Summary

Background
Health literacy and sense of coherence affects patient participation in health care decisions, adherence to medical advice and health outcome.

Objectives
Assess effect of interactive patient education versus treatment as usual (TAU) on patient work ability and perceived health in a primary care setting. Estimate incremental cost effectiveness (ICER) of intervention.

Design and methods
A cluster randomized controlled trial comparing intervention with TAU. Inclusion on intention to treat. Randomization at primary care center (PCC) level. Computer generated tables to allocate study arm, ratio 1:1. Investigator blinded to allocation during PCC recruitment. Included PCCs blinded to allocation during selection. Follow-up with validated questionnaires at baseline, 3, 6, and 12 months distributed digitally. Standard statistical methods used for descriptive statistics. Means of intraindividual activity level, and quality of life (QoL) compared using mixed model analysis with repeated measures.

Participants and power
Eligibility criteria: aged 18-64 years, health-related impaired work ability since > 60 net days last 6 months and rehabilitation barriers. Statistic power of 80% to identify a difference of 20 net inactive days and $P < 0.05$ with 400 patients from 30-40 PCCs in Region Västra Götaland, Sweden.

Intervention
Supervised study groups meeting half day a week for 8 consecutive weeks. Interactive patient education aiming to optimize participant health literacy and sense of coherence.

Main outcome measures
Net days with scheduled activity

Expected findings
Positive difference in net days with scheduled activity in intervention group.

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Introduction

Working is good for self-esteem and social relationships[1] and most individuals want to participate in both social and occupational activities.[2] Long-term disability entails emotional challenges related to loss of work and family roles[3] and the same medical diagnosis will have different consequences for different individuals.[2,4] Sickness absence is associated with loss of control of private and working life[5] and psychiatric-somatic comorbidity is common among long-term sick leavers experiencing difficulty resuming work.[6,7,8]

Sense of coherence (SOC) describes life in terms of being understandable, manageable and meaningful. SOC depends on individual factors and life circumstances. High SOC strengthens the individual and protects against malaise due to external stress whereas individuals with low SOC tend to look at themselves as victims, which has a negative effect on problem solving.[9]

Health literacy (HL) includes skills needed to be involved in health care decisions including problem solving and communication.[10] These abilities are influenced by education and socioeconomic factors contributing to an inequitable health.[11] Health literacy decreases with mental illness and stress.[10]

In rehabilitation, it is important to recognise individual needs and set goals that are meaningful to the person.[2,3] Inviting patients to actively take part in finding solutions to their problems is therapeutical[12] and will affect adherence to medical advice as well as health outcome and patient satisfaction.[13,14] Peer support[2,3] and improved social function may contribute to the ability to work despite chronic illness.[15] Uncertainty, both related to finance, own capabilities, and planning the future are known barriers to rehabilitation.[16,17,18]

Social cost for sickness absence in Sweden is huge[19] and knowledge about what interventions will promote return to work is insufficient.[20] A pilot study (in manuscript) of an intervention with interactive patient education aiming to increase sense of coherence and health literacy has shown promising results. The study with 20 patients showed reduced need for sick leave as well as statistically significant increase in health literacy, sense of meaningfulness (subscale for SOC), and social function (subscale for health-related quality of life) compared to baseline after six months (the time frame of the study). The pilot did not include a control group and the study was too small to detect change on all sub scales, but the trend was positive or neutral for all sub scales. A randomized controlled study is needed to further investigate the intervention.

Aim

To study the effect of interactive patient education versus treatment as usual (TAU) on patient net days with scheduled activity in a primary care setting including patients aged 18-64 with health-related impaired work ability since > 60 net days over the last six months. Estimate incremental cost effectiveness (ICER) of intervention.

Research questions

1. What is the effect of interactive patient education in supervised study groups on net days with scheduled activity in patients of working age with long-term health-related work impairment (measured as change in net days with work / scheduled work preparatory rehabilitation (unemployed) / scheduled work preparatory rehabilitation during sick leave (on sick leave) from baseline to 6 months after baseline). ***Primary research question.***

2. What is the effect of interactive patient education in supervised study groups on net days with scheduled activity in patients of working age with long-term health-related work impairment (measured as change in net days with work / scheduled work preparatory rehabilitation (unemployed) / scheduled work preparatory rehabilitation during sick leave (on sick leave) from baseline to 3 months after baseline).

3. What is the effect of interactive patient education in supervised study groups on net days with scheduled activity in patients of working age with long-term health-related work impairment (measured as change in net days with work / scheduled work preparatory rehabilitation (unemployed) / scheduled work preparatory rehabilitation during sick leave (on sick leave) from baseline to 12 months after baseline).

4. What is the effect of interactive patient education in supervised study groups on participants' health-related quality of life (measured by change in scores in EQ-5D[21] from baseline to 3 months after baseline).

5. What is the effect of interactive patient education in supervised study groups on participants' health-related quality of life (measured by change in scores in EQ-5D[21] from baseline to 6 months after baseline).

6. What is the effect of interactive patient education in supervised study groups on participants' health-related quality of life (measured by change in scores in EQ-5D[21] from baseline to 12 months after baseline).

7. What is the effect of interactive patient education in supervised study groups on the participants' sense of coherence (measured by changes in scores in SOC-13 scale in Swedish[9] from baseline to 3 months after baseline).

8. What is the effect of interactive patient education in supervised study groups on the participants' sense of coherence (measured by changes in scores in SOC-13 scale in Swedish[9] from baseline to 6 months after baseline).

9. What is the effect of interactive patient education in supervised study groups on the participants' sense of coherence (measured by changes in scores in SOC-13 scale in Swedish[9] from baseline to 12 months after baseline).

10. What is the effect of interactive patient education in supervised study groups on participants' health literacy (measured by change in scores in HLS-EU-Q16-SE[22] from baseline to 3 months after baseline).

11. What is the effect of interactive patient education in supervised study groups on participants' health literacy (measured by change in scores in HLS-EU-Q16-SE[22] from baseline to 6 months

after baseline).

12. What is the effect of interactive patient education in supervised study groups on participants' health literacy (measured by change in scores in HLS-EU-Q16-SE[22] from baseline to 12 months after baseline).

13. What is the effect of interactive patient education in supervised study groups on participants' general self-efficacy (measured as change in scores in S-GSE[23] from baseline to 3 months after baseline).

14. What is the effect of interactive patient education in supervised study groups on participants' general self-efficacy (measured as change in scores in S-GSE[23] from baseline to 6 months after baseline).

15. What is the effect of interactive patient education in supervised study groups on participants' general self-efficacy (measured as change in scores in S-GSE[23] from baseline to 12 months after baseline).

16. What is the effect of interactive patient education in supervised study groups on praticipants' social function (measured as change in scores in the two questions used in the sub scale "Social function" of RAND-36[24] from baseline to 3 months after baseline).

17. What is the effect of interactive patient education in supervised study groups on praticipants' social function (measured as change in scores in the two questions used in the sub scale "Social function" of RAND-36[24] from baseline to 6 months after baseline).

18. What is the effect of interactive patient education in supervised study groups on praticipants' social function (measured as change in scores in the two questions used in the sub scale "Social function" of RAND-36[24] from baseline to 12 months after baseline).

19. What is the effect of interactive patient education in supervised study groups on participants' work ability (measured as change in scores in WAI[25] from baseline to 3 months after baseline).

20. What is the effect of interactive patient education in supervised study groups on participants' work ability (measured as change in scores in WAI[25] from baseline to 6 months after baseline).

21. What is the effect of interactive patient education in supervised study groups on participants' work ability (measured as change in scores in WAI[25] from baseline to 12 months after baseline).

22. What is the effect of interactive patient education in supervised study groups on participants' job content (measured as change in score in Karasek Job Content Questionnaire[26] from baseline to 3 months after baseline).

23. What is the effect of interactive patient education in supervised study groups on participants' job content (measured as change in score in Karasek Job Content Questionnaire[26] from baseline to 6 months after baseline).

24. What is the effect of interactive patient education in supervised study groups on participants' job content (measured as change in score in Karasek Job Content Questionnaire[26] from baseline to 12 months after baseline).

25. What is the effect of interactive patient education in supervised study groups on the total number of net and gross sick leave days during the follow-up period (measured as change in measures defined by the Swedish Social Insurance Agency[27] from baseline to 3 months after baseline).

26. What is the effect of interactive patient education in supervised study groups on the total number of net and gross sick leave days during the follow-up period (measured as change in measures defined by the Swedish Social Insurance Agency[27] from baseline to 6 months after baseline).

27. What is the effect of interactive patient education in supervised study groups on the total number of net and gross sick leave days during the follow-up period (measured as change in measures defined by the Swedish Social Insurance Agency[27] in from baseline to 12 months after baseline).

28. What is the effect of interactive patient education in supervised study groups on participants' level of physical activity (measured as change in time spent on physical activities during leisure time according to LTPAI[28] from baseline to 3 months after baseline).

29. What is the effect of interactive patient education in supervised study groups on participants' level of physical activity (measured as change in time spent on physical activities during leisure time according to LTPAI[28] from baseline to 6 months after baseline).

30. What is the effect of interactive patient education in supervised study groups on participants' level of physical activity (measured as change in time spent on physical activities during leisure time according to LTPAI[28] from baseline to 12 months after baseline).

31. What is the effect of interactive patient education in supervised study groups on participants' Body Mass Index, BMI (measured as change in BMI from baseline to 3 months after baseline).

32. What is the effect of interactive patient education in supervised study groups on participants' Body Mass Index, BMI (measured as change in BMI from baseline to 6 months after baseline).

33. What is the effect of interactive patient education in supervised study groups on participants' Body Mass Index, BMI (measured as change in BMI from baseline to 12 months after baseline).

34. What is the effect of interactive patient education in supervised study groups on participants' symptoms of depression (measured as change in score in MADRS-S[29] from baseline to 3 months after baseline).

35. What is the effect of interactive patient education in supervised study groups on participants' symptoms of depression (measured as change in score in MADRS-S[29] from baseline to 6

months after baseline).

36. What is the effect of interactive patient education in supervised study groups on participants' symptoms of depression (measured as change in score in MADRS-S[29] from baseline to 12 months after baseline).

37. What is the effect of interactive patient education in supervised study groups on participants' symptoms of anxiety (measured change in score in GAD-7[30] from baseline to 3 months after baseline).

38. What is the effect of interactive patient education in supervised study groups on participants' symptoms of anxiety (measured change in score in GAD-7[30] from baseline to 6 months after baseline).

39. What is the effect of interactive patient education in supervised study groups on participants' symptoms of anxiety (measured change in score in GAD-7[30] from baseline to 12 months after baseline).

40. What is the effect of interactive patient education in supervised study groups on participants' symptoms of exhaustion (measured as change in score in KEDS[31] from baseline to 3 months after baseline).

41. What is the effect of interactive patient education in supervised study groups on participants' symptoms of exhaustion (measured as change in score in KEDS[31] from baseline to 6 months after baseline).

42. What is the effect of interactive patient education in supervised study groups on participants' symptoms of exhaustion (measured as change in score in KEDS[31] from baseline to 12 months after baseline).

43. What is the effect of interactive patient education in supervised study groups on participant pain catastrophizing (measured as change in score in PCS[32] from baseline to 3 months after baseline).

44. What is the effect of interactive patient education in supervised study groups on participant pain catastrophizing (measured as change in score in PCS[32] from baseline to 6 months after baseline).

45. What is the effect of interactive patient education in supervised study groups on participant pain catastrophizing (measured as change in score in PCS[32] from baseline to 12 months after baseline).

46. What is the effect of interactive patient education in supervised study groups on participant pain (measured as change in score in ÖMPSQ[33] from baseline to 3 months after baseline).

47. What is the effect of interactive patient education in supervised study groups on participant pain (measured as change in score in ÖMPSQ[33] from baseline to 6 months after baseline).

48. What is the effect of interactive patient education in supervised study groups on participant pain (measured as change in score in ÖMPSQ[33] from baseline to 12 months after baseline).

49. What is the effect of interactive patient education in supervised study groups on participant pain spreading (measured as change in number of painful body regions[35] from baseline to 3 months after baseline).

50. What is the effect of interactive patient education in supervised study groups on participant pain spreading (measured as change in number of painful body regions[35] from baseline to 6 months after baseline).

51. What is the effect of interactive patient education in supervised study groups on participant pain spreading (measured as change in number of painful body regions[35] from baseline to 12 months after baseline).
52. What is the effect of interactive patient education in supervised study groups on participant trust in own know-how and ability related to improving health (measured as change in score in questions about trust in own know-how and ability to improving health from baseline to 3 months after baseline).
53. What is the effect of interactive patient education in supervised study groups on participant trust in own know-how and ability related to improving health (measured as change in score in questions about trust in own know-how and ability to improving health from baseline to 6 months after baseline).
54. What is the effect of interactive patient education in supervised study groups on participant trust in own know-how and ability related to improving health (measured as change in score in questions about trust in own know-how and ability to improving health from baseline to 12 months after baseline).
55. What is the effect of interactive patient education in supervised study groups on participants being informed as patients and being a partners in health care (measured as change in score in questions about informed as a patient and being a partner in health care from baseline to 3 months after baseline).
56. What is the effect of interactive patient education in supervised study groups on participants being informed as patients and being a partners in health care (measured as change in score in questions about informed as a patient and being a partner in health care from baseline to 6 months after baseline).
57. What is the effect of interactive patient education in supervised study groups on participants being informed as patients and being a partners in health care (measured as change in score in questions about informed as a patient and being a partner in health care from baseline to 12 months after baseline).
58. What is the effect of interactive patient education in supervised study groups on participant visits to primary health care (research subjects 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 3 months. The measurement is the change in proportion of research subjects who visited the

primary health care center).

59. What is the effect of interactive patient education in supervised study groups on participant visits to primary health care (research subjects 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 research subjects who visited the primary health care center).

60. What is the effect of interactive patient education in supervised study groups on participant visits to primary health care (research subjects 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 research subjects who visited the primary health care center).

Methods

The study uses a quantitative research method common in clinical studies: a pragmatic cluster randomized controlled trial[20] with two groups (intervention and control). The study will be registered in Clinicaltrials.gov with detailed study protocol. Data will be reported according to the CONSORT checklist and flow charts for cluster randomized clinical trials.[34]

Selection of patients

The study is designed as a pragmatic cluster randomized controlled trial with two groups (intervention and control).

Inclusion criteria

- Patients of all sexes attending primary care centers included in the study
- Aged 18-64 years
- Health-related impaired work ability > 60 net days last six months

Exclusion criteria

- Acute crisis
- Serious mental disorder needing psychiatric specialist care
- Serious somatic disease a definite barrier to rehabilitation for a foreseeable future
- Cognitive impairment or not speaking / understanding Swedish

Group allocation

Patients will be included on intention to treat. Randomization will be performed at primary care center (PCC) level by a statistician who will use computer generated tables to allocate study arm in ratio 1:1. The randomization will be performed in 2-3 batches with 10-20 PCCs in each batch.

Intervention group

Interactive patient education in supervised study groups in addition to treatment as usual according to local routines.

The intervention consists of interactive patient education in supervised study groups with 6-12 participants meeting half a day a week for 8 consecutive weeks following a defined study plan. The study plan was developed by primary care professionals based on existing research about SOC and health literacy but will be delivered in cooperation with adult educational institutes. The supervisors will have previous coaching experience but no medical profession. Peer support as well as practicing social and communicative skills is part of the intervention. The participants will be engaged in group discussions as well as practical work with personal goals and action plans.

Unlike current interventions in primary care, this intervention does not focus on medical needs nor psychotherapy (although it goes in line with both general recommendations about health habits and acceptance and commitment theory), instead it focuses on problem solving strategies and communication, on basic understanding of our welfare system, and practical understanding of where to find help when needed.

Control group

Treatment as usual according to local routines.

Data collection

Data collection with validated questionnaires as well as demographic data at baseline and after 6 and 12 months. The research subjects will answer all questions and questionnaires in a web based tool approved for storing research data, esMaker (Entergate AB) on their mobile phone, iPad or computer. Individual web links to the questionnaires will be distributed via e-mail.

The following data will be collected only at baseline:

- Demographic data: age, sex, country of origin.

The following data will be collected at baseline and at follow-up after 6 and 12 months:

- Demographic data: family situation, education, smoking, alchohol consumption, substance use (all multi choice)
- Health-related quality of life: measured with EQ-5D[21]. Five questions with response alternatives on a 3-grade scale. The responses are weighed and presented as a score between 0 (dead) and 1 (optimal health). Also measured with a VAS-scale where 0 is worst possible health ant 100 is optimal health.
- Health literacy: measured with HLS-EU-Q16-SE[22]. Sixteen questions with response alternatives on a 4-grade scale. An overall HLS-EU-Q16 index (CHL) may be calculated and divided into three categories: sufficient CHL 13–16 score points, problematic CHL 9–12 score points or inadequate CHL 0–8 score points.
- General self-efficacy: measured with S-GSE[23]. Seven questions with response alternatives on a 4-grade scale. Score range 7-28. Higher value indicates higher self-efficacy.
- Social function: health related social function measured with items 20 and 32 of RAND-36[24] i.e. the sub scale ”Social function”. Each of the two items has 5 response choices valued 0, 25, 50, 75 and 100. A high score indicates lesser health-related limitation on social

functioning. The two items are be averaged together to represent the current health-related social function as a percentage of full function.

- Leisure time physical activity: measured with LTPAI[28]. This instrument measures time spent in physical activities during leisure time.
- Body Mass Index (BMI): calculated from height and weight
- Medications: research subjects are asked for a list of current medications.
- Primary health care center visits: number of visits to primary health care centers during the preceding two months.
- Current employment: profession (free text) and working hours (multi choice).
- Sick leave: history of sick leave (multi choice - duration), current sick leave (multi choice - duration), degree of sick leave (multi choice - percentage of ordinary working hours)
- Participation in scheduled rehabilitation: participation in medical rehabilitation and/or work preparatory rehabilitation (multi choice - type of activity), number of hours per week (free text), whether rehabilitation is planned but not initiated (multi choice - type of planned activity)
- Job content: measured with the Karasek Job Content Questionnaire.[26] Seventeen questions about job strain and job control. Each item with response alternatives on a 4-grade scale.
- Work ability: perceived work ability measured with WAI[25]. WAI is a VAS-scale with response alternatives on a 10-grade scale, higher number indicates higher work ability.
- Patient perception of time left before being able to return to work (multi choice - time frame)
- Questions about trust in own know-how and ability related to improving health: seventeen questions with response alternatives on a 5-grade scale.
- Questions about being informed as a patient and being a partner in health care: five questions with response alternatives on a 5-grade scale.
- Sence of coherence: measured with SOC-13[9]. Thirteen questions with response alternatives on a 7-grade scale. Score range 7-91. Higher value indicates higher sense of coherence.
- Pain: presence of pain (multiple choice).
- Pain: quantified pain measured with ÖMPSQ[33]
- Spreading of pain: measured with pain drawing with 18 predefined body regions[35]
- Pain catastrophizing: measured with the PCS scale[32]. Thirteen questions with response alternatives on a 5-grade scale. Score range 0-52. Higher value indicates increased pain catastrophizing.
- Symptoms of depression: measured with MADRS-S[29]. Nine questions with response alternatives on a 6-grade scale. Score range 0-54. Higher value indicates more symptoms of depression. Since MADRS-S contains a question indicating suicide risk (question number 9) a notification will be sent to the research assistent whenever research subjects' answer >4. The research assistant, in charge of the CodeKey, will notify the general practitioner in charge at their PCC. If the suicide risk is acute the research subject will be excluded from the study.

- Symptoms of anxiety: measured with GAD-7 scale[30]. Seven questions with response alternatives on a 4-grade scale. Score range 0-21. Higher value indicates more symptoms of anxiety. An extra question about daily life consequences of anxiety - one question with 4 response alternatives.
- Symptoms of exhaustion: measured with KEDS[31]. Nine questions with response alternatives on a 6-grade scale. Score range 0-54. Higher value indicates more symptoms of exhaustion.
- Data about sick leave will be collected from the Swedish Social Insurance Agency database MiDAS.

Procedure

The investigator will be blinded to allocation during PCC recruitment. The head of each PCC fills in written consent to participate in the study. A study start-up meeting will be held at each research PCC when an investigator will be informing the general practitioners and the rehabilitation coordinators at the PCC about the study. The investigator will be blinded to allocation when informing the PCCs.

After the start-up meeting the included PCCs will compose a list of patients eligible for study inclusion. During the selection process the PCCs will be blinded to allocation. When the PCCs have completed their list of eligible patients they will be informed about allocation by the research assistant, and then they start asking their selected patients for consent to the research assistant contacting them with more information about the study.

Names, phone numbers and addresses are collected for the patients who agree to more information. These patients will receive written information distributed by mail and the research assistant will be informing them about the study over the phone following a script based on the written patient information that has been approved by the ethical board. The research assistant will also have time to answer the patients´ questions. Patients agree to participate in the study by giving their written consent.

Baseline is set to time for inclusion. PCCs and research subjects will be included in the study in ”batches” for logistic reasons. There may only be 8-10 parallell intervention groups so only 16-20 PCCs may start at the same time, half of which in control group. All research subjects from the same PCC will be included at the same.

The research assistant will distribute individual links to the web based questionnaire at baseline and follow-up after 6 ant 12 months.

Management of personal data

Research subject identity is replaced with individual codes in esMaker. The research assistant will be in charge of the CodeKey and responsible for distributing the web links and for reminding the research subjects to fill in the questionnaires. Investigators will have access to the personal data but they will be blinded to the CodeKey and thus to research subject identities. Data will be stored in esMaker, which is approved for storing research data, linked to the primary investigator’s personal account on the Västra Götaland region password-protected network.

Statistical analysis

IBM SPSS version 20 or later will be used for statistical analysis. Data collected with esMaker may be exported directly into SPSS.

Questionnaires are summarized according to manuals. Standard statistical methods sill be used for descriptive statistics. Intraindividual change of study variables will be used to estimate the effect of the intervention on short term (6 months) and long term (12 months). Continuous variables will be analyzed by independent sample t-test or Mann-Whitney U test and categorical variables or frequencies by Pearson chi-square test. Means of intra-individual change of net inactivity days, quality of life, health literacy and sense of coherence scores will be compared between the intervention group and the TAU group by using mixed model analysis with repeated measures. These analyses will be adjusted for age, sex, education, and response variable at baseline. Statistical significance is set at p<0,05.

Power analysis

The study aims at statistic power of 80% to identify a difference of 20 net inactive days and P < 0.05. This is possible if including 400 patients from 30-40 PCCs if there are about as many patients from each PCC.

Assuming 15 health care centers (HCC) per treatment group, with an average of 12 patients per HCC (thus 180 subjects per treatment group) will have a power of at least 80 % and a significance of 5 %, using a two-sided test, to detect a difference 20 days of sick leave, with a variance of 32 days and an intercluster correlation coefficient of 0. 3. The attrition rate is assumed to be 10%, hence we will want to include 13-14 patients on average in each HCC (hence, 200 patients per treatment group).

Assuming 20 health care centers (HCC) per treatment group, with an average of 7 patients per HCC (thus 140 subjects per treatment group) will have a power of at least 80 % and a significance of 5 %, using a two-sided test, to detect a difference 20 days of sick leave, with a variance of 32 days and an intercluster correlation coefficient of 0.3. The attrition rate is assumed to be 10%, hence we will want to include 8-10 patients on average in each HCC (hence, 200 patients per treatment group).

Cost-effectiveness analysis

A cost-effectiveness analysis is included in the study to estimate the intervention's incremental cost-effectiveness (ICER), ie the additional cost of the intervention translated into cost per quality-adjusted life year (QALY). Change in health-related quality of life for the intervention, measured with the EQ-5D instrument, may be translated to QALYs using pre-calculated QALY weights for EQ-5D. The additional cost of the intervention is calculated comparing both direct and indirect costs (costs related to PCC visits, medication, treatment, rehabilitation efforts and lost work) between the intervention group and the control group.

Expected results

The expected finding is a positive difference in net days with scheduled activity in intervention group compared to control. Gain in perceived health-related quality of life translated to QALY weights is expected to stand in proportion to the incremental cost of the intervention.

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