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Ready for SDM - The effect of a digital training module for clinicians supporting the implementation of shared decision-making

Submission date 15/02/2023	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 17/02/2023	**Overall study status** Completed	
Last Edited 17/02/2023	**Condition category** Other	

Plain English summary of protocol

Background and study aims
Shared decision-making (SDM) is a strongly recommended approach for health care providers (HCPs) to use when supporting people in making decisions about their health.

Ready for SDM was developed as a comprehensive modularized curriculum for health care providers (HCP) in response to a lack of SDM professional training in Norway. The curriculum consists of several SDM training modules using various formats, providing guidance for tailoring SDM training to the different contexts and needs of HCPs. The “Ready for SDM e-learning training program was developed based on a proven effective German module, and builds on behaviour and learning theory. As didactic methods, video examples of suboptimal/optimal SDM consultations and additional exercises are applied.

There is limited formal evaluation of such training program despite the increased availability of e-learning training for HCPs internationally. This study will investigate the efficacy of a 1-hour online SDM training designed to enhance SDM competencies.

Who can participate?
Physicians working in hospital trust within the South-eastern Norway Regional Health Authority.

What does the study involve?
Clusters of physicians attending planned SDM trainings within the South – Eastern Norway Regional Health Authority are going to be included and randomized to either an intervention - or a waiting list control group. The intervention includes a 1-hour online SDM training module.

What are the possible benefits and risks of participating?
Participants taking part in this study may benefit by getting increased knowledge and skills in SDM, furthermore it may have future benefits, as the results of the study are likely to influence the implementation of SDM in Norway. There are no notable risks to participants in this study, and both groups will receive the same training.

Where is the study run from?
Helse Sør-Øst RHF - South-Eastern Norway Regional Health Authority

When is the study starting and how long is it expected to run for?
February 2023 to March 2025

Who is funding the study?
Helse Sør-Øst RHF - South-Eastern Norway Regional Health Authority

Who is the main contact?
Simone Kielin, simone.kienlin@helse-sorost.no

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Evaluation of a digital training module for clinicians supporting implementation of shared decision-making - a randomized controlled trial.

Acronym
Ready for SDM

Study objectives
A 1-hour online training module can improve clinicians' communication competencies in shared decision-making (SDM), operationalized as accuracy of observer judgements made by use of the MAPPIN´SDM observer instrument of patient involvement in a test video of a doctor-patient consultation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 16/02/2023, The ethics committee at the South-Eastern Norway Regional Health Authority (Helse Sør-Øst RHF, Postboks 404, 2303 Hamar, Norway; +47 (0)62 58 55 00; postmottak@helse-sorost.no), ref: 2017/82 C
2. Approval pending, The ethics committee at the University Hospital in North Norway (UNN; Universitetssykehuset Nord-Norge HF, Postboks 100, 9038 Tromsø, Norway; +47 (0)776 26000; personvernombudet@unn.no), ref: 2017/1461

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet.

Health condition(s) or problem(s) studied
Training in Shared Decision-making

Interventions
Intervention:
The "Ready for SDM digital training module was developed based on a proven effective German module.
Learning objectives; After the course the participants should be able to:
1. Explain background and rationale for SDM and the situations in which it is relevant
2. Explain and justify the structure of an SDM process and its quality criteria
3. Apply the structure of an SDM process in clinical practice

The course consists of films and assignments and give the clinicians the opportunity to reflect on SDM in clinical practice. The digital training module is underpinned by behavior and learning theories and contains video examples of suboptimal/optimized SDM consultations and additional exercises.

The Ready for SDM e-learning includes the following:
• Basic introduction to SDM
• SDM-relevant decisions
• Risk communication
• SDM-case in oncology
• 6 - step model of SDM including video examples
• Refection exercises on SDM in clinical practice
• Exercises about risk communication and the suboptimal/optimized video examples
• Course test

Study procedures
Clusters of physicians attending planned SDM trainings within the South – Eastern Norway Regional Health Authority are going to be included and randomized to either an intervention - or a waiting list control group. Block randomization will be used to randomize clusters. The allocation will be concealed. An independent external person will prepare sealed opaque envelopes. After baseline assessment (demographic questionnaire) of the respective cluster the sealed opaque envelope will be opened, the intervention group starts with the training module. After completion of the training module primary and secondary endpoints are assessed.

Primary and secondary endpoints will be assessed in the control group untrained (before starting the training). After assessment of the study endpoints, the training will also be conducted for participants in the control group.

Intervention Type
Behavioural

Primary outcome measure
Agreement between the participants' and an expert assessment of patient involvement in a video recorded consultation.
The extent to which a clinician evaluates observed communication accurately was determined to be a reasonable proxy for SDM communication competencies. To assess this ability, participants will be exposed to a video of a decision consultation and asked to score their observations using an the MAPPIN´SDM observer sheet. In the current study, the observer scale focusing the patient-health care provider dyad was chosen to measure the communication performance. Judgements will be made immediately after the training or the waiting condition, respectively. Accuracy is calculated using weighted T coefficients calculated pairwise between participants' judgements and an expert standard rating.

Secondary outcome measures
1. The ability to identify SDM relevant decisions will be assessed using a open-ended question within a questionnaire before (control group) or after (intervention group) the intervention.
2. Basic knowledge about SDM will be assessed using a five-item multiple choice knowledge test (questionnaire), previously used in similar studies and in other modules within the Ready for SDM framework. The level of achieved knowledge will be assessed immediately after the

training (intervention group) or before the training (control group).
3. Additional feedback regarding the intervention will be collected after the intervention using a questionnaire.

Overall study start date
15/02/2023

Completion date
01/03/2025

Eligibility

Key inclusion criteria
Physicians working in hospital trust within the South-eastern Norway Regional Health Authority.

Participant type(s)
Health professional

Age group
Adult

Sex
Both

Target number of participants
Based on a similar study our recruiting target is in total 200 participants.

Key exclusion criteria
Those already having undertaken any SDM-training in the past two years.

Date of first enrolment
01/04/2023

Date of final enrolment
01/04/2023

Locations

Countries of recruitment
Norway

Study participating centre
South-eastern Norway Regional Health Authority
Parkgata 36
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Sponsor information

Organisation
Helse Sør-Øst RHF - South-Eastern Norway Regional Health Authority

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Sponsor type
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Funder(s)

Funder type
Government

Funder Name
Helse Sør-Øst RHF - South-Eastern Norway Regional Health Authority

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed, open-access journal within 2 years after conducting the intervention. The results will also be presented at relevant national and international conferences.

Intention to publish date
01/08/2025

Individual participant data (IPD) sharing plan
The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request: Simone Kienlin (simone.kienlin@helse-sorost.no).

IPD sharing plan summary

Available on request