

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	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 17/02/2023	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 17/02/2023	Condition category Other	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

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

Contact name

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

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

Study type(s)

Other

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

- Reflection 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(s)

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.

Key secondary outcome(s)

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.

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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

Hamar

Norway

2317

Sponsor information

Organisation

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

Funder(s)

Funder type

Government

Funder Name

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

Results and Publications**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