Effect of primary care education on mental health, quality of life, need for sick leave and health care consumption in women 45-60 years with stress-related symptoms. A randomized controlled trial.

Principal investigator

Lena Rindner, RN, ADB, PhMag, PhD Student
Närhälsan, Health Care, Borås, The Research and Development Center Södra Älvsborg, Närhälsan, Research and Development, Primary Health Care Region Västra Götaland, Department of Public Health and Community Medicine/Primary Health Care, Institute of Medicine, the Sahlgrenska Academy, University of Gothenburg, Sweden
e-mail: lena.rindner@vgregion.se

Co-investigators

Lena Nordeman, RPT, PhD
Research and Development Center Södra Älvsborg, Närhälsan, Research and Development, Primary Health Care Region, Västra Götaland, Sweden
University of Gothenburg, Sahlgrenska Academy, Institute of Neuroscience and Physiology Department of Health and Rehabilitation, Unit of Physiotherapy, Sweden.
e-mail: lena.nordeman@vgregion.se

Dominique Hange, MD, PhD, Docent, Associate Professor
Närhälsan, Svenljunga Health Care Center, Department of Public Health and Community Medicine/Primary Health Care, Institute of Medicine, the Sahlgrenska Academy, University of Gothenburg, Sweden
e-post: dominique.hange@vgregion.se

Ronny Gunnarsson, MD, PhD, Adjunct Professor
Research and Development Center Södra Älvsborg, Närhälsan, Research and Development
Department of Public Health and Community Medicine/Primary Health Care, Institute of Medicine, the Sahlgrenska Academy, University of Gothenburg, Sweden
e-mail: ronny.gunnarsson@infovoice.se

Gun Rembeck, RN, RM, PhD
Närhälsan, Research and Development, Primary Health Care Region Västra Götaland, The Research and Development Center Södra Älvsborg, Borås, Närhälsan Borås Young Persons Clinic, Sweden
e-mail: gun.rembeck@vgregion.se

Åsa Premberg, RN, RM, RhD
Research and Development Primary Health Care,R&D Centre Gothenburg and Södra Bohuslän.
e-mail: asa.premberg@vgregion.se

Irene Svenningsson, RN, AND, PhD
Research and Development Primary Health Care, R,D & E Centre Fyrbodal, Sweden
e-mail: irene.sveningsson@vgregion.se

Gunilla Strömme, RN, RM, B Sc
Närhälsan Mark Antenatal Clinic, Sweden
e-mail: gunilla.stromme@vgregion.se

Arne Rindner, MD
Södra Älvsborgs Hospital, Borås, Sweden
e-mail: arne.rindner@vgregion.se

Håkan Wallgren
Frölunda sjukhus, Västra Frölunda, Sweden
e-mail: hakwa61@gmail.com

Summary

Background
Stress related ill health is today a common cause for long term sick leave among women in their midst of life as well as being a common cause for visits to the primary health care.

Aim
To investigate the effect on mental health, quality of life and sick leave of education provided within the primary health care given in group or individually for women aged 45-60 years with stress related symptoms.

Methods
This is a randomised controlled clinical trial using a two factor design.

Education is given as four sessions exploring menopause, physiology, oestrogen deficiency, cardiovascular health, consequences of stress, mental health, relationships, sexuality and lust as well as potential actions to improve the situation. In addition, the group sessions will touch base on topics like obstacles and resources, coping strategies, and behavioural changes.

The individual education will be person-centred and given as five sessions focusing on stress related symptoms, ill health, physiology and coping strategies.

Expected result
If any of these two interventions turns out to be successful it may provide low cost intervention options for a common problem often seen in primary health care.

Introduction

Stress-related ill health is today the most common cause of long-term sick leave in women in the middle of life and a common cause of primary care visits (1). It is clear that women suffer from long-term sickness and ill health to a greater degree than men (2). Women's physical and mental health in Sweden shows a marked decrease in the ages of 45-60 years (3). During this life phase, called menopause, the woman undergoes a hormonal transformation (3). Stress-related symptoms appear after a long time with high stress load without sufficient recovery (4). There are currently few studies with high evidence-based treatment on stress-related symptoms (5). Busch et al show in an evaluation that 70% of people who have undergone rehabilitation overall are satisfied with the treatment. The treatment, on the other hand, has not led to increased return to work (6).

Research shows that women often lack information about physical and mental and urogenital changes under the "middle of life" / menopause (7).

Group education is a method and participation in group education can be a good way for women to get information and exchange experiences (8).

Earlier studies evaluating patient education in hypertonia and diabetes show significant improvement (9.10). Talking can raise awareness about choices and consequences, create insight into behaviours and provide insight into the overall life situation to find the core of ill health (11). Arving et al shows that health-related quality of life increased faster in patients receiving support calls than those who received normal treatment (12).

There is a lack of primary care studies that evaluate the effect of education in group and / or individually for women 45-60 years with stress-related symptoms.

The wast number of middle aged women with ill health and subsequent high risk for disease risk and increasing number of long-term sick leave shows that it is important to study women's health in this age group.

Aim

To study the effect of education in a group or individually delivered in primary health care on mental health, quality of life and sick leave in women aged 45-60 with stress-related symptoms.

Research questions

A. Is there any effect of group information (GI) on quality of life, mental health, sick leave or visits to a primary health care centre compared to a control group?

    1. What is the effect of group education (GI) on quality of life (measured by change in scores in SF36 from baseline to 6 months after completed intervention) – ***Primary research question (other questions are secondary)***.

2. What is the effect of group education (GI) on quality of life (measured by change in scores in SF36 from baseline to 12 months after completed intervention)
3. What is the effect of group education (GI) on change in number of days on sick leave. (At baseline the number of days on sick leave up until present time is stated by women currently being on sick leave. At the 6 month follow the same information is retrieved is retrieved. The change is the difference between these measurements.)
4. What is the effect of group education (GI) on change in number of days on sick leave. (At baseline the number of days on sick leave up until present time is stated by women currently being on sick leave. At the 12 month follow the same information is retrieved is retrieved. The change is the difference between these measurements.)
5. What is the effect of group education (GI) on depressive mood (measured by change in scores in MADRS from baseline to 6 months after completed intervention)
6. What is the effect of group education (GI) on depressive mood (measured by change in scores in MADRS from baseline to 12 months after completed intervention)
7. What is the effect of group education (GI) on stress levels (measured by change in scores in PSS-14 from baseline to 6 months after completed intervention).
8. What is the effect of group education (GI) on stress levels (measured by change in scores in PSS-14 from baseline to 12 months after completed intervention).
9. What is the effect of group education (GI) on stress levels (measured by change in scores in HAD from baseline to 6 months after completed intervention).
10. What is the effect of group education (GI) on stress levels (measured by change in scores in HAD from baseline to 12 months after completed intervention).
11. What is the effect of group education (GI) on visits to primary health care? (women are asked at baseline if they had to visit the primary health care center during the preceding two months. The same question is asked at 6 months. The measurement is the change in proportion of women who visited the primary health care center).
12. What is the effect of group education (GI) on visits to primary health care? (women are asked at baseline if they had to visit the primary health care center during the preceding two months. The same question is asked at 12 months. The measurement is the change in proportion of women who visited the primary health care center).

B. Is there any effect of structured person-centered support (PCS) on quality of life, mental health, sick leave or visits to a primary health care centre compared to a control group?

13. What is the effect of Structured person-centered support (PCS) on quality of life (measured by change in scores in SF36 from baseline to 6 months after completed intervention)?
14. What is the effect of Structured person-centered support (PCS) on quality of life (measured by change in scores in SF36 from baseline to 12 months after completed intervention)?
15. What is the effect of Structured person-centered support (PCS) on change in number of days on sick leave. (At baseline the number of days on sick leave up

until present time is stated by women currently being on sick leave. At the 6 months follow the same information is retrieved is retrieved. The change is the difference between these measurements.)

16. What is the effect of Structured person-centered support (PCS) on change in number of days on sick leave. (At baseline the number of days on sick leave up until present time is stated by women currently being on sick leave. At the 12 months follow the same information is retrieved is retrieved. The change is the difference between these measurements.)
17. What is the effect of Structured person-centered support (PCS) on depressive mood (measured by change in scores in MADRS from baseline to 6 months after completed intervention)?
18. What is the effect of Structured person-centered support (PCS) on depressive mood (measured by change in scores in MADRS from baseline to 12 months after completed intervention)?
19. What is the effect of Structured person-centered support (PCS) on stress levels (measured by change in scores in PSS-14 from baseline to 6 months after completed intervention)?
20. What is the effect of Structured person-centered support (PCS) on stress levels (measured by change in scores in PSS-14 from baseline to 12 months after completed intervention)?
21. What is the effect of Structured person-centered support (PCS) on stress levels (measured by change in scores in HAD from baseline to 6 months after completed intervention)?
22. What is the effect of Structured person-centered support (PCS) on stress levels (measured by change in scores in HAD from baseline to 12 months after completed intervention)?
23. What is the effect of Structured person-centered support (PCS) on visits to primary health care (women are asked at baseline if they had to visit the primary health care center during the preceding two months. The same question is asked at 6 months. The measurement is the change in proportion of women who visited the primary health care center)?
24. What is the effect of Structured person-centered support (PCS) on visits to primary health care (women are asked at baseline if they had to visit the primary health care center during the preceding two months. The same question is asked at 12 months. The measurement is the change in proportion of women who visited the primary health care center)?

Methods

Selection of patients, inclusion criteria and logistics

Women, 45-60 years old, reached through advertisements in newspapers and on a website, are offered to participate in the study. Application for participation in the study is made electronically via Fou Primary Care Södra Älvsborg website or by telephone to research nurse. Inclusion criteria:

a. The woman has some mental and / or physical health problems such as depression, anxiety, gastrointestinal symptoms, muscular symptoms and / or cardiovascular symptoms.
b. The woman has been on sick leave for a maximum of 30 days in the last two months.
c. The woman has no major language difficulties that prevent understanding and speaking Swedish language as well as filling in forms.
d. Woman lacks serious illness such as psychosis, severe depression or dementia
e. The woman is not treated in palliative care
f. The woman has no ongoing drug or alcohol abuse.

Research nurse contacts the woman via telephone and provides further information about the study where the opportunity is given to ask questions. If the woman meets all inclusion criteria and choose to accept the study, electronically self-administered questionnaires about self-assessed health and health-related quality of life will be sent to all participants, as well as a written informed consent that is signed. Self-administered questionnaires and consent kits are filled in via link on R & D Primary Care Södra Älvsborg's website.

The research nurse is responsible for administration of questionnaires and arranging physical check-up.

Group allocation

Research randomizer is used to generate a random series based on block-randomization in blocks of four. The random series is transferred to closed sealed opaque envelopes, each containing group assignment. The manufacture of these closed envelopes is done by a person who is not involved in the study.

Randomization occurs after the woman answered all questionnaires at baseline. Then the research nurse opens the next sealed numbered envelope and the patch inside describes what group the woman is allocated to:

- Group 1: group information (GI)
- Group 2: group information (GI) + person-centred support (PCS)
- Group 3: person-centred support (PCS)
- Group 4: no GI or PCS (control group)

Intervention

Group information (GI).

Midwives and district nurses participate as group leaders. Each group training includes 12 women and comprises four one-and-a-half hours of information with topics related to physical and mental changes in the body as well as conversations aimed to make behaviour, consequences of behaviour and choices in life conscious.

The first group event contains education with the definition and myths of "middle of life" / menopause, physiology, menstrual cycle, hormonal conversion, local oestrogen deficiency symptoms, osteoporosis and information on treatment options and self-care advice.

The second group event contains teaching and information on cardiovascular health, its risk and health factors, physiology, mental health, relationships, sexuality and lust as well as information on treatment options and self-care advice.

The third group event contains insights into stress-related ill health, physiology, social relationships in family and work, sexuality and lust, insight into obstacles and resources, coping strategies and behavioural changes to promote health.

The fourth group event contains insights on relationships, sexuality and lust as well as a summary of "How do we want to live to feel good?" Insight into obstacles and resources, coping strategies and behavioural changes to promote health.

Structured person-centred support (PCS):

Individually structured person-centred education is carried out by a district nurse or midwife. It includes five sessions. The conversation contains dialogue on symptoms of stress-related ill health, what is happening in the body (physiology), relationships, coping strategies, requirements, guilt, exercise and diet. Women randomized to receive both group education and individual education will receive group education first.

Control

The research nurse informs women in all groups that they can contact the primary health care centre if they wish to explore what can be offered from there. If the woman contacts the health care centre, they are treated according to the health care centre's current routines. Hence, any education or treatment provided outside the scope of this research project can vary between health care centres. Group education and individual education for the other groups are provided on top of the primary health care centre's standard measures.

Data collection

The following information is collected at baseline.

- Demographic data: age, work, education, family situation, hormone treatment, cardiovascular disease, stress disorder, cause of healthcare contact (psychological and / or physical) and prior sick leave days. In addition, they are asked if they have visited the healthcare centre for the past two months as a patient and, if so, for what (a number of standard symptoms can be selected)
- Blood pressure: blood pressure with electronic blood pressure cuff, if necessary manual blood pressure, the mean of two blood pressure is recorded at the time of visitation.
- MRS: measures the occurrence of menopausal symptoms. The questionnaire consisting of 11 questions brings together menopause symptoms in three main groups; somatic symptoms, urogenital symptoms and mental symptoms. The questionnaire

indicates the severity of symptoms on a 5-degree scale. Low incidence of symptoms indicates 0 points and high incidence of symptoms 4 points. Total sum, individual questions and three subgroups are reported. The instrument has been tested for reliability and validity (14).

- MADRS: investigates the degree of depression and depressive symptoms. The questionnaire consists of 9 questions, which are graded on a 6-degree scale where 0 points indicate a low incidence of symptoms and 6 points indicate a high incidence of symptoms and ill health. The instrument has been tested for reliability and validity (15).
- SF-36: examines physical and mental health as well as changes over time. The questionnaire consists of 36 multiple-choice questions, divided into eight subdivisions. Scores are between 0 - 100, higher value indicates better health experience. The instrument has been tested for reliability and validity (16).
- HAD: investigates the degree of anxiety and depressive symptoms. The form consists of 14 questions with seven issues that measure anxiety (HAD-A) and seven issues that measure depression (HAD-D) and graded on a 4-degree scale. Each question can yield between 0 and 3 points and summed to give a score scale of 0-21 for respective anxiety and depressive symptoms. Higher points indicate higher incidence of symptoms. The instrument has been tested for reliability and validity (17).
- s-UMS, self-assessed fatigue syndrome. Identify individuals who have developed or may be developing a clinical fatigue syndrome with impaired work ability and increased risk of sick leave. The form has four questions with queries. The instrument has been tested for reliability and validity (18).
- PSS-14: Measurement of self-assessed general perceived stress. how often you have experienced life as unpredictable, uncontrollable and congestive in the last month. The form has fourteen questions. The Swedish translation has shown good internal validity (19).
- AUDIT: self-assessment test for alcohol consumption and consists of ten questions divided into three domains: consumption, addiction and alcohol-related injuries. Results above the cut-off limit 6 points for women and 8 points for men indicate a risky drinking. The instrument has been tested for reliability and validity (20).

Follow-up of intervention takes place six and twelve months after completion of treatment / education. Midwife and district nurse participate in the follow-up. During this visit, follow-up of quality of life, mental health, care needs and sick leave is made by the woman filling in the same questionnaire as at baseline.

Data is collected by the research nurse at baseline and six and twelve months after completion of education. Returned questionnaires are encoded and code lists will be filed at the R & D unit Södra Älvsborg in a locked and fireproof archive for more than ten years. Code key is stored separately. Access to the material has project managers and supervisors. Electronic stored data is stored on the computer's network device H so it is backed up automatically, not on the workstation hard drive. Data is stored on the Västra Götaland region password-protected computer. Tape and video recordings are not used.

Statistical analysis

Questionnaires are summarized according to manuals. Data is described descriptively with a appropriate estimates. The scientific research questions will be analysed by multivariate regression where the two interventions GI and PCS, each being an independent variable, is entered a two-factor model, where interaction effects between the two interventions is also evaluated. Moreover, age becomes an independent confounding variable. A regression is made for each outcome measure (each scientific question). The level of significance is set to ≤0.05. IBM SPSS version 20 or later will be used.

Sample size estimation

Sample size estimations are made for research questions 1, 3 and 5. When estimating sample size, we assume a significance level of 0.05, power of 0.80 and that we do a two-way test. When estimating sample sizes, we use simple group comparison for two independent groups with Mann-Whitney's test as surrogate test.

Research question	Assumptions	Assumed "Effect size"	Number required
1 (primary)	We assume that the quality of life increases by three points in the intervention group and zero points in the control group. Furthermore, the standard deviation is eight in both groups.	0,38	236
3	We assume that days on sick leave decrease by two days in the intervention group and by 0.5 days in the control group. Furthermore, the standard deviation is five days in both groups.	0.30	368
5	In a previous pilot study (13), a decrease of -0.44 (SD 5.0) in MADRS depression scores was seen in the intervention group while increasing +0.10 in the control group (SD 4.8). The pilot study had two group events. This study has four group events, which we consider to be considerably better structured. We assume that the depression score decreases by -1.5, everything else is the same.	0,33	312

We plan to include a total of 370 women.

Expected results

If any of the interventions shows an effect compared to controls it would add a low-cost tool for primary health care in the work to improve women's health. It could also be used preventative for women with stress related symptoms before there is a need for frequent visits to the primary health care or need for sick leave.

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