-up.

Outcomes at 8-Year Follow-Up

Vital status at the end of 2008 could be ascertained for all study participants, either through linkage with the Swiss National Cohort (for 2242 patients, 98.2%) or, if linkage was unsuccessful, from municipal registers (42 patients, 1.8%). Length of follow-up ranged from 6.8

years to 8.2 years; the median length of follow-up was 7.7 years in both groups. We compared the mortality data from the record linkage at 2 years with the data from the medical record abstraction at the 2-year follow-up. In 2080 participants for whom information was available from both sources, the accuracy was >99%. The mortality rate was 3.16 (95% CI 2.74-3.63) per 100 person-years in the intervention group as compared to 3.97 (95% CI 3.59-4.39) in the control group, the hazard ratio was 0.79 (95% CI 0.66-0.94; *p*=0.009; based on a Wald test from a Cox regression model) (Fig 2).Sensitivity analyses with adjustment for two key baseline variables (self-perceived health and access to informal caregiver support) yielded similar results (S10 Table).

Fig 2. Probability of survival. The primary outcome at 8-year follow-up was all-cause mortality. Based on Kaplan-Meier estimates of survival.

The estimated proportion alive at 8 years was 77.9% (95% CI 75.2%- 80.7%) in the intervention and 72.8% (95% CI 70.4%-75.2%) in the control group, for an absolute mortality difference of 4.9% (95% CI 1.3%-8.5%, *p*=0.009; based on a z-test for a risk difference).The number needed to treat was 21 (95% CI 12-79) (i.e., 21 individuals needed to receive the intervention to prevent 1 death over 8 years). Table 5 lists the detailed intervention effects for the two most frequent causes of death (i.e., circulatory system and neoplasm). Causes of death due to other types of disorders were classified as “other and unknown causes of death” because the numbers were too low for separate analyses. The combined mortality rate for diseases of the circulatory system was lower for the intervention group compared to controls (p=0.03; based on a Wald-test from a Cox regression model). There were no other statistically significant differences in cause-specific mortality rates (Table 5).

Table 5. Secondary outcomes at 8-year follow-up: mortality rates for main causes and sub-causes of death.

Cause of Death	**Intervention Group, n=874**		**Control Group, n=1410**		**Hazard Ratio**[a]	
ICD-10 codes	*no. of persons who died*	*death rate per 100 person-years (95% CI)*	*no. of persons who died*	*death rate per 100 person-years (95% CI)*	*(95% CI)*	*p-*Value
Circulatory system (category I)	**81**	**1.32 (1.07-1.65)**	**171**	**1.79 (1.54-2.07)**	**0.74 (0.57-0.97)**	**0.03**
Ischemic heart disease (I20-I25)	35	0.57 (0.41-0.80)	77	0.80 (0.64-1.01)	0.71 (0.47-1.06)	0.10
Hypertensive diseases (I10-I15)	12	0.20 (0.11-0.35)	21	0.22 (0.14-0.34)	0.89 (0.44-1.80)	0.74
Stroke (I64)	9	0.15 (0.08-0.28)	16	0.17 (0.10-0.27)	0.87 (0.39-1.97)	0.74
Neoplasm (category C)	**58**	**0.95 (0.73-1.23)**	**103**	**1.08 (0.89-1.30)**	**0.88 (0.64-1.21)**	**0.42**
Respiratory (C30-C39)	12	0.20 (0.11-0.35)	22	0.23 (0.15-0.35)	0.86 (0.43-1.73)	0.67
Digestive (C15-C26)	16	0.26 (0.16-0.43)	29	0.30 (0.21-0.44)	0.87 (0.47-1.59)	0.64
Gynaecological (C50-C58)	6	0.10 (0.04-0.22)	14	0.15 (0.09-0.25)	0.67 (0.25-1.74)	0.40
Other and unknown (other categories/ unknown)	**54**	**0.88 (0.68-1.15)**	**106**	**1.11 (0.92-1.34)**	**0.79 (0.57-1.11)**	**0.17**

CI, confidence interval; ICD-10, International Classification of Diseases Tenth Revision.

[a]Hazard ratios are based on Cox proportional-hazards models. Control group is reference group.

In an additional analysis, we compared the survival proportion observed in the present study with that of the general Swiss population of the same age for the same time period. As expected - because persons with disabilities, terminal disease and dementia were excluded from the present study population - survival in the general population was somewhat lower as compared to the survival the control group (survival proportion of general population 69.0% [95% CI 68.9%-69.1%] as compared to 72.8% in the control group) (S1 Figure).

In addition, we conducted an a-priori planned subgroup analysis according to the baseline Pra risk score [24] of study participants (high risk defined as a Pra score ≥ 0.286). In the low-risk subgroup, yearly mortality rates were low (intervention group: 1.98%; control group: 2.23%), with a hazard ratio for death of 0.89, 95% CI 0.67-1.18 (p=0.42; based on a Wald test from a Cox regression model). The yearly mortality rates were high among participants at high base-line risk (intervention group 4.99%; control group 6.67%), with a hazard ratio for death of 0.74 (95% CI 0.59-0.92; p=0.007; based on a Wald test from a Cox regression model). A Cox regression analysis including a treatment - subgroup interaction term revealed that there was no statistically significant interaction between group assignment (intervention versus control) and the 2 pre-specified subgroups (low and high base-line risk) (p=0.32), demonstrating that the relative survival effects of the intervention did not differ between low and high risk subgroups.

Cost of the Intervention

The cost of providing the full intervention over the 2-year period, based on 2014 costs for personnel and overhead in Switzerland, was USD 1017 per participant. The majority of costs was related to time and expenses of the involved health professionals. Only a small amount (USD 56) was spent for generating and administering the HRA-O questionnaires and feedback reports (S11 Table).

Discussion

In this study we evaluated the long-term effects of a collaborative model of care based on HRA in older persons as compared to usual care. After 8 years, mortality was significantly lower in persons receiving the intervention compared to persons in the control group. The early detection and successful modification of risk factors for functional status decline identified with the HRA-based intervention and the improvement of recommended preventive care likely explained this reduction in mortality. In fact, two-year follow-up confirmed that the intervention group had more favourable health behaviours and used preventive care services more frequently than persons in the control group. In addition, it is likely the intervention also had other favourable effects contributing to the survival effect, such as early interventions for health and functional impairments uncovered with the HRA system, or improved management of chronic conditions (e.g., hypertension, diabetes) with the nurse counselling integrated into the process of primary care.

A main strength of this study is the randomised controlled design with an intention-to-treat analysis and fully available long-term survival data on all study participants. Also, the study was conducted in a “real world” setting, with a study population consisting of older persons registered in PCP practices, and not of a selected group of persons highly motivated to receive preventive care. It is unlikely that the study overestimates survival effects of the intervention, on the contrary, it may have underestimated effects for several reasons. First, PCPs received training and gained experience in preventive care, which likely resulted in improved care for individuals in the control group (possible contamination effect). Second, a proportion (14.4%) of participants allocated to the intervention group did not complete the HRA-O questionnaire at base-line, and were therefore not offered the intervention as planned during the 2-year follow-up period. With the intention-to-treat design, the present study might therefore underestimate treatment effects for persons adhering with the intervention. Finally, an intervention over 8 years

likely would have had stronger effects than the intervention limited to a 2-year period as tested in this study.

An important question is whether the finding of an approximate 20% reduction of mortality is plausible and consistent with previous findings in the literature. There is no previous research on long-term outcomes of HRA for comparison. However, multiple studies had attempted to evaluate the potential effect of risk factor modification on reduction of all-cause mortality. A recent meta-analysis of influenza vaccination studies concluded that even after adjustment for potential bias the odds ratio for all-cause mortality was 0.60 (i.e., an approximately 40% reduction of mortality) when comparing vaccinated with non-vaccinated persons in years when vaccine matched the circulating virus [38]. A pooled analysis of population-based cohort studies demonstrated that physical activity is related to a 20% to 37% reduction in mortality among adults, with a dose-response association [39]. A systematic analysis of prospective studies on the combined effects of health lifestyle behaviours showed an estimated 66% reduction of all-cause mortality if four healthy risk factors were compared with four unhealthy risk factors [40]. A study of cardiovascular risk factors found that the adjusted hazard ratio for all-cause mortality was 0.49 (95% CI, 0.33-0.74) for participants with 6 or more versus 1 or fewer favourable cardiovascular health metrics [41]. Overall these recent analyses, although mostly based on non-randomized prospective studies, demonstrate that a 20% reduction of mortality as observed in our study is in the expected range for an intervention modifying health behaviours and preventive care use.

The present study has several limitations. It was conducted at one single site. However, extensive preparatory work and field tests in the U.S., Germany, and the United Kingdom confirmed that the intervention used in our trial is well accepted and feasible for use in other regions [13,14,15,23]. A further limitation is the fact that the intervention phase of this study took place between 2000 and 2004 because publication of long-term outcome data was possible only after long-term outcome data became fully available in 2014. However, the study findings are

relevant today since most risk factors and key recommendations remained unchanged since 2004. An additional limitation is the use of a brief self-report questionnaire for measuring health behaviour outcomes at 2-year follow-up. This contributed to a high response rate, but may overestimate prevalence rates of favourable health behaviours, and does not measure effects on the multiple other risk factors for functional status decline that were measured with the base-line HRA-O questionnaire. Also, the fact that we did not collect extensive base-line information among control group persons at baseline limits our ability for making detailed analyses of intervention effects on HRA-O based risk factors. In addition, the use of self-report information for the 2-year follow-up may lead to socially desirable answers and therefore overestimate the prevalence of favourable outcomes. However, since outcome assessment was blinded for group allocation, it is unlikely that this resulted in a bias between the intervention and control groups. Another limitation is the lack of information on specifically which changes in risk behaviours and use of clinical preventive services made the biggest contribution to reduced mortality in this multifactorial trial. Further limitations are the lack of other long-term outcome data (e.g. functional status, nursing home admissions) and the validity of cause of death information which relies on information coded by different attending physicians.

Our study did not evaluate long-term effects on functional status, quality of life and actual cost-effectiveness, and did not disentangle which components of the complex intervention tested in this trial were most efficacious. Future studies should address these issues, and in addition, examine the generalizability of the benefits observed in this study in other settings, and refine the HRA-O based intervention to further increase its efficiency and effectiveness. For example, practice-based instead of home-based counselling, use of other forms of reinforcement such as internet or mobile communication, use of behaviour change techniques (e.g., pedometer step-count and accelerometer) as part of counselling [42], or repetitive group sessions might be effective alternatives or add-ons to the preventive home visits by nurse counsellors.

Conclusion

Many previous studies revealed the importance of multimodal interventions and coordination of care in disabled or demented older persons. In contrast, the HRA-based approach tested in the present study was designed for the approximate 80% of the older population without pre-existing disability. The findings of this trail has important implications for policy and practice. Several countries introduced multimodal preventive programs available to healthy older persons, and are challenged to decide whether, and if so how, these programs should be continued. For example, the U.S. introduced the Welcome to Medicare and Annual Wellness Visit program for Medicare beneficiaries [43]. The favourable results of our study support that implementation should be based on a multidimensional HRA system with adequate personalised reinforcement.

For practice implementation, a key factor for success is to ensure personal reinforcement of HRA-based recommendations by specially trained counsellors who take into account personal preferences of older persons. To ensure synergies with primary care, regionally adapted approaches to ensure integration into the process of primary care need to be developed. This integration is facilitated by the use of HRA as a comprehensive self-administered tool for initial assessment, the availability of automatically generated regionally adapted feed-back reports, and delegation of health counselling to specially trained health professionals. Our study may also serve as a model for low- or middle income countries, given the importance of the demographic challenge with rapidly growing populations of older persons in these countries [44]. Regionally adapted methods of the HRA-O approach might reach large groups of older persons at relatively low cost.

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Supporting Information

S1 Fig. Comparison of 8-year survival of study population with survival in general Swiss population aged 65 years in the same time period.
Data of general population based on Swiss National Cohort Database, mean age of the population was 74.8±6.9 [SD] years with 58.1% women at census 2000. Based on Kaplan-Meier estimates of survival.

S1 Table. Definitions of risk factors and sources of instruments included in the HRA-O questionnaire.

S2 Table. Intention to change health behaviour among study participants of the intervention group at baseline.

S3 Table. Prevalence rates of deficits in recommended preventive care use among study participants of the intervention group at baseline.

S4 Table. Reasons for not having used recommended preventive care among study participants of the intervention group at baseline.

S5 Table. Survey among primary care physicians after completion of the intervention

S6 Table. Missing values of primary outcomes at 2-year follow-up.

S7 Table. Primary outcomes at 2-yr follow-up: sensitivity analysis based on complete case dataset (without imputed data).

S8 Table. Secondary outcomes at 2-yr follow-up: self-reported information.

S9 Table. Secondary outcomes at 2-yr follow-up: persons permanently admitted to nursing home.

S10 Table. Survival analyses: sensitivity analyses with adjustment for selected individual base-line variables.

S11 Table. Estimation of costs for providing the intervention.

S1 Text. PRO-AGE Solothurn study protocol and statistical analysis plan.

S2 Text. CONSORT 2010 checklist (3 pages).

S3 Text. Health Risk Appraisal for Older Persons (HRA-O) questionnaire (U.K. English version).

S4 Text. Health Risk Appraisal for Older Persons (HRA-O) questionnaire (German language version).

S5 Text. PRO-AGE Intervention manual English version).

S6 Text. PRO-AGE Solothurn intervention manual (German language version).

S7 Text. Sensitivity analysis of two-year outcome results accounting for attrition.

Figure 1

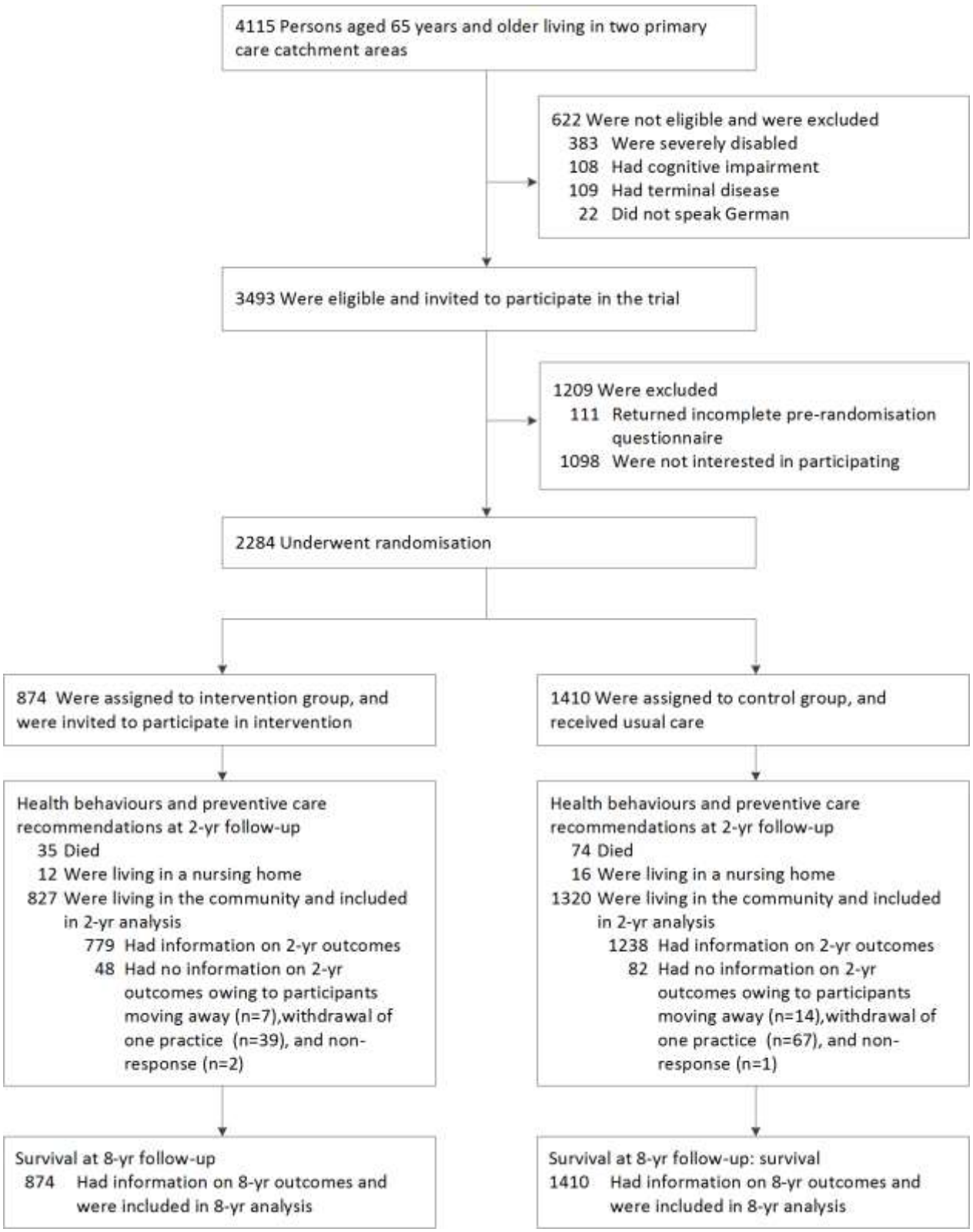
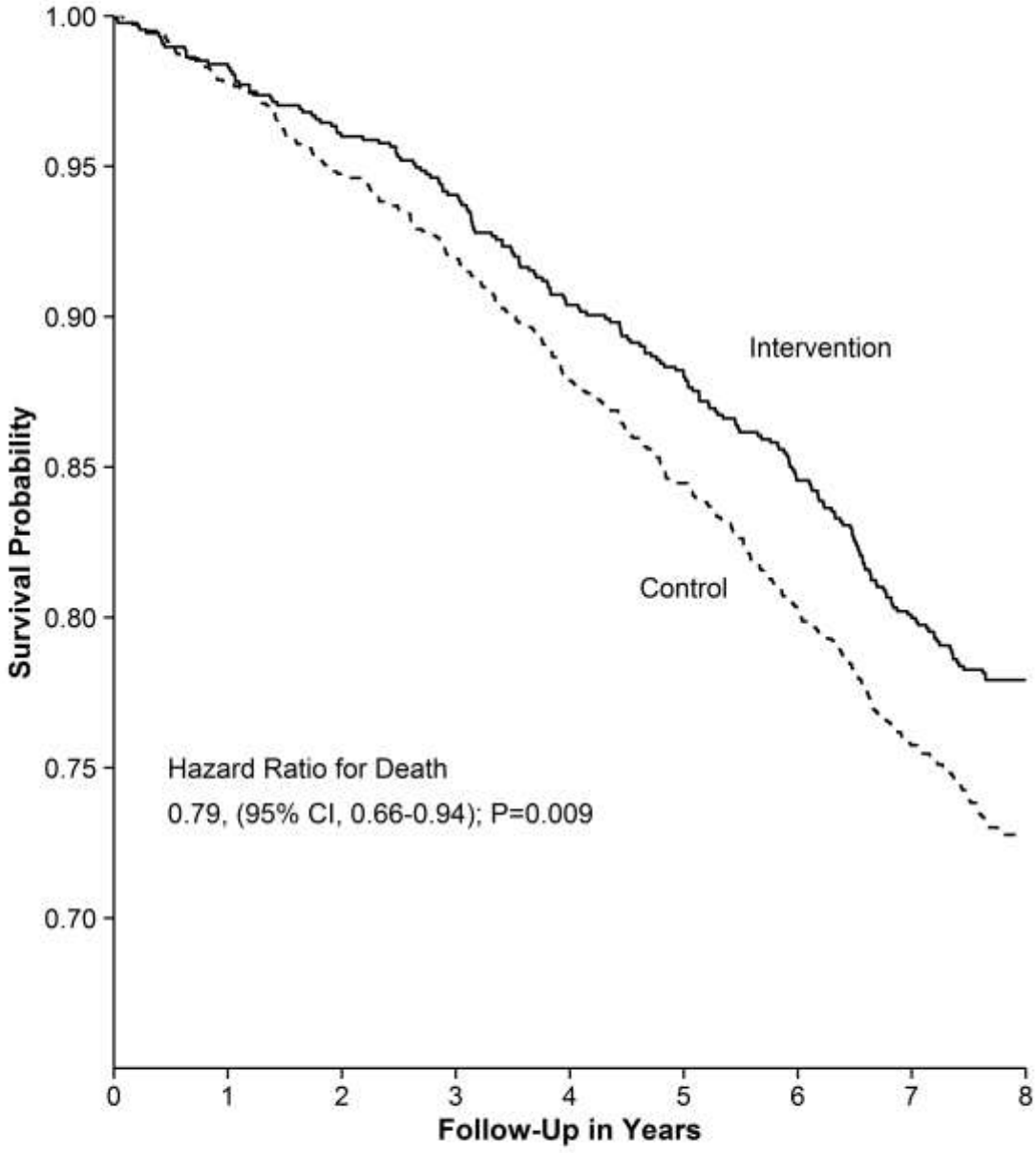

4115 Persons aged 65 years and older living in two primary care catchment areas
622 Were not eligible and were excluded
383 Were severely disabled
108 Had cognitive impairment
109 Had terminal disease
22 Did not speak German
3493 Were eligible and invited to participate in the trial
1209 Were excluded
111 Returned incomplete pre-randomisation questionnaire
1098 Were not interested in participating
2284 Underwent randomisation
874 Were assigned to intervention group, and were invited to participate in intervention
1410 Were assigned to control group, and received usual care
Health behaviours and preventive care recommendations at 2-yr follow-up
35 Died
12 Were living in a nursing home
827 Were living in the community and included in 2-yr analysis
779 Had information on 2-yr outcomes
48 Had no information on 2-yr outcomes owing to participants moving away (n=7),withdrawal of one practice (n=39), and non-response (n=2)
Health behaviours and preventive care recommendations at 2-yr follow-up
74 Died
16 Were living in a nursing home
1320 Were living in the community and included in 2-yr analysis
1238 Had information on 2-yr outcomes
82 Had no information on 2-yr outcomes owing to participants moving away (n=14),withdrawal of one practice (n=67), and non-response (n=1)
Survival at 8-yr follow-up
874 Had information on 8-yr outcomes and were included in 8-yr analysis
Survival at 8-yr follow-up: survival
1410 Had information on 8-yr outcomes and were included in 8-yr analysis

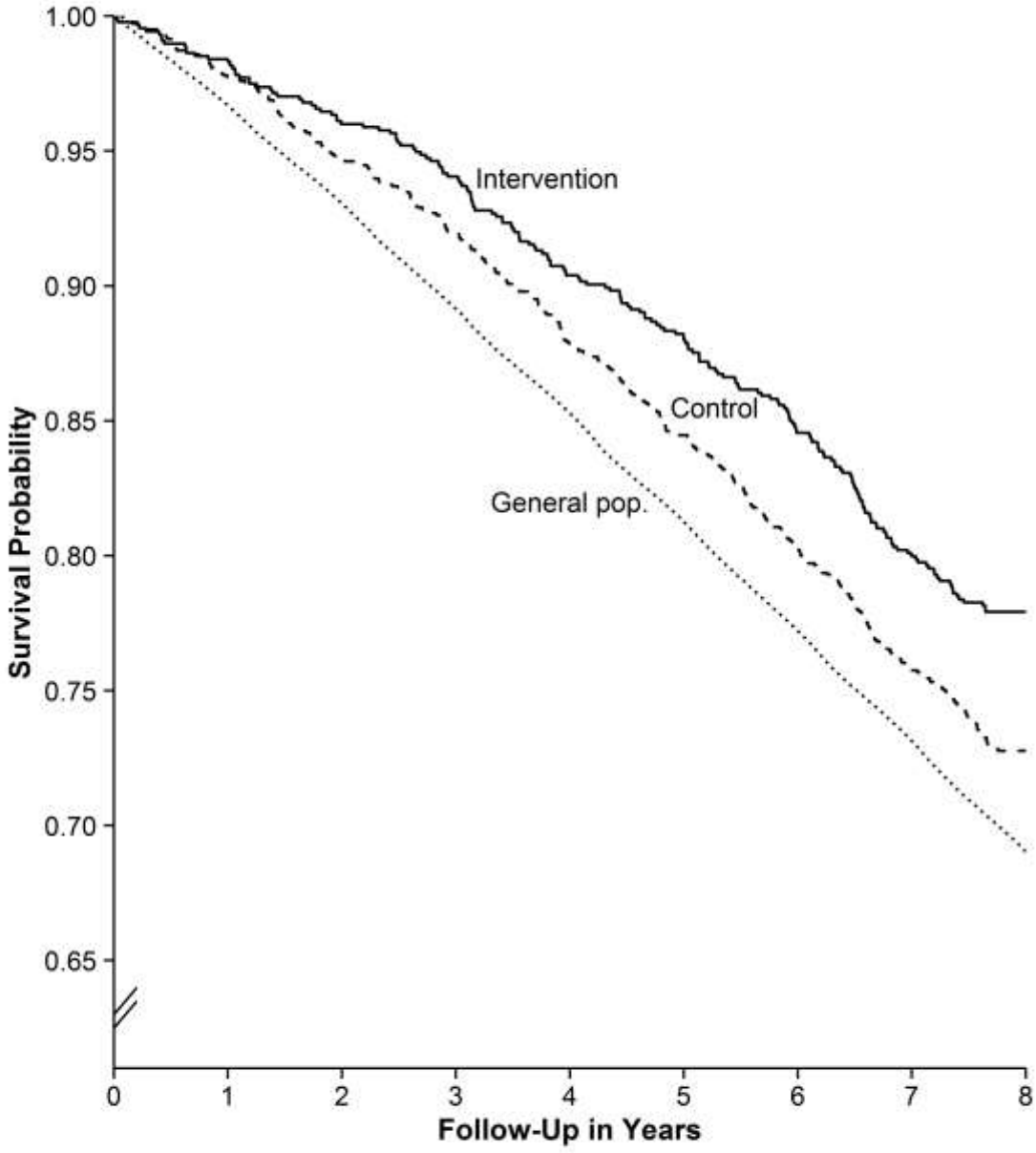
Figure 2



No. at Risk

Intervention	874	860	839	822	790	769	739	699	45
Control	1410	1378	1336	1296	1239	1191	1131	1068	37

S Figure 1 (supplemental Figure 1)



No. at Risk

General pop.	1023466	988382	950494	909739	869436	827672	786009	744029	701971
Intervention	874	860	839	822	790	769	739	699	45
Control	1410	1378	1336	1296	1239	1191	1131	1068	37

Financial disclosure

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Data availability

There are restrictions on the availability of data for this study. Individual data of the Swiss National Cohort are the property of the Swiss Federal Statistical Office (SFSO) and can only be made available by legal agreements with the SFSO. This also applies to derivatives such as the analysis files used for this study. In addition, data anonymity has to be strictly ensured based on the patient consent forms. To protect the anonymity of data and the requirements of the SFSO, an anonymized dataset with restricted information has been created for potential use of data for reproducing results or for conducting individualized patient-data meta-analyses. Researchers may apply for data access at DataRequest@ctu.unibe.ch (postal address: CTU Bern, Institute of Social and Preventive Medicine, University of Bern, Finkenhubelweg 11, CH-3012 Bern, Switzerland).

Competing interests

The authors have declared that no competing interests exist.

Authorship contribution

See next two pages

Stuck, Andreas

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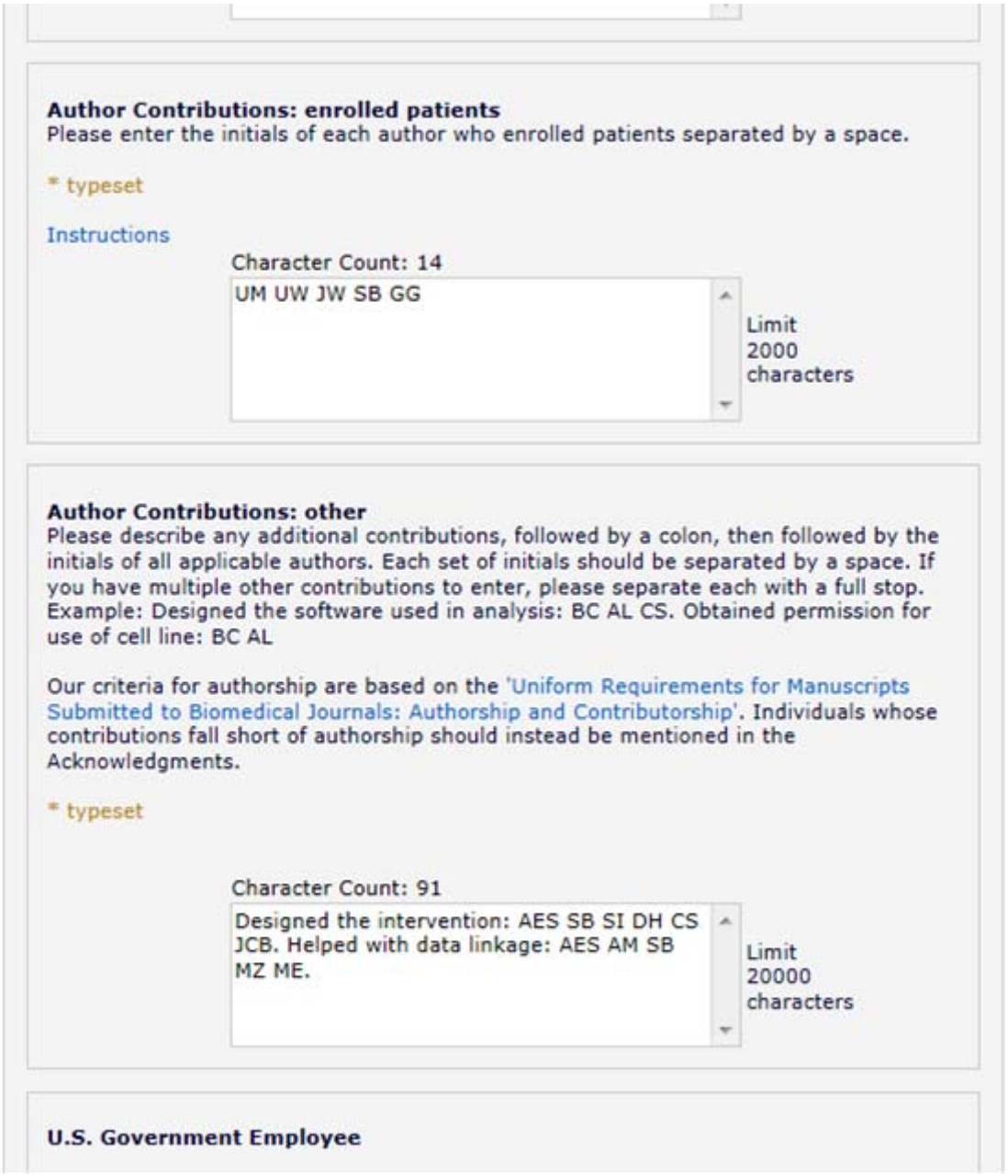

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Table S1. Definitions of Risk Factors and Sources of Instruments Included in the HRA-O Questionnaire.[a]

Risk Factor Domains (Alphabetical Order)	Instruments Used for Risk Assessment[d]	Definition of Risk
1. Accident prevention	Use of seatbelt [National Center for Chronic Disease Prevention and Health Promotion, 1993]	Does not always wear a seat belt
2. Activities of daily living	Instrumental Activities of Daily Living (IADL) [Lawton and Brody, 1969]	Difficulty/ need for human assistance in ≥ 2 items of instrumental activities of daily living (IADL)
	Item of Preclinical Mobility Disability [Fried et al., 2000]	Changed kind of mobility-related activity in past 12 months
	Item of Preclinical Mobility Disability [Fried et al., 2000]	Decreased frequency of mobility-related activity in past 12 months
2. Alcohol use	Alcohol Use Disorders Identification Test [Babor et al., 1992]	Drinking more than age- and gender-specific limits of quantity and frequency of alcohol[b]
3. Falls	Study of Osteoporotic Fractures Research Group Survey [Kelsey et al., 1992]	Repeated (≥1) falls in past 12 months
	Fear of falling [Tinetti et al., 1988]	Self-reported limitation of activities due to fear of falling
5. Health status	Self-perceived health status [Human Population Laboratory, 1965]	Self-perceived health status “fair” or “poor”
6. Hearing	Hearing Handicap Inventory for the Elderly [Lichtenstein et al., 1988]	Impaired hearing
7. Incontinence	Urinary incontinence (Medical, Epidemiological and Social Aspects of Aging Project Questionnaire) [Diokno et al., 1986]	Urinary incontinence on >5 days in past 12 months
8. Medication use	Use of medications [Breslow et al., 1997]	Use of ≥ 4 medications
	Inappropriate medication use [Beers, 1997]	Use of long-acting benzodiazepine or amitriptyline
	Medication compliance [Breslow et al., 1997]	Self-reported medication side effects
	Questionnaire on Drug-Related Symptoms in Elderly Outpatients [Wasson et al., 1992]	Possible prescribed medication adverse reaction
9. Medical history	Chronic Conditions [Human Population Laboratory, 1965]	Presence of ≥ 3 chronic condition(s)
10. Memory	Memory Self Report [Riege, 1982]	Memory problems
11. Mood	5-item Mental Health Inventory Screening Test [Stewart et al., 1988]	Depressive mood

Table S1-continued. Definitions of Risk Factors and Sources of Instruments Included in the HRA-O Questionnaire.[a]

Risk Factor Domains (Alphabetical Order)	Instruments Used for Risk Assessment[§]	Definition of Risk
12. Nutrition	Self-reported height and weight	Body mass index <20 kg/m^2
	Self-reported height and weight	Body mass index ≥ 27 kg/m^2
	Self-reported weight loss of ≥ 5 kg in past 6 months	Loss of weight (≥ 5kg in past 6 months)
	CRISP (Cholesterol Reduction in Seniors Program) Fat Food Screening Questionnaire [Stoy et al., 1995]	Consumption of >2 high fat food items per day
	CRISP (Cholesterol Reduction in Seniors Program) Plant Food Screening Questionnaire [Stoy et al., 1995]	Consumption of <5 fruit/ fiber items per day
13. Oral health	Geriatric Oral Health Assessment Index [Atchison and Dolan, 1990]	Oral health problem
14. Pain	Geriatric Pain Measure [Ferrell et al., 2000]	Presence of moderate to severe pain
15. Physical activity[c]	PASE (Physical Activity Scale for the Elderly) [Washburn et al., 1993]	Moderate or strenuous physical activity <5 times/ week
16. Social factors	Medical Outcomes Study Social Support Survey [Sherbourne and Stewart, 1991]	Low level of emotional support
	Lubben Social Network Scale [Lubben et al., 1988]	High risk of social isolation
	Subscale Lubben Social Network Scale [Lubben et al., 1988]	Marginal family ties
	Subscale Lubben Social Network Scale [Lubben et al., 1988]	Marginal friendship ties
	Single-item question [Berkman and Syme, 1979]	No participation in social groups or organizations
17. Tobacco use	Tobacco Use Questionnaire [Breslow et al., 1997]	Current tobacco use
18. Vision	Visual Functioning Questionnaire [Mangione et al., 1998]	Problem in ≥ 1 vision sub-domains

[a] HRA-O denotes Health Risk Appraisal for Older Persons (for full description of HRA-O questionnaire and sample reports see Study Protocol (supplementary material).

[b] Risk Possible misuse of alcohol was defined as drinking more than age- and gender-specific limits of quantity and frequency of alcohol (men < 70 years >14 drinks per week, men >70 years >11 drinks per week, women <70 years >11 drinks per week, women >70 years >8 drinks per week), or as meeting the criteria of binge drinking (>4 drinks at one occasion monthly or more frequently).

[c] Based on participant self-reported number of days with moderate or strenuous level of physical activity.

Table S1-continued. Definitions of Risk Factors and Sources of Instruments Included in the HRA-O Questionnaire.[a]

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Table S2. Intention to Change Health Behaviour among Study Participants of the Intervention Group at Baseline.[a]

Definition of Subgroup at Risk	Description of Question	Answer Categories	No./ Total	%
Persons with low level of physical activity (<5 times/ week moderate or strenuous physical activity according to PASE questionnaire)[b] (n=524)	Intention to increase physical activity	Plans to take steps in next month	7/524	1.3
		Plans to take steps in the next 6 months	1/524	0.2
		No plans within next 6 months	516/524	98.5
	Reasons for not increasing physical activity	Already frequent and regular exercise	331/524	63.2
		Pain with physical activity	88/524	16.8
		Illness limiting physical activity	69/524	13.2
		A physical limitation	35/524	6.7
Consumption of >2 high fat food items per day according to CRISP fat food questionnaire[b] (n=354)	Intention to decrease high fat intake	Plans to take steps in next month	3/354	0.8
		Plans to take steps in the next 6 months	3/354	0.8
		No plans within next 6 months	348/354	98.3
	Reasons for not decreasing high fat intake	Is already minimizing fat intake	239/354	67.5
		Does not think it is important to eat less fat	48/354	13.6
		Likes the taste of high-fat foods	33/354	9.3
		Has trouble to shop/ prepare low-fat foods	27/354	7.6
Consumption of < 5 fruit/ fibre items per day according to CRISP plant food questionnaire[b] (n=489)	Intention to increase fruit/fibre intake.	Plans to take steps in next month	1/489	0.2
		Plans to take steps in the next 6 months	1/489	0.2
		No plans within next 6 months	487/489	99.6
	Reasons for not increasing low fruit/fiber intake	Already eats plenty of fruits/ vegetables	458/489	93.7
Current tobacco use (n=86)	Intention to change current tobacco	Plans to quit smoking in next month	12/86	14.0
		Plans to quit smoking in next 6 months	10/86	11.6
		No plans within next 6 months	64/86	74.4

[a] HRA-O denotes Health Risk Appraisal for Older Persons. Results based on self-report answers.
[b] For references, see Table S1.

Table S3. Prevalence Rates of Deficits in Recommended Preventive Care Use among Study Participants of the Intervention Group at Baseline (n=748).[a]

Setting	Definition	No. (%).
Preventive care usually performed in PCP setting	No blood glucose measurement in past 3 years	172 (30.0)
	No blood pressure measurement in past year	35 (4.7)
	No cholesterol measurement in past 5 years and age <75 yr	99 (13.2)
	No faecal occult blood measurement in past year and age <80 yr	395 (52.8)
	No influenza vaccination in past year	395 (52.8)
	No pneumococcal vaccination (ever)	639 (85.4)
Preventive care usually performed in specialist setting	No cervical smear in past 3 years (women)	244 (32.6)
	No dental check in past year	306 (40.9)
	No hearing check-up in past year	473 (63.2)
	Women without mammography in past 2 years and age <70 yr	72 (9.6)
	No vision check-up in past year	280 (37.4)

[a] Based on the 748 of the 874 participants allocated to the intervention group who returned the baseline HRA -O (Health Risk Appraisal for Older Persons) questionnaire. PCP denotes primary care physician. The denominator includes participants with incomplete or missing self-report on individual preventive care items (number of participants with missing information is between 17 and 48).

Table S4. Reasons for Not Having Used Recommended Preventive Care Among Study Participants of the Intervention Group at Baseline. (N=731).[a]

Main Self-Reported Reason	Answer Categories	No. (%)
Does not see a need	Does not see a need/ does not think it is important / never recommended by PCP/ never thought about it	586 (80.2)
Financial barrier	Financial reason (cost, insurance)	13 (1.8)
Time constraint	Lack of time	1 (0.1)
Does not give a specific reason	No specific reason indicated/ no answer	131 (17.9)

[a] Based on self-report information of participants allocated to the intervention group. PCP denotes primary care physician. The denominator only includes persons with ≥ 1 deficits in preventive care at baseline.

Table S5. Survey among Primary Care Physicians (PCPs) after Completion of the Intervention (N=16).[a]

A. PCP-Perceived Strength of Evidence[b] **for Supporting Preventive Care Recommendations**

Recommendation	PCP-Perceived Strength of Evidence	
	very strong/ relatively strong	*relatively weak/ very weak*
Yearly blood pressure measurement, No. (%)	14 (87.5)	2 (12.4)
5-yearly cholesterol measurement, No. (%)	10 (62.5)	6 (37.5)
3-yearly blood glucose measurement, No. (%)	13 (81.3)	3 (18.7)
Yearly influenza vaccination, No. (%)	16 (100.0)	0 (0.0)
Pneumococcal vaccination (once) , No. (%)	9 (56.3)	7 (43.8)
Yearly faecal occult blood test, No. (%)	6 (37.5)	10 (62.5)

B. PCP-Perceived Impact of Resource Constraints[c] **Making it Difficult to Implement Preventive Care Recommendations.**

Recommendation	PCP-Perceived Impact of Resource Constraints	
	significant/ some constraints	*no constraints*
Yearly blood pressure measurement, No. (%)	0 (0.0)	16 (100.0)
5-yearly cholesterol measurement, No. (%)	2 (12.5)	14 (87.5)
3-yearly blood glucose measurement, No. (%)	0 (0.0)	16 (100.0)
Yearly influenza vaccination, No. (%)	1 (6.3)	15 (93.7)
Pneumococcal vaccination (once) , No. (%)	4 (25.0)	12 (75.0)
Yearly faecal occult blood test, No. (%)	1 (6.3)	15 (93.7)

[a] Sixteen of the 19 PCPs (primary care physicians) included in this study agreed to complete an anonymized self-report questionnaire after completion of the intervention at two-year follow-up.

[b] For each of the recommendations the survey question was: “Please rate the strength of evidence for supporting the recommendation by circling the most appropriate description.”

[c] For each of the recommendations the survey question was: “Which of the following preventive measures are difficult to provide in routine clinical practice because of limited resources? Circle the answer that best describes the impact of resource constraints in your practice.”

Supporting Table S6. Missing Values of Primary Outcomes at 2-Year Follow-up.

Outcome	Intervention Group	Control Group
	No./ Total (%)[a]	
Health behaviours		
Medium to high level of physical activity (≥ 30 minutes per day)[d]	108 (13.1)	159 (12.1)
Medium to high level of fruit/ vegetable/ fiber intake (≥ 2 portions per day)	100 (12.1)	146 (11.1)
Low level of fat intake (< 2 portions of high fat items per day)	93 (11.3)	135 (10.2)
Use of seat belt (always use of seat belt)	98 (11.9)	126 (9.6)
No tobacco consumption	97 (11.7)	131 (9.9)
No or little alcohol use (≤ 1 alcoholic drink per day)		
Adherence with selected preventive care recommendations		
Blood pressure measurement in past y	61 (7.4)	110 (8.3)
Cholesterol measurement (persons aged <75 y) in past 5 y [b]	38 (7.9)	62 (7.9)
Glucose measurement in past 3 y	61 (7.4)	123 (9.3)
Influenza vaccination in past y	76 (9.2)	126 (9.6)
Pneumococcal vaccination (ever)	95 (11.5)	169 (12.8)
Faecal occult blood test in past y (persons aged <80 y) [c]	74 (10.9)	113 (10.4)

[a] Calculated from the difference of all available participants surviving in the community (intervention group, n=827; control group n=1320) and the complete case denominator of Table S6.

[b] Denominator includes persons aged <75 years only: intervention group, n=482; control group, n=784.

[c] Denominator includes persons aged <80 years only: intervention group, n=680; control group, n=1089.

Table S7. Primary Outcomes at 2-Year Follow-up: Sensitivity Analysis Based on Complete Case Dataset (Without Imputed Data).[a]

Outcome	Intervention Group	Control Group	Odds Ratio (95% CI)[c]	*P* Value
	No./ Total (%)[b]			
Health behaviours				
Medium to high level of physical activity (≥ 30 minutes per day)[d]	519/719 (72.2)	731/1161 (63.0)	1.53 (1.24–1.90)	<0.001
Medium to high level of fruit/ vegetable/ fiber intake (≥ 2 portions per day)	346/727 (47.6)	456/1174 (38.8)	1.46 (1.19–1.78)	<0.001
Low level of fat intake (< 2 portions of high fat items per day)	225/734 (30.7)	297/1185 (25.1)	1.40 (1.12–1.74)	0.003
Use of seat belt (always use of seat belt)	650/729 (89.2)	1011/1194 (84.7)	1.48 (1.10–1.98)	0.009
No tobacco consumption	660/730 (90.4)	1066/1189 (89.7)	1.07 (0.78–1.48)	0.66
No or little alcohol use (≤ 1 alcoholic drink per day)	685/733 (93.5)	1072/1191 (90.0)	1.61 (1.13–2.30)	0.008
Adherence with selected preventive care recommendations[e]				
Blood pressure measurement in past y	705/766 (92.0)	1069/1210 (88.3)	1.52 (1.11–2.10)	0.009
Cholesterol measurement (persons aged <75 y) in past 5 y	400/444 (90.1)	624/722 (86.4)	1.43 (0.98–2.07)	0.06
Glucose measurement in past 3 y	622/766 (81.2)	925/1197 (77.3)	1.28 (1.02–1.61)	0.04
Influenza vaccination in past y	496/751 (66.1)	707/1194 (59.2)	1.36 (1.11–1.68)	0.003
Pneumococcal vaccination (ever)	225/732 (30.7)	221/1151 (19.2)	2.00 (1.59–2.51)	<0.001
Faecal occult blood test in past y (persons aged <80 y)	167/606 (27.6)	205/976 (21.0)	1.45 (1.14–1.85)	0.003

[a] CI denotes confidence interval.

[b] Total is the number of persons with available data per outcome. One reason for the variable denominators is the variable definition of the target participant group for cholesterol measurement and faecal occult blood test. For cholesterol measurement, the target group was persons aged <75 yr, and for fecal occult blood testing, the target group was persons aged <80 yr, respectively. The other reason for the variable denominators is different numbers of missing data per outcome. An example: The denominator for the physical activity outcome in the intervention group is 719. As indicated in the flow diagram (Fig 1), 779 of 827 surviving persons in the intervention group answered the 2-yr follow-up questionnaire. Among the 779 person, 60 did not respond to the physical activity question, leaving 719 persons with complete data on physical activity at the 2-yr follow-up.

[c] Control group is reference group.

[d] Based on participant self-reported answers to average daily duration of moderate or strenuous level of physical activity.

[e] Based on abstraction of primary care physicians' patient charts.

Table S8. Secondary Outcomes at 2-Year Follow-up: Self-Reported Information.[a]

Outcome	Intervention Group	Control Group	Odds Ratio (95% CI)	*P* Value
Main Analysis with Imputed Data[b]				
Self-perceived health			n.a.	0.04[c]
Excellent, No. / Total (%)	14/827 (1.7)	12/1320 (0.9)		
Very good, No. / Total (%)	121/827 (14.6)	159/1320 (12.0)		
Good, No. / Total (%)	548/827 (66.3)	856/1320 (64.8)		
Fair, No. / Total (%)	136/827 (16.4)	267/1320 (20.2)		
Poor, No. / Total (%)	8/827 (1.0)	26/1320 (2.0)		
Self-reported basic activities of daily living				
Need for human assistance, No. / Total (%)	38/827 (4.6)	62/1320 (4.7)	0.97 (0.61–1.54)	0.91
Sensitivity Analysis with Complete Case Dataset (No Imputed Data)				
Self-perceived health			n.a.	0.04‡
Excellent, No. / Total (%)	13/764 (1.7)	12/1215 (1.0)		
Very good, No. / Total (%)	114/764 (14.9)	148/1215 (12.2)		
Good, No. / Total (%)	507/764 (66.4)	790/1215 (65.0)		
Fair, No. / Total (%)	123/764 (16.1)	242/1215 (19.9)		
Poor, No. / Total (%)	7/764 (0.9)	23/1215 (1.9)		
Self-reported basic activities of daily living				
Need for human assistance, No/ Total (%)	32/763 (4.2)	53/1212 (4.4)	0.94 (0.60-1.49)	0.81

[a] CI denotes confidence interval; n.a. not applicable. Odds Ratio based on logistic general estimation equation (GEE) model adjusted for cluster household. Control group is reference group.
[b] Missing information was imputed for the analyses, using a multiple imputation technique.
[c] *P* Value from overall test using logistic regression adjusted for cluster household.

Table S9. Secondary Outcomes at 2-Year Follow-up: Persons Permanently Admitted to Nursing Home.[a]

Outcome	Intervention Group (n=874)	Control Group (n=1410)	Odds Ratio (95% CI)[b]	*P* Value[c]
Nursing home admission				
Nursing home admission, No./ Total (%)	12/831 (1.4)	26/1338 (1.9)	0.74 (0.37-1.48)	0.39

[a] This Table does not include imputed data. CI denotes confidence interval. Information was missing for persons of practice withdrawn from the project (see Fig 1, for numbers of persons withdrawn). The denominator also includes persons who died within the two-year follow-up period; for these persons we recorded whether they were permanently admitted to a nursing home prior to death.
[b] Odds ratio based on logistic general estimation equation (GEE) model adjusted for cluster household. Control group is reference group.
[c] P Value from overall test using logistic regression adjusted for cluster household with intervention as outcome.

Table S10 Survival Analyeses: Sensitivity Analyses with Adjustment for Selected Individual Base-Line Variables

Table S10A. Survival Analysis Adjusted for Availability of Caregiver at Base-Line.

Parameter	Level	Hazard Ratio[a] (95%CI)	*P* value
Group allocation	Control	Reference	
	Intervention	0.79 (0.67, 0.94)	0.009
Availability of caregiver if needed	Yes	Reference	
	No	1.18 (0.92, 1.51)	0.20

[a]Hazard ratios from Cox regression model adjusted for household cluster. CI denotes confidence interval.

Table S10B. Survival Analysis Adjusted for Base-Line Self-Perceived Health Status.

Parameter	Level	Hazard Ratio* (95%CI)	*P* value
Group allocation	Control	Reference	
	Intervention	0.83 (0.70, 0.98)	0.03
Self-perceived health	Excellent	Reference	<0.001[b]
	Very good	1.07 (0.49, 2.35)	
	Good	1.75 (0.84, 3.67)	
	Fair	3.98 (1.89, 8.35)	
	Poor	8.18 (3.09, 21.67)	

[a]Hazard ratios from Cox regression model adjusted for household cluster. CI denotes confidence interval.
[b]p-value from Wald test of composite hypothesis that all self-perceived health levels are equal to zero on log hazard scale

Table S11. Estimation of Costs for Providing the Intervention.[a]

Cost Element	Basis for Calculation	Year 1: Mean Time per Participant (Minutes)	Year 1: Cost per Participant (CHF)	Year 2: Mean Time per Participant (Minutes)	Year 2: Cost per Participant (CHF)
1. HRA-O questionnaire and reports	**Administrative intervention costs related to use of the HRA-O system**				
Selecting patients from practice register and generating an address list of patients to be invited for the intervention	Reimbursement given to primary care physicians	n.a.	CHF 2.65	n.a.	CHF 0.00
Mailing of personal invitation with brief questionnaire to participants, and data entry of completed brief questionnaires	Amount charged by service provider	n.a.	CHF 5.90	0.0	CHF 0.00
Mailing of HRA-O questionnaire to participants, return mailing of completed HRA-O questionnaires to service provider, and data entry of completed HRA-O questionnaires	Amount charged by service provider	n.a.	CHF 15.90	n.a.	CHF 15.90
Generating individualized computer-generated HRA-O participant and provider reports, mailing participant reports to participants, and mailing of provider reports to primary care physicians and nurse counsellors	Amount charged by service provider	n.a.	CHF 7.64	n.a.	CHF 7.64
Subtotal for HRA-O questionnaire and reports			**CHF 32.09**		**CHF 23.54**
2. Health professionals[b]	**Costs for health professionals (nurse counsellors, PCPs, and geriatricians)**				
A. Nurse counsellors					
Home visits	Time of nurse counsellor per participant used for conducting home visits based on intervention records of participants who received the full intervention	105.2 minutes	CHF 97.31	128.1 minutes	CHF 118.49
Travel time	Time of nurse counsellor per participant used for travel (calculated from number of home visits per participant multiplied by estimated average travel time of 15 minutes per visit)	33.9 minutes	CHF 31.36	45.0 minutes	CHF 41.63

Table S11-continued. Estimation of Costs for Providing the Intervention.[a]

Telephone contacts	Time of nurse counsellor per participant used for telephone contacts based on intervention records of participants who received the full intervention	18.6 minutes	CHF 17.21	1.2 minutes	CHF 1.11
Case reviews with geriatricians and primary care physicians	Time of nurse counsellor per participant for conducting case reviews	20.0 minutes	CHF 18.50	20.0 minutes	CHF 18.50
Weekly training sessions with senior nurse counselor	Time of nurse counsellor per participant for participating in weekly training (estimate is 40 one-hour training sessions per year, case load 200 participants per nurse counsellor)	12.0 minutes	CHF 11.10	12.0 minutes	CHF 11.10
Administrative time	Calculated as 60% of time used for counselling and conducting case reviews (includes preparation and documentation)	86.3 minutes	CHF 79.81	89.6 minutes	CHF 82.88
Overhead	25% of nurse counsellor salary costs	n.a.	CHF 63.83	n.a.	CHF 68.43
Travel expenses	Includes travel expenses (number of home visits per participant multiplied by CHF 16.50, based on an average travel distance of 15 km per home visits and part of per diem reimbursement for meals)	n.a.	CHF 37.52	n.a.	CHF 49.50
Cost for support by senior nurse counselor	Cost for senior nurse counsellor for weekly one-hour training (40 one-hour training sessions per year, case load 200 participants per nurse counsellor; cost of senior health counsellor time CHF 60.95/hour plus 25% overhead)	n.a.	CHF 15.24	n.a.	CHF 15.24
Initial one-week training	Total cost per participant for time of nurse counsellor preparing and attending the initial one-week training, and for providing this training (calculated for a two-year employment period, case load of 200 participants)	n.a.	CHF 17.28	n.a.	CHF 17.28

Table S11-continued. Estimation of Costs for Providing the Intervention.[a]

B. PCPs[c]					
Case reviews with nurse counsellors	Time of PCP per participant per study year (estimate)	5.0 minutes	CHF 14.95	5.0 minutes	CHF 14.95
Participation in initial and quarterly training session with geriatrician	Time of PCP back-calculated per participant for participating in initial (2 hour) and quarterly (1/2 hour) training session (case load of 50 participants per PCP)	4.8 minutes	CHF 14.35	2.4 minutes	CHF 7.18
C. Geriatricians					
Case reviews with nurse counsellors	Time of geriatrician per participant per study year (estimate)	15.0 minutes	CHF 25.98	15.0 minutes	CHF 25.98
Training sessions with PCPs and specialist advice to PCPs	Time of geriatrician per participant per study year (estimate)	5.0 minutes	CHF 8.66	5.0 minutes	CHF 8.66
Overhead	25% of geriatrician salary costs	n.a.	CHF 8.66	n.a.	CHF 8.66
Subtotal for health professionals		**n.a.**	**CHF 461.76**	**n.a.**	**CHF 489.59**
3. Total		**n.a.**	**CHF 493.85**	**n.a.**	**CHF 513.13**

Conversion to USD (Conversion Rate, Mar 16, 2015: 1 CHF [Swiss Franc] = 1.01 USD [U.S. Dollar]).

	Year 1: Cost per Participant	**Year 2: Cost per Participant**	**Year 1 + 2: Cost per Participant**
Subtotal for HRA-O questionnaire and reports	**USD 32.41**	**USD 23.78**	**USD 56.19**
Subtotal for health professionals	**USD 466.38**	**USD 494.49**	**USD 960.87**
Total	**USD 498.79**	**USD 518.27**	**USD 1017.06**

[a] HRA-O denotes Health Risk Appraisal for Older Persons, PCP denotes primary care physician, n.a. denotes not applicable.

[b] The following salary costs per one hour health professional time were used: nurse counsellor CHF 55.50; geriatrician CHF 103.90. Costs for conducting the research part of the project, and licensing fees for commercial use of instruments and software are not included in the calculation.

[c] PCP time does not take into account time used for counselling or for implementing the intervention as part of routine clinical care. For cost of PCPs, the reimbursement covered by basic health insurance (2014) for a 5 minute primary care physician consultation was used in this calculation (costs are hypothetical, PCPs did not receive additional reimbursement for implementing the intervention; PCP time for case discussions and training sessions were recognized as part of compulsory continuing medical education