

# Ready for SDM - evaluation of a multidisciplinary training module in Shared Decision Making

<b>Submission date</b> 17/04/2018	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 09/05/2018	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 10/06/2024	<b>Condition category</b> Other	<input type="checkbox"/> Individual participant data

## Plain English Summary

### Background and study aims

In response to an obvious lack of professional training about shared decision making (SDM) in Norway, a draft of the “Ready for SDM” program was developed based on a proven effective German module (doktormitSDM). Two applications (Norw. “Klar for samvalg”) (M1 / M2) have recently been tested in a pilot study, indicating a need for better adaptation to various health professions and inter-professional learning. This study aims at testing the effectiveness of the revised M2 regarding improvement of SDM-related evaluation competences.

### Who can participate?

6-10 District Psychiatric Centers recruited from the South – Eastern Norway Regional Health Authority and the Western Norway Regional Health Authority

### What does the study involve?

Participating District Psychiatric Centers are randomly allocated to either an intervention or a waiting control group. After a demographic questionnaire, the intervention group starts with the introduction module A, followed by B: SDM in-depth, and C: interactive training. After completion of modules A-C the intervention group participants are assessed, and the control group participants are assessed as long as the group is untrained (has not yet received the training module). After the study, the training module is also conducted for participants in the control group.

### 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 receive the same training.

### Where is the study run from?

University Hospital of North Norway

When is the study starting and how long is it expected to run for?  
March 2016 to June 2019

Who is funding the study?  
Northern Norway Regional Health Authority

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

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Ms Simone Kienlin

**ORCID ID**  
<http://orcid.org/0000-0001-7367-2009>

**Contact details**  
Enggata 66  
Hamar  
Norway  
2317  
+47 (0)93642406  
simone.kienlin@gmail.com

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
15154

## Study information

**Scientific Title**  
Evaluation of a multidisciplinary training module in Shared Decision Making (Ready for SDM): a cluster randomized controlled trial

**Acronym**  
Ready for SDM

**Study hypothesis**

The specialist health service in Norway includes the district Psychiatric Outpatient Services (DPS), where both patients with acute problems and those who need long-term follow-up can receive help. The intervention provided in this study addresses patient involvement in making medical decisions. The overarching aim of this approach is to enhance patient involvement by provision of evidence-based patient information, alongside with the patients' encouragement to participate in the decision process and thereby to increase the frequency of patient led informed choices. Patient involvement in this study is approached to via training of health professionals' communication skills. The psychiatric domain has been chosen as the medical context for the study, to demonstrate efficacy of the intervention.

Hypothesis: A 2-hour group training module can improve health professionals' communication competencies in Shared Decision Making (SDM), operationalized as accuracy of observer judgements regarding realized SDM made by use of the MAPPIN'SDM observer instrument.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

1. The local ethics committee at the University Hospital in Northern Norway (UNN), ref: 2017/1461
2. South-eastern regional ethics committee, ref: 2017/82 C

### **Study design**

Cluster randomized waiting control group trial

### **Primary study design**

Interventional

### **Secondary study design**

Cluster randomised 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

### **Condition**

Shared decision making

### **Interventions**

Participants are randomized to either an intervention or a waiting control group:

Intervention: an SDM training module addressing health professionals, which includes the following:

1. 30-min didactics, introduction to SDM
2. 30-min deepening in SDM

3. Interactive SDM observer training using a video-recording of a psychiatric consultation and a set of evaluation criteria

After administering a demographic questionnaire, the intervention group starts with the introduction module A, followed by B: SDM in-depth, and C: interactive training. After completion of modules A-C, primary and secondary endpoints are assessed.

Control: waiting/no intervention

Primary and secondary endpoints will be assessed as long as the group is untrained (has not yet received the training module). After the study, the training module will also be conducted for participants in the control group.

## **Intervention Type**

Behavioural

## **Primary outcome measure**

Accuracy of observation-based judgements made on SDM performance in a given medical consultation, which is provided as a video-recorded consultation. Judgements will be made in terms of the dyadic MAPPIN<sup>®</sup> SDM immediately after provision of the SDM training module 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**

SDM related knowledge assessed by using a five-item multiple choice knowledge test, previously used in a similar study. The level of achieved knowledge will be assessed immediately after provision of the SDM training module or the waiting condition, respectively.

## **Overall study start date**

15/03/2016

## **Overall study end date**

16/06/2019

# **Eligibility**

## **Participant inclusion criteria**

1. Health professional teams from District Psychiatric Centers
2. Actively involved in psychiatric patient care

## **Participant type(s)**

Health professional

## **Age group**

Adult

## **Sex**

Both

## **Target number of participants**

6-8 District Psychiatric Centers representing clusters in the study design, recruited from the South-Eastern Norway Regional Health Authority and the Western Norway Regional Health

Authority. Power calculation was made using G-Power program software. Based on data (mean values and SDs) from a previous comparable study, a given alpha of 0.05 and a power of 0.95 and allowing for use of two-tailed analysis, N=54 is needed per study group. Considering a cluster factor of 0.25 and an estimated drop-out rate of 25%, total sample size is N = 158 participants (control group: N=79; Intervention group: N=79), to not oversee a difference of 0.15 weighted T coefficient.

### **Total final enrolment**

357

### **Participant exclusion criteria**

1. Non-health professionals and professionals from other settings than the pre-defined institutions
2. Health professionals working in administrative functions

### **Recruitment start date**

16/04/2018

### **Recruitment end date**

16/06/2018

## **Locations**

### **Countries of recruitment**

Norway

### **Study participating centre**

#### **Betanien District Psychiatric Center**

Bergen

Norway

5145

### **Study participating centre**

#### **Bjørgvin District Psychiatric Center**

Bergen

Norway

5113

### **Study participating centre**

#### **Øyane District Psychiatric Center**

Straume

Norway

5353

**Study participating centre**  
**Kronstad District Psychiatric Center**  
Bergen  
Norway  
5054

**Study participating centre**  
**Solli District Psychiatric Center**  
Bergen  
Norway  
5228

**Study participating centre**  
**Voss District Psychiatric Center**  
Voss  
Norway  
5705

**Study participating centre**  
**Gjøvik District Psychiatric Center**  
Gjøvik  
Norway  
2819

## **Sponsor information**

**Organisation**  
University Hospital of North Norway

**Sponsor details**  
Sykehusvegen 38  
Tromsø  
Norway  
9019  
+47 (0)77 62 60 00  
post@unn.no

**Sponsor type**  
Hospital/treatment centre

**Website**

<https://unn.no/om-oss/university-hospital-of-north-norway>

## ROR

<https://ror.org/030v5kp38>

## Funder(s)

### Funder type

Government

### Funder Name

Helse Nord RHF

### Alternative Name(s)

Northern Norway Regional Health Authority

### Funding Body Type

Government organisation

### Funding Body Subtype

Local government

### Location

Norway

## Results and Publications

### Publication and dissemination plan

Planned publication in a high-impact peer reviewed, open access journal within one year after the overall trial end date. The results will also be presented at relevant national and international conferences.

### Intention to publish date

16/06/2020

### Individual participant data (IPD) sharing plan

The data sharing plans for the current study are unknown and will be made available at a later date.

### IPD sharing plan summary

Data sharing statement to be made available at a later date

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/04/2020	04/06/2020	Yes	No

<a href="#">Results article</a>	30/04/2021	04/10/2022	Yes	No
<a href="#">Results article</a>	17/03/2022	10/06/2024	Yes	No