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The effect of preventive consultations on young adults with psychosocial problems. A randomized trial

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Abstract

Patients with many problems often face difficulties in modifying their behavior as desired. Uncovered basic needs may be an important barrier. This research tests the effect of patient-centered consultations for 20- to 44-year-old patients with multiple psychosocial and lifestyle problems. We focus on resources and barriers for obtaining self-chosen goals within life circumstances and lifestyle. At 28 general practitioners, 2056 patients aged 20–44 years were screened with a 33-item problem-score on resources, network, lifestyle and social conditions. The 30% who had most problems were invited to complete a more comprehensive questionnaire at home. Intervention was preventive consultation with a 3-month follow-up. A total of 495 patients were randomized. One-year questionnaire follow-up showed significant improvement in Short Form Health-related Quality of Life Mental (MCS-SF12) in the intervention group (7.3) compared with the control group (3.0); the difference was 4.3 (95% confidence interval 1.6–7.0, \( P = 0.002 \)). The number of problems was reduced significantly more in the intervention than in the control group (1.8 versus 0.8, \( P = 0.03 \)). Preventive consultation focusing on resources and barriers to self-chosen goals may improve MCS-SF12 and decrease the number of problems in patients with many psychosocial and lifestyle problems. This may be an indicator of improved specific self-efficacy and a key to lifestyle changes.

Background

We are currently witnessing a worldwide increase in lifestyle diseases, e.g. obesity, type 2 diabetes, vascular diseases and psychological and psychiatric problems [1, 2]. Changes in lifestyle regarding food, exercise and tobacco and alcohol consumption are widely recommended, but improvements are rarely achieved [1, 3]. Political regulation is recommended to make the healthy choice an easy choice [1]. Most people with multiple psychosocial problems find it difficult to change their behavior in response to information about risky lifestyle, in some cases because the user perceives the behavior, e.g. use of a stimulant like nicotine and alcohol, as a solution rather than a problem. Sometimes, an adverse reaction to information and advice is seen [4, 5].

Maslow’s theory ‘Hierarchy of needs’ offers some explanation about why people with unmet basic needs may not profit from preventive counseling focused on risk (Fig. 1) [6]. Maslow’s hierarchy implies that lower needs must be met before higher needs emerge. Unmet needs result in a state of tension and anxiety, that is, they hinder self-esteem, which lies at the root of self-actualization [7, 8]. Self-efficacy theory as described and explored in several studies provides explicit guidelines for how to enable people to exercise some influence over...
how they live their lives and how to foster desired change [9]. Perceived self-efficacy is concerned with judgment of personal capacity. Belief in own capability has a powerful effect on behavior [10, 11].

According to Antonovsky [12], attention should be paid to the origin of health (salutogenesis) rather than solely to the origin of disease (pathogenesis). A salutogenetic perspective seems to be especially important in health promotion targeted at people with extensive psychosocial problems since coping is related to social gradients such as knowledge, intelligence, social network, self-rated health, self-identity, security and confidence.

In 1987–88, we carried out a non-randomized study on the effect of a preventive health consultation offered to a random sample of 1000 adults at 20, 35, 55 and 75 years of age at 45 general practitioners (GPs) [13, 14]. The participants completed a postal questionnaire at home about their lifestyle, social, physical and mental situation as a basis for a patient-centered consultation at their GP, where illness, problems, goals and possible solutions were written down during the consultation. At the 6-month postal follow-up, a more positive attitude to own responsibility for health improvement was found and more than 15% had made changes. Another 10% considered undertaking some changes in lifestyle or living conditions. Especially young people with social problems made changes with regard to social aspects [13].

The Secretary of Health and Prevention in the County of Northern Jutland asked us to design a new preventive study in general practice targeted at younger adults with psychosocial and lifestyle problems in order to identify and change lifestyle or life circumstances that might result in problems or illness. So we grasped the opportunity to design a new working method focused on young patients with many problems and lack of resources who find it difficult to make the healthy choices.

**Aim of the study**

The aim of the present study is to evaluate the effect of two preventive health consultations on health-related quality of life and lifestyle among 20- to 44-year-olds with multiple psychosocial and lifestyle problems measured by the Short Form Health-related Quality of Life Mental (MCS–SF–12) and on their goal setting, self-rated health and changes in unhealthy lifestyle.

**Methods**

In 1998, motivational interviewing (MI) was not in focus in general practice in Denmark, but the
patient-centered approach to consultation was being advocated [15]. This approach implies that responsibility for defining problems and making change resides with the patient. MI is a client-centered directive method for enhancing a patient’s internal motivation for change by exploring and resolving the patient’s ambivalence toward a specific problem. MI was developed to be used in the addiction field, but it may be used for less directive purposes as well, such as defining and prioritizing among problems. It has three main components: collaboration, evocation and autonomy [16]. The approach used in this study deploys these three elements. It does not focus on a predetermined problem, but on those problems prioritized by the patient after filling in a questionnaire at home about his or her psychosocial and lifestyle situation. MI was conducted within the context of two structured health consultations that sought to strengthen the patient’s specific self-efficacy to reach self-chosen goals by describing his or her perception of specific resources and barriers to goal achievement [9, 16–18].

**Consort statement**

The study was planned, performed and reported in accordance with Stuart Pocock and the Consort Statement [19, 20].

**General practitioners**

In 1997, all 325 GPs in the County of North Jutland, which has a total catchment population of 410,000, were invited to participate. A total of 50 GPs, 15% of those invited, attended a pre-study weekend course and 28 of these GPs included patients into the study. Most of the GPs were working in group practices with two to four GPs. Ten GPs (36%) were working in a single-handed practice, which is a percentage share representative of Denmark as such. Danish primary health care was and still is organized as a fully tax-financed list system, where GPs are paid a fee for each consultation (about two-thirds of salary) and each patient on the list (about one-third of salary). The GPs were separately paid by the County for the time they used on courses and health consultations in this study.

**GP education**

All participating GPs attended an initial weekend course and were offered another three 4- to 8-hour sessions for discussion of issues related to cardiovascular disease, alcohol, smoking and drug addiction, and two evening follow-up courses to discuss the study and the GP’s new role. A total of 40 hours of preventive health education was thus provided. The topics of the courses reflected the eclectic everyday of general practice and contained elements from development psychology, understanding the interaction between personality and behavior, illness and disease models, gate-control theory in chronic pain, occupational medicine and lifestyle diseases. Emphasis was placed on the patient’s responsibility for defining his or her own problems and desires in a process where the GP served as facilitator. The ‘stages of change’ model was discussed [21]. The issue of patients’ self-assessed health resources was raised and discussed [22]. Lectures, group discussion, case studies and written material were used during these courses. MI was not mentioned, but the three elements of MI were thoroughly discussed as fundamental to the communication style in order to guide and elicit internal motivation for change.

**Patients and setting**

On specific days of each month from May 1998 to November 1999, patients aged from 20 to 44 years were consecutively invited to participate in the study when they visited the clinic for an ordinary consultation [23]. The staff enrolled participants, obtained informed written consent and handed out a pre-trial screening questionnaire (SQ) to be completed at the clinic. Only patients with difficulties understanding Danish, patients with severe psychiatric problems or severe acute illness were excluded. All patients had the scheduled consultation with their GP on the day they completed the SQ but did not discuss the SQ with the GP on that occasion. Recruitment stopped after 18 months as planned.

**Questionnaires**

The 33-item pre-trial SQ was constructed using standardized questions from Danish and international
questionnaires about personal resources, network, lifestyle, social and family problems. A few self-constructed questions in accordance with these studies were added to the SQ (see appendix) [24–28]. A pre-trial pilot study conducted in four clinics with seven to eight patients each indicated that a cutoff at seven problems would include the most problematic quartile of the patients. In the study, this cut-off included 30% of the total patient population. Patients with seven or more problems in SQ were invited to participate in the study and to complete a 23-page baseline questionnaire (BQ) with 84 questions. The BQ was completed at home and included questions on desires for change in lifestyle and social situation and goals for the coming year. The BQ was constructed similarly to SQ using standardized questions on social information, SF12, self-rated health, diet, lifestyle, use of alcohol, tobacco and medicine [12–14,24–31]. To describe resources, we had to construct some questions in relation to these international studies and our more than 20 years of experience as GPs [13, 14, 23]. These questions are not used for statistical purpose, but they offer a holistic picture of the participant. One year after the first health consultation, a comparable postal 1-year questionnaire (Q1) with a few additional questions on the participant’s evaluation of the health consultations was returned by the participant.

**Patient randomization and allocation concealment**

When the completed BQ was returned to the clinic, the staff phoned the project secretary to get a patient number from a GP-related computer-generated list of random numbers used consecutively [20]. All even numbers were controls and odd numbers intervention patients. Thus, the GPs had no influence on allocation, and neither GPs nor the patients were blinded.

**Patient intervention**

The intervention was a structured 1-hour preventive consultation with the patient’s own GP and a 20-min follow-up within 3 months based on the BQ. The topics for the consultations were chosen by the patient. GPs were recommended to skim the BQ and then start by asking the following questions ‘How was it like to complete the questionnaire?’ and ‘What do you prefer to discuss?’ Completing the BQ was supposed to facilitate insight into the relationship between social life, health, lifestyle, own reaction on stressors and resources and barriers for gaining control and changing behavior. This insight made it easier for the GPs to offer patient-centered counseling. At the end of the consultation, the GP and the patient together made a written report of their general impression of the consultation, general health, resources, network and lifestyle. The patient might choose one or two goals for a better life among 14 predetermined choices and one free choice. Goals setting, time schedule and specific resources and barriers for reaching the goals were discussed and shortly described in the three-page report. A follow-up at 3 months was arranged. Needs for other interventions were discussed. Blood pressure and body mass index (BMI) were measured and, if indicated, blood sugar, cholesterol and urine were examined.

**Control**

The control group had no specific health consultations. They saw their GP for the predetermined consultation on the day of inclusion and had the possibility to see their GP later as usual.

**Outcome measures**

The primary endpoint was change in health-related quality of life after 1 year measured with the internationally standardized and validated SF12 survey. Self-rated health is an independent predictor of mortality [29]. Self-rated health and health-related quality of life are often used as outcome measures in intervention studies [29–31]. The scoring of the SF12 questionnaire is constructed to give a score of 50 and a standard deviation (SD) of 10 in a standardized American population for the Mental Component Score (MCS) and the same for the Physical Component Score (PCS). The higher the score, the better the quality of life [30].

Secondary outcomes were (i) participation in the preventive health consultation, (ii) goal-setting, (iii)
self-rated health, (iv) changes in number of problems and (v) lifestyle changes.

Sample size calculation
A clinically relevant difference in SF12 score was defined as half a SD (five points) or an effect size (z-score) of 0.5, categorized as a medium effect size by Cohen [32]. With a power of 90% and a significance level of 5%, this means that at least 160 patients in each group should be evaluated.

Statistical methods
Data analysis was carried out according to a pre-established plan as intention-to-treat analysis using SPSS version 16 and confidence interval (CI) analysis for windows [33]. The 95% CI is stated whenever relevant. SF12 scores were calculated according to the SF12 recommendations at baseline and after one year.

Differences in change were compared by using Student t-test, Mann–Whitney U-test, Kendall’s tau and Chi-square test. Two-sided significance tests were used throughout and \( P < 0.05 \) was considered statistically significant. The analyses were carried out for all who returned the 1-year questionnaire. Analysis comparing baseline information on completers and dropouts was performed. To test the absence of cluster effect (consistency between GPs), we performed a subgroup analysis on the MCS-SF12 score for GPs with 10 or more included patients using ANOVA and a box plot. A linear regression model was used to analyze the effect of intervention on the MCS-SF12 while controlling for sex and age group.

Results

Participation
We intended to screen 2073 patients by using the SQ. A total of 2056 completed the SQ of whom 625 (30%) had seven or more problems; 75% were women. The most common problems were ‘Difficulties in finding solutions to daily life problems’ (65%), ‘Lack of time to oneself’ (64%), ‘Low physical activity’ (58%), ‘Being a daily smoker’ (57%) and ‘Having fair or poor self-rated health’ (56%) [23]. All 625 patients were invited to participate in the randomized trial by completing the BQ. A total of 130 (21%) did not return the BQ, which left 495 for randomization: 240 in the intervention group and 255 in the control group (Fig. 2). The 130 baseline non-responders were 1.5 years younger (95% CI 0.2–2.8) and they were more often smokers (93/130, 72%) than the responders (265/485, 55%) (Difference = 17%, 95% CI 7–25) (Table I).

No differences in baseline demographic and clinical characteristics of the intervention and control groups were found (Table I). The outcome analysis after 1 year involved all randomized patients meeting the inclusion criteria who returned the 1-year questionnaire (\( n = 364, 74\% \)). Seventy-one patients (28%) in the control group and 60 (25%) in the intervention group were lost to follow-up after 1 year (Fig. 2); 46 of the 60 had a preventive health consultation. The reasons for missing follow-up were: moved to another district (\( n = 24 \)), did not want to participate (\( n = 16 \)) and unknown (\( n = 91 \)).

Thirty-one (13%) of the 240 patients randomized to a health consultation did not receive the preventive consultation for different reasons (no problems anymore, withdrew their consent, no time, or moved to another location). Another 58 (24%) did not have the 3-month follow-up consultation for similar reasons (\( n = 43 \)) or after agreement with their GP (\( n = 15 \)) (Fig. 2). Nobody in the control group received the formal 1-hour health consultation or the follow-up consultation.

Main outcome measures
One year after the consultation, we found improvement in MCS-SF12 both in the control and in the intervention group (Table II). The intervention group improved about twice as much as the control group. The difference of 4.3 (1.6–6.9) was significant (\( P = 0.002 \)). No difference was found in the PSC-SF12 (Table II). A total of 12 patients (three interventions and nine controls) had no SF12 scores because a value was missing in one or more questions in the SF12-questionnaire.

An ANOVA analysis at the GP level on the 21 GPs with 10 or more included patients found that the improvement in MCS-SF12 was consistent
among the GPs. The box plot (Fig. 3) showed mean improvement in 19 of the 21 GPs.

**Secondary outcomes**

**Goal setting**

During the preventive health consultations, 191 of the 209 participants (91%) (95% CI 87–95) chose one or two goals for a better life for the coming year. The most frequent goals were weight loss ($n = 58/209, 28\%$), better psychological health ($n = 51, 21\%$), better partner relationship ($n = 41, 20\%$), better work situation ($n = 38, 18\%$) and less tobacco consumption ($n = 33, 16\%$). Only 18 (9\%) set no goals.

**Self-rated health**

In both groups (intervention and control), self-rated health had improved (intervention: 54/180, 30%; control: 46/184, 25\%) more than it had deteriorated (intervention: 26/180, 14%; control: 38/184, 21\%) after 1 year (Table III). A trend toward better
Table I. Baseline characteristics of all pre-trial screened patients, dropouts before randomization and the randomized groups

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>All pre-trial screened patients (n = 2056)a</th>
<th>Not randomizedb (n = 130)</th>
<th>Randomized to health consultation group (n = 240)</th>
<th>Randomized to control group (n = 255)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, mean (SD)</td>
<td>32.7 (6.7)</td>
<td>33.2 (6.8)</td>
<td>34.2 (6.7)</td>
<td>35.1 (6.6)</td>
</tr>
<tr>
<td>Female, n/total</td>
<td>1505/2056 (73%)</td>
<td>91/130 (70%)</td>
<td>171/240 (71%)</td>
<td>192/255 (75%)</td>
</tr>
<tr>
<td>Not good self-rated health (fair, poor or very poor), n/total</td>
<td>579/2056 (28%)</td>
<td>64/130 (49%)</td>
<td>139/234 (59%)</td>
<td>143/249 (57%)</td>
</tr>
<tr>
<td>Number of problems in pre-trial SQ of a maximum of 33, mean (SD)</td>
<td>5.2 (4.0)</td>
<td>10.3 (3.6)</td>
<td>10.0 (3.1)</td>
<td>10.3 (3.2)</td>
</tr>
<tr>
<td>Unemployed (patient or partner &gt; 1 year the last 3 years)</td>
<td>276/2056 (13%)</td>
<td>31/130 (24%)</td>
<td>62/235 (26%)</td>
<td>66/250 (26%)</td>
</tr>
<tr>
<td>Problems in partner relationship, n/total</td>
<td>186/2056 (9%)</td>
<td>39/130 (30%)</td>
<td>54/235 (23%)</td>
<td>58/250 (23%)</td>
</tr>
<tr>
<td>Daily use of tobacco, n/total</td>
<td>760/2056 (37%)</td>
<td>93/130 (72%)</td>
<td>127/235 (54%)</td>
<td>138/250 (57%)</td>
</tr>
<tr>
<td>MCS SF-12 scorec, mental health, mean (SD)</td>
<td>Not asked</td>
<td>Not asked</td>
<td>40.0 (11.4)</td>
<td>40.2 (11.1)</td>
</tr>
<tr>
<td>PCS SF-12 scorec, physical health, mean (SD)</td>
<td>Not asked</td>
<td>Not asked</td>
<td>48.1 (10.8)</td>
<td>47.7 (10.7)</td>
</tr>
</tbody>
</table>

a17 patients did not complete the pre-trial SQ.
b130 not randomized because of no consent or no completed BQ.
c12 patients had missing value in the SF12 score, n = number of patients.

Table II. Physical component score and mental component score SF12 after 1 year

<table>
<thead>
<tr>
<th>Intervention n = 177</th>
<th>Control n = 176</th>
<th>Difference between groups, Student t-test (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>SF12 PCS (SD)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline</td>
<td>47.2 (11.4)</td>
<td>47.3 (10.8)</td>
</tr>
<tr>
<td>1 year</td>
<td>48.2 (10.0)</td>
<td>48.3 (10.0)</td>
</tr>
<tr>
<td>Difference (1-year baseline)</td>
<td>1.0</td>
<td>1.0</td>
</tr>
<tr>
<td>Difference = 0.01 (−1.8 to 1.9), P = 0.99, NS</td>
<td>Difference = 4.3 (1.6–6.9), P = 0.002</td>
<td></td>
</tr>
</tbody>
</table>

| SF12 MCS (SD)        |                |                                                   |
| Baseline             | 39.6 (11.2)    | 41.5 (10.8)                                       |
| 1 year               | 46.8 (10.6)    | 44.5 (11.1)                                       |
| Difference (1-year baseline) | 7.3           | 3.0                                                |

n = number of patients

self-evaluated health in the intervention group was seen (Mann–Whitney test, P = 0.085).

Number of problems

At 1-year follow-up, the total number of problems revealed in the SQ was significantly reduced in the intervention group (10.0–8.2 = 1.8 problems) compared with the control group (10.1–9.3 = 0.8 problems), difference = 1.0 (95% CI 0.17–1.83) (Table III).

Lifestyle changes

The 85 participants in the intervention group with a BMI of 25 or more had a mean weight loss of 2.9 kg compared with 1.5 kg among 75 overweight
participants in the control group. This difference of 1.4 kg was not statistically significant, but a weight loss like this over 1 year can be clinically important if continued (Table III). A trend toward reported healthier lifestyle was seen in the intervention group compared with the control group: they ate more fiber, did more exercise and smoked and drank less (Table III).

**Positive or adverse effects**

At the 1-year follow-up, participants were asked: ‘Has completing the questionnaires or participating in the health consultations had any effect on your life during the past year?’ In the intervention group, 92 (51%) said yes compared with 27 (15%) in the control group. This difference of 0.36 was significant (Table IV).

In the intervention group, 72/92 (78%) experienced a positive effect on well-being and only three (3%) reported a negative effect on mood, resources, sleep and relations to children or work.

In the intervention group, 91/180 (51%) had experienced some positive effects of their participation while 24 (13%) reported some negative effect (Table IV). In summary, 80 (44%) in the intervention group experienced more positive than negative effects, 9 (5%) were more negative than positive and 91 (51%) were neutral compared with 22 (12%) positive and two (1%) negative in the control group (Table IV). Thus, the number needed to treat (benefit) was $1/(0.44-0.12) = 3.1$ and the number needed to harm was $1/(0.05-0.01) = 25$.

The intervention group was asked, ‘Do you think that the preventive health consultations were worth the trouble?’ A total of 75 (42%) answered ‘Yes, to a high degree’, 67 (37%) said ‘Yes, to some degree’, 21 (12%) said ‘No’ and 17 of the 180 (9%) respondents did not answer this question.
Dropouts at 1 year

Among the 131 dropouts at the 1-year follow-up, significantly more were men than women and the dropout group had significantly better physical health measured by the PCS SF12 at baseline (Table V); but no significant difference in lifestyle, that is use of tobacco, was observed.

A linear regression analysis showed that after controlling for gender and age group, the intervention still had a significant effect on differences in mental score (MCS-SF12) between intervention and control group (Beta = −0.16, P = 0.003).

Discussion

Principal findings

In a group of 20- to 44-year-olds with several problems experienced a significant positive effect of a 1-hour patient-centered structured preventive consultation and a 20-min follow-up with their own GP on their mental health-related quality of life (MCS-SF12) when measured after 1 year. The intervention group also reported fewer resource problems and lifestyle problems than the control group. The patients did not focus mainly on physical health and we found no effect on this measure (PCS-SF12). We found tendencies toward improvement in some lifestyle factors. At the consultation, 91% (191/209) defined one or two goals for a better life for the coming year. A total of 79% (142/180) of the intervention group found that their participation had been ‘worth the trouble’.

Strengths and weaknesses

Outcome measures are ‘self-reported’ without blinding. The results can therefore be biased in several ways, for example, in the perception of own lifestyle and changes over time. The perception of lifestyle and change achieved could be influenced by the allocation group. On the other hand, numerous trials have shown that the SF12-questionnaire is a valid measure of health-related quality of life within different health specialties [34–36]. The bias that would arise if patients wished to please their GP was minimized by using a postal questionnaire at the 1-year assessment and by the sender being a research institution.

The ‘dropout’ in the trial is a problem. The non-participation of 130 eligible patients before the randomization represents a minor problem. Interestingly, this group comprised more smokers (72%) than the group of participants (55%) (Difference = 17%, 95% CI 8–25%) (Table I).

The 131 1-year dropouts is a problem, but they had the same problem profile, the same number of problems and the same mental health score (MCS-SF12). They were more often men and had a better
Table IV. Positive and negative effect of participation in the study

<table>
<thead>
<tr>
<th>Question 1</th>
<th>Health consultation, n = 180</th>
<th>Control group, n = 184</th>
<th>Difference, (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Effect of participation?</td>
<td>Yes 92 (51%)</td>
<td>Yes 27 (15%)</td>
<td>Differences = 36% (27–45), Chi-square test: P &lt; 0.0001</td>
</tr>
<tr>
<td>If yes</td>
<td>No 84 (47%)</td>
<td>No 152 (82%)</td>
<td></td>
</tr>
<tr>
<td>(No answer 4)</td>
<td>(No answer 5)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>A1: Effect on physical health</td>
<td>Positive effect 50 (54%)</td>
<td>Positive 14 (52%)</td>
<td>Not relevant</td>
</tr>
<tr>
<td>(mood, resources, sleep, relation to my children and work)</td>
<td>Negative effect 14 (15%)</td>
<td>Negative 3 (11%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>No answer 28</td>
<td>No answer 10</td>
<td></td>
</tr>
<tr>
<td>A2: Effect on well-being</td>
<td>Positive effect 72 (78%)</td>
<td>Positive 21/27 (78%)</td>
<td>Not relevant</td>
</tr>
<tr>
<td></td>
<td>Negative effect 3 (3%)</td>
<td>Negative 2/27 (7%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>No answer 17</td>
<td>No answer 4</td>
<td></td>
</tr>
<tr>
<td>A3: Effect on use of tobacco, alcohol or misuse of drugs</td>
<td>Positive effect 33 (36%)</td>
<td>Positive 10/27 (37%)</td>
<td>Not relevant</td>
</tr>
<tr>
<td></td>
<td>Negative effect 15 (16%)</td>
<td>Negative 5/27 (19%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>No answer 44</td>
<td>No answer 12</td>
<td></td>
</tr>
<tr>
<td>A4: Other effects</td>
<td>Positive effect 19 (11%)</td>
<td>Positive 6/27 (22%)</td>
<td>Not relevant</td>
</tr>
<tr>
<td></td>
<td>Negative effect 4 (2%)</td>
<td>Negative 0/27</td>
<td></td>
</tr>
<tr>
<td></td>
<td>No answer 69</td>
<td>No answer 21</td>
<td></td>
</tr>
<tr>
<td>All randomized</td>
<td>n = 180</td>
<td>n = 184</td>
<td></td>
</tr>
<tr>
<td>Some positive effect in A1 to A4 (Scale 1–4)</td>
<td>Some positive effect 91/180 (51%)</td>
<td>Some positive 24/184 (13%)</td>
<td>Differences = 38%, (28–46), Kendall’s tau: P &lt; 0.0001</td>
</tr>
<tr>
<td>Some negative effect in A1 to A4 (Scale 1–4)</td>
<td>Some negative effect 24/180 (13%)</td>
<td>Some negative 8/184 (4.3%)</td>
<td>Differences = 9% (3–15), Kendall’s tau: P = 0.002</td>
</tr>
<tr>
<td>Sum of A1 to A4 (positive effects – negative effects)</td>
<td>Sum positive 80/180 (44%)</td>
<td>Sum positive 22/184 (12%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Sum neutral 91/180 (51%)</td>
<td>Sum neutral 160/184 (87%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Sum negative 9/180 (5%)</td>
<td>Sum negative 2/184 (1%)</td>
<td></td>
</tr>
</tbody>
</table>

Answers to question 1: ‘Has completing the questionnaires or participation in the health consultation had any positive or negative effect on your life the past year?’.

n = number of patients, NS = not significant.

Table V. Comparison at baseline between 364 patients completing the study and 131 dropouts after the randomization

<table>
<thead>
<tr>
<th>Baseline value</th>
<th>Completed the study, n = 364</th>
<th>Dropout after randomization, n = 131</th>
<th>Differences, Student-t or Chi–Square test (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female, numbers</td>
<td>277/364 (76%)</td>
<td>86/131 (65%)</td>
<td>Differences = 11% (2 to 20), P = 0.02</td>
</tr>
<tr>
<td>Age (year), mean (SD)</td>
<td>34.3 (6.6)</td>
<td>33.4 (6.8)</td>
<td>Differences = −0.9 (−2.3 to 0.4), P = 0.17 (NS)</td>
</tr>
<tr>
<td>Total number of problems at baseline, mean (SD)</td>
<td>10.1 (3.0)</td>
<td>10.4 (3.2)</td>
<td>Differences = 0.35 (−0.3 to 1.0), P = 0.26 (NS)</td>
</tr>
<tr>
<td>Daily smoker (missing n = 10)</td>
<td>190/357 (53%)</td>
<td>75/128 (59%)</td>
<td>Differences = 5.4% (−5 to 15), P = 0.30 (NS)</td>
</tr>
<tr>
<td>n = 355</td>
<td>n = 128</td>
<td></td>
<td></td>
</tr>
<tr>
<td>MCS SF12, mean (SD)</td>
<td>40.6 (11.0)</td>
<td>38.7 (11.7)</td>
<td>Differences = −1.8 (−4.1 to 0.47), P = 0.12 (NS)</td>
</tr>
<tr>
<td>PCS SF12, mean (SD)</td>
<td>47.3 (11.1)</td>
<td>49.5 (9.6)</td>
<td>Differences = 2.3 (0.2 to 4.3), P = 0.04</td>
</tr>
</tbody>
</table>

n = number of patients, NS = not significant, MCS-SF12 = Mental Component Score of SF12, PCS-SF12 = Physical Component Score of SF12.
physical health (PCS-SF12) than the participants (Table V). The dropout rate was about the same in the two groups: 71/255 (28%) in the control and 60/240 (25%) in the intervention group (Fig. 2). The regression analysis controlling for sex and age group did not change the found effect of intervention. We therefore believe that the difference between intervention and control is not affected by dropouts. A dropout of 20–30% was expected in this group of young patients, which had been selected because they had many problems and few resources. In this light, a follow-up rate of 0.74 must be considered satisfactory.

The questionnaires were based on previous research. They were pilot-tested in four clinics before the trial. We had no resources to conduct a new genuine psychometric validation process. We find this acceptable because the questionnaires were mainly used to prime the patient before the consultation and only for some validated questions to compare their status before and after the intervention.

Some of the found improvement could represent ‘regression to the mean’, both in number of problems and in the SF12, as the participants were selected from among those who had many problems. Some of the improvement in the control group might be an effect of completing the questionnaires and their GPs’ participation in the project. This ‘rub-off effect’ might have decreased the difference between the groups. The ‘individually block-controlled randomized design’ with telephone randomization and comparable groups at baseline is a solid contribution to the internal validity of the trial. The use of a standardized well-validated and frequently used MCS-SF12 and PCS-SF12 strengthens the study [30]. The analysis at the GP level among 21 GPs with 10 or more included patients indicates a certain consistency of the findings. The CONSORT statement has been respected and intention to treat analysis was performed whenever data were available. The question may, of course, be raised whether our findings are unique. The intervention was carried out by ordinary ‘GPs with an interest in preventive health care’ as a part of their daily work in their clinics after courses (about 40 hours) that focused on lifestyle psychosocial aspects of life and individual reasons for making healthy and unhealthy choices. The questionnaires primed and helped patients and GPs to form a holistic view and the GP to be non-authoritative. Completion of the evaluation report during the last part of the consultation formed a supporting structure for clarifying general health, goals, resources and barriers. This structure supported the use of the three elements of MI in a patient-centered atmosphere. This working method can be adapted by most GPs.

Why did it take more than 10 years to report this study? Because clinical work had top priority, and the writing process have been more time consuming than expected.

Comparison with other studies

Many studies on MI have been published during the past 20 years. A systematic review of 72 studies using MI found a positive effect in 74% (53/72) [38]. None of the publications reported any adverse effects. One study was comparable with our study in several ways [39]. Their target group was the most affected (upper quartile in cholesterol). The physicians were trained in patient-centered counseling with elements of MI. After 1 year, the intervention group had a significantly better total cholesterol/high density lipoprotein ratio and a 2.3 kg larger weight loss than the non-intervention group. Their intervention required 8–10 minutes extra. The health subjects explored in our study were not predetermined but reflected the problems revealed during the consultation. Approximately 20 of the 60 minutes were used for completing the evaluation report.

Studies related to specific diseases show that change in cognitive measures predict change in health-related behavior [38, 40]. A small prospective study of psychological determinants of quality of life in patients with whiplash found a high correlation between the SF12 score and the self-efficacy scale (SES). Variation in SES could explain about 40% of the variation in the SF-12 [41].

Our study has a very different idea and study population than a Danish randomized study from primary care [42], which focused on biomedical
screening for traditional risk factors among 30- to 49-year-old inhabitants of the Ebeltoft municipality. About 25% had fair or bad self-rated health [43]. The patients’ goals were often related to weight, exercise or tobacco and only about 2–8% had goals involving psychological or family problems. In our study, 28% of the screened and 58% of the randomized patients had fair or bad self-rated health (Table I). The difference in self-rated health in the two study populations indicates that our design managed to include patients with most need of a preventive health consultation [23]. The high prevalence of smokers dropping out before randomization in our trial may indicate that even if our invitation underlined the individual support to achieve a better quality of life, some people with risky lifestyle will refuse the offer [4, 5]. The lack of lifestyle difference among the dropouts after randomization might, on the other hand, indicate that the holistic patient-centered approach was accepted by the randomized patients.

Studies have shown that a close relationship to the GP is essential for achieving improvements in health and for a well-functioning health care system and low health care costs [44, 45]. ‘Iatrogenesis’ where health professionals take responsibility for health and individual values may do damage to people’s health [46]. Self-esteem, which is fundamental to self-efficacy, will often be undermined and become negative if internal motivation to change is not elicited [47, 48].

We find that that the following factors are important in a health preventive consultation aiming at supporting self-efficacy: individual invitation from own GP to those in need, priming the patient with BQ revealing holistic aspects of life and filled in at home, patient-centered consultation using elements of MI regarding self-chosen goals and an evaluation scheme completed at the end of the consultation to describe resources, barriers and time schedule to obtain the goals. This provides a clear structure that supports specific self-efficacy in patients with many problems. Our finding of a marginally better self-rated health and a significantly improved MCS-SF12 indicates that the participants were empowered to better manage their psychosocial life as fundamental to improve their lifestyle.

### Conclusions

In a group of 20- to 44-year-olds with many unmet basic needs, two preventive health consultations with their own GP have shown to have an effect on mental health (MCS-SF12). This psychological improvement may be a key to reaching a higher level in the hierarchy of basic needs and hence to developing a solid basis for self-esteem and self-efficacy, for gaining more control, and maybe for developing healthier ways of living. GPs have to be aware of fundamental needs and problems among patients when changes in lifestyle or daily life are discussed.

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Conflict of interest statement

None declared.

References


People with few resources and unhealthy lifestyle have problems in profiting from advice on how to reduce risk factors. Basic needs have to be met before interest in lifestyle changes can be raised.

Box 1

What is already known on this topic

What this study adds

In structured patient-centered consultation focusing on psychosocial situation, resources and barriers, 9 of 10 participants with few resources chose one or two goals for a better life or lifestyle, achieved a better mental health (MCS SF12) and had fewer problems after 1 year. The number needed to benefit by health consultations was 3.1 and the number need to harm 25.
Appendix 1.

Problem Screening Questionnaire

In order to decide if you may profit from a one-hour preventive health consultation, I will kindly ask you to fill in this questionnaire as well as possible.

The questionnaire covers areas that are particularly important to thriving and to maintaining good health.

Please answer each question by ticking off the box that you feel best describes your situation.

**Please fill in the questionnaire as follows:**

Most of the questions should be answered by ticking off the box next to the answer that you feel best describes your situation.

- We prefer that you use a black roller or pencil
- Do not use a cross, but a big point.
- Figures and letters are best done like this:
- 

```
0123456789
A B C D E F G H I J K L M N O P Q R S T U V W X Y Z
```

What are you:  Male  Female
When were you born: Date  Month  Year

The GP fills in this section:

GP-number:  Number of problems:

Has the baseline questionnaire (BQ) been handed out:  Yes  No
If Yes, when  Date  Month  Year
I Yes, the number of the BQ
Resources

Please answer the following questions as well as you can by ticking off the box that best describes your situation:

1. In general, would you say your health is:

<table>
<thead>
<tr>
<th>Very good</th>
<th>Good</th>
<th>Fair</th>
<th>Poor</th>
<th>Very poor</th>
</tr>
</thead>
</table>

2. Do you feel well enough to be able to do what you would like to do?

<table>
<thead>
<tr>
<th>All the time</th>
<th>Most of the time</th>
<th>Some of the time</th>
<th>A little of the time</th>
<th>None of the time</th>
</tr>
</thead>
</table>

3. Do you think you know enough to be able to improve your thriving and your health?

<table>
<thead>
<tr>
<th>All the time</th>
<th>Most of the time</th>
<th>Some of the time</th>
<th>A little of the time</th>
<th>None of the time</th>
</tr>
</thead>
</table>

4. Do you feel appreciated by those you see on a daily basis?

<table>
<thead>
<tr>
<th>All the time</th>
<th>Most of the time</th>
<th>Some of the time</th>
<th>A little of the time</th>
<th>None of the time</th>
</tr>
</thead>
</table>

5. If you have a job, do you feel appreciated at work?

<table>
<thead>
<tr>
<th>All the time</th>
<th>Most of the time</th>
<th>Some of the time</th>
<th>A little of the time</th>
<th>None of the time</th>
</tr>
</thead>
</table>

6. Do you find it easy to find solutions to the problems and difficulties you meet in your everyday life?

<table>
<thead>
<tr>
<th>All the time</th>
<th>Most of the time</th>
<th>Some of the time</th>
<th>A little of the time</th>
<th>None of the time</th>
</tr>
</thead>
</table>

7. Do you feel that you are encountering significant mental problems during your everyday life?

<table>
<thead>
<tr>
<th>None of the time</th>
<th>A little of the time</th>
<th>Some of the time</th>
<th>Most of the time</th>
<th>All the time</th>
</tr>
</thead>
</table>

8. If you are having problems, do you then have somebody in your family whom you trust and with whom you talk about these problems?

<table>
<thead>
<tr>
<th>All the time</th>
<th>Most of the time</th>
<th>Some of the time</th>
<th>A little of the time</th>
<th>None of the time</th>
</tr>
</thead>
</table>

9. If you are having problems, do you then have somebody among your friends whom you trust and with whom you talk about these problems?

<table>
<thead>
<tr>
<th>All the time</th>
<th>Most of the time</th>
<th>Some of the time</th>
<th>A little of the time</th>
<th>None of the time</th>
</tr>
</thead>
</table>
Effect of preventive health consultation

**Lifestyle**

10. Do you feel so stressed-up several times during the week that you feel physically uncomfortable?  

11. Do you need time to tend to yourself during your daily life?  

12. Have you ever felt that you should reduce your consumption of beer, wine and spirits?  

13. Do you use tobacco on a daily basis?  

14. Do you use pain killers on a daily basis?  

15. Do you use drugs that have an addictive effect on a weekly basis (sleep medication, tranquilizers, hash, or narcotics)?  

16. Are vegetables only rarely part of your main course (i.e. less than three times a week)?  

17. Do you rarely exercise, i.e. less than four hours a week (walking, biking, sports, garden work and similar activities)?

**Family Life**

18. Are you living alone?  

19. Are you living alone with one or more children?  

Have you or have your partner been unemployed for a longer period, e.g.

20. For more than six months within the past year?  

21. For more than one year within the past three years?  

**Are there or have there been any problems with consumption of beer, wine and spirits, drugs or medicine during the past year**

22. For you or our partner?  

23. For your child or any of your children?  

**Is daily life influenced by significant problems**

24. As far as you are concerned?  

25. In your relationship?  

26. As far as your child or your children are concerned?  

27. Do you need to feel more secure in your everyday life?
The following questions should only be answered if you have a child or children (irrespective of their age)

28. How do you evaluate your relationship with your children?

<table>
<thead>
<tr>
<th>Very good</th>
<th>Good</th>
<th>Fair</th>
<th>Poor</th>
<th>Very poor</th>
<th>Not relevant</th>
</tr>
</thead>
</table>

29. If your child falls ill (e.g. has influenza) for a short period, do you then feel that you can cope with this and have a normal everyday life (at home and at work)?

<table>
<thead>
<tr>
<th>All of the time</th>
<th>Most of the time</th>
<th>Some of the time</th>
<th>A little of the time</th>
<th>None of the time</th>
<th>Not relevant</th>
</tr>
</thead>
</table>

30. Are you actively trying to support and improve your child’s physical environment? (school transportation, institution, friends)

<table>
<thead>
<tr>
<th>All of the time</th>
<th>Most of the time</th>
<th>Some of the time</th>
<th>A little of the time</th>
<th>None of the time</th>
<th>Not relevant</th>
</tr>
</thead>
</table>

31. Within the past year, have you often felt that you lacked energy to set down your foot towards your children even if you think it is important?

<table>
<thead>
<tr>
<th>None of the time</th>
<th>A little of the time</th>
<th>Some of the time</th>
<th>Most of the time</th>
<th>All of the time</th>
<th>Not relevant</th>
</tr>
</thead>
</table>

32. How would you evaluate the childcare you have for your children?

<table>
<thead>
<tr>
<th>Very good</th>
<th>Good</th>
<th>Fair</th>
<th>Poor</th>
<th>Very poor</th>
<th>Not relevant</th>
</tr>
</thead>
</table>

33. How often do you think you are having problems in making your child/children eat regularly and eat healthy food?

<table>
<thead>
<tr>
<th>None of the time</th>
<th>A little of the time</th>
<th>Some of the time</th>
<th>Most of the time</th>
<th>All of the time</th>
<th>Not relevant</th>
</tr>
</thead>
</table>
How to count number of problems

All questions with a five-grad scale count as a problem when the answer is one of the three most problematic. That means answers in one of the two left boxes = nil problem, and answers in the three right boxes = one problem.

In all yes or no questions yes = one problem and no = no problem.

Maximum score = 33 problems.

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